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**A critical examination of the policy process,  
implementation, and institutionalization of  
explicit healthcare priority-setting at the  
macro-level in Kenya.**

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## DECLARATION

I, Rahab Mbau, 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. I have read and understood the school's definition of plagiarism and cheating given in the research degrees handbook.

Date: 25<sup>th</sup> October 2023.

## STATEMENT CONCERNING CONJOINT WORK

Chapters 6-8 of this thesis are in the format of journal manuscripts. Chapter 6 is undergoing review in the International Journal of Health Policy and Management. Chapters 7 and 8 were accepted for publication in the Health Policy and Planning journal and BMC Health Services Research respectively. I co-authored these chapters with my supervisors- Professor Anna Vassall, Professor Lucy Gilson, and Professor Edwine Barasa. My advisor- Associate professor Kathryn Oliver- is also a co-author of Chapter 7. I have therefore written Chapters 6-8 in the plural 'we' to recognize their contribution. I was responsible for conceiving and designing the study, data collection, data analysis and interpretation, and drafting and critical revision of these chapters. My supervisors and advisor were involved in the critical revision and final approval of these chapters. Chapters 6 and 7 were also presented as oral and poster presentations at the 7<sup>th</sup> Global Symposium on Health Systems which took place between October 31<sup>st</sup> and 4<sup>th</sup> November 2022.

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## COVID-19 IMPACT STATEMENT

The Covid-19 global pandemic began during the 1<sup>st</sup> year of my PhD studies. The associated lockdown restrictions that were imposed to curb the spread of the pandemic not only disrupted my day-to-day work schedule but also caused delays in data collection well into the spring term of my 3<sup>rd</sup> year (January to April 2022). These disruptions and delays further interfered with my PhD timelines.

Taking this into consideration, the LSHTM Covid-19 support scheme granted me a 1-year extension. This extension was incredibly helpful in enabling me to finish my PhD given the delays associated with the Covid-19 global pandemic. I therefore wish to thank the LSHTM Covid-19 support scheme for this wonderful consideration.

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## LIST OF ABBREVIATIONS

BIA	Budget Impact Analysis
CASP	Critical Appraisal Skills Programme
CEA	Cost Effectiveness Analysis
EBM	Evidence-Based Medicine
EUnetHTA	European network for Health Technology Assessment
HBPAP	Health Benefits Package Advisory Panel
HICs	High-income Countries
HTA	Health Technology Assessment
IDSI	International Decision Support Initiative
INAHTA	International Network of Agencies for Health Technology Assessment
ISTAHC	International Society of Technology Assessment in Health Care
KEMRI	Kenya Medical Research Institute
JICA	Japan International Cooperation Agency
LICs	Low-income countries
LMICs	Low- and middle-income countries
L-MICs	Lower-middle-income countries
LSHTM	London School of Hygiene and Tropical Medicine
MAPAC	Medicines Affordability Pricing Advisory Committee
MOH	Ministry of Health
NHIF	National Health Insurance Fund
PBMA	Programme Budgeting and Marginal Analysis
SSA	Sub-Saharan Africa
UHC	Universal Health Coverage



U-MICs      Upper-middle income countries

UK            United Kingdom

USA          United States of America

## ABSTRACT

### **Background**

Globally, there is a growing interest in explicit healthcare priority-setting processes such as Health Technology Assessment (HTA) to inform resource allocation decisions within the health sector. However, few studies have examined the policy process, implementation, and institutionalization of explicit healthcare priority-setting at the macro (national)-level in low and lower-middle income countries. This thesis critically examined the factors that influenced the: - a) policy process for the formulation of the policy on the Health Benefits Package Advisory Panel (HBPAP), b) implementation of HBPAP's healthcare priority-setting process; and c) institutionalization of HTA as an approach for explicit healthcare priority-setting in Kenya.

### **Study methods**

I conducted three qualitative case studies related to the three sub-studies of this PhD namely the policy process, implementation, and institutionalization of explicit healthcare priority-setting in Kenya. I collected data using in-depth interviews (n=70) and document reviews. I analyzed these data thematically. Both data collection and analysis were informed by Kingdon's theory, Barasa et al., evaluative framework, and my own framework (developed from a scoping literature review) as appropriate to the three sub-studies.

### **Findings**

The policy process that led to the gazettelement of the HBPAP policy idea was influenced by technocrats who not only identified the issues of fragmented and implicit healthcare priority-setting processes but also developed the policy solution of establishing an independent expert panel and acted as policy entrepreneurs when a policy window opened following the political prioritization of universal health coverage (UHC). The implementation of HBPAP's healthcare priority-setting process partially met the normative procedural and outcome conditions of a

“good” healthcare priority-setting process. While HBPAP had put in place “good” procedural practices such as use of evidence, transparency, stakeholder involvement, stakeholder empowerment, appeals and enforcement, their fulfilment was undermined by internal factors such as short timelines and limited financial resources, and external factors such as limited data quality and availability, limited technical expertise and/ or experience in healthcare priority-setting among external stakeholders, and stakeholders’ interests. Lastly, institutionalization of HTA as an approach for explicit healthcare priority-setting in Kenya was influenced by factors that both supported and constrained the process. The supportive factors included presence of: - organizational structures for HTA; short-term capacity-building activities; awareness creation initiatives; policymakers’ interests in UHC and optimal allocation of resources; technocrats’ interests in evidence-based processes; and international collaboration. On the other hand, factors that constrained institutionalization included: - limited availability of financial, information, and skilled human resources; lack of HTA guidelines and decision-making frameworks; limited availability of long-term capacity-building activities; limited HTA awareness among subnational stakeholders; and industries’ interests in safeguarding their revenue.

## **Conclusions**

The policy process, implementation, and institutionalization of explicit healthcare priority-setting in Kenya occurred in political environments characterized by varying stakeholders’ interests and other contextual factors related to resource constraints that both supported and constrained the processes. This study shows that proponents of policy ideas on explicit healthcare priority-setting should not only examine which policymakers may be most supportive of these ideas but also identify synergies of interest that could be explored to facilitate uptake of these ideas in the health system. It also shows that policymakers can support implementation of explicit healthcare priority-setting processes by developing strategies to

manage internal and external factors that might undermine fulfilment of normative procedural and outcome conditions. Lastly, it shows that policymakers can nurture and sustain institutionalization of HTA as an explicit approach for health care priority-setting in Kenya by adopting a systemic approach that not only ensures availability of organizational resources; legislation & policies; learning & advocacy; and collaborative support but also identifies and aligns supportive stakeholders' interests.

## STRUCTURE OF THE THESIS

This research paper style thesis is organized into 9 chapters: -

- **Chapter 1** introduces healthcare priority-setting at the global level then at the country-level using Kenya as an example. This chapter also outlines the PhD's problem statement, research question, and research objectives.
- **Chapter 2** discusses the theoretical approaches for conducting and examining healthcare priority-setting processes.
- **Chapter 3** is a scoping review that identifies gaps and summarizes evidence from empirical studies on policy processes and evaluation of healthcare priority-setting processes at the macro-level globally.
- **Chapter 4** is a scoping review that summarizes evidence on factors influencing the institutionalization of Health Technology Assessment across countries of different income levels globally.
- **Chapter 5** discusses the methods used in this PhD study.
- **Chapter 6** provides results of the first PhD sub-study on the policy process for developing the HBPAP policy in the format of a journal manuscript.
- **Chapter 7** provides results of the second PhD sub-study on qualitative evaluation of the healthcare priority-setting process by HBPAP in the format of a published manuscript.
- **Chapter 8** provides results of the third PhD sub-study on factors influencing the institutionalization of Health Technology Assessment in Kenya in the format of a journal manuscript.
- **Chapter 9** provides a synthesis of the findings from the three sub-studies and their significance to policy and research followed by a conclusion.

# CHAPTER 1: INTRODUCTION TO HEALTHCARE PRIORITY-SETTING

## 1.1 What is healthcare priority-setting?

In health economics, healthcare priority-setting refers to the process of making decisions regarding allocation of healthcare resources across competing uses such as health services, programs, patients, and patient groups (McKneally et al., 1997). Some literatures view healthcare priority-setting and rationing as synonymous in practice since they both involve making allocation decisions in the face of scarce resources (Coulter and Ham, 2000). However, other literatures view the two terms as different in that rationing involves limiting access to healthcare resources due to scarcity (Martin and Singer, 2003, Ham and Glenn, 2003, Coulter and Ham, 2000) while healthcare priority-setting involves making informed choices about resource allocation based on evidence and societal values to achieve the best possible health outcomes for the population (Chalkidou et al., 2016, World Health Organization, 2014, Glassman and Chalkidou, 2012, Mitton and Donaldson, 2004, McKneally et al., 1997). This thesis ascribes to the latter interpretation.

Healthcare priority-setting is inevitable given that healthcare needs are unlimited and often exceed available healthcare resources (Williams et al., 2012, Mitton and Donaldson, 2009, Wikler, 2003). It occurs at all levels of the health system such as the micro-level (bedside/frontline), the meso-level (organizations e.g., hospitals or sub-national levels e.g., counties, districts, provinces, regions) and, the macro-level (international or national-level e.g., National Government; National Health or Social Health Insurance Fund; or Cabinet, Department or Ministry of Health) (Coulter and Ham, 2000, McKneally et al., 1997, Klein et al., 1996).

Healthcare priority-setting can be done implicitly or explicitly. In implicit healthcare priority-setting, it is unclear how and by whom decisions on allocation of resources are made. Implicit

healthcare priority-setting processes are ad hoc, non-transparent, unsystematic, and driven by historical allocations and/ or competing interests from stakeholders (Chalkidou et al., 2016). These processes may lead to wastage or inefficient use of limited healthcare resources through the prolonged funding of cost-ineffective interventions (Chalkidou et al., 2016, World Health Organization, 2014, Glassman and Chalkidou, 2012, Mitton and Donaldson, 2004).

On the contrary, explicit healthcare priority-setting processes are inclusive, systematic, transparent, and driven by evidence, social values, and deliberation among relevant stakeholders (Chalkidou et al., 2016). In explicit healthcare priority-setting, there is greater emphasis on the institutional setting of the process. For example, an explicit healthcare priority-setting process should have a defined set of principles and criteria to provide normative guidance to decision-makers on how to conduct resource allocation processes that are consistent, fair, systematic, and socially acceptable (Ham and Glenn, 2003, Ham and Coulter, 2001, Coulter and Ham, 2000, Tragakes and Vienonen, 1998, Mechanic, 1997, Klein, 1993). The institutional setting of an explicit priority-setting process should also allow involvement and participation of all relevant stakeholders including experts and members of the public (Coulter and Ham, 2000). This not only leads to the integration of technical expertise and social values (Ham and Coulter, 2001, Coulter and Ham, 2000), but also improves deliberation and acceptance of the decisions thus amplifying the legitimacy of the process (Daniels, 2016).

## 1.2 Healthcare priority-setting for Universal Health Coverage (UHC) at the global level

Countries globally are committed to achieving UHC by 2030 as part of the Sustainable Development Goals (United Nations Development Program, 2017). UHC means ensuring that everyone in need can obtain good-quality promotive, preventive, diagnostic, curative, palliative, and rehabilitative health services without financial troubles (World Health

Organization, 2010). To achieve and maintain UHC, countries must progress along three key dimensions of coverage as shown in the UHC cube (Figure 1.1). This involves covering more people, expanding services, and reducing out-of-pocket payments (World Health Organization, 2014, World Health Organization, 2010).

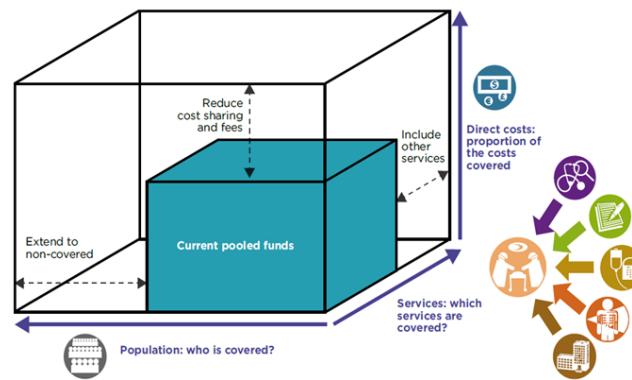


Figure 1.1: The three dimensions of coverage towards achieving UHC (World Health Organization, 2017b)

Expanding services is typically approached by developing a health benefits package which refers to a set of defined health services for a specified population group that is funded from pooled resources (Glassman et al., 2017, Glassman et al., 2016, Bobadilla et al., 1994). Making decisions on which services to buy through a health benefits package is a key aspect of purchasing arrangements which can facilitate attainment of UHC in a health system (World Health Organization, 2000). Purchasing refers to the process through which pooled funds are transferred to healthcare providers for delivery of health services (World Health Organization, 2010, World Health Organization, 2000). During purchasing, the process of identifying which services to buy is a form of healthcare priority-setting process as it involves making choices regarding healthcare services whose demand often outstrips available resources (World Health Organization, 2000).



Progress towards UHC is uneven across the globe with 12-27% of the population in low-income countries (LICs) having coverage for essential health services compared to 59-75% in high-income countries (HICs) (World Health Organization, 2020b). Attaining and maintaining UHC is constrained by the reality that resources in every country (irrespective of income level) are insufficient to meet the cost of providing all effective health services (World Health Organization, 2020b, World Health Organization, 2014, World Health Organization, 2013, World Health Organization, 2010, Bobadilla et al., 1994). Resource constraints are more pronounced in LICs. For example, in 2019, the average government health expenditure per capita in LICs was only US\$ 39 which was 81 times lower than that of HICs (World Health Organization, 2021). It was also lower than the US\$ 86 government health expenditure per capita required to provide a minimum package of key primary healthcare services in LICs (Mcintyre et al., 2017).

In addition to resource scarcity, approximately 20-40% of health system spending is wasted through inefficient allocation such as inappropriate coverage of cost-ineffective medicines and health services among others (World Health Organization, 2010). Resource wastage has partly been attributed to implicit healthcare priority-setting processes that are non-transparent and driven by historical patterns and stakeholder interests (Glassman and Chalkidou, 2012, World Health Organization, 2010).

Health system resource constraints and continued resource wastage have led to growing interest in explicit healthcare priority-setting approaches to inform UHC-related decisions (Chalkidou et al., 2016, World Health Organization, 2014, World Health Assembly, 2014). One such explicit healthcare priority-setting approach is health technology assessment (HTA) which was endorsed by the 67<sup>th</sup> World Health Assembly (World Health Assembly, 2014). HTA is defined as *“a multidisciplinary process that uses explicit methods to determine the value of a health technology to inform decision-making towards an equitable, efficient and high-quality health*

*system*” (O'Rourke et al., 2020). A health technology is an intervention that can either promote health; prevent, diagnose or treat disease; or inform health service delivery (O'Rourke et al., 2020, World Health Assembly, 2007). Examples of health technologies include medicines, vaccines, tests, procedures (medical and surgical), policies, and programs (O'Rourke et al., 2020, World Health Assembly, 2007).

Introducing and implementing explicit healthcare priority-setting processes are intrinsically political acts, recognizing conflicting interests in what processes and criteria should be followed, which stakeholders should be involved, and what roles and responsibilities stakeholders should fulfil (Smith et al., 2014, Hauck et al., 2004, Ham and Glenn, 2003). However, the policy process through which countries come to adopt explicit healthcare priority-setting processes largely remains unanalyzed (Smith et al., 2016, Smith et al., 2014). A review of literature [*See Chapter 3*] shows that policy analysis studies of the policy process for introducing healthcare priority-setting processes at the macro-level remain limited globally. Given this gap, conducting a policy analysis study on how policies on healthcare priority-setting processes emerge in the health system is therefore substantively relevant to health policy and systems research.

As countries adopt explicit healthcare priority-setting processes, there is an accompanying demand to evaluate them (Smith et al., 2012). This demand is driven by the public's interest in decisionmakers demonstrating the fairness, legitimacy, accountability, and transparency of healthcare priority-setting processes given the complexity and distributive conflicts of allocating scarce resources across competing uses (Martin and Singer, 2003, Ham and Coulter, 2001). Evaluation refers to the “*systematic collection and analysis*” of data to determine the merit of a policy, process, or program (Smith et al., 2012). Evaluation of healthcare priority-setting processes is done against evaluative frameworks outlining normative procedural and outcome conditions [*See Chapter 2, Subheading 2.4*]. Fulfilment of these normative procedural

and/ or outcome conditions enables a healthcare priority-setting process to be considered as fair (Daniels and Sabin, 1997), legitimate (Daniels and Sabin, 1997), socially justifiable (Clark and Weale, 2012), or successful (Sibbald et al., 2009, Barasa et al., 2015).

Globally, empirical studies on evaluation of healthcare priority-setting processes remain limited (Smith et al., 2012, Martin and Singer, 2003). Furthermore, a literature review conducted in 2015 showed that there were few studies evaluating macro-level healthcare priority-setting processes in low- and middle-income countries (LMICs) (Barasa et al., 2015). An update of this literature review [*See Chapter 3*] shows that studies evaluating macro-level healthcare priority-setting processes against normative procedural and outcome conditions remain limited in LMICs. Given this gap, evaluating macro-level healthcare priority-setting processes in LMICs is therefore substantively relevant.

The impact and sustainability of explicit healthcare priority-setting processes such as HTA is dependent on their institutionalization (Bertram et al., 2021a, World Health Organization, 2011, World Health Organization, 2001). Institutionalization of HTA refers to the process of conducting and utilizing HTA as a normative practice for guiding decisions on allocation of resources among competing uses within the health system (World Health Organization, 2001). In countries where HTA has been institutionalized, it is routinely conducted as a way of informing health policy decisions on:- a) development and revision of health benefits packages for pharmaceutical and non-pharmaceutical products; b) development of clinical guidelines; c) market authorization of health technologies; and d) pricing and reimbursement regulations for health technologies (Bertram et al., 2021a, World Health Organization, 2011, World Health Organization, 2001).

More high-income and upper-middle-income countries have institutionalized HTA in their health systems as an explicit approach to healthcare priority-setting than low-income and

lower-middle-income countries, particularly in Sub-Saharan Africa (Hollingworth et al., 2021, Chalkidou et al., 2017). Examining and identifying which country or context specific factors are influencing institutionalization of HTA is important as it enables policymakers and technocrats to introduce appropriate measures to address them (Suharlim et al., 2022, Rajan et al., 2011). However, studies examining factors that influence institutionalization of HTA as an explicit approach to healthcare priority-setting in LMICs remain limited [*See Chapter 4*]. Given this gap, identifying factors that are influencing institutionalization of HTA in LMICs is therefore a substantively relevant policy and research question.

### 1.3 Healthcare priority-setting for UHC in Kenya

Kenya- a lower-middle-income country- aims to achieve UHC by 2030 (Ministry of Health, 2020c). To this end, Kenya's Ministry of Health (MOH) has introduced several reforms. One such reform aimed to introduce an explicit healthcare priority-setting process for health benefits package development. On 8<sup>th</sup> of June 2018, the MOH gazetted the Health Benefits Package Advisory Panel (HBPAP), a committee of 15 members, to develop a UHC health benefits package using an explicit and evidence-based healthcare priority-setting process (The Kenya Gazette, 2018). HBPAP was also tasked with developing and recommending a framework for institutionalizing HTA as an approach for explicit healthcare priority-setting (The Kenya Gazette, 2018). HBPAP was constituted for a period of two years beginning from 8th June 2018 to 8<sup>th</sup> June 2020.

The HBPAP policy was a procedural policy as it sought to influence how and by whom the healthcare priority-setting process for health benefits package was conducted in Kenya. A procedural policy refers to any course of action that changes how and by whom processes or functions of an organization or government are conducted (Howlett, 2017, Commonwealth of Learning, 2012). The introduction of the HBPAP policy was the first attempt by the MOH to

establish an explicit and systematic healthcare priority-setting process for developing a health benefits package in Kenya. During its tenure, HBPAP submitted a report on the proposed UHC health benefits package and a draft framework for institutionalization of HTA in Kenya to the MOH.

## 1.4 Problem statements

Three problems informed this PhD study. Firstly, little is known about the policy process that led to the gazettelement of the HBPAP policy idea in Kenya. Examining the policy process that led to the gazettelement of the HBPAP policy idea using policy analysis theory will be important in explaining and improving our understanding of the contextual factors and actor dynamics that influenced the gazettelement of the HBPAP policy.

Secondly, studies on evaluation of healthcare priority-setting processes at the macro-level in Kenya remain limited. A recent publication includes a multi-country study on evaluation of macro-level priority-setting for Covid-19 preparedness plans (Kapiriri et al., 2021). No study has been conducted to evaluate the macro-level healthcare priority-setting process for health benefits package development by the HBPAP.

Lastly, no study has been conducted to examine the factors influencing institutionalization of HTA as an explicit approach for healthcare priority-setting in Kenya. This PhD study seeks to address these three problem statements.

## 1.5 Research purpose

This PhD study focuses on critically examining the policy process, implementation, and institutionalization of explicit healthcare priority-setting at the macro-level Kenya. Specifically, I set out to: - a) examine how and why was the HBPAP policy idea was gazetted in Kenya; b) qualitatively evaluate the healthcare priority-setting process conducted by HBPAP; and c) identify what factors were influencing institutionalization of HTA in Kenya.

Examining Kenya's experience might offer wider value to policy and research on explicit healthcare priority-setting processes at the macro-level in other LMICs where such literature remains limited.

## 1.6 Research question

The main research question for this PhD study was: - What factors influenced the policy process, implementation, and institutionalization of explicit healthcare priority-setting processes at the macro-level in Kenya?

The sub-questions include: -

1. What led to the gazettement of the HBPAP policy idea in Kenya?
2. To what extent did HBPAP's healthcare priority-setting process for health benefits package development meet the normative conditions of a good healthcare priority-setting process, and why?
3. What factors were influencing the institutionalization of HTA in Kenya?

## 1.7 Study objectives

The specific objectives for the study are: -

1. To examine the policy process that led to the gazettement of the HBPAP policy idea using Kingdon's Multiple Streams Theory.
2. To describe and qualitatively evaluate the extent to which HBPAP's healthcare priority-setting process for health benefits package development met the procedural and outcome conditions of a good healthcare priority-setting process.
3. To identify factors that were influencing institutionalization of HTA as an approach for explicit healthcare priority-setting in Kenya.

4. To generate policy recommendations on how explicit healthcare priority-setting processes can be introduced, implemented, and institutionalized in Kenya.

## 1.8 Background information on Kenya

This PhD study was conducted in Kenya- a country in the East Africa region of Sub-Saharan Africa (SSA) (Figure 1.2). Kenya's population is approximately 53.8 million people which makes it one of the top 10 countries with the highest population in SSA (The World Bank, 2022). The governance structure in Kenya is devolved with administrative, fiscal, and political roles split across 1 national and 47 semi-independent county governments (The Republic of Kenya, 2010).



Figure 1.2: Kenya's location on the Map of Africa. Source- Google Images

Functions of the health sector are also devolved between this two-tiered governance structure. Within the national government, the MOH represents the highest political office for the health sector. Its responsibilities include formulating national health policies, building capacity,

providing technical assistance, and overseeing service delivery in national referral healthcare facilities (The Republic of Kenya, 2010). Within the county governments, the County Departments of Health are responsible for implementing national health policies and overseeing health service delivery in county public healthcare facilities namely primary healthcare facilities (community units, dispensaries and health centres) and secondary healthcare facilities (primary and secondary referral hospitals) (The Republic of Kenya, 2010).

Resources for Kenya's health sector come from three main sources namely public (tax and public health insurance), private (household out-of-pocket payments and voluntary health insurance) and donors. In 2019, these sources contributed 46%, 35.5%, and 18.5% of the total health expenditure respectively (World Health Organization, 2019). Kenya's health sector faces significant resource constraints. For example, in 2020, per capita government health expenditure in Kenya was only US\$ 40 (World Health Organization, 2022) which was below the average per capita government spending of US\$ 61 in lower-middle income countries (L-MICs) (World health organization, 2020a). In addition, Kenya's general government health expenditure as a percentage of the gross domestic product was 2% (World Health Organization, 2022, Barasa et al., 2018) which was less than the average of 4.9% in L-MICs (World Health Organization, 2021). Therefore Kenya's health expenditure falls below the recommended government spending of US\$ 86 per capita and 5% of GDP required to achieve UHC in LICs (Mcintyre et al., 2017).

In Kenya, purchasing is done through three models. The first model is the integrated public model where the MOH purchases services (or health benefits) from tertiary public referral hospitals while the County Departments of Health purchase services from county public healthcare facilities. The second model is the public contract model where the National Health Insurance Fund (NHIF) - a state corporation- purchases services from both public and private (for-profit and not-for-profit) healthcare facilities. The third model is the private contract model



where private health insurers purchase services from private healthcare facilities (Mbau et al., 2020, Mbau et al., 2018, Munge et al., 2015). Prior studies on purchasing arrangements in Kenya (Mbau et al., 2020, Mbau et al., 2018) and benefits packages in LMICs (Glassman et al., 2012) showed that health benefits in Kenya were not explicitly defined.

## 1.9 Chapter Summary

In this Chapter, I have introduced and defined healthcare priority-setting. I followed this introduction with a discussion on the growing interest in explicit healthcare priority-setting processes at the international level. I then highlighted Kenya's interest in explicit healthcare priority-setting processes, and outlined the study's problem statement and, research questions and objectives. I concluded the chapter by providing a brief background on Kenya which formed the study setting for this PhD.

## CHAPTER 2: THEORETICAL APPROACHES FOR CONDUCTING AND EXAMINING HEALTHCARE PRIORITY-SETTING PROCESSES

### 2.1 Introduction

In this Chapter, I discuss three main subjects. Firstly, I discuss the theoretical approaches for increasing explicitness in healthcare priority-setting processes given the global interest in explicit priority-setting processes to inform resource allocation decisions. Secondly, I discuss policy analysis theories since healthcare priority-setting processes are procedural policies whose policy-making processes can be better understood using these theories. Thirdly, I discuss conceptual frameworks for evaluating healthcare priority-setting processes given the growing demand to evaluate the fairness and legitimacy of existing healthcare priority-setting processes. These theories and conceptual frameworks constituted key search terms for the literature review in Chapter 3.

### 2.2 Theoretical approaches for increasing explicitness in healthcare priority-setting processes

Choices on how to allocate scarce resources across competing healthcare uses demand consideration of various values by decision-makers. Examples of these values include clinical and economic impact, ethics, and justice. However, decisionmakers face difficulties in achieving consensus on which values should inform how resources are allocated (Coulter and Ham, 2000, Tragakes and Vienonen, 1998, Daniels and Sabin, 1997). Decision-makers need to find a balance between providing innovative health technologies on one hand while managing budgets and maintaining equitable access on the other hand (Sorenson et al., 2008). These difficulties bring to the fore the need for discipline-specific and multi-disciplinary theoretical approaches in healthcare priority-setting.

Each discipline-specific approach provides its own normative guiding principle for increasing explicitness in healthcare priority-setting processes (Maluka, 2011, Sibbald, 2008, Martin and Singer, 2000, Tragakes and Vienonen, 1998). Each of these principles offers an alternative that decisionmakers can utilize to inform choices during healthcare priority-setting processes. The type of discipline-specific approach chosen affects the type of priority-setting decisions made given the differences in the principles underpinning each discipline (Maluka, 2011, Sibbald, 2008, Martin and Singer, 2000, Tragakes and Vienonen, 1998). On the other hand, a multidisciplinary approach combines multiple discipline-specific approaches, hence combining multiple guiding principles to inform choices and decisions during healthcare priority-setting processes (Barasa, 2014, Sibbald, 2008, Martin and Singer, 2000). These disciplinary approaches are summarised in Table 2.1 and discussed further below.

Table 2.1: Disciplinary and multi-disciplinary theoretical approaches to healthcare priority-setting

<b>Discipline-specific approach</b>	<b>Guiding principle or value</b>	<b>Examples of theories or methods within the disciplinary approach</b>
Philosophy	Justice	Utilitarianism, egalitarianism, libertarianism, and communitarianism
Political science	Negotiation	Rational choice theory, bounded rationality, incrementalism, and public choice theory.
Law	Reasonableness	Right to health, no discrimination
Economics	Efficiency	Economic evaluation, Programme budgeting and Marginal Analysis, Budget Impact Analysis
Evidence-based medicine	Effectiveness	Comparative Effectiveness Research
<b>Multi-disciplinary approach</b>	<b>Guiding principles or values</b>	<b>Examples of approaches within the disciplinary approach</b>

HTA	A combination of the discipline-specific guiding principles	Comparative Effectiveness Research, Economic Evaluation, and Multi-Criteria Decision analysis
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## 2.2.1 Discipline-specific approaches

### 2.2.1.1 Philosophy

Philosophical approaches recognize that at the heart of healthcare priority-setting lies ethical and moral value judgements which inform the acceptability or rightness of the resource allocation decisions made (Tragakes and Viononen, 1998). The core principle underpinning philosophical approaches is justice (Sibbald, 2008, Martin and Singer, 2000, Tragakes and Viononen, 1998, Olsen, 1997). Justice in healthcare priority-setting is concerned with “*who should get what healthcare and when*” with the aim of promoting fair and just allocation and distribution of scarce resources (Cookson and Dolan, 2000, Tragakes and Viononen, 1998).

There are several philosophical theories on justice that provide ethical and moral guidance on how to conduct healthcare priority-setting (Williams et al., 2012, Martin and Singer, 2000, Cookson and Dolan, 2000, Tragakes and Viononen, 1998). The pluralism of justice theories is a reflection of the multiple views of ethics and moral judgements held in the society (Tragakes and Viononen, 1998). These theories are mutually exclusive with each theory arguing for a different aspect of justice resulting in different outcomes, none of which is considered superior to the other (Tragakes and Viononen, 1998). Some theories focus on distributive justice which is concerned with the outcome of the distribution or allocation of resources while others focus on procedural justice which is concerned with the processes used in the distribution or allocation of resources (Olsen, 1997). These philosophical theories of justice include communitarianism, egalitarianism, libertarianism, and utilitarianism.

Communitarianism, a theory of procedural justice, emphasizes that the healthcare priority-setting process for resource allocation should involve dialogue with members of the public being served (Williams et al., 2012). Therefore, decisions on allocation of resources should not only incorporate opinions and preferences of the members of the public, but also the wider social values that influence peoples' expectations of healthcare such as improved well-being or health outcomes (Williams et al., 2012).

Libertarianism, a theory of procedural justice, emphasizes individualism or individual choice, right, or freedom in the distribution of resources (Williams et al., 2012, Sandel, 2009, Williams, 1988). The classic principles for justice in this theory are willingness and ability to pay (Williams, 1988). In this theory, access to healthcare is considered as a reward and therefore individuals have the autonomy to use their wealth to access more and better care to their desires (Williams, 1988).

Egalitarianism, a theory of distributive justice, emphasizes equality in the distribution of resources across population groups (Williams et al., 2012, Martin and Singer, 2000, Cookson and Dolan, 2000, Olsen, 1997). The aim of the egalitarian principle in healthcare priority-setting is to ensure that resources are allocated to the choice that leads to equal distribution of benefits (Olsen, 1997) or reduction of inequalities (Cookson and Dolan, 2000, Olsen, 1997) or, the choice that *"treats equals equally and unequals unequally"* (Tragakes and Vienonen, 1998).

Utilitarianism, a theory of distributive justice, aims to generate the greatest *"possible happiness or welfare for the greatest number of people"* in the society or population group (Williams et al., 2012, Cookson and Dolan, 2000, Tragakes and Vienonen, 1998, Olsen, 1997, Bentham, 1970). Utilitarianism therefore gives priority to societal or collective gains over individual gains (Tragakes and Vienonen, 1998). The classic principle in this theory is the maximizing

principle (Cookson and Dolan, 2000, Olsen, 1997). Based on this theory, decision-makers should allocate resources to the option that generates maximum utility, health benefit, or best possible outcomes in terms of population health (Williams et al., 2012, Cookson and Dolan, 2000, Olsen, 1997).

#### *2.2.1.2 Political science*

Political science approaches recognize that healthcare priority-setting processes are inevitably debatable given the inherently complex and political nature of the processes due to conflicting values on how to allocate scarce resources (Coulter and Ham, 2000) and, conflicting claims and interests on available resources (Ham and Glenn, 2003, Klein, 1993). The value underpinning the political science approach is negotiation which refers to ‘*reasoned, informed, and open arguments drawn from a variety of perspectives*’ (Klein, 1993). Based on political science theory, existing healthcare priority-setting processes reflect resource allocation decisions that arise from pluralistic bargaining by multiple stakeholders and shifting interest group pressures (Klein, 1993). Several political science theories explain the behaviour of stakeholders involved in decision-making namely rational choice theory, bounded rationality, incrementalism, and public choice theory.

Rational choice theory argues that people make decisions rationally by calculating the costs and benefits of any course of action before deciding which option to take (Scott, 2000). While human behaviour displays both rational and non-rational actions, this theory considers human behaviour as “*purely rational and calculative*” (Scott, 2000). The term rational means that, when asked, people will have reasons for the decisions they make such as meeting desired objectives (Simon, 1995, Lindblom, 1959). This theory argues that since peoples’ behaviours are rational and calculative, they are likely to select options that reflect their wants and maximize their preferences and interests during decision-making (Scott, 2000, Simon, 1995).

Bounded rationality theory, unlike rational choice theory, recognizes that rationality of human behaviour during decision-making is much more complicated (Simon, 1995). According to bounded rationality theory, while decision-makers seek to be rational when making decisions, they may fail to do so (Jones, 1999). This may be due to individual factors such as cognitive and emotional factors and/or organizational factors such as procedural requirements laid out in the institutional settings of an organization, availability of information, and presence of multiple and sometimes conflicting goals (Jones, 1999, Simon, 1995). These individual and external factors therefore create bounds or limits on rationality (Jones, 1999, Simon, 1995). Given these bounds, decision-makers satisfice- select options that are satisfactory- rather than maximize their preferences or interests (Jones, 1999, Simon, 1995).

Incrementalism argues that since decision-makers are bound by internal and external factors, they make decisions using small, incremental acts instead of large, drastic changes (Lindblom, 1979, Lindblom, 1959). Incrementalism is defined as “*political change by small steps*” (Lindblom, 1979). Thus given the complex nature of decision-making, incrementalism recognizes that change is best achieved through small, phased, and progressive steps (Lindblom, 1979).

Lastly, public choice theory argues that the behaviour of decision-makers during decision-making is motivated by self-interests and maximization of their utility or preferences (Buchanan and Tullock, 2003, Buchanan and Tollison, 1984). Therefore, the final or collective decisions made by organizations or administrative units such as governments are the result of the negotiations of the interests and preferences of the individuals involved in decision-making in these units and not the organizations themselves (Buchanan and Tullock, 2003, Buchanan and Tollison, 1984).

### *2.2.1.3 Legal approaches*

The normative principle underpinning legal approach is reasonableness which is based on the fulfilment of the requirements stipulated in the law of a particular jurisdiction (Sibbald, 2008). Legal approaches, such as national and/ or international laws, can inform resource allocation decisions by highlighting legal issues that are relevant to healthcare priority-setting and resource allocation (Rumbold et al., 2017a, Dittrich et al., 2016, Martin and Singer, 2000, McKneally et al., 1997).

Two legal issues of relevance to healthcare priority-setting include the right to health and the no discrimination principles. The right to health principle creates a legal, moral, and social mandate for policy makers to ensure that health systems offer accessible, affordable, and timely healthcare (Rumbold et al., 2017a, World Health Organization, 2017a, Dittrich et al., 2016, Gruskin and Daniels, 2008, Coulter and Ham, 2000). The no discrimination principle creates a legal, moral, and social mandate to ensure that people access care without prejudice (Rumbold et al., 2017a, World Health Organization, 2017a). The no discrimination principle is enshrined in human rights codes which forbid unfairness based on identities such as age, disability, ethnicity, race, sexual orientation, and place of origin (Martin and Singer, 2000, McKneally et al., 1997). The moral underpinnings of the right to health and no discrimination reflect the principle of distributive justice that characterizes the philosophical theory on egalitarianism. These legal issues are vital to countries as they prioritize expansion of services towards attaining UHC (World Health Organization, 2017a).

### *2.2.1.4 Economic approaches*

The economic approach to healthcare priority-setting recognizes the reality of resource scarcity (Donaldson and Mooney, 1991). The normative principle underpinning economic approaches is efficiency which refers to the state of maximizing outcomes from available resources (Mitton and Donaldson, 2009). In the case of healthcare priority-setting, maximizing outcomes means



maximizing health gains or well-being from a given resource envelope (Mitton and Donaldson, 2009, Byford and Raftery, 1998, Donaldson and Mooney, 1991). The maximization principle of economic approaches reflects the maximization principle of the philosophical theory on utilitarianism.

Since resources are scarce, choices must be made. This brings to the fore two economic concepts: opportunity cost and margin. Opportunity cost refers to the lost or forgone benefit of the option or alternative not chosen (Mitton and Donaldson, 2009, Palmer and Raftery, 1999, Maynard and Bloor, 1998, Donaldson and Mooney, 1991). Therefore, the allocation of resources for a certain use prevents the use of these resources in other ways leading to the loss of the benefits of the foregone option. The margin refers to the benefit obtained or lost from using or removing the next unit of available resources respectively (Mitton and Donaldson, 2009). Thinking of the margin allows decision makers to shift the mix of resources during resource allocation decisions based on the available budget (Mitton and Donaldson, 2009). Based on these economic principles, a healthcare priority-setting process should minimize opportunity costs and maximize benefits at the margin (Mitton and Donaldson, 2009, Donaldson and Mooney, 1991).

Three economic approaches have been used to make healthcare priority-setting processes more explicit namely economic evaluation; programme budgeting and marginal analysis; and budget impact analysis.

### **1. Economic evaluation**

Economic evaluation is *“the comparative analysis of alternative courses of action in terms of both their costs and consequences”* (Drummond et al., 2015). The comparison of costs and consequences allows decision-makers to make informed trade-offs on the benefits and losses of alternative health technologies when allocating scarce resources thus addressing the

economic principle of opportunity cost (Weinstein et al., 1996, Donaldson and Mooney, 1991). This comparison allows decision-makers to select the option that gives the best value for money hence contributing to efficiency in resource allocation (Drummond et al., 2015, Byford and Raftery, 1998).

There are three types of economic evaluations namely cost-effectiveness analysis (CEA), cost-utility analysis, and cost-benefit analysis. In all three evaluations, costs are valued in monetary terms while consequences are valued in monetary and non-monetary terms as shown in Table 2.2 (Drummond et al., 2015). Studies that only include costs without comparisons to alternatives such as cost of illness studies do not fall under economic evaluation (Drummond et al., 2015).

Table 2.2: Examples of economic evaluation studies

<b>Example of study</b>	<b>Valuation of costs</b>	<b>Valuation of consequences</b>
<b>Cost-effectiveness analysis</b>	Monetary units	Natural effects or physical units relevant to the intervention (e.g., life years gained, cases diagnosed correctly)
<b>Cost-utility analysis</b>	Monetary units	Generic health outcomes e.g., quality-adjusted life years or disability-adjusted life years
<b>Cost-benefit analysis</b>	Monetary units	Monetary units

The World Bank and the World Health Organization (WHO) have long since championed the use of economic evaluation, particularly CEA, for healthcare priority-setting processes such as health benefits package development (World Bank, 1993). These organizations have produced tools such as the World Health Organization-Choosing interventions that are Cost-Effective (WHO-CHOICE) initiative (Bertram et al., 2021b) and the Disease Control Priorities (Jamison

et al., 2018) to support countries to conduct CEA. Over the years, CEA has been used increasingly to inform healthcare priority-setting across countries of all income levels (World Health Organization, 2014, Shillcutt et al., 2009). This use has become more important as countries prioritize services to obtain good value for money on their journey towards achieving UHC within resource-constrained budgets (Jamison et al., 2018).

CEA can be conducted from one of three perspectives namely patient/ household, provider, and societal (Drummond et al., 2015). The perspective determines the types of costs considered. The patient perspective considers the costs incurred by patients or their households while seeking healthcare. The provider perspective considers the costs incurred by the healthcare provider when providing healthcare services. The societal perspective considers the costs incurred by all the actors involved in seeking and providing healthcare services (Drummond et al., 2015). The results of a CEA are presented as incremental cost-effectiveness ratios which are summary measures that show additional costs of producing one unit of effect between alternative choices. The alternative that produces more benefits per unit cost is considered more cost-effective and therefore efficient (Drummond et al., 2015, Mitton and Donaldson, 2009, Weinstein et al., 1996).

While there is consensus that scarce resources should be allocated in a way that produces maximum benefits, it is important that the benefits are distributed equitably (Ham and Glenn, 2003, Tragakes and Vienonen, 1998, Klein et al., 1996). While CEA ensures efficiency (maximization of benefits during allocation of resources), it has been criticized for failing to consider whether the benefits are distributed equally (Drummond et al., 2015, Ham and Glenn, 2003, Coulter and Ham, 2000). Failure to consider equity and other social values may result in suboptimal and, politically and socially undesirable priority-setting decisions (Ham and Glenn, 2003, Coulter and Ham, 2000, Weinstein et al., 1996). To accommodate other principles beyond efficiency, the World Bank has modified the Disease Control Priorities tool to

incorporate the principle of financial risk protection which is particularly important in priority-setting processes for health benefits package as countries pursue UHC (Jamison et al., 2018, Baltussen et al., 2016).

## **2. Programme budgeting and marginal analysis**

As an economic method, Programme budgeting and marginal analysis (PBMA) considers both opportunity cost and margin to support explicit healthcare priority-setting processes (Mitton and Donaldson, 2009, Ruta et al., 2005, Mitton and Donaldson, 2001). It recognizes that the best way to allocate resources is by examining the costs and benefits of alternative programs at the margin where an extra unit of resource is added or removed. Using PBMA, resources are allocated to the program that yields the greatest benefit from the allocation of an extra unit of resource at the margin (Mitton and Donaldson, 2009, Ruta et al., 2005). In this way, PBMA can maximize the health benefits of the population by enabling decision makers to select the optimal mix of choices within or across programs upon which to allocate resources from a given resource envelope (Ruta et al., 2005, Mitton and Donaldson, 2001).

PBMA consists of two components namely the programme budget and the marginal analysis. In practice, PBMA is operationalized through 5 questions related to these two components as shown in Table 2.3 (Tsourapas and Frew, 2011, Mitton and Donaldson, 2001, Madden et al., 1995). Questions on the programme budget seek to explore how current resources are used across different programmes of care while questions on the margin seek to explore ways in which changes at the margin can be made to maximize health benefits and to minimize opportunity costs (Tsourapas and Frew, 2011, Mitton and Donaldson, 2001, Madden et al., 1995).

Table 2.3: Questions for operationalizing PBMA

<b>Component</b>	<b>Questions related to component</b>
<b>Programme budget</b>	<ol style="list-style-type: none"> <li>1. What resources are currently available?</li> <li>2. How are these resources being spent?</li> </ol>
<b>Marginal analysis</b>	<ol style="list-style-type: none"> <li>3. Which services (programmes of care) require more resources and what is the effectiveness of these services?</li> <li>4. Which services (programmes of care) can be provided with the same level of effectiveness but with fewer resources hence releasing resources for services identified in 3?</li> <li>5. Which services, although effective, should receive fewer resources because a service from 3 is more effective per unit of money spent?</li> </ol>

PBMA has been applied widely in high-income countries such as the United Kingdom, Canada, Australia among others (Mitton and Donaldson, 2003, Mitton and Donaldson, 2001, Scott et al., 1999). It is carried out by an advisory or expert panel whose composition depends on the context, the scope of the resource allocation decisions, and the skills required to complete the process (Tsourapas and Frew, 2011, Mitton and Donaldson, 2001, Madden et al., 1995). Literature shows that implementation of PBMA is dependent on contextual factors such as political buy-in, availability of resources to conduct the exercise, and an organisational culture that is receptive to change (Tsourapas and Frew, 2011, Mitton and Donaldson, 2009, Mitton and Donaldson, 2003).

### **3. Budget Impact Analysis**

While CEA provides decision makers with evidence on how to allocate resources efficiently, it fails to demonstrate whether such resource allocation decisions are affordable and sustainable given limited health budgets (Garattini and van de Vooren, 2011, Trueman et al., 2001). Budget

Impact Analysis (BIA) is an economic evaluation method that fills this gap by enabling decision-makers to approximate the likely financial impact and sustainability, hence affordability, of allocating resources to a cost-effective health technology given annual financial healthcare budgets (Sullivan et al., 2014, Garattini and van de Vooren, 2011, Trueman et al., 2001). Information on affordability is important to decision makers and budget holders to ensure that resource allocation decisions do not lead to overspending (Garattini and van de Vooren, 2011, Trueman et al., 2001).

BIA can be conducted as an independent analysis or as a complement to CEA in a comprehensive economic assessment (Sullivan et al., 2014, Trueman et al., 2001). The perspective adopted in a BIA is that of the budget holder or payer (Sullivan et al., 2014, Garattini and van de Vooren, 2011). Time horizons considered in a BIA should also be relevant to the decision makers' budgeting cycle and process (Sullivan et al., 2014). BIA has been used in high-income countries such as Australia, Belgium, Canada, Hungary, Netherlands and United Kingdom (Sullivan et al., 2014, Garattini and van de Vooren, 2011, Trueman et al., 2001), and in middle-income countries such as Taiwan and Thailand (Sullivan et al., 2014) as a complement to economic evaluation in healthcare priority-setting processes for developing health benefits packages and national drug formularies.

#### *2.2.1.5 Evidence-based medicine*

Evidence-based medicine (EBM) refers to the “*conscientious, explicit and judicious use of best clinical evidence*” to inform decisions on the choice of health technologies for the care of patients (Gupta, 2003, Sackett et al., 1996). The best clinical evidence, considered more valid and reliable, is obtained from randomized control trials and systematic reviews of randomized control trials (Gupta, 2003, Sackett et al., 1996). The normative principle underpinning EBM is effectiveness which refers to the extent to which a health technology leads to a desired effect

(Gupta, 2003, Martin and Singer, 2000). Therefore, under EBM, decision-makers should select the health technology that provides the most effective way to achieve health (Gupta, 2003).

EBM can inform resource allocation decisions at all levels of the health system. At the micro-level, healthcare providers use EBM to decide whether to continue or discontinue providing a particular health technology to a patient based on the evidence of its effectiveness (Dickenson, 1999, Sackett et al., 1996). At the meso- or macro-level, decision-makers, policymakers or purchasers use EBM to make resource allocation decisions on whether or not to invest in resources for health technologies based on their effectiveness (Dickenson, 1999). This can be achieved by using comparative effectiveness research where the effectiveness of a new health technology is compared with that of an existing health technology (Daniels, 2016). The decision to remove less effective or ineffective health technologies from the list of admissible technologies in the health system reduces wastage and releases resources that can be invested in other effective interventions (Baltussen and Niessen, 2006, Tragakes and Vienonen, 1998).

While discipline-specific approaches provide useful frameworks for making healthcare priority-setting processes and decisions more explicit, they have been criticized for oversimplifying the array of factors or values that decisionmakers are required to take into consideration during healthcare priority-setting processes (Martin and Singer, 2000).

### 2.2.2 Multi-disciplinary approaches

A multi-disciplinary approach offers a procedural way of purposively combining different discipline-specific approaches to inform healthcare priority-setting. In this way, it marries the core principles of discipline-specific approaches. A multi-disciplinary approach recognizes that decision-makers cannot rely solely on a single principle provided by each discipline-specific approach given the complex, value-laden, and political nature of healthcare priority-setting processes (Baltussen and Niessen, 2006, Martin and Singer, 2003, Ham and Glenn, 2003,

Klein, 1993). Multi-disciplinary approaches also recognize that health systems aim to achieve multiple goals which cannot be achieved through healthcare priority-setting processes that rely on a single discipline-specific principle (Coulter and Ham, 2000). An example of a multi-disciplinary approach described in literature is HTA.

#### *2.2.2.1 HTA*

HTA offers a formal, structured, transparent, and inclusive process to ascertain explicitly whether resources will be allocated to a health technology based on its value (O'Rourke et al., 2020). This value is determined based on several dimensions of evidence namely safety, effectiveness, and economic, social, legal, and ethical aspects (O'Rourke et al., 2020, World Health Assembly, 2014).

Three approaches are used to determine value in HTA namely:- a) comparative effectiveness research which compares the health benefits and harms of alternative health technologies; b) economic evaluation through CEA which compares the costs and health benefits of alternative health technologies and, BIA which assesses the affordability of the health technology given available resource envelope; and, lastly, c) multi-criteria decision analysis which compares multiple attributes of alternative health technologies (Caro et al., 2019). Some of the criteria considered in MCDA include ethical, legal, and social implications of health technologies also commonly abbreviated as ELSI (Goodman, 2004).

During the HTA process, all stakeholders (or their representatives) who are likely to be affected by the resource allocation decisions arising from the healthcare priority-setting process should be involved (Jansen et al., 2017). By involving stakeholders, HTA enables negotiation and consideration of stakeholder values, expertise, and interests alongside technical evidence (Jansen et al., 2017). In this way, HTA also considers the discipline-specific approach on political science to increase explicitness. Given the consideration of multiple criteria and the



inclusion of multiple stakeholders, HTA provides a procedural framework for combining multiple discipline-specific approaches to expand the principles that inform explicit healthcare priority-setting processes and decisions. A HTA process typically consists of the following core steps namely topic (here in health technology) nomination; topic selection; assessment; appraisal; and decision making (Teerawattananon et al., 2019).

HTA has been widely applied in numerous high- and upper-middle-income such as Netherlands, New Zealand, Norway, Sweden, United Kingdom (UK), Thailand among others (World Health Organization, 2014, Ham and Glenn, 2003, Maynard and Bloor, 1998). HTA is conducted by priority-setting agencies, bodies, committees, or units. A global survey conducted by the World Health Organization (WHO) showed that only 39% of WHO member states had HTA agencies, bodies, committees, or units at the national or sub-national level (World Health Organization, 2015). This survey also showed that the highest number of countries without HTA agencies were in the African region (World Health Organization, 2015).

### 2.3 Healthcare priority-setting process as a procedural policy, and theoretical approaches for examining policy processes.

As indicated in Chapter 1, explicit healthcare priority-setting process is an example of a procedural policy, as such a policy refers to any course of action that changes how and by whom processes or functions of an organization or government are conducted (Howlett, 2017, Commonwealth of Learning, 2012). Processes through which policies are developed are referred to as policy processes (Buse et al., 2005). To examine policy processes that lead policymakers to formulate or develop policies on healthcare priority-setting, analysts can use policy analysis frameworks and theories (Smith et al., 2016, Smith et al., 2014).

Policy analysis frameworks and theories are useful in conducting either descriptive policy analysis (i.e., narrating how a policy is developed) or explanatory policy analysis (i.e., explaining how and why a policy is developed) (Moloughney, 2012). These frameworks and theories increase our understanding of how policies are formulated and enacted in real world contexts. According to recent literature reviews have identified the following policy analysis frameworks and theories as commonly used in examining policy processes in the health sector namely: - the Stages Heuristic Framework, the Policy Triangle Framework, Framework on determinants of political priority for global health initiatives, Punctuated Equilibrium Theory, Advocacy Coalition Framework, and the Multiple Streams Theory (Jones et al., 2021, Moloughney, 2012, Walt et al., 2008). These frameworks and theories are described further below.

### 2.3.1 The Stages Heuristic Framework

The Stages Heuristic Framework (Figure 2.1), proposed by Lasswell in 1956, is a descriptive framework that divides the policy process into six discrete stages: “*agenda-setting; policy formulation; legitimation; implementation; evaluation; and policy maintenance, succession, or termination*” (Moloughney, 2012, Cairney, 2011, Sabatier and Weible, 2007).

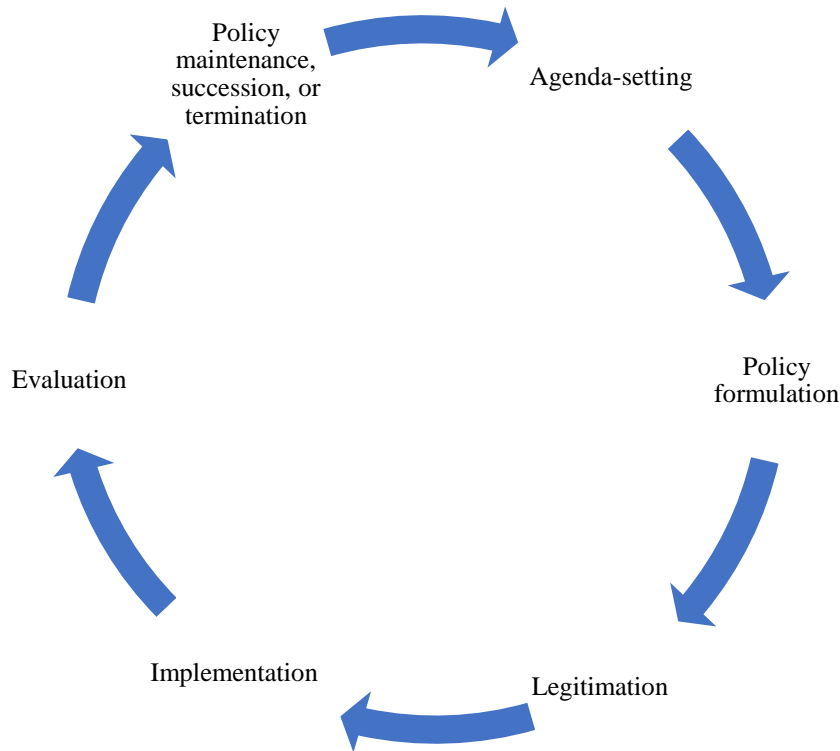


Figure 2.1: The Stages Heuristic Framework (Cairney, 2011).

The first stage is agenda-setting where problems or issues rise to or fall from the public agenda based on their importance or the interests of policymakers. The second stage is policy formulation in which solutions are developed in response to the problems or issues identified in the agenda-setting stage. The third stage is legitimation in which policy solutions receive support or approval from different arms of government (e.g., legislature or executive), interest groups, members of the public, and other relevant stakeholders. The fourth stage is implementation where legitimized policy solutions are enacted (put into effect). The fifth stage is evaluation where enacted policy solutions are assessed against desired goals and objectives. The last stage is policy maintenance, succession, or termination in which decisions are made on whether to uphold, modify, or discontinue the enacted policy based on the evaluation findings (Moloughney, 2012, Cairney, 2011, Sabatier and Weible, 2007).

While the Stages Heuristic Framework offers a simple model for describing policy processes, it has been criticized for being overly simplistic, inherently biased towards a top-down

approach that assumes linearity in the steps, as well as failing to recognize interactions between the stages and factors that may influence the policy process (Moloughney, 2012, Cairney, 2011, Sabatier and Weible, 2007). It therefore cannot explain how or why a policy comes into place.

### 2.3.2 The Policy Triangle Framework

The Policy Triangle Framework (Figure 2.2), proposed by Walt and Gilson in 1994, is another descriptive framework that identifies four key factors that may influence the politics of a policy process (Buse et al., 2005, Walt and Gilson, 1994). The four elements include content, context, actors, and process. Content refers to the substance of a policy in terms of ideas, objectives, and details. Context refers to economic, cultural, and socio-political factors within the system or environment. Actors refer to individuals, groups, organizations, or networks whose actions, interests, values, and locations in power structures can influence policy. Lastly, process refers to how policies are formulated, enacted, and evaluated (Buse et al., 2005, Walt and Gilson, 1994).

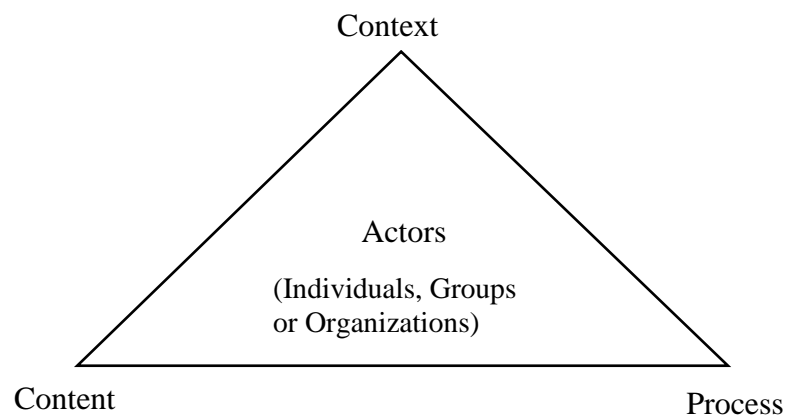


Figure 2.2: The Policy Triangle Framework (Walt and Gilson, 1994)

This framework has been applied widely in empirical studies to analyze numerous health policies, such as those on human resources for health, health service delivery (ante-natal, post-natal, mental health services), communicable and non-communicable diseases, health financing, health sector reforms, others across many countries of different income levels

(O'Brien et al., 2020, Gilson and Raphaely, 2008). For these reasons, the framework is considered adaptable and generalizable to different policies (O'Brien et al., 2020), different contexts irrespective of income level (Buse et al., 2005), and different stages of the policy cycle (Gilson and Raphaely, 2008). However, it has been criticized for being broad and simplified (O'Brien et al., 2020, Moloughney, 2012, Buse et al., 2005).

### 2.3.3 Framework on determinants of political priority for global health initiatives

The Framework on determinants of political priority for global health initiatives (Table 2.4), proposed by Shiffman and Smith in 2007, is an explanatory framework that identifies factors that may explain what influences the political priority for global health initiatives (Shiffman and Smith, 2007). Political priority refers to the extent to which political leaders take notice of and dedicate resources (technical, financial, or human) to issues or problems while a global health initiative refers to a coordinated activity at the national or international level that is aimed at dealing with issues or problems of worldwide concern (Shiffman and Smith, 2007).

This framework identifies four categories of factors namely actor power, ideas, political contexts, and issue characteristics. Actor power refers to the strength of actors (individuals and organizations) interested in the issue. Ideas refer to framing or the way in which an issue is defined, portrayed, and understood by interested actors. Political contexts refer to the conditions under which the actors work in. Lastly, issue characteristics refer to the features or attributes of the problem under consideration. Each of these categories is further characterized by different factors as shown in Table 2.4 (Shiffman and Smith, 2007).

Table 2.4: Framework on determinants for political priority for global health initiatives

<b>Category</b>	<b>Factor shaping political priority</b>	<b>Explanation</b>
<b>Actor power</b>	Policy Community cohesion	Extent of collaboration among actors concerned with the issue internationally

	Leadership	Champions and/ or individuals with the capacity to unite policy communities
	Guiding institutions	Strength of the organizations with the authority to guide the initiative
	Civil Society mobilization	Extent to which organized voluntary non-state institutions have rallied to persuade political authorities at the international and national level to deal with the issue.
<b>Ideas</b>	Internal Frame	How a policy community defines a problem, its causes, and solutions.
	External Frame	Ways in which the issue is publicly portrayed to increase its resonance with the public particularly political leaders who oversee resources.
<b>Policy context</b>	Policy windows	Windows of opportunity that are created when conditions for an issue align favourably thereby presenting advocates with opportunity to influence policymakers.
	Global governance structure	The extent to which the institutional structure allows for effective collective action at the global level
<b>Issue characteristics</b>	Credible indicators	Valid measurements that can be used for indicating gravity of an issue and/or tracking progress
	Severity	The magnitude of the issue relative to other issues as shown by an objective indicator
	Effective interventions	The extent to which potential solutions for addressing the issue are cost-effective, simple to implement, and inexpensive

While this framework is useful for cross-national and cross-policy analysis, it has been criticized for failing to recognize the inter-relationships that may exist between the different categories and factors (Walt and Gilson, 2014).

### 2.3.4 Punctuated Equilibrium Theory

The Punctuated Equilibrium Theory (Figure 2.3), proposed by Baumgartner and Jones in 1991, is an explanatory framework that explains what causes periods of stability and change in policymaking processes (Kuhlmann and van der Heijden, 2018, National Collaborating Centre for Healthy Public Policy, 2018, Baumgartner and Jones, 2010). According to this theory, stasis and change are shaped by four core concepts namely policy image, policy venue, attention allocation, and forces of resistance (Kuhlmann and van der Heijden, 2018, National Collaborating Centre for Healthy Public Policy, 2018, Baumgartner and Jones, 2010).

Policy image refers to how issues or problems and associated solutions are conceptualized based on facts, empirical knowledge, and/ or beliefs (Baumgartner and Jones, 2010, National Collaborating Centre for Healthy Public Policy, 2018). Policy venue refers to a group of actors (individuals or organizations) with the authority to make decisions on issues or problems of interest (Baumgartner and Jones, 2010). Attention allocation recognizes that policymakers can only focus on a few issues at a time given cognitive and time constraints (Kuhlmann and van der Heijden, 2018). Lastly, forces of resistance refer to organizations within political systems that may influence the process (Kuhlmann and van der Heijden, 2018).

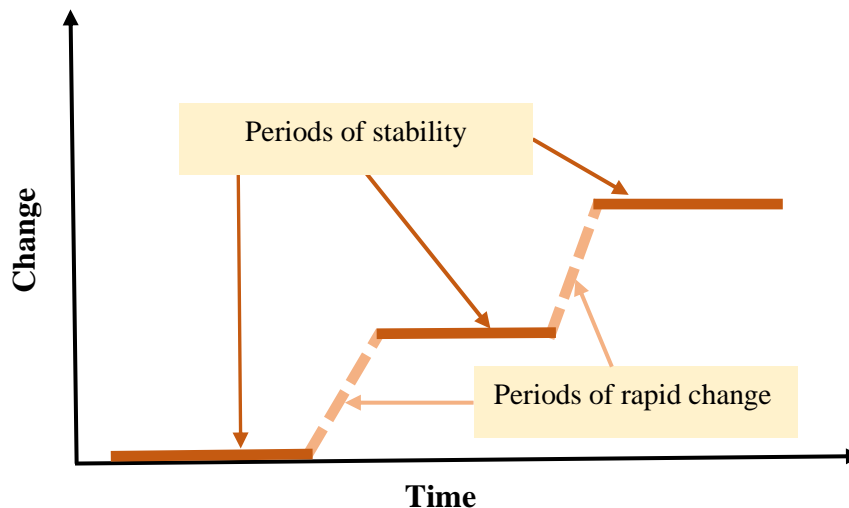


Figure 2.3: Graphic representation of the Punctuated Equilibrium Theory (National Collaborating Centre for Healthy Public Policy, 2018)

According to the punctuated equilibrium theory, periods of stasis (stability or equilibrium) in a policy process occur when a policy image and policy venue dominate or remain unchallenged over a lengthy period thus reinforcing existing policies. On the other hand, periods of change (instability or disequilibrium) occur when a policy image or policy venue changes thus questioning existing policies and stimulating changes in the policy process (National Collaborating Centre for Healthy Public Policy, 2018, Baumgartner and Jones, 2010). Change may also occur when actors strategically shop for or seek alliance with new policy venues (National Collaborating Centre for Healthy Public Policy, 2018).

While Punctuated Equilibrium Theory has been applied widely to study public policies on topics such as tobacco, nuclear energy, budget allocations (Baumgartner and Jones, 2010), its major criticism includes concerns over its universality or application in other political systems outside of the United States of America (USA) where it was first developed. These concerns arise from the theory's focus on federalist structures which offer a suitable milieu for punctuation given numerous policy venues (Kuhlmann and van der Heijden, 2018, National



Collaborating Centre for Healthy Public Policy, 2018). The framework has also been criticized for overlooking the influence of institutions on the policy process (National Collaborating Centre for Healthy Public Policy, 2018).

### 2.3.5 Advocacy Coalition Framework

The Advocacy Coalition Framework (Figure 2.4), proposed by Sabatier and Jenkins-Smith (1988), explains causes of policy stability and/ or change by examining policy processes over protracted periods of time. It contends that a policy process is influenced by the beliefs held by multiple policy actors and by factors in the wider environment in which the actors operate in (Cairney, 2011, Weible et al., 2009, Sabatier and Weible, 2007). These beliefs include shared values, assumptions, or perceptions about problems or issues and their solutions (Cairney, 2011, Weible et al., 2009, Sabatier and Weible, 2007). As a result of their shared beliefs, policy actors form advocacy coalitions within a policy subsystem. A policy subsystem refers to a group of actors involved in addressing a policy issue or problem. Shared beliefs enable advocacy coalitions to work together over long periods of time (Cairney, 2011).

During a policy process, different advocacy coalitions (with different beliefs) compete within the policy subsystem to ensure that selected policies reflect their beliefs. They achieve this by influencing how policymakers perceive and respond to issues or problems (Cairney, 2011, Sabatier and Weible, 2007). According to this framework, stability in the policy process arises due to difficulties in changing beliefs held by actors and domination of one advocacy coalition over others for extended periods of time. Nevertheless, policy changes may occur due to policy learning and external shocks (such as change of government, environmental disasters, and other socio-economic changes) which may prompt policy actors to question their beliefs or undermine the authority of the dominating advocacy coalition (Cairney, 2011, Sabatier and Weible, 2007).

The Advocacy Coalition Framework has been widely applied in policy analysis studies across different sectors including health (Pierce et al., 2017, Cairney, 2011, Weible et al., 2009), and different political contexts and levels of government (Pierce et al., 2017, Weible et al., 2009). While this framework avoids a linear representation of the policy process, it has been criticized for being complex thereby inadvertently limiting application of some of the concepts outlined in the framework (Weible et al., 2009). For example, a recent review found that several empirical studies had overlooked some components such as stable parameters and policy brokers (Weible et al., 2009). This framework has also been criticized for assuming that individual public health policies may be addressed within a single policy subsystem which is not often the case (Moloughney, 2012).

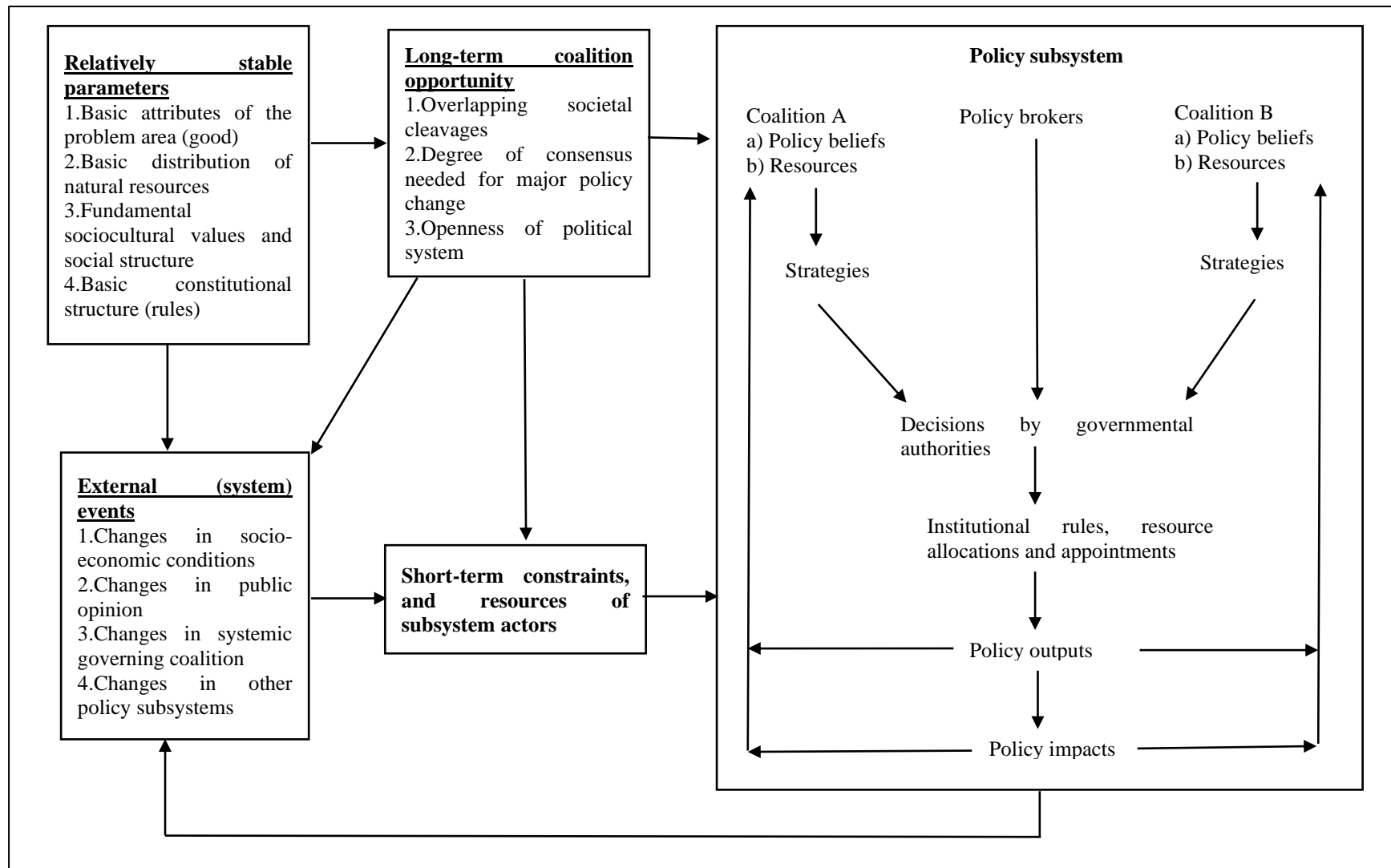


Figure 2.4: The Advocacy Coalition Framework (Weible et al., 2009)

### 2.3.6 Multiple Streams Theory

The Multiple Streams Theory (Figure 2.5), proposed by Kingdon in 1984, is an explanatory framework that explains how and why agenda-setting occurs. Agenda-setting refers to the process through which issues and potential policy solutions earn policymakers' attention leading to policy formulation (Kingdon, 1993, Kingdon, 1984).

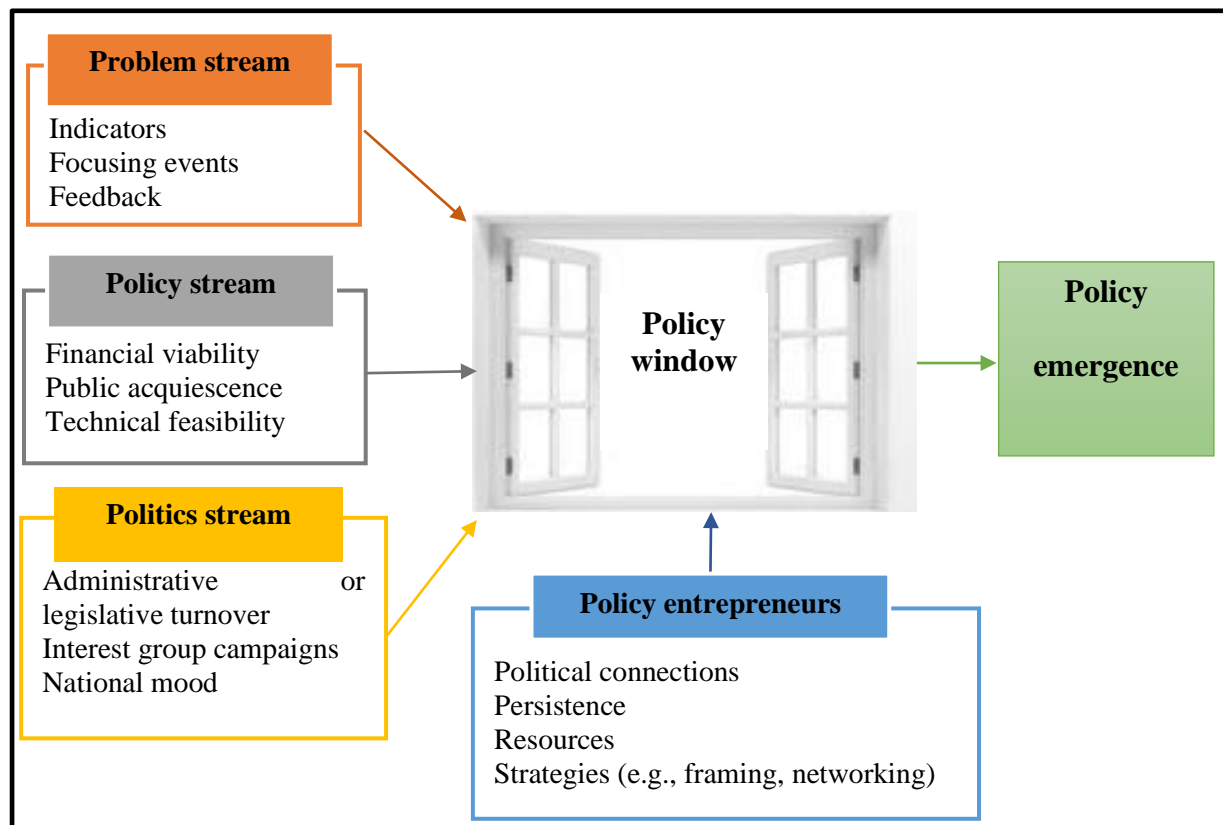


Figure 2.5: Kingdon's Multiple Streams Theory (Kingdon, 1993, Kingdon, 1984)

The three streams in Kingdon's theory are problem, policy, and politics. The problem stream refers to situations that deviate from what is considered normal or unrealized needs that require improvement through public (government) efforts (Kingdon, 1993). Problems become visible through indicators (measures of the level or severity of a problem), focusing events (unexpected occurrences such as crises or disasters that highlight a problem) and, feedback

(information given back on the performance of similar policies and programs) (Kingdon, 1993, Kingdon, 1984).

The policy stream refers to potential solutions for addressing the problems (Kingdon, 1993, Kingdon, 1984). Policy solutions are developed by policy communities which are composed of individuals who are interested in influencing a specific policy area (Kingdon, 1993). Since policy communities often develop numerous policy solutions, several factors influence which solution might be considered for adoption by policymakers. These factors include technical feasibility (whether the proposed solution works), public acquiescence (whether the general public or attentive publics- individuals who are better informed and keenly interested in a particular issue than the general public- find the proposed policy solution acceptable) and, financial viability (whether the proposed policy solution has acceptable cost implications given the existing budget) (Kingdon, 1993).

The politics stream refers to the political context surrounding the policy under consideration. This stream is characterized by factors such as administrative or legislative turnover (changes in administration or legislation arising from campaigns, elections and/or nominations), national mood (the general public's and/ or elected government officials' orientation towards issues) and, interest group pressure (demands for action by groups such as civil societies) (Kingdon, 1993, Kingdon, 1984).

According to the multiple streams theory, successful agenda-setting follows coupling of the problems, policy, and politics streams. Coupling refers to the matching of a potential policy solution to an identified problem within favorable political conditions (Kingdon, 1993, Kingdon, 1984). Coupling of the three streams occurs during a 'policy window', defined as a fleeting window of opportunity that expands or contracts the space for policymaking or adoption (Kingdon, 1993, Kingdon, 1984). A policy window opens due to compelling events

in the problem or politics stream which may influence the set of subjects on the decision agenda that policymakers pay attention to (Kingdon, 1993). Given the short nature of policy windows, timing is crucial: policy entrepreneurs must recognize them and act by introducing their preferred policy proposals when the political environment is receptive to change (Kingdon, 1993, Kingdon, 1984).

Policy entrepreneurs are actors within policy communities who are committed to engendering support for their preferred policy solutions from the public, other policy communities, and policymakers (Kingdon, 1993, Kingdon, 1984). They can be found inside or outside of government (Kingdon, 1984, Kingdon, 1993). The ability of policy entrepreneurs to achieve policy influence is determined by their political connections or access to key decision-makers. It is also determined by their persistence and willingness to invest resources (time, money, technical skills) into the process. Policy entrepreneurs can also influence policy by employing strategies such as:- a) framing (the structuring and presentation of information on problems or policies to generate specific views, meanings, or perceptions (Kingdon, 1993)); b) collecting evidence (Mintrom and Vergari, 1996, Mintrom, 2019); and, c) networking (engaging other relevant actors within policy communities to strengthen their likelihood of generating policy changes (Mintrom and Vergari, 1996, Mintrom, 2019).

Since its inception, multiple streams theory has been applied widely in individual and comparative policy analysis studies across multiple sectors and countries including LMICs (Gilson et al., 2018, Jones et al., 2016). Although this theory was originally developed to analyze the agenda-setting stage of the policy process, its application in empirical studies has extended beyond its original theorization to include other stages of the policy process (Nikolaos, 2007). While this framework does not assume linearity, it has been criticized for assuming that the three streams flow independently which is not often the case. For example,

the same actors may be involved in the problems identification and development of solutions (Moloughney, 2012).

### 2.3.7 Summary on the policy analysis theories and frameworks

Of the 6 conceptual frameworks and theories discussed here, only the Stages Heuristic and the Policy analysis triangle are descriptive. The other frameworks and theories namely the Advocacy Coalition Framework, Framework on determinants of political priority for global health initiatives, Punctuated Equilibrium Theory, and the Multiple Streams Theory are explanatory. These explanatory frameworks offer explanations of policy change as they clarify how the concepts outlined in the frameworks work as mechanisms of change. The policy analysis theories and frameworks outlined in this section constituted key search terms for the literature review provided in Chapter 3.

## 2.4 Conceptual frameworks for evaluating healthcare priority-setting processes

As countries implement explicit healthcare priority-setting processes, there is accompanying demand to evaluate them (Smith et al., 2012). Existing frameworks on evaluation of healthcare priority-setting processes depict normative conditions drawn from two philosophical traditions- proceduralism and consequentialism (Coulter and Ham, 2000). Proceduralism judges whether a healthcare priority-setting process follows acceptable procedures or ways of doing things while consequentialism judges whether a healthcare priority-setting process leads to acceptable outcomes (Jan, 2014). Evaluation of healthcare priority-setting processes highlights what happens in practice and provides opportunities for improvement where actual practice deviates from normative procedural or outcome conditions (Smith et al., 2012).

Since none of the discipline-specific guiding principles can be considered the overarching principle for guiding healthcare priority-setting processes given the complexity of allocating

scarce resources and the multiplicity of health systems goals, it is important that healthcare priority-setting processes follow procedures that are considered fair, legitimate, transparent, and publicly defensible (Daniels, 2000, Coulter and Ham, 2000, McKneally et al., 1997). Several frameworks have been developed to guide healthcare priority-setting processes to meet the normative procedural and outcome conditions that would make the processes fair, legitimate, transparent, and publicly defensible. These frameworks, described below, have also been used to qualitatively evaluate healthcare priority-setting processes.

#### 2.4.1 Accountability for reasonableness framework

The Accountability for Reasonableness framework (Figure 2.6), proposed by Daniels and Sabin, was developed from empirical findings of a case study on meso-level healthcare priority-setting by Managed Care Organizations in the USA (Daniels and Sabin, 1997). In this framework, a healthcare priority-setting process is considered fair and legitimate if its procedure meets four conditions namely publicity, reasonableness, appeals, and enforcement. These conditions are drawn from principles of deliberative democracy (Daniels and Sabin, 1997). A fifth procedural condition on empowerment was added to this framework following a case study on meso-level healthcare priority-setting process by a hospital in Toronto, Canada (Gibson et al., 2005). Empowerment refers to the creation of an enabling environment by minimizing power differences among stakeholders involved in the healthcare priority-setting process and providing equal opportunities for participation (Gibson et al., 2005).

The Accountability for Reasonableness framework has been used to qualitatively evaluate macro-level healthcare priority-setting processes across high-income countries such as Canada (Martin et al., 2002, Ham and Glenn, 2003), UK, Norway, and Netherlands (Ham and Glenn, 2003). It has also been applied in qualitative evaluations of meso-level healthcare priority-setting processes in high-income countries such as Canada (Madden et al., 2005) and lower-middle income countries such as Tanzania (Maluka et al., 2010), Kenya (Bukachi et al., 2014),



and Zambia (Zulu et al., 2014). Lastly, this framework has also provided the theoretical underpinnings of other evaluation frameworks such as the Social Values Framework (Clark and Weale, 2012), the Sibbald et al., framework (Sibbald et al., 2009), and the Barasa et al., framework (Barasa et al., 2015).

1. **Publicity**- Decisions regarding coverage for new technologies (and other limit-setting decisions) and their rationales must be made publicly accessible.
2. **Reasonableness**- The rationale for coverage decisions should be based on reasons and principles that are considered acceptable, reasonable, and contextually relevant by fair-minded people.
3. **Appeals**- There is a mechanism for challenge and dispute resolution regarding limit-setting decisions, including opportunity for revising decisions based on further evidence or arguments.
4. **Enforcement** – There is either a voluntary or public regulation of the process to ensure that publicity, reasonableness, and appeals are met.

Figure 2.6: Accountability for Reasonableness framework (Daniels and Sabin, 1997)

#### 2.4.2 Social Values Framework

The Social Values Framework (Figure 2.7), proposed by Clark and Weale, was developed from a review of bioethics and decision-making literature, as well as values outlined in the Accountability for Reasonableness framework (Clark and Weale, 2012). This framework defines a healthcare priority-setting process as socially justifiable and legitimate if its procedure meets the social values related to process and content (Clark and Weale, 2012).

In this framework, social values refer to the moral and ethical judgements that are shared by a community of people while process values refer to *'how decisions are made'*, and content

values refer to the *'rationale or criteria upon which decisions are made'* (Clark and Weale, 2012). The process values, which are based on the principles of democratic decision-making and procedural justice, include transparency, participation, and accountability. The process values are closely linked, for example, participation may influence transparency and vice versa. Content values include cost-effectiveness, clinical effectiveness, equity/ justice, autonomy, and solidarity (Clark and Weale, 2012).

The Social Values Framework has been applied in empirical studies to qualitatively examine macro-level healthcare priority-setting processes in high-income countries such as Australia (Whitty and Littlejohns, 2015), UK (Littlejohns et al., 2012) and Korea (Ahn et al., 2012) and, middle-income countries such as Iran (Rashidian et al., 2018).

### **PROCESS VALUES**

1. **Transparency**- information on who makes the decisions, what reasons (criteria) they considered, and what processes they followed should be publicly available.
2. **Accountability**- who is held accountable, for what and how and, who does the holding to account.
3. **Participation**- Different members of the public can participate and contribute to the priority-setting process.

### **CONTENT VALUES**

1. **Clinical effectiveness**- A principle that provides scientific evidence of the additional benefits (effectiveness) of a new technology over existing alternative(s).
2. **Cost-effectiveness**- A principle that seeks to establish whether differences in costs between alternative health technologies can be justified in terms of the health benefits they produce.
3. **Justice/ equity**- A principle that aims to promote fairness by minimizing differences by treating like cases as like and unlike as unlike.
4. **Autonomy**- A principle that refers to the ability of individuals to be self-directing and to make decisions for themselves about how to spend their money and what healthcare services they should purchase.
5. **Solidarity**-A principle that implies commitment of all members of the society to stand together without leaving anyone behind.

Figure 2.7: The Social Values Framework (Clark and Weale, 2012)

#### 2.4.3 Sibbald et al., conceptual framework for successful priority-setting

The Sibbald et al., conceptual framework for successful priority-setting (Figure 2.8) was developed from empirical findings of a qualitative study based on interviews with stakeholders who were directly involved in healthcare priority-setting processes (decision-makers, patients and, priority-setting scholars) in four high-income countries (Canada, Norway, UK and USA) and one low-income country (Uganda) (Sibbald et al., 2009).

According to this framework, a successful healthcare priority-setting process is characterized by the fulfilment of separate but interconnected process and outcome conditions. The process conditions include stakeholder engagement, explicitness, information management, context and values, and revisions/appeals mechanism. The outcome conditions are stakeholder understanding, stakeholder acceptance and satisfaction, shifted priorities, positive externalities and, improved decision making quality (Sibbald et al., 2009). The Sibbald et al., framework has been used in empirical studies to evaluate meso-level healthcare priority-setting processes in high-income countries such as Canada (Sibbald et al., 2010).

### **PROCESS CONDITIONS**

1. **Stakeholder engagement-** Identification and effective involvement of relevant internal and external stakeholders.
2. **Explicit process-** A transparent process where it is clear to all stakeholders who is making the decisions, how the decisions will be made, and why the decisions were made.
3. **Information management-** Information/ evidence made available for the priority-setting and decision-making process as well as its management including collection, collation, and presentation.
4. **Consideration of context and values-** Application of the values of the priority-setting organization and stakeholders (community members, decision-makers, patients and, policymakers).
5. **Revisions and appeals-** A formal mechanism for reviewing decisions and addressing disagreements constructively based on new information or errors to be corrected.

### **OUTCOME CONDITIONS**

6. **Stakeholder understanding-** Stakeholders gain insight into the goals and rationales of the priority-setting process and decisions. Stakeholder understanding increases stakeholder acceptance and confidence.
7. **Shifted priorities and /or reallocation of resources-** The priority-setting process leads to changes in the allocation and use of resources.
8. **Improved decision-making quality-** The priority-setting process improves the quality of decision-making through appropriate and consistent use of evidence, compliance with the prescribed process, and institutionalization of an evidence-based approach.
9. **Stakeholder acceptance and satisfaction-** The experience of the priority-setting process increases internal and external stakeholders' contentment and continued willingness to participate in future priority-setting processes.
10. **Positive externalities-** The priority-setting process is accompanied by peer emulation, health sector recognition and/ or changes in health sector policies and practice.

Figure 2.8: Sibbald et al.'s framework (Sibbald et al., 2009)

#### 2.4.4 Kapiriri and Martin framework for evaluation of priority-setting

The Kapiriri and Martin framework for evaluation of priority-setting outlines measures of a successful healthcare priority-setting process based on document reviews and interviews with researchers and policymakers in twelve low- and middle-income countries (Kapiriri and Martin, 2010). These measures were classified as internal or external relative to the priority-setting organisation and, immediate or delayed based on the timing of their achievement relative to the budget year (Figure 2.9). Immediate parameters were achieved within a budget year while delayed parameters were expected beyond three fiscal years (Kapiriri and Martin, 2010).

<b>Immediate</b>	<b>Delayed</b>
<i>Internal</i>	
<ul style="list-style-type: none"> <li>○ Increased efficiency of the process</li> <li>○ Improved quality of the decisions</li> <li>○ More appropriate allocation of resources</li> <li>○ Increased use of evidence</li> <li>○ Fairer priority-setting process               <ul style="list-style-type: none"> <li>▪ Availability of clear priority-setting criteria</li> <li>▪ Increased participation</li> <li>▪ Availability of explicit relevant priority-setting criteria</li> <li>▪ Functional mechanisms for appeal</li> <li>▪ Functional mechanisms for enforcement</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>○ Increased stakeholder understanding, satisfaction and compliance</li> <li>○ Reduced dissensions</li> <li>○ Reduced resource wastage</li> <li>○ Improved internal accountability/reduced corruption</li> <li>○ Strengthened institutional capacity</li> <li>○ Impact on institutional goals and objectives</li> </ul>
<i>External</i>	
<ul style="list-style-type: none"> <li>○ Reflection of public values</li> <li>○ Increased public awareness</li> <li>○ Increased public confidence in and acceptance of decisions</li> </ul>	<ul style="list-style-type: none"> <li>○ Impact on health policy and practice</li> <li>○ Achievement of health system goals</li> <li>○ Improved financial and political accountability</li> <li>○ Increased investment in the health sector and strengthening of the healthcare system</li> </ul>

Figure 2.9: Kapiriri and Martin framework for priority-setting (Kapiriri and Martin, 2010)

In 2017, the Kafiriri and Martin framework was validated and reorganized into five domains namely contextual factors, pre-requisites, the priority-setting process, implementation and, outcome and impact (Figure 2.10) (Kafiriri, 2017).

<b>Domains</b>	<b>Parameters of successful priority-setting</b>
<b>Contextual factors</b>	<ul style="list-style-type: none"> <li>○ Conducive political, economic, social, and cultural context</li> </ul>
<b>Pre-requisites</b>	<ul style="list-style-type: none"> <li>○ Political will</li> <li>○ Resources</li> <li>○ Legitimate and credible institutions</li> <li>○ Availability of incentives</li> </ul>
<b>The priority-setting process</b>	<ul style="list-style-type: none"> <li>○ Stakeholder participation</li> <li>○ Use of clear priority-setting process, tools, or methods</li> <li>○ Use of explicit relevant priority-setting criteria</li> <li>○ Use of evidence</li> <li>○ Reflection of public values</li> <li>○ Publicity of priorities and criteria</li> <li>○ Functional mechanisms for appealing the decisions</li> <li>○ Functional mechanisms for enforcement</li> <li>○ Efficiency of the priority-setting process</li> <li>○ Decreased resource wastage/ misallocation</li> <li>○ Improved internal accountability/ reduced corruption</li> <li>○ Increased stakeholder understanding, satisfaction, and compliance with the priority-setting process</li> <li>○ Reduced dissensions</li> </ul>
<b>Implementation</b>	<ul style="list-style-type: none"> <li>○ Allocation of resources according to priorities</li> <li>○ Improved internal accountability</li> <li>○ Strengthening of the priority-setting institution</li> <li>○ Impact on priority-setting institutional goals and objectives</li> </ul>
<b>Outcome and impact</b>	<ul style="list-style-type: none"> <li>○ Impact on health policy and practice</li> <li>○ Attainment of health systems goals</li> <li>○ Improved financial and political accountability</li> <li>○ Increased investment in the health sector and strengthening of the healthcare system</li> </ul>

Figure 2.10: Kafiriri and Martin validated framework for priority-setting (Kafiriri, 2017)

This validated framework has been used in empirical studies to qualitatively evaluate macro-level priority-setting processes in 18 low, lower-middle, and upper-middle income countries in Africa (Kapiriri et al., 2021) and in Uganda (Essue and Kapiriri, 2018, Wallace and Kapiriri, 2019, Kapiriri and Be LaRose, 2019, Kapiriri et al., 2019, Wallace and Kapiriri, 2017). In applying the Kapiriri and Martin framework, authors noted that not all parameters identified in the framework could be assessed within the scope of the studies. Examples of parameters which could not be assessed included extent of political accountability (Wallace and Kapiriri, 2019), achievement of health systems goals (Wallace and Kapiriri, 2019, Wallace and Kapiriri, 2017), internal accountability (Kapiriri and Be LaRose, 2019), increased public awareness (Wallace and Kapiriri, 2017), and reduced resource wastage (Kapiriri and Be LaRose, 2019, Wallace and Kapiriri, 2017).

#### 2.4.5 Barasa et al., framework for evaluating healthcare priority-setting processes

The Barasa et al., framework (Figure 2.11) is based on a synthesis of conceptual and empirical literature on evaluation of healthcare priority-setting processes. It incorporates normative procedural and outcome conditions of the following evaluative frameworks: - Accountability for reasonableness, Kapiriri and Martin, Sibbald et al., and the Social Values Framework (Barasa et al., 2015).

According to the Barasa et al., framework, a healthcare priority-setting process should meet the procedural conditions and yield the outcome conditions. The procedural conditions include transparency, use of evidence, stakeholder engagement, empowerment, community values, revisions, and enforcement. The outcome conditions include efficiency, equity, stakeholder satisfaction, stakeholder understanding, reallocation of resources and implementation of decisions (Barasa et al., 2015). The framework recognizes interconnections between procedural and outcome conditions as shown on Figure 2.11.



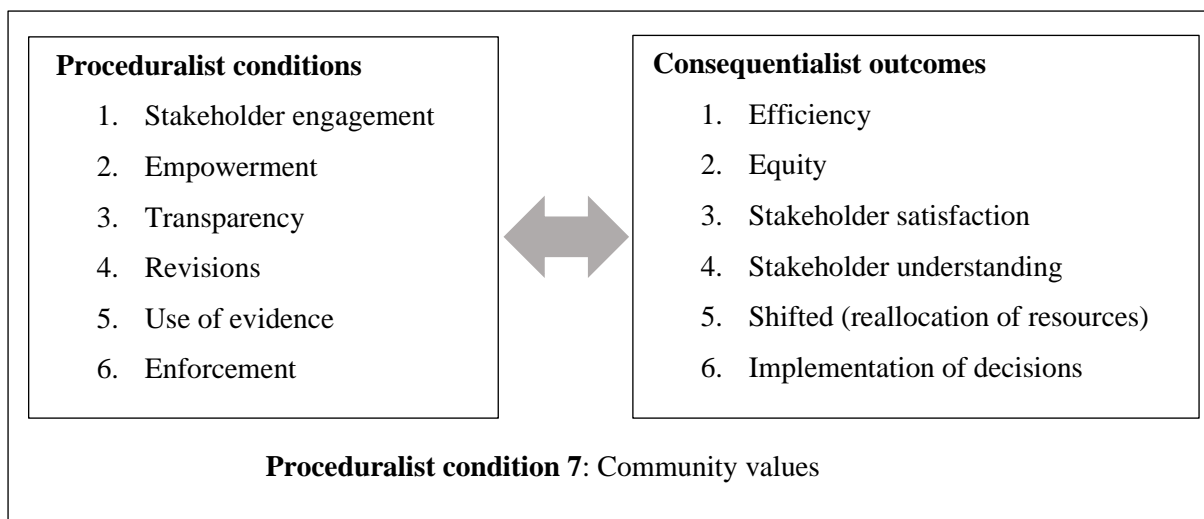


Figure 2.11: Barasa et al., framework for evaluating priority-setting processes (Barasa et al., 2015).

The definitions of the procedural and outcome conditions outlined in this framework are provided in Table 2.5.

Table 2.5: Definitions of the conditions outlined in Barasa et al., Framework

<b>Procedural condition</b>	<b>Definition</b>
Stakeholder involvement	Relevant stakeholders are effectively involved in the healthcare priority-setting process.
Empowerment	Stakeholders have power to contribute and influence decisions during the priority-setting process.
Transparency	The procedures, decisions and reasons for priority-setting decisions are accessible to all stakeholders.
Revisions	The presence of a mechanism for revising priority-setting decisions based on new evidence.
Use of evidence	Quality evidence/information should be used to inform the healthcare priority-setting process and decisions
Enforcement	A mechanism for ensuring that all the other procedural conditions are adhered to.
Incorporation of community values	The healthcare priority-setting process should be based on values determined by the community
<b>Outcome condition</b>	<b>Definition</b>

Efficiency	A principle of priority-setting that enables allocation of resources in a manner that maximizes community's welfare
Equity	A principle of priority-setting that enables allocation of resources based on need
Stakeholder understanding	Stakeholders demonstrate understanding of the structure, content, and process of healthcare priority-setting.
Stakeholder satisfaction	Stakeholders report their satisfaction with the adopted healthcare priority-setting process.
Shifted (reallocation of resources)	The priority-setting process results in real movement of resources and real changes in priorities
Implementation of decisions	Priority-setting process results in accountable implementation of decisions

The Barasa et al., framework has been applied in empirical studies to qualitatively evaluate meso-level healthcare priority-setting processes in Kenya (Waithaka et al., 2018, Barasa et al., 2017). In the application of the framework, it was noted that equity and efficiency were explored in terms of their use as priority-setting criteria but not as outcomes of the process (Barasa et al., 2017, Waithaka et al., 2018). In addition, in developing this framework, Barasa et al., noted that attributing equity, efficiency, and improvement of health systems goals to a specific healthcare priority-setting process was challenging as these factors could be influenced by other processes within the health system (Barasa et al., 2015).

#### 2.4.6 Comparison of the evaluation frameworks

A comparison of these frameworks for evaluating healthcare priority-setting (Table 2.5) reveals the following. Firstly, while the terms used to describe priority-setting processes - fair, legitimate, successful, or socially justifiable- differed across the frameworks, the fundamental meaning of these terms was similar as it lay in the fulfilment of the procedural and/ or outcome conditions outlined in the frameworks. Therefore, a healthcare priority-setting process is

described as fair, legitimate, successful, or socially justifiable if it fulfils the procedural and/ or outcome conditions outlined in the framework of choice.

Secondly, there were similarities and differences in the procedural conditions across the evaluative frameworks. All 5 frameworks recognized two procedural conditions namely publicity/ transparency and reasonableness/use of evidence/content values. Four frameworks recognized appeals/revisions mechanism (Accountability for Reasonableness, Sibbald et al., Kapiriri and Martin and, Barasa et al., frameworks) and stakeholder engagement/participation (Social Values Framework, Sibbald et al., Kapiriri and Martin and, Barasa et al., frameworks). Three frameworks recognized community/ public values (Sibbald et al., Kapiriri and Martin and, Barasa et al., frameworks) which were dependent on the range of stakeholders involved in the process. Two frameworks recognized accountability (Social Values Framework and Kapiriri et al., framework) and empowerment (Accountability for Reasonableness, and Barasa et al., frameworks).

Thirdly, there were similarities and differences in the outcome conditions across the evaluative frameworks. While the Accountability for Reasonableness and Social Values Frameworks do not outline any outcome conditions, the Sibbald et al., the Kapiriri and Martin, and the Barasa et al., frameworks recognized three similar outcome conditions namely stakeholder understanding; stakeholder acceptance and satisfaction; and shifted priorities/ reallocation of resources/ impact on health policy and practice/ implementation of decisions. The latter conditions were merged given the similarities in the meanings of the conditions as used in the individual frameworks. This broader classification of the criteria can also accommodate multiple interpretations based on healthcare priority-setting process and the context under consideration. Only one framework recognized accountability (Kapiriri and Martin framework) and equity and efficiency (Barasa et al., framework). However, as noted in Section 2.4.5, during

empirical application of the Barasa et al., framework, equity and efficiency were considered as priority-setting criteria that were used in the priority-setting process.

Lastly, none of these frameworks is universally accepted as the gold standard for evaluating healthcare priority-setting practices. The choice of the framework depends on its suitability to the healthcare priority-setting process and context under consideration. These evaluation frameworks were used as key search terms for the literature review in Chapter 3.

Table 2.6: Comparison of the procedural and outcome conditions across the evaluation frameworks

	<b>Accountability for Reasonableness Framework</b>	<b>Social values Framework</b>	<b>Sibbald et al., Framework</b>	<b>Kapiriri and Martin Framework</b>	<b>Barasa et al., Framework</b>
<b>Description of priority-setting process</b>	Fair & legitimate	Socially justifiable & legitimate	Successful	Successful	
<b>Sources of data</b>	Empirical	Literature review	Empirical	Empirical	Literature review
<b>Procedural or process conditions</b>	Publicity	Transparency	Explicitness	Explicitness	Transparency
	Reasonableness	Content values (autonomy, clinical effectiveness, cost-effectiveness, equity, solidarity)	Information management	Use of evidence	Use of evidence
	Appeals	-	Appeals/Revisions	Appeals & revisions	Revisions
	Enforcement	-	-	Enforcement	Enforcement
	-	Participation	Stakeholder engagement	Stakeholder Participation	Stakeholder engagement
	-	Accountability	-	Accountability	-
	-	-	Consideration of context and values	Reflection of public values	Community values
	Empowerment	-	-	-	Empowerment
	-	-	-	-	Equity
	-	-	-	-	Efficiency

<b>Outcome conditions or parameters</b>	-	-	-	Accountability	-
	-	-	Stakeholder understanding	Stakeholder understanding	Stakeholder understanding
	-	-	Shifted priorities/ reallocation of resources	Appropriate allocation of resources	Shifted priorities/ reallocation of resources
	-	-	Improved decision- making quality	Improved quality of decisions	-
	-	-	Stakeholder acceptance and satisfaction	Stakeholder & public acceptance, satisfaction & confidence	Stakeholder satisfaction
	-	-	Positive externalities	Impact on health policy and practice; Achievement of health system goals	Implementation of decisions

## 2.5 Chapter summary

In this Chapter, I have highlighted three key things. Firstly, explicitness in healthcare priority-setting can be achieved through discipline-specific or multi-disciplinary approaches. While each discipline-specific approach provides a single normative guiding principle, multidisciplinary approaches combine multiple guiding principles to inform healthcare priority-setting decisions. Given the complex, value-laden, and inherently political nature of healthcare priority-setting, a multidisciplinary approach such as HTA offers a better procedural and analytical approach for conducting healthcare priority-setting by combining multiple principles.

Secondly, an explicit healthcare priority-setting process is an example of a procedural policy, as such a policy refers to any course of action that changes how and by whom processes, or functions of an organization or government are conducted. To analyse processes that lead to the development of policies on explicit healthcare priority-setting processes, analysts can use any of the policy analysis theories and conceptual frameworks outlined in this Chapter. These theories and conceptual frameworks informed the key search terms for the literature review in Chapter 3.

Thirdly, once a healthcare priority-setting process has been implemented, it is vital that it is evaluated to determine its quality in terms of fulfilment of normative procedural and outcome conditions of a good, fair, legitimate, socially justifiable, or successful healthcare priority-setting process. This evaluation can be done qualitatively using one of the conceptually and empirically derived evaluative frameworks outlined in this Chapter. These evaluative frameworks also informed the key search terms for the literature review in Chapter 3.

## CHAPTER 3: A SCOPING LITERATURE REVIEW ON POLICY PROCESSES AND EVALUATION OF HEALTHCARE PRIORITY-SETTING PROCESSES AT THE MACRO-LEVEL.

### 3.1 Introduction

While there is growing interest in the introduction and evaluation of explicit healthcare priority-setting processes, several authors have indicated that studies on the process of introducing healthcare priority-setting processes (Smith et al., 2016, Smith et al., 2014) and studies evaluating existing healthcare priority-processes remained limited (Barasa et al., 2015, Smith et al., 2012, Martin and Singer, 2003). In this chapter, I present a scoping literature review which had the aim of guiding the PhD by identifying gaps and synthesizing evidence from empirical studies on policy processes and evaluation of healthcare priority-setting processes at the macro-level globally.

### 3.2 Methods

#### 3.2.1 Study design

I conducted a scoping literature review as it is suitable for identifying the extent of existing research work, synthesizing and disseminating research findings, and identifying research gaps in a topic of interest (Arksey and O'Malley, 2005). These reasons matched the objectives of this literature review.

#### 3.2.2 Literature search

I searched for relevant literature in six databases namely PubMed, Embase, CINAHL, Scopus, EconLit and Google Scholar. I derived the key search terms (Table 3.1) from the research objective. I conducted the first search in PubMed using MESH terms (where applicable) and/or free-text terms in all fields (titles, abstract and full text). The search terms were combined with relevant Boolean characters to form a broad search string. This search strategy was then



translated to other databases using appropriate database thesaurus, subject headings, and truncations. The 1st search was conducted in 2019 and later updated in December 2021. The key search terms and the search strategy were reviewed and approved by the supervisory team.

Table 3.1: Key search terms applied in the review

Aspect of the search term	Examples of key search terms used
<b>1. Policy analysis</b>	Policy triangle framework OR framework on determinants of political priority OR advocacy coalition framework OR punctuated equilibrium theory OR multiple streams theory OR agenda setting OR policy analysis
	OR
<b>2. Evaluation</b>	Fair* OR legitima* OR ethic* OR success* OR accountability for reasonableness OR social values framework OR evaluat*
	AND
<b>3. Process of interest</b>	Healthcare priority-setting OR health care priority setting OR healthcare rationing OR resource allocation
	AND
<b>4. Health system level</b>	Macro OR nation* OR country-level

### 3.2.3 Article selection

I selected articles using the following three-pronged process. Firstly, I reviewed titles of articles identified through the search for relevance to the eligibility criteria (Table 3.2). Any titles that failed to meet the inclusion criteria were excluded. Secondly, I assessed the abstracts of potentially relevant articles against the eligibility criteria and excluded those that failed to meet the inclusion criteria. Lastly, I assessed full articles against the eligibility criteria and excluded those that failed to meet the inclusion criteria. The full list of retrieved literature was reviewed and approved of by the supervisory team. This process is summarised in the search flow diagram in Figure 3.1.

Table 3.2: Eligibility criteria

<b>Criteria</b>	<b>Include</b>	<b>Exclude</b>
<b>Level</b>	Macro-level	Micro or meso-level
<b>Sector</b>	Health	Non-health
<b>Language</b>	English	Non-English
<b>Type of literature</b>	Empirical	Opinion pieces, grey literature, commentaries, books, chapters
<b>Access</b>	Full access	No full access

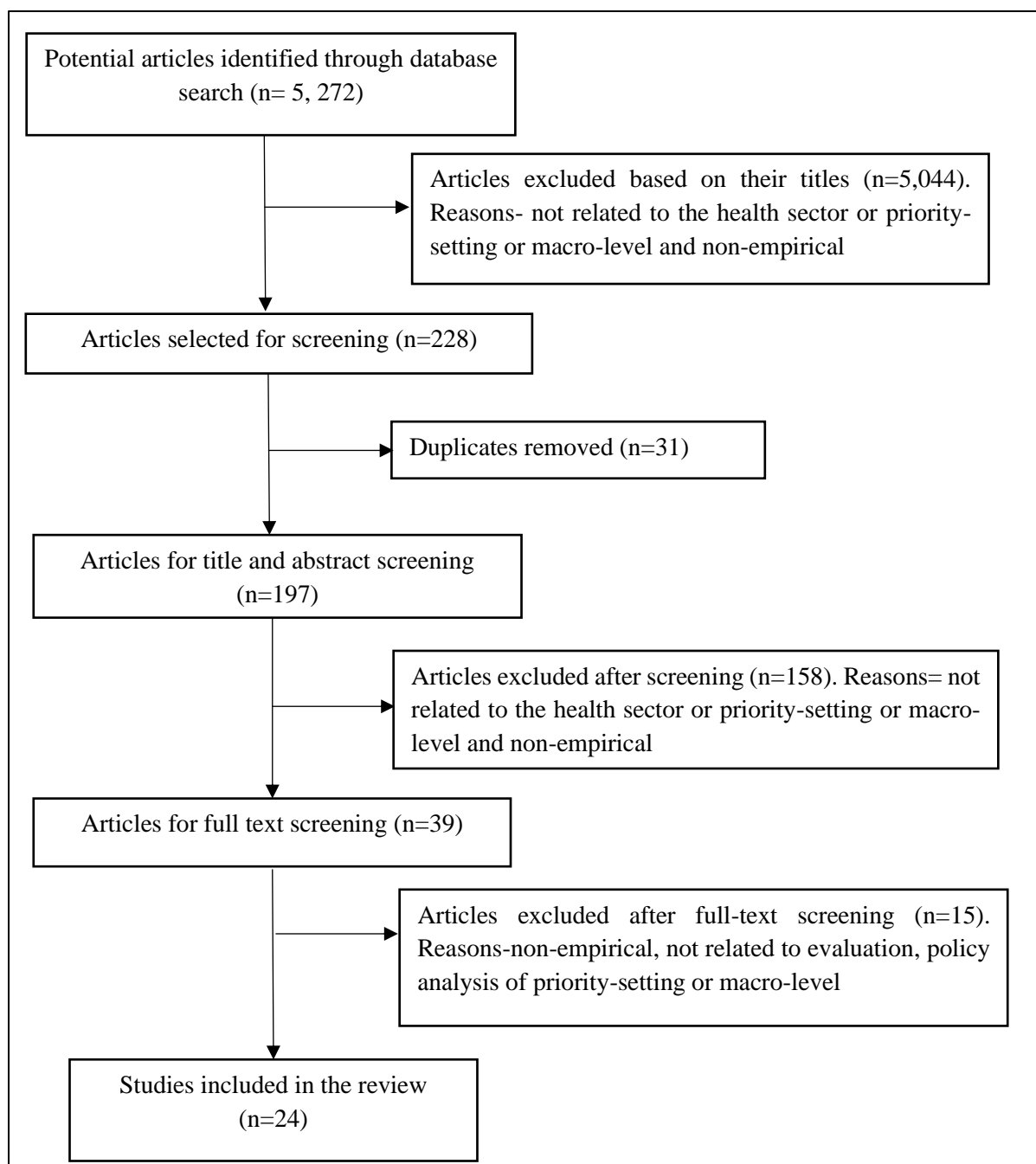


Figure 3.1: Search flow diagram

### 3.2.4 Quality appraisal

I appraised the quality of the 24 articles that met the inclusion criteria using the Critical Appraisal Skills Program (CASP) checklist for qualitative studies (Critical Appraisal Skills

Programme, 2018). Some criteria such as ethical requirements were not applicable in studies that only reviewed documents. None of the studies discussed researcher positionality. The supervisory team reviewed the appraisal results and agreed that the quality of the articles was acceptable and therefore no studies were excluded (Table 3.3).

Table 3.3: CASP Quality appraisal checklist

<b>Appraisal criteria</b>	<b>Yes</b>	<b>Some what</b>	<b>No/Not clear/ Not applicable</b>
1. Clear statement of the study aims	24	0	0
2. Appropriate methodology for the study	24	0	0
3. Appropriate research design for the study	24	0	0
4. Appropriate recruitment strategy for the study	24	0	0
5. Appropriate data collection methods and settings for the study	24	0	0
6. Adequate consideration of the role, potential bias, and influence of the researcher during formulation of study, data collection, and analysis	0	0	24
7. Consideration of ethical issues	13	1	10
8. Rigorous and in-depth description of data analysis, and presentation of sufficient data to support the study findings	21	1	2
9. Clear statement of research findings	24	0	0
10. Clear statement of the value of the research	24	0	0

### 3.2.5 Data extraction

I analyzed the retrieved literature thematically using Braun and Clarke’s 6-step approach (Braun and Clarke, 2006). In step 1, I immersed myself in the data through reading and re-reading. In Step 2, I generated a primary list of codes from the data based on the concepts outlined in the studies. In Step 3, I developed themes by grouping like codes together. In Step

4, I reviewed the themes for coherence with the coded data extracts. In Step 5, I applied the themes across the retrieved literature to generate study findings. In Step 6, I synthesized the findings into a report which was reviewed and approved by the supervisory team.

### 3.2.6 Characteristics of the retrieved literature

I included 24 articles in this review (Appendix 1). All the articles used qualitative methods to collect data. The articles covered 40 countries of different income levels (Table 3.4). The number of countries exceeds the number of articles since 7 of the 24 articles were multi-country studies (Charvel et al., 2018, Cleemput et al., 2012, Greß et al., 2005, Kapiriri et al., 2021, Kapiriri et al., 2007, Mitton et al., 2006, Sabik and Lie, 2008).

Table 3.4: Countries examined in the retrieved articles by continent and income-level

<b>By continent</b>	<b>Income-level</b>	<b>Examples of countries</b>	<b>Number</b>
<b>Africa</b>	Upper-middle-income countries (U-MICs)	South Africa	1
	Lower-middle-income countries (L-MICs)	Algeria, Angola, Cameroon, Cape Verde, Ghana, Kenya, Nigeria, Tanzania	8
	Low-income countries (LICs)	Burkina Faso, Chad, Democratic Republic of Congo, Ethiopia, Mali, Mozambique, Niger, Rwanda, Uganda, Zambia	10
<b>Asia</b>	High-income countries (HICs)	Israel, Korea	2
	U-MICs	Thailand	1
	L-MICs	Iran	1
<b>Europe</b>	HICs	Austria, Belgium, Denmark, France, Germany, Netherlands, Norway, Sweden, Switzerland, United Kingdom (UK)	10
<b>North America</b>	HICs	Canada	1
	U-MICs	Costa Rica	1

<b>Oceania</b>	HICs	Australia, New Zealand	2
<b>South</b>	HICs	Chile	1
<b>America</b>	U-MICs	Brazil, Mexico	2
<b>Total</b>			<b>40</b>

While 18 LICs and L-MICs in Africa were included in the retrieved literature (Figure 3.2), 17 of these countries were included in one study that examined priority-setting for Covid-19 plans in the World Health Organization-African Region (Kapiriri et al., 2021).

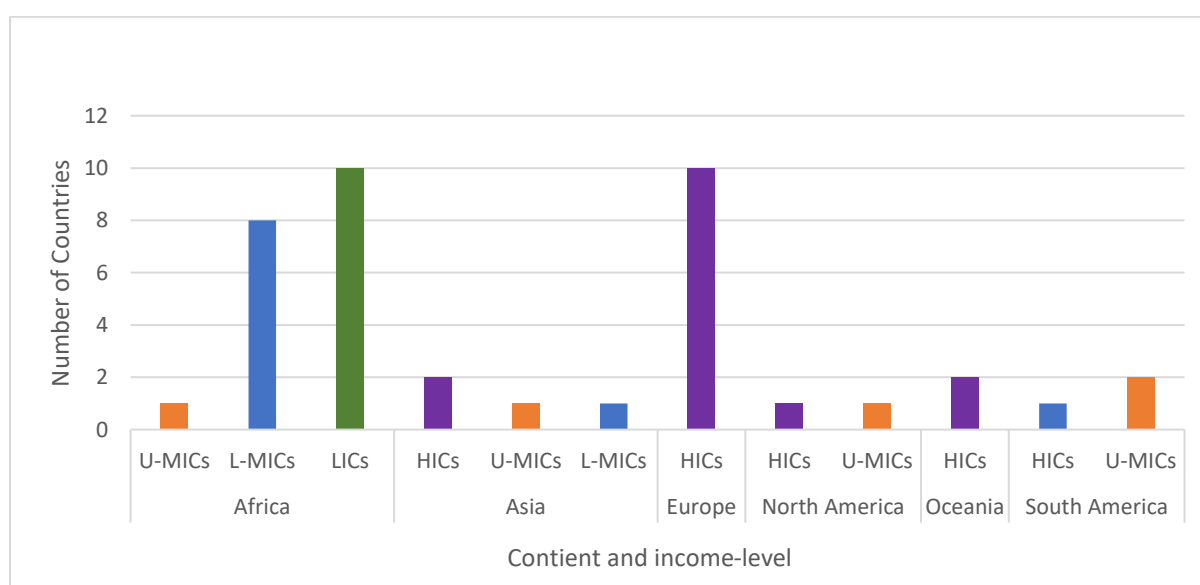


Figure 3.2: Distribution of countries by income level

Examples of healthcare priority-setting processes considered in the retrieved literature are shown in table 3.5.

Table 3.5:- Healthcare priority-setting processes

Example of healthcare priority-setting process or activity	Countries	
	HICs	Austria, Australia, Belgium, Brazil, Canada, Chile, Denmark,

Development or revision of health benefits packages/ lists of health technologies such as drugs, health services, and vaccines		France, Germany, Israel, Korea, Netherlands, Norway, Sweden, Switzerland, UK
	U-MICs	Costa Rica, Mexico, Thailand
	L-MICs	Iran, Tanzania
	LICs	Uganda
Development of pandemic or disease outbreak plans	U-MICs	South Africa
	L-MICs	Algeria, Angola, Cameroon, Cape Verde, Ghana, Kenya, Nigeria
	LICs	Burkina Faso, Chad, Democratic Republic of Congo, Ethiopia, Mali, Mozambique, Niger, Rwanda, Zambia, Uganda

### 3.3 Synthesis of the findings

The findings of this review are presented in two sections. Section 3.3.1 presents findings on policy analysis of introduction of healthcare priority-setting processes at the national level while Section 3.3.2 presents findings on qualitative evaluation of healthcare priority-setting processes at the national level.

#### 3.3.1 Policy analysis of introduction of healthcare priority-setting processes

Only one of the 24 studies examined the policy process for introducing healthcare priority-setting at the national level using Kingdon's multiple streams theory (Mohamadi et al., 2020). In this study, the authors examined the process that led to the inclusion of the policy for Health Insurance Benefit Package development on the government's agenda in Iran (Mohamadi et al., 2020). The authors found that the problem stream was characterized by epidemiological transitions which had resulted in rising demand for healthcare services and rising healthcare costs. The policy stream was characterized by the development of policy ideas on the need for

a basic health benefits package by various health system stakeholders. The stakeholders also recognized the need for a clear, evidence-based priority-setting process for determining coverage of services within the benefit package. Lastly, the politics stream was characterized by prioritization of health and health-related policies after several decades which elevated policies on health insurance benefit package development onto policymakers' agenda (Mohamadi et al., 2020). However, this study did not explicitly outline which stakeholders were involved in identifying the issues in the problem stream or solutions in the policy stream. This study also did not discuss the influence of policy entrepreneurs on the policy process.

### 3.3.2 Qualitative evaluation of healthcare priority-setting processes

23 of the 24 articles used evaluative criteria (Table 3.6) to describe and evaluate existing healthcare priority-setting processes. Some of these criteria were based on existing evaluative frameworks previously discussed in Chapter 2, subsection 2.4. These evaluative criteria were used to assess the legitimacy and fairness of healthcare priority-setting processes in countries of different income levels. The findings of this section have been outlined according to the evaluative criteria applied across the retrieved literature. These evaluative criteria included: - a) reasonableness (*subsection 3.3.2.1*); b) transparency and publicity (*subsection 3.3.2.2*); c) stakeholder involvement (*subsection 3.3.2.3*); d) revisions and appeals (*subsection 3.3.2.4*); e) enforcement (*subsection 3.3.2.5*); f) impact on policy and practice (*subsection 3.3.2.6*); and g) stakeholder understanding and satisfaction (*subsection 3.3.2.7*). The study findings showed that the evaluative criterion on accountability was influenced by other evaluative criteria such as transparency, publicity, and revisions and appeals. I therefore did not discuss accountability on its own.



Table 3.6: - Similarities in the evaluative criteria applied across the studies

<b>Conceptual framework or evaluative criteria</b>	<b>Comparison of criteria used to evaluate the priority-setting process</b>							
Accountability for reasonableness	Reasonableness	Publicity	Appeals	Enforcement	-	-		
Kapiriri and Martin's framework	Use of evidence	Publicity	Revisions and appeals	Enforcement	Accountability	Stakeholder involvement	Impact on policy and practice	Stakeholder understanding and, satisfaction
Social Values Framework	Content values	Transparency	-		Accountability	Participation		
Legitimacy criteria	Use of criteria	Transparency				Stakeholder representation		
Rawl's conception of reasonableness	Reasonableness							
Triple criteria	Appropriate principles					Public input	Effect on policy and practice	

### *3.3.2.1 Reasonableness*

Reasonableness refers to criteria, principles or rationales informing the priority-setting process and associated resource allocation decisions. Reasonableness was the most applied evaluative criteria across the retrieved studies. Examples of criteria that informed choices in priority-setting processes across the retrieved literature included technical criteria (defined as objective or scientific criteria), social values (defined as values shared by the community or society), and informal criteria (defined as subjective criteria) (Table 3.7).

Of the technical criteria, economic and clinical criteria were the most used by high and upper-middle-income countries across different continents. The choice of technical criteria and social values was, in some cases, influenced by a country's constitution, national laws, and policies irrespective of its income level (Charvel et al., 2018, Kieslich, 2012, Jansson, 2007, Mostafavi et al., 2016). Informal criteria included stakeholders' interests which mainly influenced the decision-making stage of the priority-setting process.

Systematic and consistent application of criteria in the priority-setting process increased transparency in the process (Jansson, 2007) while ad hoc and inconsistent application undermined transparency (Greß et al., 2005). Across the retrieved literature, systematic and consistent application of criteria in the priority-setting process was limited by several factors that were common to countries irrespective of their income level. These factors included limited availability of data (Kapiriri and Be LaRose, 2019, Essue and Kapiriri, 2018, Greenberg et al., 2009, Mitton et al., 2006), limited technical expertise (Essue and Kapiriri, 2018, Mostafavi et al., 2016, Greenberg et al., 2009), and limited availability of priority-setting tools or guidelines (Kapiriri et al., 2021). Without data for criteria, the priority-setting processes tended to occur implicitly (Essue and Kapiriri, 2018). Other barriers to the systematic and consistent use of criteria were country specific such as short timelines assigned to the priority-

setting process in Israel (Greenberg et al., 2009) and lack of alignment between national priorities and stakeholders' interests in Uganda (Essue and Kapiriri, 2018).

Table 3.7: Examples of criteria considered in priority-setting processes across the retrieved literature

Technical criteria	Country of application	
Affordability (budget impact)	HICs	Austria (Cleemput et al., 2012); Belgium (Cleemput et al., 2012); France (Cleemput et al., 2012); Israel (Greenberg et al., 2009); Korea (Ahn et al., 2012); Netherlands (Cleemput et al., 2012); Sweden (Cleemput et al., 2012)
	U-MICs	Thailand (Youngkong et al., 2012)
Burden of disease	U-MICs	Thailand (Tantivess et al., 2012, Youngkong et al., 2012)
	L-MIC	Ghana (Kapiriri et al., 2021); Iran (Mostafavi et al., 2016)
	LICs	Uganda (Essue and Kapiriri, 2018, Wallace and Kapiriri, 2019, Wallace and Kapiriri, 2017)
Clinical/ medical criteria (clinical effectiveness, safety, efficacy)	HICs	Austria (Cleemput et al., 2012); Australia (Whitty and Littlejohns, 2015, Mitton et al., 2006); Belgium (Cleemput et al., 2012); Canada (Mitton et al., 2006); Chile (Charvel et al., 2018); France (Cleemput et al., 2012); Germany (Kieslich, 2012, Greß et al., 2005); Israel (Sabik and Lie, 2008, Greenberg et al., 2009); Korea (Ahn et al., 2012); Netherlands (Sabik and Lie, 2008); New Zealand (Sabik and Lie, 2008, Mitton et al., 2006); Norway (Sabik and Lie, 2008); Sweden (Cleemput et al., 2012); Switzerland (Greß et al., 2005); UK (Charlton, 2019, Littlejohns et al., 2012)
	U-MICs	Brazil (Charvel et al., 2018); Costa Rica (Charvel et al., 2018); Mexico (Charvel et al., 2018); Thailand (Youngkong et al., 2012)

	L-MICs	Iran (Mostafavi et al., 2016); Tanzania (Mori and Kaale, 2012)
Economic criteria (cost-effectiveness, efficiency)	HICs	Austria (Cleemput et al., 2012), Australia (Whitty and Littlejohns, 2015, Mitton et al., 2006); Belgium (Cleemput et al., 2012); Canada (Mitton et al., 2006); Chile (Charvel et al., 2018); Germany (Kieslich, 2012, Greß et al., 2005); Korea (Ahn et al., 2012); Netherlands (Sabik and Lie, 2008); New Zealand (Sabik and Lie, 2008, Mitton et al., 2006); Norway (Sabik and Lie, 2008); Sweden (Sabik and Lie, 2008, Jansson, 2007); Switzerland (Greß et al., 2005); UK (Littlejohns et al., 2012, Charlton, 2019, Rumbold et al., 2017b).
	U-MICs	Brazil (Charvel et al., 2018); Costa Rica (Charvel et al., 2018); Mexico (Charvel et al., 2018); Thailand (Tantivess et al., 2012)
	LICs	Uganda (Kapiriri and Be LaRose, 2019, Essue and Kapiriri, 2018)
Feasibility (e.g., capacity considerations)	HICs	Korea (Ahn et al., 2012)
	LICs	Uganda (Kapiriri et al., 2021)
Financial risk protection	U-MICs	Thailand (Youngkong et al., 2012, Tantivess et al., 2012)
Severity of disease	HICs	Austria (Cleemput et al., 2012); Belgium (Cleemput et al., 2012); France (Cleemput et al., 2012); Netherlands (Cleemput et al., 2012); Norway (Sabik and Lie, 2008); Sweden (Cleemput et al., 2012)
	U-MICs	South Africa (Kapiriri et al., 2021); Thailand (Youngkong et al., 2012)
	L-MICs	Algeria, Angola, Cameroon, Cape Verde, Ghana, Kenya, Nigeria (Kapiriri et al., 2021) and, Tanzania (Mori and Kaale, 2012)
	LICs	Burkina Faso, Chad, Democratic Republic of the Congo, Ethiopia, Mali, Mozambique, Niger, and Rwanda

		(Kapiriri et al., 2021), and Uganda (Kapiriri et al., 2021, Kapiriri and Be LaRose, 2019)
<b>Social values</b>	<b>Country of application</b>	
Equity/ justice	HICs	Australia (Whitty and Littlejohns, 2015); Chile (Charvel et al., 2018); Denmark (Sabik and Lie, 2008); New Zealand (Sabik and Lie, 2008); UK (Littlejohns et al., 2012)
	U-MICs	Brazil (Charvel et al., 2018); Costa Rica (Charvel et al., 2018); Mexico (Charvel et al., 2018); Thailand (Youngkong et al., 2012, Tantivess et al., 2012)
	L-MICs	Iran (Mostafavi et al., 2016)
	LICs	Uganda (Wallace and Kapiriri, 2019, Wallace and Kapiriri, 2017)
End of life rules / rules of rescue/ life saving	HICs	Australia (Whitty and Littlejohns, 2015); Israel (Greenberg et al., 2009); UK (Charlton, 2019)
Human dignity	HICs	Sweden (Sabik and Lie, 2008, Jansson, 2007)
Religious and/ or cultural values	L-MICs	Algeria, Ethiopia and Mali (Kapiriri et al., 2021)
Solidarity	HICs	Australia (Whitty and Littlejohns, 2015); Chile (Charvel et al., 2018); Germany (Kieslich, 2012); Sweden (Sabik and Lie, 2008, Jansson, 2007, Cleemput et al., 2012); UK (Littlejohns et al., 2012)
	U-MICs	Brazil (Charvel et al., 2018); Costa Rica (Charvel et al., 2018);
Vulnerable population groups or regions	HIC	New Zealand (Mitton et al., 2006)
	L-MIC	Angola, Cape Verde, Ghana, and Zambia (Kapiriri et al., 2021)
	LIC	Mozambique (Kapiriri et al., 2021); and Uganda (Wallace and Kapiriri, 2019, Kapiriri et al., 2021)
<b>Informal criteria</b>	<b>Country of application</b>	
Industry interests e.g., pharmaceutical companies	HICs	Korea (Ahn et al., 2012)

International, global or donor guidelines, interests and/or priorities	L-MICs	Tanzania (Mori and Kaale, 2012)
	LICs	Uganda (Kapiriri et al., 2021, Kapiriri et al., 2007, Kapiriri and Be LaRose, 2019, Wallace and Kapiriri, 2019)
Lobbying, advocacy, or interest group pressures	HICs	Canada (Kapiriri et al., 2007)
	LICs	Uganda (Kapiriri and Be LaRose, 2019, Kapiriri et al., 2007)
Political stakeholders and/ or policymakers' interests or needs	HICs	Canada (Kapiriri et al., 2007); Norway (Kapiriri et al., 2007); Korea (Ahn et al., 2012);
	L-MICs	Iran (Mohamadi et al., 2020)
	LICs	Uganda (Kapiriri et al., 2007)

### 3.3.2.2 Transparency and publicity

Transparency refers to the openness of the priority-setting process while publicity refers to the public availability and accessibility of information on the priority-setting process. Transparency and publicity enhanced accountability, justifiability, and legitimacy of healthcare priority-setting processes which further generated stakeholder acceptance and support (Whitty and Littlejohns, 2015, Greenberg et al., 2009, Kapiriri et al., 2007, Mitton et al., 2006). Countries used the following communication platforms to promote transparency and publicity of their healthcare priority-setting processes namely: - web media (e.g., organizational websites) (Whitty and Littlejohns, 2015, Littlejohns et al., 2012, Youngkong et al., 2012, Kieslich, 2012, Kapiriri et al., 2007); audio media (e.g., radio) (Mori and Kaale, 2012); audio-visual media (e.g., television) (Mori and Kaale, 2012); organizational correspondence (e.g., circulars) (Kapiriri et al., 2007); and print media (e.g., newspapers, newsletters) (Mori and Kaale, 2012, Youngkong et al., 2012).

In the retrieved literature, transparency and publicity were examined based on various aspects. Firstly, transparency and publicity were examined with respect to selection of members of the

priority-setting bodies. Only a few HICs and U-MICs had legal and policy documents that openly and publicly described how members of priority-setting bodies were selected (Charvel et al., 2018). Secondly, transparency and publicity were examined with respect to the role of criteria in the priority-setting process. In this regard, transparency and publicity were high in several HICs in Europe because information on the criteria underlying the priority-setting process and decisions was explicitly and publicly available (Mitton et al., 2006, Greß et al., 2005, Kieslich, 2012, Jansson, 2007). However, in most countries irrespective of their income level, transparency and publicity of the role played by criteria in priority-setting processes and decisions were low since this information was not openly or publicly available which further undermined accountability (Kapiriri et al., 2021, Essue and Kapiriri, 2018, Wallace and Kapiriri, 2017, Whitty and Littlejohns, 2015, Ahn et al., 2012, Cleemput et al., 2012, Mori and Kaale, 2012, Greenberg et al., 2009, Kapiriri et al., 2007, Mitton et al., 2006, Greß et al., 2005, Mostafavi et al., 2016, Youngkong et al., 2012).

The level of transparency and publicity was influenced by several factors. Firstly, it was influenced by the availability of procedural and methodological guidelines which standardized how the healthcare priority-setting process was conducted, documented, and publicised. These documents were mainly available in HICs (Whitty and Littlejohns, 2015, Mitton et al., 2006, Charlton, 2019, Greß et al., 2005). Secondly, it was influenced by laws and policies which dictated aspects of the healthcare priority-setting processes that were to be made openly and publicly available. These laws and policies were mainly available in HICs in Europe (Jansson, 2007, Greß et al., 2005), and middle-income countries (MICs) in North and South America (Charvel et al., 2018). Thirdly, it was influenced by confidentiality clauses that allowed for concealment or redaction of sensitive information from public reports of the priority-setting processes. These confidentiality clauses were found in several HICs in Europe and Oceania (Mitton et al., 2006, Whitty and Littlejohns, 2015, Cleemput et al., 2012). Lastly, it was

influenced by the choice of communication platform. For example, access to online publications was undermined by limited internet availability in some LICs (Kapiriri and Be LaRose, 2019, Kapiriri et al., 2007).

### *3.3.2.3 Stakeholder participation*

Stakeholder participation refers to the involvement of relevant stakeholders in the healthcare priority-setting process. Countries involved stakeholders in healthcare priority-setting process for the following reasons: - a) to promote transparency and to reflect the values and needs of the community at large (Sabik and Lie, 2008, Littlejohns et al., 2012, Greenberg et al., 2009, Whitty and Littlejohns, 2015); and b) to promote acceptability, confidence, legitimacy, and trust in the priority-setting process and decisions (Tantivess et al., 2012, Cleemput et al., 2012, Greß et al., 2005, Mitton et al., 2006). Stakeholder participation was achieved through stakeholder representation in the priority-setting body and/ or external stakeholder consultation (Cleemput et al., 2012, Mori and Kaale, 2012, Greenberg et al., 2009).

Stakeholder representation refers to the inclusion of multiple stakeholders with different professional and organizational backgrounds in the priority-setting body (Mori and Kaale, 2012). The extent of stakeholder representation in priority-setting bodies varied across countries (Table 3.8). It was broad in several HICs in Europe (Whitty and Littlejohns, 2015, Greenberg et al., 2009, Greß et al., 2005) and several LMICs in Africa (Kapiriri et al., 2021, Essue and Kapiriri, 2018). In a few countries, the extent of stakeholder representation was narrow consisting of a single group of stakeholders as was the case in Brazil (Charvel et al., 2018).



Table 3.8: Stakeholder representation in priority-setting bodies

<b>Income level</b>	<b>Country</b>	<b>Priority-setting body</b>	<b>Stakeholder representation</b>
<b>HICs</b>	Australia	Pharmaceutical Benefits Advisory Committee and Medical Services Advisory Committee	Clinical experts, consumers' advocate, epidemiologists, health economists (Whitty and Littlejohns, 2015)
	Israel	Public National Advisory Committee	Health economists and representatives of the Ministry of Health, Ministry of Finance, Health Management Organizations and the public (Greenberg et al., 2009)
	Sweden	Swedish Pharmaceutical Benefits Board	Representatives of authorities, patients, payers and medical experts (Jansson, 2007)
	UK	National Institute for Health and Care Excellence	Healthcare providers, health economists, health systems specialists, data analysts, and representatives of manufacturers, patient organizations, and health authorities (Greß et al., 2005)
<b>U-MICs</b>	Brazil	The National Committee for Health Technology Incorporation	Ministry of Health officials only (Charvel et al., 2018)
<b>L-MICs</b>	Tanzania	Taskforce	Medical doctors (paediatricians, pharmacologists, obstetricians/gynaecologists) and pharmacists partners (Mori and Kaale, 2012)
<b>LICs</b>	Uganda	Taskforce	Ministry of Health, Ministry of Agriculture, representatives of

			non-governmental organizations (Kapiriri and Be LaRose, 2019)
	Uganda	Uganda National Immunization Technical Advisory Group	Academics, Civil Society Economists, officers, Paediatricians, Politicians, technical advisors Vaccinologists, WHO representative (Wallace and Kapiriri, 2017)
<b>HICs, MICs, and LICs</b>	Angola, Cape Verde, Ghana, Kenya, Mozambique, Nigeria, Rwanda, and Uganda	Inter-sectoral committees/ taskforces	Representatives of Ministries of Health, Agriculture, Environment, Education, Finance, Information, and Trade and Industry; Religious organizations; Development partners; private sector (Kapiriri et al., 2021)

Stakeholder consultation refers to discussions between the priority-setting body and various health system stakeholders with the aim of incorporating stakeholders' opinions and values in the priority-setting process. The extent of external stakeholder consultation varied across countries (Table 3.9). Stakeholder consultation was broad in HICs and U-MICs where multiple groups of stakeholders including the lay public were consulted (Charlton, 2019, Mitton et al., 2006, Greß et al., 2005). However, stakeholder consultation particularly with the public remained low across all countries but more so in LICs and L- MICs (Essue and Kapiriri, 2018, Mori and Kaale, 2012, Kapiriri and Be LaRose, 2019, Kapiriri et al., 2021, Mostafavi et al., 2016, Wallace and Kapiriri, 2019, Wallace and Kapiriri, 2017).

Table 3.9: Examples of stakeholders consulted across the retrieved literature

Stakeholder group	Country	
Academic or research (scientific) centres	HICs	Korea (Ahn et al., 2012); Germany (Greß et al., 2005); UK (Charlton, 2019)
	U-MICs	Thailand (Tantivess et al., 2012)
Civil society organisations, labour unions	U-MICs	Thailand (Tantivess et al., 2012)
	L-MICs	Uganda (Essue and Kapiriri, 2018);
Development partners or donors	LICs	Uganda (Essue and Kapiriri, 2018, Wallace and Kapiriri, 2019)
General public or lay people	HICs	Denmark (Sabik and Lie, 2008); Germany (Greß et al., 2005); Israel (Sabik and Lie, 2008); Korea (Ahn et al., 2012); New Zealand (Mitton et al., 2006); Norway (Sabik and Lie, 2008); Sweden (Sabik and Lie, 2008); UK (Littlejohns et al., 2012, Greß et al., 2005)
	U-MICs	Thailand (Tantivess et al., 2012)
Health professionals (e.g., general practitioners, specialists, primary healthcare practitioners, public health professionals) and/ or their professional associations/ representatives	HICs	Denmark (Sabik and Lie, 2008); Germany (Greß et al., 2005, Kieslich, 2012); Israel (Sabik and Lie, 2008); Korea (Ahn et al., 2012); Switzerland (Greß et al., 2005); Netherlands (Sabik and Lie, 2008); New Zealand (Sabik and Lie, 2008); Norway (Sabik and Lie, 2008); Sweden (Sabik and Lie, 2008); UK (Greß et al., 2005, Sabik and Lie, 2008)
	U-MICs	Chile (Charvel et al., 2018); Mexico (Charvel et al., 2018); Thailand (Tantivess et al., 2012);
	LICs	Uganda (Essue and Kapiriri, 2018)

Industries, manufacturers, or their representatives	HICs	Korea (Ahn et al., 2012); Germany (Greß et al., 2005); Switzerland (Greß et al., 2005); UK (Greß et al., 2005)
	U-MICs	Thailand (Tantivess et al., 2012);
Ministry of Finance	U-MICs	Chile (Charvel et al., 2018)
Ministry of the interior	HICs	Switzerland (Greß et al., 2005)
Patient groups or representatives	HICs	Korea (Ahn et al., 2012); Switzerland (Greß et al., 2005); UK (Greß et al., 2005, Littlejohns et al., 2012)
	U-MICs	Chile (Charvel et al., 2018); Thailand (Tantivess et al., 2012);
Payers (e.g., sickness funds, insurers) or their representatives	HICs	Germany (Kieslich, 2012, Greß et al., 2005); Switzerland (Greß et al., 2005)
Policymakers or their representatives (e.g., Ministry officials, health authorities, or parliament members)	HICs	Australia (Whitty and Littlejohns, 2015); Korea (Ahn et al., 2012); UK (Greß et al., 2005);
	U-MICs	Chile (Charvel et al., 2018); Mexico (Charvel et al., 2018); Thailand (Tantivess et al., 2012)
	L-MICs	Iran (Mostafavi et al., 2016);
	LICs	Uganda (Essue and Kapiriri, 2018)

Countries consulted stakeholders using different methods as shown in Table 3.10. UK was the only country that had instituted a structure for systematically consulting lay people referred to as the citizen council (Rumbold et al., 2017b).

Table 3.10: Stakeholder consultation methods

<b>Method</b>	<b>Country</b>
<b>Meetings</b>	Brazil (Charvel et al., 2018); Denmark (Sabik and Lie, 2008); New Zealand (Sabik and Lie, 2008); Sweden (Sabik and Lie, 2008),

	Tanzania (Mori and Kaale, 2012), Thailand (Tantivess et al., 2012) and UK (Mitton et al., 2006, Charlton, 2019)
<b>Surveys</b>	Netherlands and Sweden (Sabik and Lie, 2008); Thailand (Tantivess et al., 2012);
<b>Citizens council</b>	UK (Sabik and Lie, 2008, Charlton, 2019, Mitton et al., 2006, Rumbold et al., 2017b)
<b>Conferences</b>	Brazil (Charvel et al., 2018, Littlejohns et al., 2012); Sweden (Sabik and Lie, 2008)
<b>Health parliaments</b>	Israel (Greenberg et al., 2009)
<b>Health councils</b>	Costa Rica (Charvel et al., 2018)

The extent of stakeholder participation (representation and consultation) was influenced by the requirements outlined in legal or policy instruments in countries of all income levels (Charvel et al., 2018, Kieslich, 2012, Kapiriri et al., 2007). It was also influenced by stakeholders' awareness and technical knowledge in priority-setting. For example, low awareness and technical knowledge in priority-setting among lay public and civil society organizations undermined their involvement across countries of different income levels (Tantivess et al., 2012, Youngkong et al., 2012, Mostafavi et al., 2016, Greenberg et al., 2009). Lastly, stakeholder participation was influenced by the availability of financial resources for stakeholder consultation. For example, limited availability of funding led to the discontinuation of health parliaments in Israel (Greenberg et al., 2009).

#### *3.3.2.4 Appeals and revisions mechanisms*

Appeals refer to systems through which stakeholders can challenge the priority-setting process while revisions refer to systems through which priority-setting decisions can be changed. According to the retrieved literature, appeals and revisions were made on two grounds namely: - a) content grounds whereby priority-setting decisions were questionable; and b) procedural conditions whereby aspects of the priority-setting process were questionable (Cleemput et al.,

2012). The availability of appeals and revisions mechanisms influenced accountability of the priority-setting process and decisions (Littlejohns et al., 2012).

Only a few countries had formal, well-established, or systematic internal mechanisms for handling appeals and revisions based on content or procedural grounds. For example, the UK had an appeals panel that handled appeals on procedural grounds such as NICE's failure to act fairly or NICE's failure to adhere to the scope of its mandate. UK's appeals panel also handled appeals on content grounds such as NICE's failure to justify its priority-setting decisions (Littlejohns et al., 2012, Mitton et al., 2006, Greß et al., 2005). Other countries in which appeals and revisions were made on both procedural and content basis included HICs such as Austria (Cleemput et al., 2012), Australia (Whitty and Littlejohns, 2015, Mitton et al., 2006), and Canada (Mitton et al., 2006). In the following HICs, appeals and revisions were made on procedural grounds only- Belgium, France, Netherlands, Sweden (Cleemput et al., 2012). In Thailand, appeals were made on content arguments such as inaccurate or unreliable rationales for coverage decisions (Tantivess et al., 2012). Some countries also had external mechanisms for appeals such as judicial/ court appeals in HICs such as Australia (Mitton et al., 2006), Germany (Kieslich, 2012, Greß et al., 2005), and the UK (Mitton et al., 2006).

Most countries, irrespective of their income level, lacked functional internal and/or external mechanisms for appeals and revisions which undermined accountability of their priority-setting processes and decisions (Kapiriri et al., 2021, Mohamadi et al., 2020, Kapiriri and Be LaRose, 2019, Wallace and Kapiriri, 2019, Charvel et al., 2018, Essue and Kapiriri, 2018, Cleemput et al., 2012, Mori and Kaale, 2012, Ahn et al., 2012, Kieslich, 2012, Greenberg et al., 2009, Mitton et al., 2006, Kapiriri et al., 2007).

### *3.3.2.5 Enforcement*

Enforcement refers to mechanisms for ensuring that transparency, reasonableness, and appeals are upheld in the priority-setting process. Only a few HICs and U-MICs had enforcement mechanisms such as audits by State controller in Israel (Greenberg et al., 2009); regulation under laws or State Acts in Israel (Greenberg et al., 2009) and Sweden (Jansson, 2007); and lastly, supervision and sanctions in Chile and Mexico (Charvel et al., 2018). Enforcement mechanisms were weak or absent in most of the countries described in the retrieved literature irrespective of their income-level (Kapiriri et al., 2021, Charvel et al., 2018, Essue and Kapiriri, 2018, Mori and Kaale, 2012, Kapiriri et al., 2007).

### *3.3.2.6 Impact on policy and practice*

Impact on policy and practice refers to changes in policy and practice that can be credibly linked to the priorities identified through the healthcare priority-setting process. A few studies examined whether the healthcare priority-setting processes had influenced policy and practice. In the UK and New Zealand, the priority-setting decisions influenced clinical guidelines and practice through provision of prioritized health technologies (Sabik and Lie, 2008). In a multi-country study on priority-setting for Covid-19, 10 of the 18 African countries allocated their resources according to the priority-setting decisions (Kapiriri et al., 2021).

Stakeholders' interests and powers influenced the impact of priority-setting processes on policy and practice in several countries irrespective of their income level. For example, stakeholder interests limited the implementation of the proposed health benefits package in Iran (Mohamadi et al., 2020). In Korea, the interests and strength of pharmaceutical industries led to radical changes in the priorities determined through the priority-setting process thus influencing the outcome of the process (Ahn et al., 2012). In Uganda, political interests affected extent of resource allocation for identified priorities (Kapiriri and Be LaRose, 2019). Lastly, in Tanzania, stakeholders with greater power due to their professional and organizational affiliations

influenced what technologies were prioritized and how they were implemented (Mori and Kaale, 2012).

### *3.3.2.7 Stakeholder understanding and satisfaction*

Stakeholder understanding refers to increased insight of the priority-setting process among stakeholders while stakeholder acceptance refers to stakeholders' contentment and willingness to participate in healthcare priority-setting processes.

Only studies that applied the Kafiriri and Martin framework examined the level of stakeholder understanding and satisfaction. In LICs such as Uganda, studies reported improved stakeholder understanding of the priority-setting process but limited satisfaction with the priority-setting process due to poor transparency (Essue and Kafiriri, 2018), limited stakeholder involvement (Wallace and Kafiriri, 2017), and dominance of donors' and industries' interests over technical criteria on the final priority-setting decision (Wallace and Kafiriri, 2017).

## **3.4 Discussion**

The aim of this scoping review was to guide the PhD by identifying gaps and by synthesizing evidence from empirical studies on policy processes and evaluation of healthcare priority-setting processes at the macro-level globally. This review offers the following key insights.

Firstly, empirical studies on analysis of processes for developing policies on healthcare priority-setting at the macro-level remain limited globally. This gap is substantively relevant to policy and research given that the macro-level is not only the highest governance structure in any health system but is also responsible for formulating policies that influence functions of the health system. Given this gap, there is a need to conduct more policy analysis studies to understand how and why policies on healthcare priority-setting processes are introduced in a system.



Secondly, empirical studies on evaluation of healthcare priority-setting processes at the macro-level remain limited particularly in LICs and L-MICs. This gap is also substantively relevant to policy and research given the tight fiscal spaces and low spending on health in LICs and L-MICs. For example, in 2019 the average per capita government expenditure on health in LICs and L-MICs was only US\$ 39 and US\$ 116 which was 81 and 26 times lower than that of HICs respectively (World Health Organization, 2021). In these resource limited contexts, it is important to understand how well healthcare priority-setting processes are conducted against normative evaluative criteria. This calls for more studies on evaluation of healthcare priority-setting processes at the macro-level in these contexts.

Lastly, the review shows that evaluating how well healthcare priority-setting processes are conducted in practice helps to identify factors that may limit a country's capacity to fulfil the conditions outlined in the evaluative criteria. By understanding the shortcomings of what happens in practice, better strategies can be put in place to enable healthcare priority-setting processes meet the evaluative criteria. For example, to improve reasonableness, countries should develop explicit and systematic guidelines on how to apply and arbitrate technical, social, and informal criteria. To improve stakeholder participation, there should be wider representation in priority-setting bodies and wider consultation of external stakeholders. To improve publicity and transparency, all aspects of the priority-setting process should be made openly and publicly accessible using contextually appropriate channels of communication. To improve appeals and enforcement, there should be explicit conditions as well as functional internal and external mechanisms for appeals and revisions. To improve stakeholder understanding and satisfaction, there should be greater stakeholder participation, transparency, publicity, and functional appeals and revisions mechanisms.

### 3.5 Limitations

This review suffers from selection bias based on the exclusion of non-English publications and grey literature. The findings of this review were also based on the study's date of publication which may be dated in some contexts. It is therefore important that further empirical studies are conducted to update the status of institutionalization and factors influencing it.

### 3.6 Chapter summary

In this Chapter, I have synthesized evidence from empirical studies on policy processes and evaluation of healthcare priority-setting processes at the macro-level globally. Examining macro-level healthcare priority-setting processes is substantively relevant for health policy and practice as it highlights why these processes are introduced, how they are conducted and what influences how they are introduced and conducted. However, this review has shown that the number of studies examining the processes of developing policies on healthcare priority-setting processes as well as studies evaluating existing healthcare priority-setting processes remain limited. These gaps informed the first two sub questions of this PhD which were: 1) What led to the gazettement of the HBPAP policy idea in Kenya? and, 2) To what extent did HBPAP's healthcare priority-setting process for health benefits package development meet the normative conditions of a good healthcare priority-setting process, and why?

# CHAPTER 4: FACTORS INFLUENCING THE INSTITUTIONALIZATION OF HEALTH TECHNOLOGY ASSESSMENT: A SCOPING LITERATURE REVIEW

As mentioned in Chapter 1, the impact and sustainability of explicit healthcare priority-setting processes such as Health Technology Assessment (HTA) is dependent on their institutionalization (Bertram et al., 2021a, World Health Organization, 2011, World Health Organization, 2001). Institutionalization of HTA refers to conducting and utilizing HTA as a normative practice for guiding decisions on allocation of resources among competing uses within the health system (World Health Organization, 2001). HTA is a multi-disciplinary approach that has been endorsed by the WHO as an explicit approach for healthcare priority-setting (World Health Assembly, 2014). Understanding what factors influence how HTA becomes embedded in a health system as a routine approach for informing resource allocation decisions is important as these factors may support or hinder this process (Bertram et al., 2021a, World Health Organization, 2001).

In this Chapter, I present a scoping review which aimed to guide the PhD by: - a) synthesizing evidence on factors that influenced institutionalization of HTA at the macro-level globally; b) identifying gaps in empirical studies that examined factors influencing institutionalization of HTA; and c) informing the development of a conceptual framework for use in the third sub-study of this PhD.

## 4.1 Methods

### 4.1.1 Study design

I conducted a scoping literature review as it is suitable for identifying the extent of existing research work, synthesizing and disseminating research findings, and identifying research gaps

in a topic of interest (Arksey and O'Malley, 2005). These reasons matched the objectives of this literature review.

#### 4.1.2 Literature search

I searched for relevant literature in six databases- PubMed, Embase, CINAHL, Scopus, EconLit, and Google Scholar. The choice of these databases was informed by the multidisciplinary nature of HTA which inevitably meant that research articles would emerge from different scholarly backgrounds.

I derived the key search terms (Figure 4.1) from the research objective and existing conceptual and empirical literature. I conducted the first search in PubMed using MESH terms (where applicable) and/ or free-text terms in all fields (titles, abstract and full text). The use of free terms is recommended when the key word/ phrase does not have a MeSH term (Baumann, 2016) and for multidisciplinary topics (Papaioannou et al., 2010) like HTA. I combined the search terms with relevant Boolean characters to form a search string which I translated to other databases using appropriate database thesaurus, subject headings, and truncations. The first search was done in 2019 but was later updated in December 2021. The key search terms and the search strategy were reviewed and approved by the supervisory team.

Institutionalization OR institutionalisation OR development OR implementation
AND
Health technology assessment OR medical technology assessment OR healthcare technology assessment
AND
National level OR country level OR macro- level

Figure 4.1: Key search terms

### 4.1.3 Article selection

Articles were selected using the following three-pronged process. Firstly, titles of articles identified through the search were reviewed for relevance to the eligibility criteria (Table 4.1). Any titles that did not meet the inclusion criteria were excluded. Secondly, all potentially relevant abstracts were assessed against the inclusion criteria and excluded if they did not meet the criteria. Lastly, full articles were retrieved and further assessed against the inclusion criteria. Full articles were excluded if they did not meet the inclusion criteria. The full list of retrieved literature was reviewed and approved of by the supervisory team. This process is summarised in the search flow diagram in Figure 4.2.

Table 4.1: Eligibility criteria

<b>Criteria</b>	<b>Include</b>	<b>Exclude</b>
Sector	Health	Non-health sector
Level	National (macro)	Meso (organizational) and micro (frontline) level
Language	English	Non-English (due to time constraints and translation challenges)
Study method	Empirical	Conceptual papers, books/ book chapters, opinion or position papers, editorials, reports, commentaries, literature reviews
Publication status	Peer-reviewed	Grey literature
Access	Full access	No full access
Publication year	No limit	

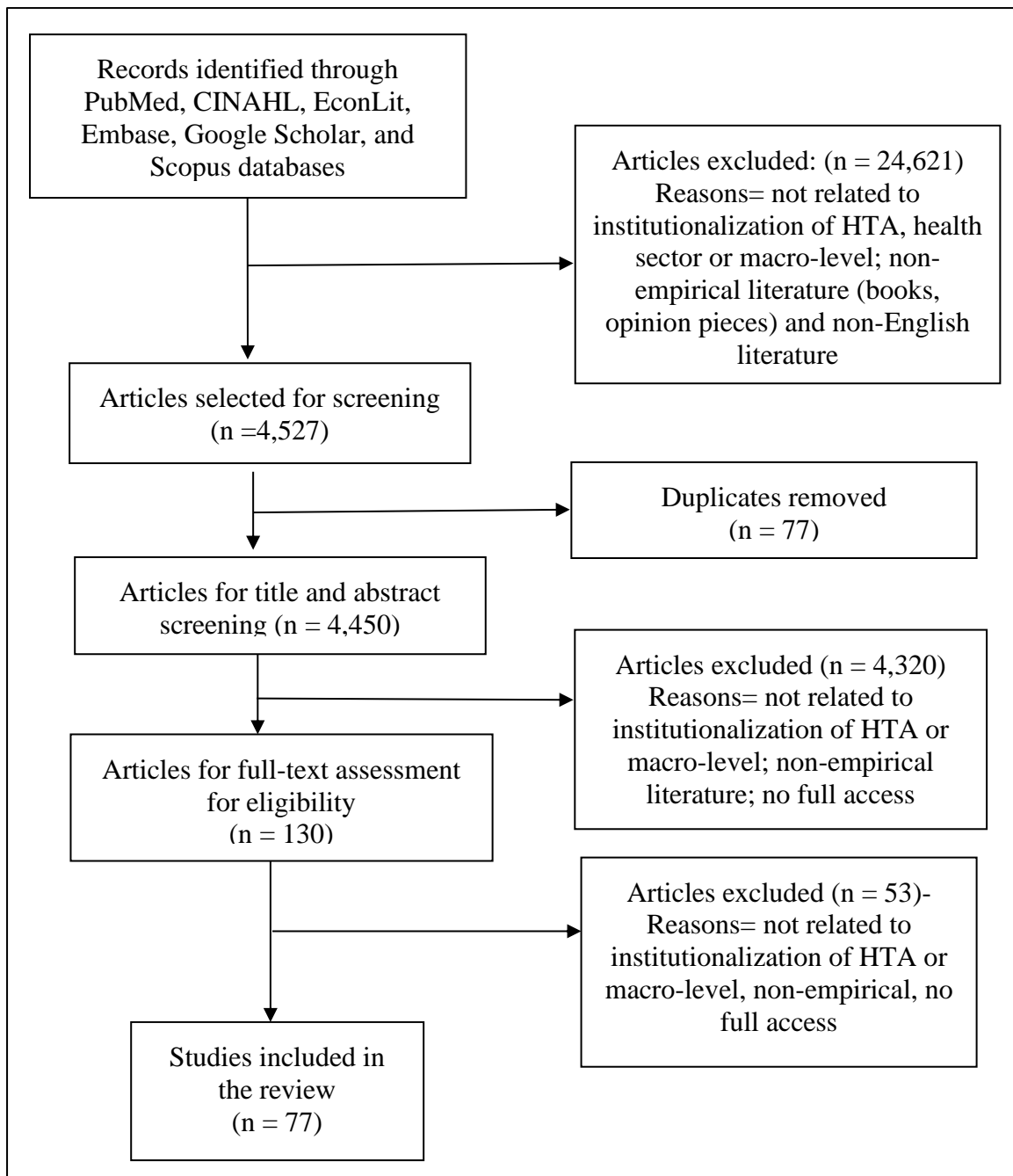


Figure 4.2: Search flow diagram

#### 4.1.4 Quality appraisal

I appraised the quality of the 77 articles that met the inclusion criteria using the CASP checklist for qualitative studies (Critical Appraisal Skills Programme, 2018). Some criteria such as ethical requirements were not applicable in studies that only reviewed documents. While none of the studies discussed researcher positionality, the supervisory team reviewed the appraisal

results and agreed that the quality of the articles was acceptable and therefore no studies were excluded (Table 4.2).

Table 4.2: CASP Quality appraisal checklist

<b>Appraisal criteria</b>	<b>Yes</b>	<b>Somewhat</b>	<b>No/Not clear/ Not applicable</b>
1. Clear statement of the study aims	77	0	0
2. Appropriate methodology for the study	77	0	0
3. Appropriate research design for the study	77	0	0
4. Appropriate recruitment strategy appropriate for the study to the aims of the study?	72	1	4
5. Appropriate data collection methods and settings for the study	69	3	5
6. Adequate consideration of the role, potential bias, and influence of the researcher during formulation of study, data collection, and analysis	0	0	77
7. Consideration of ethical issues	28	4	45
8. Rigorous and in-depth description of data analysis, and presentation of sufficient data to support the study findings	70	4	3
9. Clear statement of the research findings	77	0	0
10. Clear statement of the value of the research	77	0	0

#### 4.1.5 Data analysis, and synthesis

I analyzed the retrieved literature thematically using Braun and Clarke’s 6-step approach (Braun and Clarke, 2006). In step 1, I familiarized herself with the data through reading and re-reading. In Step 2, I generated a primary list of codes from the data. In Step 3, I developed themes by grouping like codes together. In Step 4, I reviewed the themes for coherence with the coded data extracts. In Step 5, I applied the themes across the retrieved literature to generate

study findings. In Step 6, I synthesized the findings into a report which was reviewed and approved by the supervisory team.

## 4.2 Findings

### 4.2.1 Characteristics of the literature included in the review

I included 77 articles in this review. Concerning study methodology, 71 articles (92.2%) employed qualitative methods such as document reviews, interviews, authors' experiences, and historical accounts; 4 articles (5.2%) used quantitative methods such as surveys; and 2 articles (2.6%) employed mixed methods by combining document reviews and questionnaires. A summary of these articles is provided in Appendix 2. Figure 4.3 provides a distribution of the 77 articles based on the income-level of the country(ies) examined. There were more articles on high-income countries than articles on countries of other income levels.

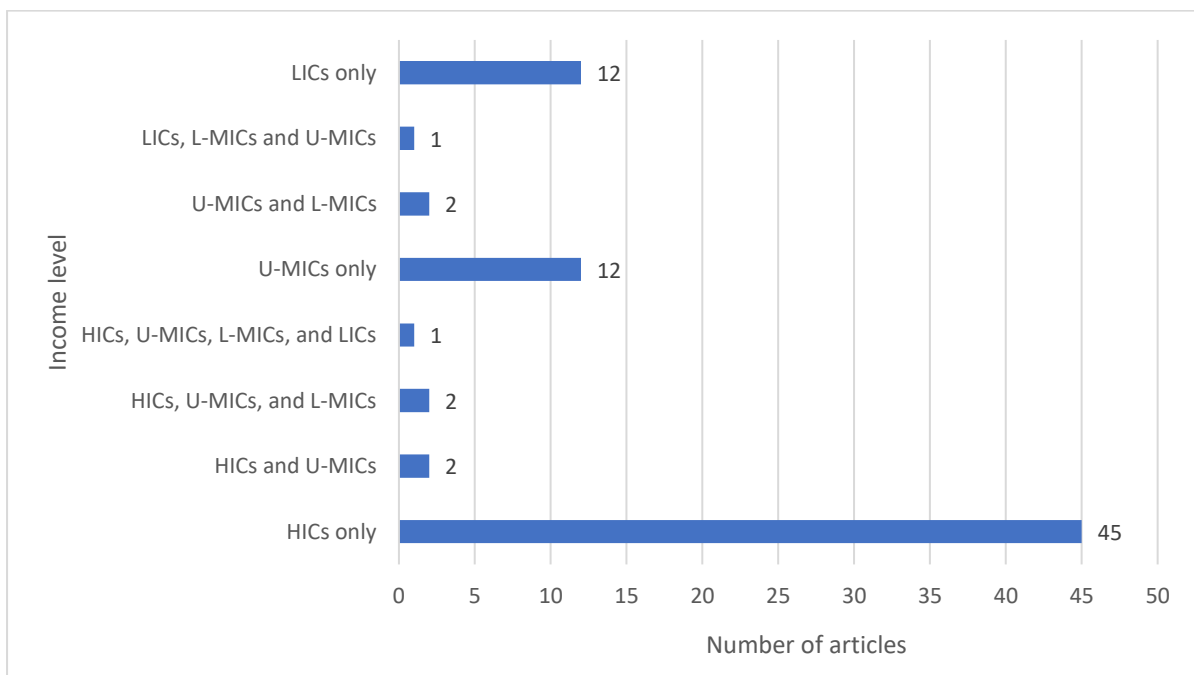


Figure 4.3: Distribution of reviewed articles based on income level of countries considered



The retrieved literature covered 135 countries of different income levels (Table 4.3). The number of countries exceeds the number of articles included in the review since 12 of these articles included studies of multiple countries (Kim et al., 2021, Liu et al., 2020, MacQuilkan et al., 2018, Babigumira et al., 2016, World Health Organization, 2015, Gulácsi et al., 2014, Rajan et al., 2011, Banta et al., 2009, Banta, 2009, Sivalal, 2009, Chinitz, 2004, Banta, 2003) (See Appendix 4.1). One of these studies involved a survey of 111 high, middle, and low-income countries (World Health Organization, 2015).

Table 4.3: Countries studied in the retrieved literature by continent and income level

<b>Continent</b>	<b>Income-level</b>	<b>Examples of countries</b>	<b>Number</b>
<b>Africa</b>	U-MICs	Libya, Namibia, South Africa	3
	L-MICs	Benin, Cameroon, Cape Verde, Comoros, Côte d'Ivoire, Egypt, Ghana, Kenya, Swaziland, Tanzania	10
	LICs	Central African Republic, Democratic Republic of Congo, Eritrea, Ethiopia, Madagascar, Mali, Mozambique, Rwanda, Somalia, Sudan, The Gambia, Zambia	12
<b>Total</b>			<b>25</b>
<b>Asia</b>	HICs	Bahrain, Brunei, Hong Kong, Israel, Japan, Kuwait, Qatar, Russia, Saudi Arabia, Singapore, South Korea, Taiwan	12
	U-MICs	Armenia, Azerbaijan, China, Georgia, Iraq, Kazakhstan, Jordan, Malaysia, Maldives, Thailand, Turkey	11
	L-MICs	Bangladesh, Bhutan, Cambodia, India, Indonesia, Iran, Laos, Lebanon, Mongolia, Nepal, Pakistan, Philippines, Sri Lanka, Timor-Leste, Vietnam	15
	LICs	Afghanistan, Syria	2
<b>Total</b>			<b>40</b>

<b>Europe</b>	HICs	Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom (UK)	32
	U-MICs	Albania, Belarus, Bulgaria, Moldova, Montenegro, North Macedonia, Serbia	7
	L-MICs	Ukraine	1
<b>Total</b>			<b>40</b>
<b>North America</b>	HICs	Barbados, Canada, Panama, Trinidad and Tobago, United States of America (USA)	5
	U-MICs	Costa Rica, Cuba, Dominican Republic, Guatemala, Jamaica, Mexico, Saint Vincent and the Grenadines,	7
<b>Total</b>			<b>12</b>
<b>Oceania</b>	HICs	Australia, Nauru, New Zealand	3
	U-MICs	Fiji, Tuvalu	2
	L-MICs	Kiribati, Micronesia	2
<b>Total</b>			<b>7</b>
<b>South America</b>	HICs	Chile, Uruguay	2
	U-MICs	Argentina, Brazil, Colombia, Ecuador, Mexico, Paraguay, Peru, Venezuela	8
	L-MICs	Bolivia	1
<b>Total</b>			<b>11</b>
<b>Total number of countries</b>			<b>135</b>

There were more high-income countries from Europe considered in the reviewed literature than countries of other income levels (Figure 4.4).

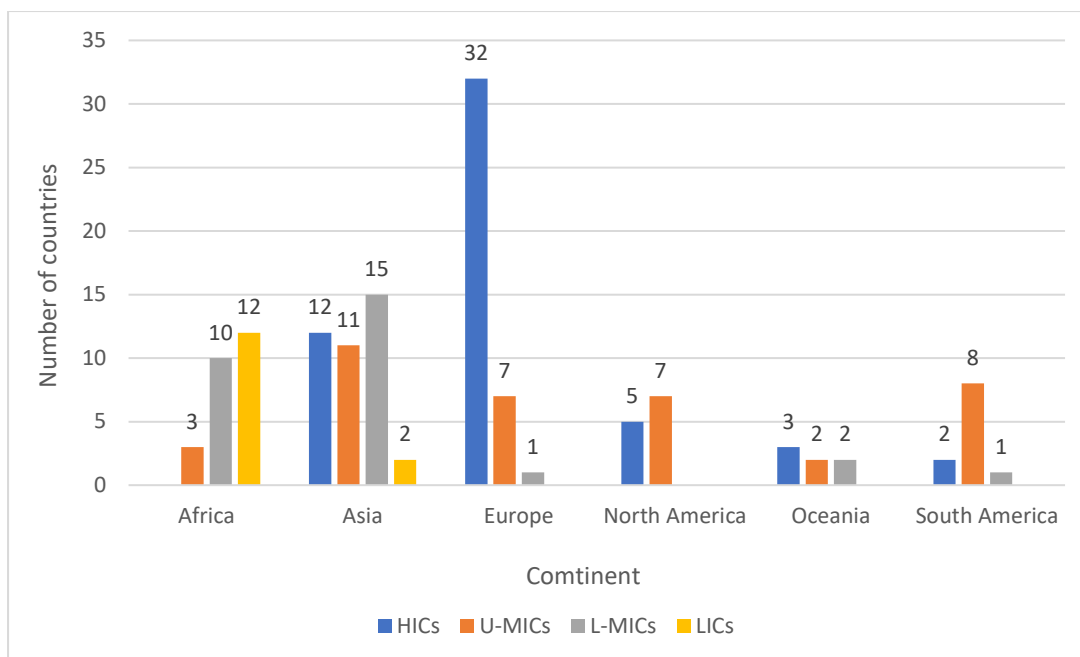


Figure 4.4: Number of countries by income level and continent

#### 4.2.2 Factors affecting institutionalization of HTA

According to the retrieved literature, HICs and U-MICs had demonstrated greater progress towards institutionalizing HTA than LICs and L-MICs (World Health Organization, 2015, Rajan et al., 2011). Irrespective of the income level, each country's journey towards institutionalizing HTA has been (or is still being) influenced by several factors that have either supported or undermined institutionalization of HTA. These factors are discussed further below under five thematic groups namely: - organizational resources for HTA; legal frameworks and guidelines for HTA; learning and advocacy for HTA; stakeholder-related factors; and collaborative support for HTA.

##### 4.2.2.1 Organizational resources for HTA

Factors in this thematic group included establishment of organizational structures for HTA and availability of resources for HTA such as skilled human resources, financial resources, and information resources.

#### 4.2.2.1.1 *Establishment of organizational structures for HTA*

Organizational structures for HTA were formally established HTA agencies or bodies dedicated to performing HTA for policy- and decision-making (Babigumira et al., 2016, World Health Organization, 2015, Banta et al., 2009). These structures were situated either independently or within the Ministry of Health and/ or academic and research organizations. There were more HICs from Europe with organizational structures for HTA than countries of other income levels, globally (Table 4.4). A survey conducted in 2015 showed that 81-83% of countries from the World Health Organization (WHO) region of Europe had a national organizational structure for HTA (World Health Organization, 2015).

Table 4.4: Countries with organizational structures for HTA according to the retrieved literature

Income-level	Examples of countries with organizational structures for HTA
<b>HICs</b>	<p data-bbox="469 1066 1390 1216"><b>Asia:</b> Hong Kong (Sivalal, 2009), Israel (Shemer et al., 2009, Tamir et al., 2008), Singapore (Sivalal, 2009, Pwee, 2009), South Korea (Liu et al., 2020), Taiwan (Sivalal, 2009).</p> <hr/> <p data-bbox="469 1234 1390 1877"><b>Europe:</b> Austria(Banta et al., 2009), Belgium (Cleemput and Van Wilder, 2009), Denmark (Sigmund and Kristensen, 2009, Banta et al., 2009), Finland (Banta et al., 2009), France (Fleurette and Banta, 2000, Banta et al., 2009), Germany (Perleth et al., 2009, Banta et al., 2009, Fricke and Dauben, 2009), Hungary (Németh et al., 2017, Gulácsi et al., 2009), Ireland (Banta et al., 2009), Italy (Ciani et al., 2012), Netherlands (Chinitz, 2004, Banta, 2003, Bos, 2000), Latvia (Banta et al., 2009), Norway (Banta et al., 2009), Poland (Banta et al., 2009), Spain (Granados et al., 2000, Sampietro-Colom et al., 2009), Sweden (Banta et al., 2009, Carlsson, 2004, Banta, 2003), Switzerland(Banta et al., 2009), UK (Raftery and Powell, 2013, Banta et al., 2009, Drummond and Banta, 2009, Chinitz, 2004)</p> <hr/> <p data-bbox="469 1895 1390 1984"><b>North America:</b> Canada (Battista et al., 2009, Menon and Stafinski, 2009)</p>

	<b>South America:</b> Chile (Banta, 2009)
	<b>Oceania:</b> - Australia (Hailey, 2009), New Zealand (Sivalal, 2009)
<b>U-MICs</b>	<b>Asia:</b> - China (Liu et al., 2020, Chen et al., 2009), Malaysia (Roza et al., 2019, Sivalal, 2009), Thailand (Leelahavarong et al., 2019, Teerawattananon et al., 2009), Turkey (Kahveci et al., 2017, Dilmaç et al., 2012)
	<b>South America:</b> - Brazil (Kuchenbecker and Polanczyk, 2012, Banta and Almeida, 2009), Colombia (Jaramillo et al., 2016), Mexico (Banta, 2009)
<b>L-MICs</b>	<b>Asia:-</b> Indonesia (Sharma et al., 2020), Iran (Arab-Zozani et al., 2020, Doaee et al., 2012, Sivalal, 2009), Vietnam (Lee et al., 2021)

The establishment of organizational structures was an important driver of the institutionalization of HTA irrespective of a country's income level or continent. This is because it expanded the organizational capacity of governments and/ or Ministries of Health not only to conduct HTA but also to link HTA research to policy- and decision-making on coverage, regulation and/ or reimbursement of health technologies (Leelahavarong et al., 2019, Raftery and Powell, 2013, Sigmund and Kristensen, 2009, Tamir et al., 2008). HTA organizational structures also developed, standardized, and disseminated HTA process and methods guidelines to relevant actors which enabled production of HTA (Arab-Zozani et al., 2020, Liu et al., 2020, Banta and Almeida, 2009, Fricke and Dauben, 2009, Drummond and Banta, 2009, Shemer et al., 2009, Teerawattananon et al., 2009, Tamir et al., 2008). Furthermore, they conducted HTA awareness and capacity-building initiatives which helped to raise awareness and skills, respectively (Ciani et al., 2012, Dilmaç et al., 2012, Doaee et al., 2012, Banta and Almeida, 2009, Perleth et al., 2009, Teerawattananon et al., 2009, Carlsson, 2004). Lastly, they maintained specialised databases which contained repositories of HTA outputs such as HTA reports which supported the use of HTA (Shemer et al., 2009).

Irrespective of a country's geographical location and income-level, the lack of organizational structures for HTA undermined the capacity of Ministries of Health and/or governments to conduct and utilize HTA in policymaking (Liu et al., 2020, Babigumira et al., 2016). It also led to fragmentation of HTA activities due to lack of coordination, supervision, and regulation which undermined institutionalization of HTA (Danguole, 2009, Dilmaç et al., 2012, Banta, 2003). Furthermore, in some countries, it undermined allocation of budgets for HTA activities which limited the capacity to conduct of HTA processes (Liaropoulos and Kaitelidou, 2000). Lastly, it limited spaces for practice for human resources with HTA skills which caused them to migrate to other fields in the private sector (Hisashige, 2009).

#### 4.2.2.1.2 Availability of skilled human resource for HTA

Skilled human resource for HTA referred to individuals with technical competence to conduct good-quality HTA and to generate policy relevant conclusions. They possessed knowledge and skills in clinical research, epidemiology, evidence synthesis, ethics, health economics, health policy analysis, and statistics (Jaramillo et al., 2016, World Health Organization, 2015).

Although HICs and U-MICs had more skilled human resource for HTA than LICs and L-MICs, the numbers of skilled HTA human resource remained limited, globally (World Health Organization, 2015, Rajan et al., 2011). The availability of skilled human resource for HTA in several high and upper-middle income countries strengthened the capacity of organizational structures to produce and utilize HTA (Raftery and Powell, 2013, Banta and Almeida, 2009, Teerawattananon et al., 2009, Banta, 2003, Fleurette and Banta, 2000, Bos, 2000). Skilled human resources for HTA also produced HTA publications, process and methods guidelines which informed how HTA processes were conducted (Gómez-Dantés and Frenk, 2009, Ciani et al., 2012).

The limited availability of skilled human resource for HTA undermined institutionalization of HTA in several ways that were common to many countries regardless of income-level. Firstly, it undermined a country's capacity to conduct HTA processes (World Health Organization, 2015) or to meet the demand for conducting HTA given the ever-increasing number of health technologies requiring assessment (Lee et al., 2021, Csanádi et al., 2019a, Rajan et al., 2011, Banta et al., 2009). Secondly, it undermined the perceived quality of HTA processes and outputs by policy- and decision-makers which limited the use of HTA in policy-and decision-making (Jain et al., 2014, Mohtasham et al., 2016, Danguole, 2009, Liu et al., 2020). Lastly, it undermined a country's capacity to adopt, where need be, internationally generated HTA research to the local context (Lee et al., 2021, Csanádi et al., 2019a, Rajan et al., 2011, Banta et al., 2009).

#### 4.2.2.1.3 Availability of financial resources for HTA

Financial resources for HTA came from public sources such as the government and/ or private sources such as fees charged to manufacturers submitting dossiers of health technologies for assessment (Leelahavarong et al., 2019, Roza et al., 2019, Raftery and Powell, 2013, Tamir et al., 2008). While financial resources for HTA remain limited globally irrespective of a country's income-level (World Health Organization, 2015, Rajan et al., 2011), the limitation was worse for low and lower-middle income countries in Africa and Asia (Babigumira et al., 2016).

The availability of financial resources for HTA in some HICs and U-MICs promoted institutionalization of HTA by supporting establishment of organizational structures for HTA (Raftery and Powell, 2013, Rajan et al., 2011, Banta et al., 2009, Sigmund and Kristensen, 2009). It also enabled these countries to fund HTA processes thereby enabling production of HTA (Menon and Stafinski, 2009, Fleurette and Banta, 2000, Ciani et al., 2012, Hisashige, 2009, Banta et al., 2009, Banta, 2003, Sampietro-Colom et al., 2009, Raftery and Powell, 2013,

Leelahavarong et al., 2019). Lastly, it enabled these countries to fund HTA capacity-building initiatives which strengthened the HTA human resource capacity (Ciani et al., 2012, Rajan et al., 2011, Sigmund and Kristensen, 2009, Banta and Oortwijn, 2009, Sampietro-Colom et al., 2009).

On the other hand, the limited availability of financial resources for HTA undermined institutionalization of HTA by preventing countries- irrespective of income-level- from meeting the costs required to establish organizational structures for HTA (Mueller, 2020, Mohtasham et al., 2016, Olyaeemanesh et al., 2014, Corabian et al., 2005). It also undermined a country's capacity to meet the costs associated with the production, dissemination, and utilization of HTA (Kim et al., 2021, Addo et al., 2020, Mueller, 2020, Surgey et al., 2019, Csanádi et al., 2019a, Németh et al., 2017, Mohtasham et al., 2016, Babigumira et al., 2016). In 2015, 69% of 111 high, middle, and low-income countries identified the lack of budget availability as one of the main barriers to HTA production (World Health Organization, 2015). Lastly, it undermined a country's capacity to meet the costs of conducting capacity-building activities for HTA (Leelahavarong et al., 2019).

#### *4.2.2.1.4 Availability of information resources for HTA*

HTA processes require good quality data to enable assessment and appraisal of health technologies. To generate good quality data for HTA, countries need access to complete health information systems (i.e., without missing data) and, databases with primary and secondary studies of relevance to HTA. Examples of data required for HTA include burden of disease, costs, cost-effectiveness, effectiveness, equity, ethical issues, feasibility, safety, and utilization (Leelahavarong et al., 2019, Jaramillo et al., 2016, World Health Organization, 2015).

The availability of good quality data for HTA was limited in all countries irrespective of income level (World Health Organization, 2015, Rajan et al., 2011). The limited availability,



completeness and/ or access to local data and databases for HTA undermined institutionalization of HTA in two ways that were common to many countries irrespective of continent or income-level. Firstly, it limited a country's capacity to conduct or produce HTA (Liu et al., 2020, MacQuilkan et al., 2018, World Health Organization, 2015). 53% of 111 high, middle and low-income countries identified limited availability of information as a barrier to HTA production in their countries (World Health Organization, 2015). Secondly, it diminished the acceptability of HTA outputs by policy- and decision-makers which further undermined utilization of HTA in policy- and decision-making (Jaramillo et al., 2016, Chen et al., 2009).

#### *4.2.2.2 Legal frameworks, policies, and guidelines for HTA*

Factors in this thematic group included: - a) availability of legislation and policies for HTA; and b) availability of process and methods guidelines, and decision-making frameworks for HTA.

##### *4.2.2.2.1 Availability of legislation and/ or policies for HTA*

Legislation for HTA was available in the form of laws while policies for HTA were available in the form of presidential or ministerial decrees, parliamentary statements, national strategies, health reforms. In 2015, a survey showed that less than 50% of 111 high, middle, and low-income countries had legislation that formalized HTA processes and integration of HTA outputs in healthcare priority-setting and decision-making (World Health Organization, 2015). Of the countries that had legislation, 63% were from the WHO region of Europe and 55% were high-income countries (World Health Organization, 2015).

The availability of legislation and/ or policies for HTA in some HICs and U-MICs- irrespective of the continent- supported institutionalization of HTA in the following ways. *Firstly*, it supported establishment of organizational structures for HTA (Banta et al., 2009, Banta and Almeida, 2009, Shemer et al., 2009). *Secondly*, it facilitated allocation of financial resources

for HTA processes through budgetary allocations (Löblová, 2018a, Jaramillo et al., 2016). *Thirdly*, it fostered national collaboration of multiple HTA organizational structures thereby reducing fragmentation and/or duplication of HTA processes (Battista et al., 2009, Ciani et al., 2012). *Fourthly*, it led to international collaboration for HTA which enabled sharing of HTA expertise and data (Sigmund and Kristensen, 2009, Jørgensen et al., 2000). *Fifthly*, it specified criteria for use during the HTA process which enabled HTA processes to be conducted in a harmonized fashion (Fleurette and Banta, 2000, Sigmund and Kristensen, 2009, Németh et al., 2017, Chinitz, 2004). *Sixthly*, it supported the development of methodological guidelines, decision-making thresholds and/or databases for HTA processes which enabled HTA processes to be conducted (Chen et al., 2009, Perleth et al., 2009, Fricke and Dauben, 2009, Teerawattananon et al., 2009). *Lastly*, it supported the use of HTA in policymaking by formalizing the role of HTA (advisory or regulatory) in health policy decisions (World Health Organization, 2015, Raftery and Powell, 2013, Kuchenbecker and Polanczyk, 2012, Banta and Almeida, 2009, Sampietro-Colom et al., 2009).

On the other hand, the lack of legislation and/or policies on HTA limited institutionalization of HTA in ways that were common to countries irrespective of their income-level or geographical location. *Firstly*, it undermined institutionalization of HTA by failing to protect the HTA process from undue political interference which hindered production and utilization of HTA (Arab-Zozani et al., 2020, Olyaeemanesh et al., 2014). *Secondly*, it undermined the use of HTA through lack of formalization of the role of HTA outputs in policy or decision-making (Babigumira et al., 2016, MacQuilkan et al., 2018, Mohtasham et al., 2016, Sharma et al., 2020, Csanádi et al., 2019a). *Lastly*, it undermined introduction of capacity-building initiatives for HTA (Kuchenbecker and Polanczyk, 2012).

#### 4.2.2.2.2 Availability of process and methods guidelines, and decision-making frameworks for HTA

Process and methods guidelines for HTA offered structured and systematic approaches for guiding topic (herein health technology) nomination, topic selection, assessment, appraisal, and decision-making stages of the HTA process (Lee et al., 2021, Leelahavarong et al., 2019, Roza et al., 2019). These guidelines outlined the procedures, principles, and criteria for the HTA process (Liu et al., 2020, Roza et al., 2019, Banta and Oortwijn, 2009, Hailey, 2009). Decision-making frameworks guided how HTA results were integrated into decisions in the decision-making stage of the HTA process (Lee et al., 2021, Leelahavarong et al., 2019, Roza et al., 2019).

The availability of process and methods guidelines as well as decision-making frameworks in several HICs and U-MICs in Asia, Europe, and North America facilitated institutionalization of HTA in the following ways. Firstly, it enabled organizational structures for HTA and HTA practitioners to conduct HTA processes (Liu et al., 2020, Leelahavarong et al., 2019, World Health Organization, 2015, Gulácsi et al., 2014, Hailey, 2009, Fricke and Dauben, 2009, Banta and Oortwijn, 2009, Bos, 2000). Secondly, it enabled standardization of HTA processes and/or reporting which increased acceptability and utilization of HTA outputs by policymakers (Gulácsi et al., 2014, Leelahavarong et al., 2019).

On the other hand, the lack of HTA process and methods guidelines undermined institutionalization of HTA in several ways that were common to many countries irrespective of continent or income-level. Firstly, it undermined the capacity of governments or ministries of health to conduct HTA processes (Lee et al., 2021, Liu et al., 2020, Csanádi et al., 2019a, Leelahavarong et al., 2019, Mohtasham et al., 2016, Gulácsi et al., 2009, Corabian et al., 2005, Babigumira et al., 2016). Secondly, it led to variations in HTA practice which resulted in different HTA outputs which undermined HTA uptake (Lee et al., 2021). Thirdly, the lack of

standardized guidelines for assessing ethical and social aspects of health technologies undermined the consideration of these aspects in HTA processes (Leelahavarong et al., 2019). Lastly, the lack of decision-making frameworks such as financing thresholds undermined utilization of HTA outputs in policy- and decision-making (Gulácsi et al., 2009).

#### *4.2.2.3 Learning and advocacy for HTA*

Factors in this thematic group included availability of capacity-building initiatives and awareness creation activities for HTA.

##### *4.2.2.3.1 Availability of capacity-building initiatives for HTA*

Countries employed multiple types of capacity-building initiatives to build HTA capacity both in the short-term (e.g., training seminars, apprenticeship) and in the long-term (e.g., graduate and post-graduate training) (Teerawattananon et al., 2009). These initiatives covered subjects relevant to HTA. They were targeted at stakeholders and organizations that conducted HTA (HTA doers) such as academics and researchers, and those that utilized HTA (HTA users) such as policymakers (Kim et al., 2021, Leelahavarong et al., 2019). Examples of HTA capacity-building initiatives identified in the retrieved literature are provided in Table 4.5.

Table 4.5: Examples of capacity-building initiatives identified in the retrieved literature

Type of capacity-building initiative	Examples	HICs	U-MICs	L-MICs
<b>Short-term initiatives</b>	Training seminars, short courses, scientific conferences and/ or workshops	<ul style="list-style-type: none"> <li>• Denmark(Sigmund and Kristensen, 2009)</li> <li>• Germany (Perleth et al., 2009)</li> <li>• Italy (Ciani et al., 2012)</li> <li>• Lithuania (Danguole, 2009)</li> <li>• Spain (Sampietro-Colom et al., 2009)</li> <li>• Sweden (Banta et al., 2009)</li> <li>• Hungary (Gulácsi et al., 2009)</li> </ul>	<ul style="list-style-type: none"> <li>• Argentina (Banta, 2009)</li> <li>• Brazil (Banta and Almeida, 2009)</li> <li>• China (MacQuilkan et al., 2018, Chen et al., 2009)</li> <li>• Malaysia (Sivalal, 2009)</li> <li>• South Africa (Mueller, 2020, MacQuilkan et al., 2018)</li> <li>• Thailand (Teerawattananon et al., 2009)</li> <li>• Turkey (Dilmaç et al., 2012)</li> </ul>	<ul style="list-style-type: none"> <li>• India (MacQuilkan et al., 2018, Mueller, 2020)</li> <li>• Indonesia (Sharma et al., 2020)</li> <li>• Iran (Arab-Zozani et al., 2020, Doaee et al., 2012)</li> <li>• Tanzania (Surgey et al., 2019)</li> <li>• Ukraine (Csanádi et al., 2019a)</li> </ul>
	Study tour visits to countries with more established HTA systems such as UK and Thailand.	<ul style="list-style-type: none"> <li>• Spain (Sampietro-Colom et al., 2009)</li> </ul>	<ul style="list-style-type: none"> <li>• China (Chen et al., 2009)</li> </ul>	
	Apprenticeship, mentorship and/ or on-job-training programs	<ul style="list-style-type: none"> <li>• Romania (Corabian et al., 2005)</li> </ul>	<ul style="list-style-type: none"> <li>• Thailand (Teerawattananon et al., 2009, Leelahavarong et al., 2019),</li> </ul>	<ul style="list-style-type: none"> <li>• Vietnam (Lee et al., 2021)</li> </ul>

<b>Long-term initiatives</b>	Academic training- Graduate and post graduate training in health economics and other HTA-related courses	<ul style="list-style-type: none"> <li>• Canada (Battista et al., 2009)</li> <li>• Germany (Perleth et al., 2009)</li> <li>• Hungary (Németh et al., 2017)</li> <li>• Israel (Shemer et al., 2009)</li> <li>• Lithuania (Danguole, 2009)</li> <li>• Spain (Sampietro-Colom et al., 2009)</li> <li>• Sweden (Carlsson, 2004)</li> </ul>	<ul style="list-style-type: none"> <li>• Brazil (Banta and Almeida, 2009)</li> <li>• China (Chen et al., 2009)</li> <li>• Malaysia (Sivalal, 2009)</li> <li>• Turkey (Dilmaç et al., 2012).</li> </ul>	<ul style="list-style-type: none"> <li>• Iran (Arab-Zozani et al., 2020),</li> </ul>
	HTA publications such as textbooks, reports, or journals	<ul style="list-style-type: none"> <li>• Germany (Perleth et al., 2009)</li> <li>• Hungary (Gulácsi et al., 2009)</li> <li>• Lithuania (Danguole, 2009)</li> <li>• Netherlands (Bos, 2000)</li> <li>• Spain (Sampietro-Colom et al., 2009)</li> </ul>	<ul style="list-style-type: none"> <li>• Brazil (Banta and Almeida, 2009)</li> <li>• China (Chen et al., 2009)</li> <li>• Mexico (Gómez-Dantés and Frenk, 2009)</li> <li>• Thailand (Teerawattananon et al., 2009).</li> </ul>	

The availability of HTA capacity-building initiatives was limited globally. In 2015, less than 50% of 111 high, middle, and low-income countries had long-term and/or short-term capacity building initiatives for HTA (World Health Organization, 2015). The limited availability of HTA capacity-building initiatives undermined institutionalization of HTA in two ways that were common to countries irrespective of their income-level or geographical location. Firstly, it undermined a country's capacity to build sufficient numbers of human resources with the technical skills to conduct HTA processes (Mueller, 2020, Darawsheh and Germeni, 2019, Kahveci et al., 2017, Jaramillo et al., 2016, Babigumira et al., 2016, World Health Organization, 2015, Jain et al., 2014, Liaropoulos and Kaitelidou, 2000). Secondly, it undermined understanding of the benefits of HTA by potential HTA users which limited the integration of HTA outputs into policy- and decision-making (Sharma et al., 2020, Darawsheh and Germeni, 2019, Lee et al., 2021, Shi et al., 2017, World Health Organization, 2015, Jain et al., 2014).

#### 4.2.2.3.2 Availability of awareness creation activities for HTA

Examples of awareness creation activities for HTA included conferences, seminars (Banta and Almeida, 2009, Gómez-Dantés and Frenk, 2009), policy dialogues (Teerawattananon et al., 2009), workshops (Banta et al., 2009) and, audio or audio-visual presentations in radios and televisions respectively (Teerawattananon et al., 2009).

Several high and middle-income countries had used HTA awareness creation activities to promote institutionalization of HTA by increasing the visibility of the value of HTA in decision-making among health workers, policymakers, and the public. In turn, increased visibility led to greater understanding and acceptance of HTA which motivated policy and decisionmakers to demand for and utilize HTA (Banta and Almeida, 2009, Banta et al., 2009, Pwee, 2009, Sampietro-Colom et al., 2009, Granados et al., 2000, Carlsson, 2004, Banta, 2003, Bos, 2000).

#### *4.2.2.4 Collaborative support for HTA*

Factors in this thematic group included international collaboration for HTA, and involvement of bilateral and multi-lateral agencies.

##### *4.2.2.4.1 International collaboration for HTA*

Considerations of the potential benefits of international collaboration began in the 1970s when the European Union recognized that European countries embarking on institutionalization of HTA were facing similar challenges (Banta et al., 2009). According to the retrieved literature, international collaboration for HTA occurred through membership of national HTA agencies in international HTA networks such as the International Network of Agencies for Health Technology Assessment ((INAHTA) which is currently referred to as the Health Technology Assessment International (HTAi)); the International Society of Technology Assessment in Health Care (ISTAHC); the European network for Health Technology Assessment (EUnetHTA); Health Technology Assessment Network of the Americas; and the Asia HTA Network. *Secondly*, it occurred through global health policy networks such as the International Decision Support Initiative (iDSI). *Lastly*, it occurred through political and economic unions such as the European Union (Table 4.6).



Table 4.6: Examples of international collaborations for HTA

<b>Collaborative network</b>	<b>Examples</b>	<b>Beneficiaries of the collaboration</b>	
<b>International HTA networks</b>	Asia HTA Network	<b>Asia</b>	Bangladesh, Brunei, China, Hong Kong, India, Indonesia, Korea, Malaysia, Nepal, Pakistan, Philippines, Singapore, and Thailand (Sivalal, 2009)
	EUnetHTA	<b>Europe</b>	Italy (Ciani et al., 2012), Germany (Perleth et al., 2009) and members of the European Union (Banta et al., 2009)
		<b>North America</b>	Canada and USA (Banta et al., 2009)
		<b>Asia</b>	Turkey (Kahveci et al., 2017), Israel (Banta et al., 2009)
		<b>Oceania</b>	Australia (Banta et al., 2009)
	INAHTA/ HTAi	<b>Asia</b>	Israel (Tamir et al., 2008), Malaysia (Roza et al., 2019) Turkey (Kahveci et al., 2017).
		<b>Europe</b>	Netherlands (Bos, 2000)
		<b>South America</b>	Brazil (Banta and Almeida, 2009),
	ISTAHC	<b>Europe</b>	Hungary (Gulácsi et al., 2009); Lithuania (Danguole, 2009); Netherlands (Bos, 2000); Romania (Corabian et al., 2005); Spain (Sampietro-Colom et al., 2009)
		<b>Asia</b>	Israel (Shemer et al., 2009)
	Health Technology Assessment Network of the Americas	<b>South America</b>	Colombia (Jaramillo et al., 2016)
<b>Global health policy networks</b>	iDSI	<b>Africa</b>	Ghana (Hollingworth et al., 2019, Addo et al., 2020), Kenya (Kim et al., 2021), South Africa (MacQuilkan et al., 2018), Zambia (Kim et al., 2021)
		<b>Asia</b>	China (MacQuilkan et al., 2018); India (MacQuilkan et al., 2018); Indonesia (Sharma et al., 2020); Vietnam (Lee et al., 2021)
<b>Political and economic unions</b>	European Union	<b>Europe</b>	Member countries of the European Union (Banta et al., 2009)

The presence of international collaboration supported institutionalization of HTA across countries in the collaborative networks in the following ways. *Firstly*, it led to the availability of funds that supported joint HTA work across countries in the European Union (Banta et al., 2009, Banta, 2003) and the Asia Pacific region (Liu et al., 2020, Sivalal, 2009) which reduced duplication of HTA studies and facilitated utilization of HTA recommendations (Banta et al., 2009, Sivalal, 2009). *Secondly*, it led to the development of HTA policies which supported establishment of organizational structures for HTA in countries within the European Union (Banta et al., 2009, Löblová, 2018b). These policies also informed how HTA processes were conducted in countries in Asia (Sharma et al., 2020, Sivalal, 2009). *Thirdly*, it facilitated standardization of HTA process and methods guidelines which minimized variation in HTA practice in countries involved in collaborative networks (Banta et al., 2009, Perleth et al., 2009, Sivalal, 2009, Banta, 2003). *Fourthly*, it supported awareness creation activities for HTA which increased the awareness, interest, visibility, and political priority for HTA by policy-and decision-makers in countries involved in collaborative networks globally (Liu et al., 2020, MacQuilkan et al., 2018, Banta et al., 2009, Banta, 2009, Sivalal, 2009). *Lastly*, it supported capacity-building initiatives which built and/ or strengthened HTA capacity in countries within the collaborative networks globally (Lee et al., 2021, Hollingworth et al., 2019, Surgey et al., 2019, MacQuilkan et al., 2018, Banta et al., 2009).

#### 4.2.2.4.2 *Involvement of multilateral agencies and non-governmental organizations*

Several multilateral agencies and non-governmental organizations supported countries globally to institutionalize HTA. For example, the Access Delivery Partnership (ADP)- a multilateral agency- influenced institutionalization of HTA in Indonesia by supporting capacity-building activities and development of HTA policies (Sharma et al., 2020).

The WHO- a multilateral agency- influenced institutionalization of HTA by: - a) creating an organizational structure for HTA in China (Shi et al., 2017, Chen et al., 2009); b) funding HTA

projects in Indonesia (Sharma et al., 2020); c) creating a database platform for member countries within the WHO European Region (Banta et al., 2009); and d) financially and/ or technically supporting HTA capacity-building initiatives in high, middle and/ or low-income countries in Central Europe (Danguole, 2009); South America (Banta and Almeida, 2009); and Asia (Sharma et al., 2020, Jain et al., 2014, Sivalal, 2009).

The World Bank- a multilateral agency- supported institutionalization of HTA by providing funds to establish and/ or run HTA agencies in China (Chen et al., 2009), Lithuania (Danguole, 2009) and Latvia (Banta et al., 2009). It also supported capacity-building initiatives in several high and upper-middle income countries in Central and Eastern Europe which built a set of skilled human resource for HTA (Banta et al., 2009).

Lastly, non-governmental organizations such as Program for Appropriate Technology in Health (PATH) supported institutionalization of HTA by conducting HTA awareness creation and capacity-building initiatives in Tanzania (Surgey et al., 2019).

#### *4.2.2.5 Stakeholder-related factors*

Factors in this thematic group included: - a) varying policy and decision-maker awareness and understanding of the value of HTA; and b) varying stakeholder interests.

##### *4.2.2.5.1 Varying policy and decision-makers awareness and understanding of the value of HTA*

The presence of policy-and decision-makers' awareness and understanding of the value of HTA supported institutionalization of HTA in several high and middle-income countries globally in the following ways. Firstly, it led to financial allocation for HTA activities which facilitated production and utilization of HTA outputs in decision-making (Menon and Stafinski, 2009, Banta, 2003, Bos, 2000). Secondly, it led to the establishment of organizational structures

for HTA (Gulácsi et al., 2009, Granados et al., 2000). Lastly, it supported capacity-building initiatives for HTA (Granados et al., 2000).

On the other hand, limited awareness and understanding of the value of HTA among policy- and decision-makers undermined institutionalization of HTA in ways that were common to many countries irrespective of their income level or continent. Firstly, it undermined demand for HTA and integration of HTA outputs in policy- and decision-making (Mueller, 2020, Addo et al., 2020, Surgey et al., 2019, Babigumira et al., 2016, World Health Organization, 2015, Liu et al., 2020, Danguole, 2009, Jaramillo et al., 2016). In 2015, 59% of 111 high, middle and low-income countries reported lack of awareness of the value of HTA as a barrier to the use of HTA in policymaking (World Health Organization, 2015). Secondly, it undermined political support for HTA capacity-building initiatives (Mueller, 2020, Csanádi et al., 2019a). Lastly, it undermined budgetary allocations for HTA (Kim et al., 2021, Darawsheh and Germeni, 2019).

#### *4.2.2.5.2 Varying stakeholders' interests*

Examples of stakeholders whose interests influenced institutionalization of HTA included policymakers, health professionals, HTA epistemic communities, patients or patient groups, industries/ manufacturers associations, payers, and civil society organizations.

##### **A. Policy-and decision-makers' interests**

In 2011, 78% of 35 high and middle-income countries from Asia, Europe, North America, South America and Oceania identified policy-and decision-makers' as a key driver of institutionalization of HTA (Rajan et al., 2011). Policy-and decision-makers' interests influenced institutionalization of HTA as follows.

Firstly, policy-and decision-makers' interest in managing rising healthcare expenditures led to the establishment of organizational structures for HTA in several high-and upper-middle-income countries in Asia, Europe, North America, and Oceania (Liu et al., 2020,

Leelahavarong et al., 2019, Rajan et al., 2011, Banta et al., 2009, Drummond and Banta, 2009, Pwee, 2009, Sampietro-Colom et al., 2009, Banta, 2003, Bos, 2000);

Secondly, policy-and decision-makers' interests in improving effectiveness and/ or quality of care stimulated development of HTA policies in HICs and U-MICs in Asia, Europe, and North and South America. These policies supported institutionalization of HTA by :- a) earmarking financial resources for HTA activities (Jaramillo et al., 2016, Bos, 2000); b) specifying resource allocation decisions to be informed by HTA (Perleth et al., 2009); and c) granting establishment of organizational structures for HTA (Rajan et al., 2011, Hisashige, 2009, Cleemput and Van Wilder, 2009, Fleurette and Banta, 2000).

Thirdly, policy-and decision-makers' interests in improving efficiency of spending allocations led to the creation of organizational structures for HTA (Callahan, 2012, Luce and Cohen, 2009, Hisashige, 2009, Liu et al., 2020) and the use of HTA outputs in policy- and decision-making (Banta, 2003, Ciani et al., 2012, Perleth et al., 2009) in several HICs and U-MICs in Asia, Europe, and North America. It also led to HTA awareness creation and capacity building initiatives in several middle-income countries in Africa (Mueller, 2020, Surgey et al., 2019) and, upper-middle and high-income countries in Europe (Banta et al., 2009, Sampietro-Colom et al., 2009).

Lastly, policy-and decision-makers' interests in UHC led to the development of policies and legislation on HTA in several lower- and upper-middle-income countries in Africa (Mueller, 2020, Hollingworth et al., 2019, Surgey et al., 2019) and Asia (Teerawattananon et al., 2009). Similarly, policymakers' interests in defining a health benefits package or in regulating introduction of new health technologies led to the development of HTA policies and/or establishment of organizational structures for HTA in several high and upper-middle-income

countries in Asia (Pwee, 2009, Leelahavarong et al., 2019) and Europe (Chinitz, 2004, Bos, 2000).

On the other hand, policy-and decision-makers' interests in preserving existing practices for decision-making was identified as a limitation to the use of HTA in several low, middle, and high-income countries globally (Addo et al., 2020, Liu et al., 2020, Jaramillo et al., 2016, Rajan et al., 2011). In 2015, 40.5% of high, middle and low-income countries globally reported that lack of political support prevented utilization of HTA in decision-making in their countries (World Health Organization, 2015).

### **B. Health professionals and their associations**

In several high-income countries, interests of health professionals and their associations supported institutionalization of HTA. For example, health professionals' interest in improving quality of care led them to support institutionalization of HTA as they recognized HTA as an appropriate approach for improving quality of care in Netherlands (Bos, 2000). In Spain, health professionals' interest in objective allocation of health technologies led them to lobby for the introduction of HTA as they recognized HTA as an objective approach for resource allocation (Sampietro-Colom et al., 2009). In Italy, clinical engineers' interest in rationalizing the use of expensive health technologies stimulated development of HTA to assess costs and safety concerns (Ciani et al., 2012). Lastly, in Japan, physicians' interests in addressing healthcare crisis in the system led them to form an association for HTA through which they conducted HTA awareness creation and capacity-building initiatives (Hisashige, 2009).

In other countries, some health professionals did not express a clear position on institutionalization of HTA while in other countries, health professionals opposed institutionalization of HTA. For example, in Czech Republic, health professionals did not express a clear position on institutionalization of HTA because they believed it was not their

concern (Löblová, 2018b, Löblová, 2018a). However, in the USA, medical professional associations opposed the use of HTA in decision-making because they perceived it as bureaucratic interference. The medical professional associations took this stance because they were interested in safeguarding their autonomy in decisions involving patient management (Callahan, 2012, Luce and Cohen, 2009).

### **C. Manufacturers, industries, and other private sector organizations**

In some countries, manufacturers, industries, and other private sector organizations responsible for producing health technologies supported institutionalization of HTA because of their interests. For example, in India, industries supported HTA because it would encourage competition by increasing availability of information on best available options (Jain et al., 2014). In Israel, industries supported HTA as it would enhance accountability and transparency in healthcare priority-setting processes (Shemer et al., 2009, Tamir et al., 2008).

However, in other countries, the interests of manufacturers, industries, and other private sectors had a negative influence on the institutionalization of HTA. For example, in the USA, manufacturer associations and other private sectors were more interested in safeguarding the pricing of their health technologies through free markets. They therefore opposed the use of HTA in decision-making as they perceived it as bureaucratic interference (Callahan, 2012, Luce and Cohen, 2009) and a threat to innovation (Luce and Cohen, 2009). This opposition led to limited utilization of HTA in decision-making and subsequent defunding and inactivation of the HTA centre in the USA (Callahan, 2012, Luce and Cohen, 2009). In several high and middle-income countries in Europe (Löblová, 2018a, Löblová, 2018b, Banta, 2003), South America (Jaramillo et al., 2016) and Asia (Arab-Zozani et al., 2020), manufacturers, industries and/ or importers of health technologies opposed institutionalization of HTA because of their interests in preserving profits, market access and/ or predictable disbursements.

#### **D. Patients and patient advocacy groups**

The interests of patients and patient groups undermined institutionalization of HTA in several countries. For example, in the USA, patients and patient advocacy groups opposed implementation of HTA because they perceived it as government's interference in the autonomy of doctor-patient relationships as well as a threat to patients' access to health technologies when in need (Callahan, 2012, Luce and Cohen, 2009). In Czech Republic, patient groups for rare diseases opposed HTA due to fears that it would apply rigid cost-effectiveness thresholds at the expense of other benefits thus limiting access to care (Löblová, 2018b). Other countries in which patients' interests were perceived as a barrier to the development and utilization of HTA included Colombia (Jaramillo et al., 2016) and Vietnam (Lee et al., 2021).

#### **E. HTA epistemic communities**

HTA epistemic communities were identified as networks of experts with technical competence, knowledge, and skills in HTA as well as shared beliefs of the value and validity of HTA as an approach for evidence-based decision-making (Löblová, 2018a). They were either civil servants (Löblová, 2018a) and/ or academics or researchers (Löblová, 2018a, Sivalal, 2009).

HTA epistemic communities in several high and middle-income countries in Asia, Europe, North America and South America expressed the following interests with regards to institutionalization of HTA namely: - a) interests in the appropriateness of HTA as a multi-disciplinary and evidence-based solution to resource allocation decisions (Löblová, 2018a); b) interests in the use of HTA to improve health systems performance (Gómez-Dantés and Frenk, 2009); c) interests in the judicious evaluation and administration of health technologies (Teerawattananon et al., 2009); and d) financial and reputational interests as institutionalization of HTA would enable them to secure employment and influence policy decisions (Löblová, 2018a).



Based on their interests, HTA epistemic communities supported institutionalization of HTA in the following ways. *Firstly*, they advocated for the establishment of organizational structures for HTA in several countries in Europe (Löblová, 2018a, Löblová, 2018b, Wild, 2009, Jonsson, 2009, Banta et al., 2009); South America (Gómez-Dantés and Frenk, 2009); and Asia (Teerawattananon et al., 2009); and North America (Luce and Cohen, 2009). *Secondly*, they developed HTA policies in several high- and middle-income countries in Asia (Sivalal, 2009, Hisashige, 2009). *Thirdly*, they developed HTA methodological guidelines and checklists in several high and middle-income countries in Europe (Németh et al., 2017, Banta et al., 2009) and Asia (Liu et al., 2020, Sivalal, 2009). *Fourthly*, they conducted HTA capacity-building initiatives in high and middle-income countries in Asia (Chen et al., 2009, Hisashige, 2009, Pwee, 2009, Teerawattananon et al., 2009); Europe (Banta et al., 2009, Löblová, 2018a, Gulácsi et al., 2009, Carlsson, 2004); and South America (Banta and Almeida, 2009). *Lastly*, they conducted HTA awareness creation activities in several high and middle-income countries in South America (Banta and Almeida, 2009, Gómez-Dantés and Frenk, 2009); Asia (Chen et al., 2009, Hisashige, 2009, Sivalal, 2009); and Europe (Löblová, 2018a, Gulácsi et al., 2009, Banta et al., 2009, Danguole, 2009).

#### **F. Civil society groups**

Interests of civil society organizations supported institutionalization of HTA in some countries. For example, in Thailand, civil societies' interests in transparency and participation in decision-making led them to support HTA in policymaking (Teerawattananon et al., 2009). In India, civil societies' interests in evidence-informed decision-making led them to advocate for the use of HTA in decision-making (Jain et al., 2014).

#### **G. Payers/ insurers**

The influence of payers' or insurers' interests on institutionalization of HTA varied across countries. In Czech Republic, payers' interests in preserving their authority in the pricing and

regulation of health technologies led them to oppose the establishment of an organizational structure for HTA as they perceived this as bureaucratic interference and loss of power (Löblová, 2018a, Löblová, 2018b). In Poland, payers' interests in managing expenses, preserving profits and, retaining existing procedures for resource allocation caused them to oppose HTA (Löblová, 2018a). However, in India, insurers' interests in competition and transparency of information caused them to support institutionalization of HTA (Jain et al., 2014).

### 4.3 Discussion

This scoping review had three main aims namely: - to identify factors that influenced institutionalization of HTA at the macro-level across different contexts; to identify gaps in empirical studies that examined factors influencing institutionalization of HTA; and lastly, to develop a conceptual framework on factors influencing institutionalization of HTA. This review offers the following key insights.

This literature review shows that empirical studies on factors influencing institutionalization of HTA remain limited in low- and lower-middle income countries. This is of concern given that resource constraints are more pronounced in these contexts. For example, the average government health expenditure per capita in LICs and L-MICs was 81 and 27 times lower than that of HICs respectively (World Health Organization, 2021). With these limited resources, LICs and L-MICs are in greater need of explicit approaches such as HTA to inform resource allocation decisions.

This review also shows that countries embarking on institutionalizing HTA faced similar challenges irrespective of a country's income level. These challenges included limited availability of skilled human resources, limited establishment of organizational structures for HTA, limited availability of information resources, limited availability of financial resources,

limited stakeholder awareness and understanding of the value of HTA, and limited capacity-building initiatives. However, with greater political support and international collaboration, HICs and U-MICs in Asia, Europe, North America, South America, and Oceania have become better resourced for HTA which facilitated institutionalization of HTA in these contexts.

Importantly, the cross-country experiences show that institutionalization of HTA is influenced by five sets of factors that are linked and/or interlinked in a complex way. The first set of factors was organizational resources for HTA namely organizational structures, skilled human resources, financial resources and, information resources for HTA. These factors influenced a country's capacity to establish and conduct HTA processes. At the same time, the availability of these organizational resources was influenced by other sets of factors. For example, learning and advocacy support for HTA influenced the availability of skilled human resource for HTA. Policymakers' interests and international collaboration not only led to the establishment of organizational structures for HTA but also influenced availability of financial resources for HTA. On the other hand, organizational structures for HTA influenced the availability of other sets of factors such as learning and advocacy for HTA by conducting HTA awareness creation and capacity-building initiatives. They also influenced availability of HTA guidelines by developing HTA process and methods guidelines.

The second set of factors was legal frameworks, policies, and guidelines for HTA which also influenced a country's capacity to establish and conduct HTA by: - a) influencing availability of organizational resources for HTA; b) supporting international collaboration; and c) supporting learning activities for HTA. On the other hand, the development and availability of legal frameworks, policies, and guidelines was influenced by other factors such as international collaboration, skilled human resource for HTA, and policymakers' interests and awareness of the value of HTA.

The third set of factors was learning and advocacy for HTA which influenced a country's capacity to conduct HTA processes by building human resource capacity for HTA. It also influenced a country's capacity to utilize HTA in decision-making by increasing stakeholder awareness and knowledge of the value of HTA in decision-making. On the other hand, the availability of learning and advocacy for HTA was influenced by international collaboration, interests of policymakers and HTA epistemic communities, legislative frameworks, and organizational structures for HTA.

The fourth set of factors was stakeholder-related factors such as stakeholders' interests and awareness which influenced how HTA processes were established, conducted, and utilized by creating political support for provision of organizational resources, learning and advocacy for HTA, international collaboration and, development of legal frameworks and guidelines for HTA.

The fifth set of factors was collaborative support for HTA which influenced how HTA processes were conducted by providing organizational resources for HTA, developing HTA process and methods guidelines and by supporting learning and advocacy for HTA. Collaborative support also influenced how HTA was utilized by raising stakeholder awareness and understanding through awareness creation activities.

Based on the findings of this review, countries that seek to institutionalize HTA should consider the availability of the five sets of factors which may influence a country's capacity to conduct and utilize HTA. These factors are summarized into a conceptual framework on Figure 4.5. This framework also shows the complex linkages between the sets of factors. The presence of a one-way arrow shows one factor influences another while the presence of a two-way arrow shows the factors influence each other. These interlinkages are based on the findings of this scoping review.

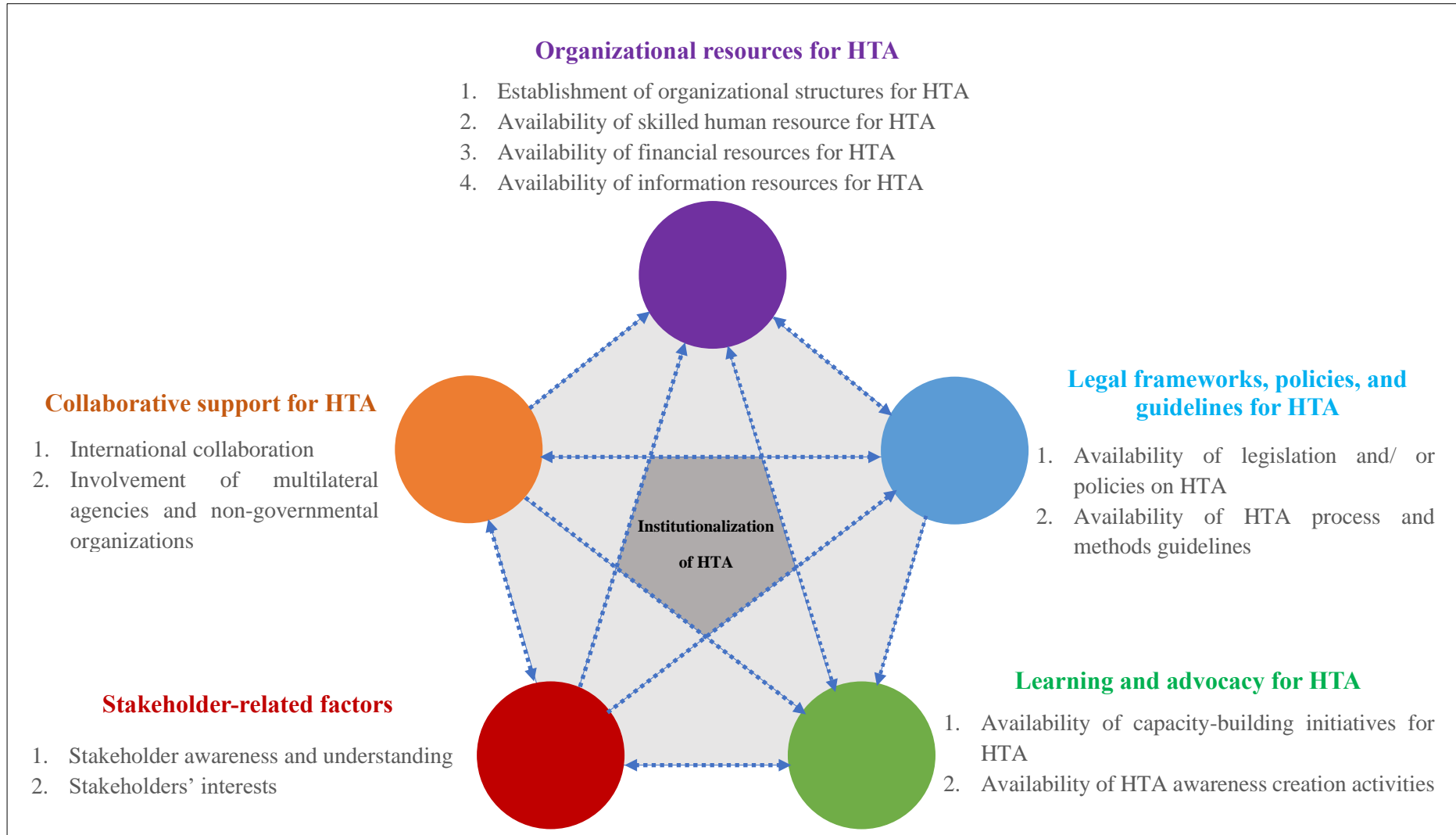


Figure 4.5: Conceptual framework of factors influencing institutionalization of HTA

## 4.4 Limitations

This review suffers from selection bias based on exclusion of non-English publications and grey literature. However, given the inclusion of numerous studies from countries of different income levels, it is likely that the review captured majority of the key factors influencing institutionalization of HTA. Nevertheless, future reviews should consider non-English publications and grey literature.

## 4.5 Chapter summary

In this Chapter, I conducted a scoping review with the aim of guiding the PhD by: - a) synthesizing evidence on factors that influenced institutionalization of HTA at the macro-level across different contexts; b) identifying gaps in empirical studies that examined factors influencing institutionalization of HTA; and c) informing the development of a conceptual framework for use in the third sub-study of this PhD. This review offers two key highlights.

Firstly, this review shows that institutionalization of HTA was influenced by 5 sets of factors that were linked and/or interlinked in complex ways. These factors were common to countries irrespective of their income levels and they included: - a) organizational resources for HTA; b) legal frameworks, policies, and guidelines for HTA; c) learning and advocacy for HTA; d) stakeholder-related factors; and e) collaborative support for HTA. I organized these factors into a framework to direct attention to the key aspects that influence institutionalization of HTA, and the complex linkages among them.

Secondly, this review shows that the number of studies examining factors influencing institutionalization of HTA in low and lower-middle-income countries remain limited. This gap is important given that these countries are yet to institutionalize HTA. This gap informed the third sub question of this PhD which was: What were the factors influencing institutionalization of HTA in Kenya? To address this question, I used the conceptual

framework developed from the findings of this review to identify the key factors that were influencing institutionalization of HTA in Kenya.

## CHAPTER 5: METHODOLOGY

### 5.1 Introduction

In this chapter, I discuss the methodology employed to answer the three sub-questions which formed the three sub-studies of this PhD namely: - a) What led to the gazettelement of the HBPAP policy idea in Kenya? b) To what extent did HBPAP's healthcare priority-setting process for health benefits package development meet the normative conditions of a good healthcare priority-setting process, and why? and, c) What were the factors influencing the institutionalization of HTA in Kenya? This chapter is structured into the following sections: - research methodology, methodological limitations, and concluding summary.

### 5.2 Research methodology

The description of this PhD's methodology is informed by the "research onion" framework (Figure 5.1). This framework outlines 6 critical features that inform a study's methodology namely "*research philosophy, approach to theory development, methodological choice, research strategy(ies), time horizon, and techniques and procedures*" (Saunders et al., 2019). I chose the "research onion" framework for two reasons. Firstly, it provided me with a systematic approach for describing and organizing how I conducted my research study. Secondly, it allowed me to be explicit about the assumptions and values that informed the choices I made with regards to the research design employed in this PhD study. This framework therefore enabled me to create an audit trail of the study's methodology which instilled rigour into the study by providing the reader with the rationales and decisions behind the study methodology (Houghton et al., 2013, Shenton, 2004, Long and Johnson, 2000). Rigour refers to the process of "*ensuring that the research design, methods, and conclusions are explicit, public, replicable, open to critique, and free of bias*" (Johnson et al., 2020).



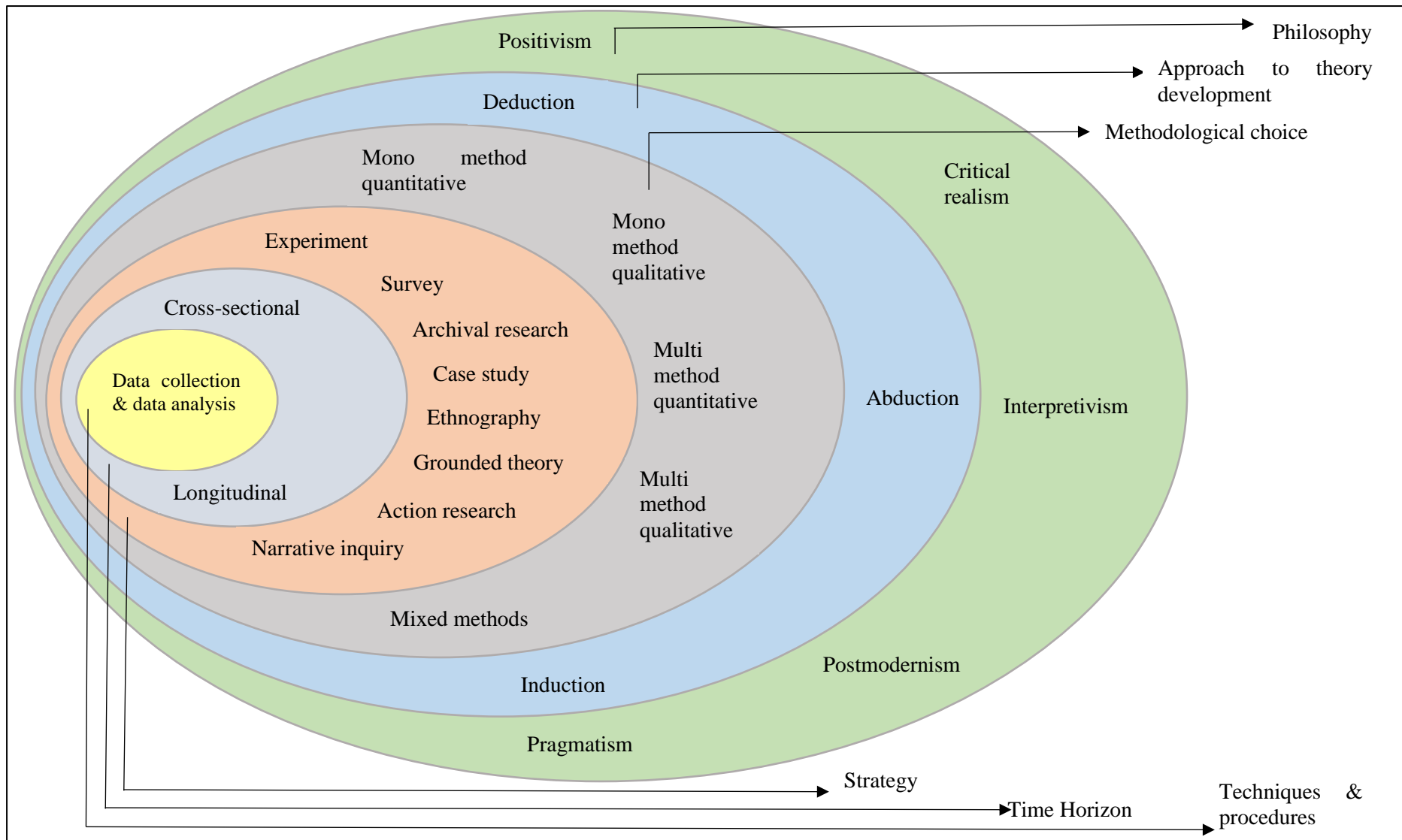


Figure 5.1: The Research "onion" framework (Saunders et al., 2019)

### 5.2.1 Research philosophy

Research philosophy is defined as a set of assumptions and beliefs that guide how a researcher views and develops knowledge of the world or phenomenon they wish to investigate (Saunders et al., 2019). The choice of a research philosophy is critical as it informs the inner aspects of the “research onion” shown in Figure 5.1 (Saunders et al., 2019).

The research philosophy that I employed in this study was interpretivism. Interpretivism is a set of assumptions and beliefs that the world (or phenomenon under investigation) and knowledge of it are socially constructed via meanings that people (or actors) attach to experiences and situations (Saunders et al., 2019, Gilson et al., 2012). Interpretivism further recognizes that there is more than one reality of the world (or phenomenon under investigation) because reality is created by people’s perceptions, actions, and interactions (Saunders et al., 2019, Gilson et al., 2012). In other words, according to interpretivism, the world (or phenomenon under investigation) does not exist independently of people (Gilson et al., 2012). Lastly, interpretivism recognizes that researchers construct knowledge of the world (or phenomenon under investigation) based on their interpretation of what they see and/or hear (Gilson et al., 2012).

In this PhD study, I used interpretivism for two reasons. Firstly, it aligned with my assumptions, beliefs, and understanding that the social and political nature of healthcare priority-setting processes- the phenomenon of inquiry in this PhD- were due to the actions, interactions, and perceptions of actors involved in the processes. These assumptions, beliefs, and understanding were based on my engagement with conceptual and empirical literature on healthcare priority-setting processes as presented in Chapters 1 to 4. Secondly, it aligned with my perspective of generating knowledge regarding the phenomenon under inquiry which involved interpreting what I saw and heard from data sources.

## 5.2.2 Approach to theory development

An approach to theory development refers to whether a research study draws inferences to create a new theory (*inductive approach*) or, builds upon (or tests) an existing theory (*deductive approach*) (Saunders et al., 2019).

In this PhD, I employed a deductive approach to draw inferences from the study findings that built upon existing theoretical and conceptual frameworks. I chose a deductive approach for the following reasons. Firstly, the use of conceptual and theoretical frameworks in a deductive approach provided me with a structured approach for collecting and analyzing data by informing the types of questions asked and the types of themes generated respectively (Saunders et al., 2019, Collins and Stockton, 2018). Secondly, the use of conceptual and theoretical frameworks in a deductive approach strengthened the credibility (trustworthiness) of the findings enabling me to display explicitly to the reader the assumptions and beliefs that underpinned data collection and analysis (Saunders et al., 2019, Collins and Stockton, 2018, Gilson et al., 2012). The reader is therefore able to use the theories and conceptual frameworks to critically evaluate or judge the trustworthiness of the study findings and inferences for themselves (Collins and Stockton, 2018, Gilson et al., 2012). Lastly, as shown in the discussion sections of Chapters 6-8, the use of the conceptual and theoretical frameworks associated with the deductive approach enabled analytic generalizability or transferability of the inferences drawn from the study findings to other studies that had applied similar conceptual and theoretical frameworks (Saunders et al., 2019, Collins and Stockton, 2018, Gilson et al., 2012). For this PhD study, I employed one theory and two conceptual frameworks as appropriate to the three sub-studies. These are described further below.

### 5.2.2.1 Kingdon's Multiple Streams Theory

For sub-study 1, I used Kingdon's Multiple Streams Theory (Figure 5.2) (Kingdon, 1993, Kingdon, 1984). I chose Kingdon's theory given its utility in explaining how and why agenda-

setting and other policy formulation stages occurred, as shown in multiple empirical studies that have employed this theory to explain policy processes across different sectors, different levels of governance, and different countries (Jones et al., 2016, Nikolaos, 2007). The explanatory power associated with Kingdon’s theory made it relevant to Objective 1 of this PhD which aimed to explain how and why the HBPAP policy was gazetted in Kenya. Furthermore, the broad application of Kingdon’s theory to different policies across different sectors and countries of different income levels, highlighted its adaptability and generalizability which further contributed to its suitability to my study which looked at a procedural policy at the national level in a lower-middle-income country. A detailed description of this theory is provided in *Chapter 2, Subsection 2.3.6*, and *Chapter 6*.

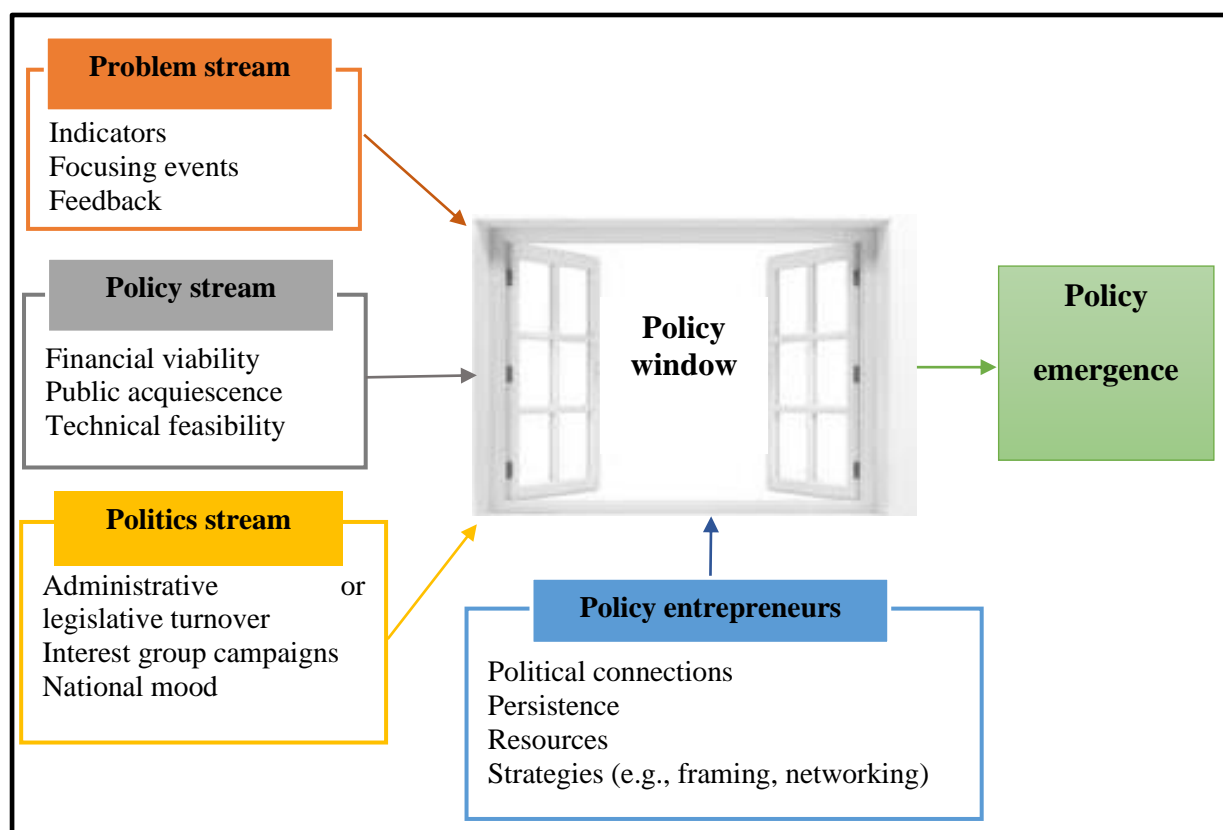


Figure 5.2: Kingdon’s Multiple Streams Theory (Kingdon, 1993, Kingdon, 1984)

#### 5.2.2.2 *Barasa et al.'s framework for evaluating healthcare priority-setting processes*

For sub-study 2, I adapted the Barasa et al., conceptual framework (Barasa et al., 2015) to describe and qualitatively evaluate the extent to which HBPAP's healthcare priority-setting process fulfilled the normative procedural and outcome conditions of a healthcare priority-setting process.

I chose the Barasa et al., framework given the credibility of its concepts. This credibility was founded on the fact that the framework was developed from a synthesis of recurrent procedural and outcome conditions outlined in existing evaluative frameworks (for example, the Accountability for Reasonableness framework, the Kipiriri and Martin Framework, and the Sibbald et al., framework) as well as empirical studies on evaluation of healthcare priority-setting processes based on these existing frameworks. The framework's credibility was further strengthened by the fact that its concepts were drawn from theoretical literature on deliberative democracy and procedural justice which contributed to the fairness and legitimacy of the concepts (Barasa et al., 2015). I also chose the Barasa et al., framework because it has been used to qualitatively evaluate healthcare priority-setting processes in Kenya at the hospital (Barasa et al., 2017) and county (Waithaka et al., 2018) levels. This empirical application strengthened the framework's appropriateness to my study which was based in Kenya.

For this study, I adapted the Barasa et al., framework [*Described in Chapter 2, Subsection 2.4.5*] in 4 ways. Firstly, I merged some of the conditions outlined in the framework given the similarities in the meaning and application of the concepts. For example, while Barasa et al., recognize the outcome conditions of shifted (reallocated) priorities and implementation of decisions, I merged these into impact on health policy and practice. This broader classification could accommodate multiple interpretations based on the healthcare priority-setting process and the context under consideration. Secondly, while the framework considered incorporation of community/public values and stakeholder participation separately, I merged these two

conditions given the dependence of incorporation of community/ public views on stakeholder involvement in healthcare priority-setting processes (Coulter and Ham, 2000, Mooney, 1998). Thirdly, as indicated by Barasa et al., while they identified equity and efficiency as outcome conditions, they noted that it was challenging to attribute these goals to a specific healthcare priority-setting process (Barasa et al., 2015). Furthermore, in empirical applications of this framework, it was noted that equity and efficiency were explored in terms of whether they were applied as priority-setting criteria and not as outcomes of the process (Barasa et al., 2017, Waithaka et al., 2018). Therefore, in the adapted framework, equity and efficiency were considered as part of the procedural condition on use of evidence. Lastly, I adopted the term “good” to describe a healthcare priority-setting process that fulfilled the procedural and outcome conditions outlined in the Barasa et al., framework. Importantly, a “good” healthcare priority-setting process was also fair, legitimate, socially justifiable, and successful. This is because the Barasa et al., framework incorporated procedural and outcome conditions from other evaluative frameworks that made a healthcare priority-setting process: - a) fair and legitimate according to the Accountability for Reasonableness Framework; and b) successful according to the Sibbald et al., framework (*See Chapter 2, Subsection 2.4.3*) and the Kipiriri and Martin framework (*See Chapter 2, Subsection 2.4.4*). It also reflected values that made a healthcare priority-setting process socially justifiable according to the Social Values Framework (*See Chapter 2, Subsection 2.4.2*). The adapted framework is shown in Figure 5.3.

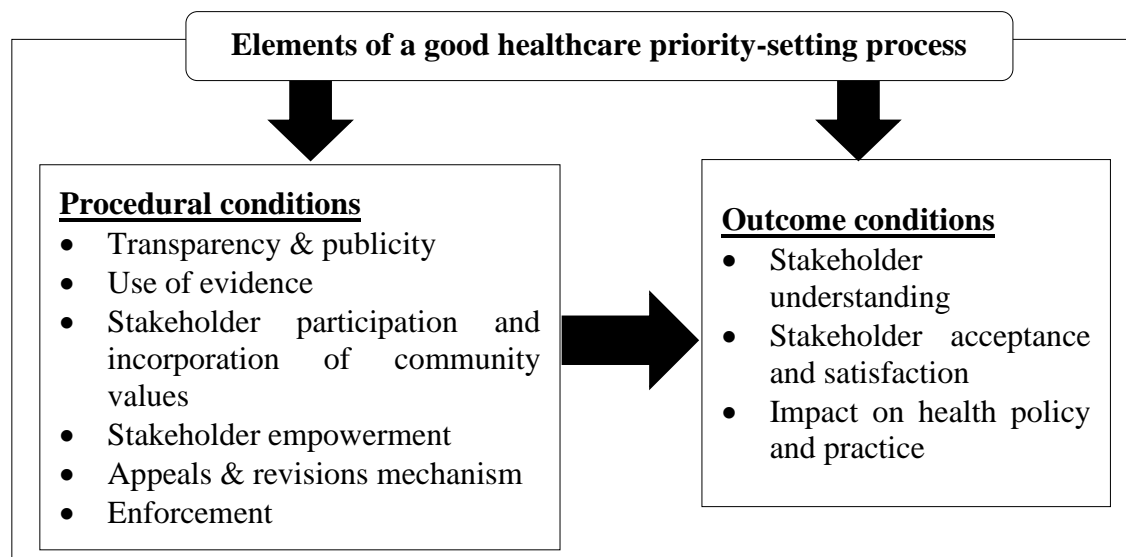


Figure 5.3: Framework for evaluating healthcare priority-setting processes. Adapted from Barasa et al., (Barasa et al., 2015).

As with other evaluative frameworks, the Barasa et al., framework is a descriptive framework that outlines concepts that provide a common language for those interested in describing and qualitatively evaluating healthcare priority-setting processes. According to Barasa et al., the fulfilment of the procedural conditions enhances the achievement of the outcome conditions. The definitions of the procedural and outcome conditions are provided in Table 5.1.

Table 5.1: Definition of the concepts used in the adapted Barasa et al., Framework

<b>Procedural condition</b>	<b>Definition</b>
<b>Transparency and Publicity</b>	Information on the healthcare priority-setting process (such as information on procedures followed, evidence considered, stakeholders involved, decisions made, and rationales for the decisions made) is openly and publicly available.
<b>Use of evidence</b>	The reasons (such as economic, scientific, or social considerations) upon which the healthcare priority-setting and resource allocation decisions are made.
<b>Stakeholder participation and</b>	Relevant health system stakeholders attend meetings, provide inputs (shared beliefs, values, and principles), and contribute to

<b>incorporation of community values</b>	setting priorities and making decisions on the allocations of resources.
<b>Empowerment</b>	The extent to which power differences among stakeholders are minimized and opportunities for stakeholder participation are maximized to enable contribution and ability to influence the healthcare priority-setting process.
<b>Appeals and revisions mechanism</b>	A mechanism through which the healthcare priority-setting process and resource allocation decisions can be challenged, reconsidered, and amended given emerging evidence or concerns over the validity of the process or evidence used.
<b>Enforcement</b>	A mechanism for ensuring that all the other procedural conditions are adhered to.
<b>Outcome condition</b>	<b>Definition</b>
<b>Stakeholder understanding</b>	Stakeholders gain knowledge of the goals, structure, rationales, and outcomes of the healthcare priority-setting process.
<b>Stakeholder acceptance and satisfaction</b>	The extent to which stakeholders regard the healthcare priority-setting process and decisions as valid (adequate or suitable) and the extent to which they are willing to support and participate in similar processes in the future.
<b>Impact on health policy and practice</b>	Extent to which changes in priorities, distribution of resources and/ or health system policies can be credibly linked to the healthcare priority-setting process.

### *5.2.2.3 Conceptual framework on factors influencing institutionalization of HTA*

For sub-study 3, I used a conceptual framework (Figure 5.4) developed from a scoping review on factors influencing institutionalization of HTA as presented in Chapter 4 of this thesis. Institutionalization of HTA refers to conducting and utilizing HTA as a normative practice for guiding decisions on allocation of resources across competing uses within the health system (World Health Organization, 2001).



In the scoping literature review, a factor was defined as any feature whose presence or absence could either enable or hinder institutionalization of HTA respectively. From the reviewed literature, I identified 5 sets of factors that influenced institutionalization of HTA across high, middle, and low-income countries globally. These factors influenced a country's capacity to conduct and utilize HTA as a way of allocating resources in the health sector. The review showed that the factors were linked and/or interlinked in complex ways meaning that the presence or absence of one set of factors could influence the presence or absence of another set of factors. While in Chapter 4 the framework had one-way and two-way arrows to show direction of influence in the linkages and/or interlinkages between factors (which were based on the findings of the literature review), in sub-study 3 I did not include these one-way or two-way arrows because I recognized that the direction of influence between factors could vary based on the findings of a particular context.

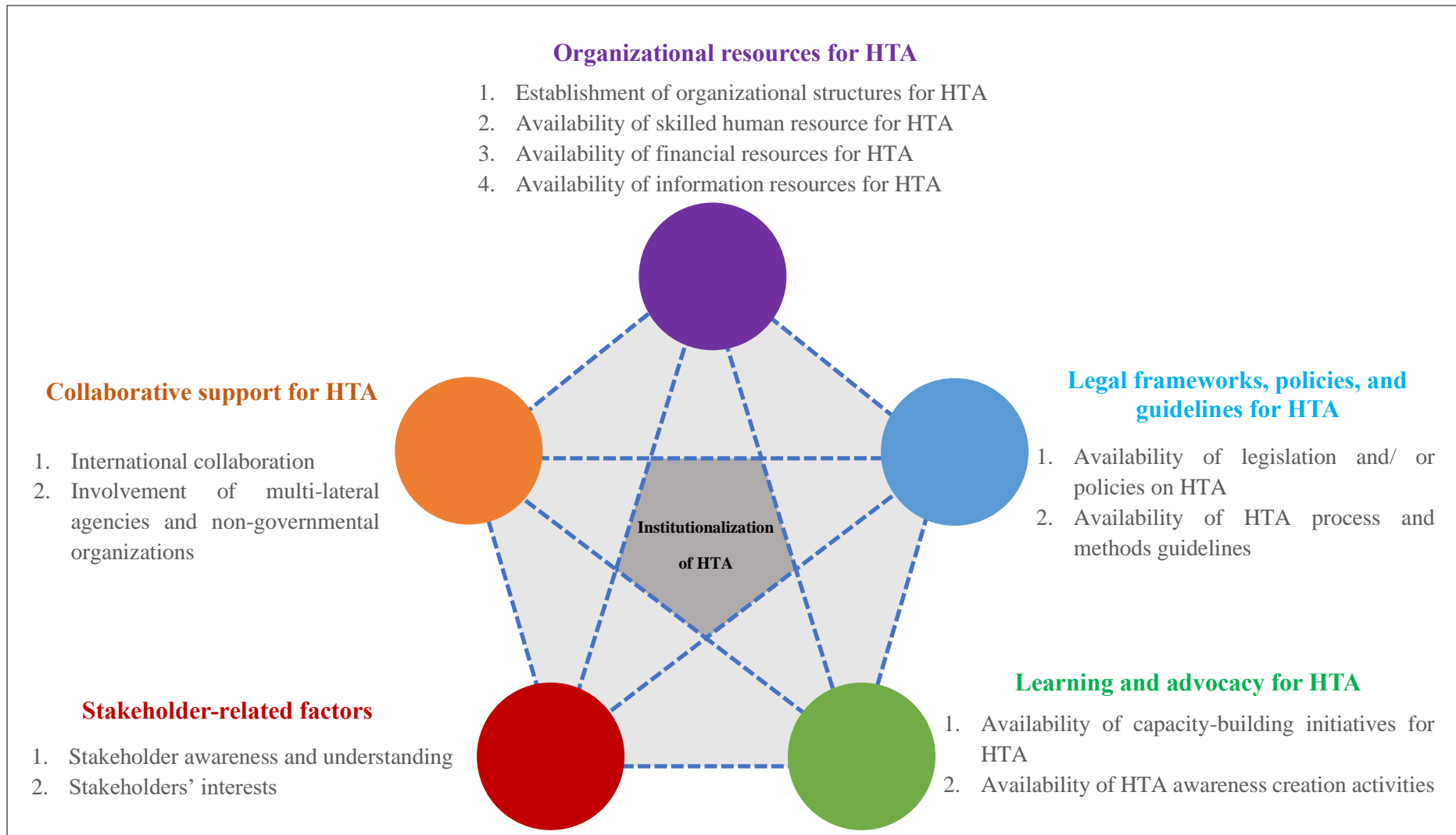


Figure 5.4: A conceptual framework on factors influencing institutionalization of HTA

### 5.2.3 Methodological choice

The methodological choice is influenced by the research philosophy adopted in the study (Saunders et al., 2019). With interpretivism as my research philosophy, the most appropriate methodological choice for this study was therefore qualitative research. Qualitative research involves data collection and analysis methods that rely on non-numerical data such as text/ word and/ or audio, visual, and audio-visual materials (Saunders et al., 2019).

I chose qualitative research as the methodology of choice for my study because it allows a researcher to examine the phenomenon of interest within its natural context and to engage with people involved in this phenomenon. This engagement allows the researcher to capture-through hearing and observation- people's perceptions, stories, and socially constructed meanings of the phenomenon under investigation (Saunders et al., 2019, Ritchie et al., 2013). In this study, qualitative research allowed me to engage with the participants involved in the policy process, implementation, and institutionalization of explicit healthcare priority-setting processes in Kenya which subsequently allowed me to capture participants' perceptions on what happened and why.

Secondly, I chose qualitative research as it has been shown to be suitable for uncovering the complex nature of healthcare priority-setting processes (Coulter and Ham, 2000). As shown in the findings sections of Chapters 6-8, the use of qualitative research was useful for providing rich descriptions of the complex nature of the policy process, implementation, and institutionalization of explicit healthcare priority-setting process in Kenya given the involvement of multiple actors and the influence of multiple contextual factors.

### 5.2.4 Research strategies

Research strategies refer to the plans that the researcher puts in place to collect data for their study (Saunders et al., 2019). The research strategy that I chose for my PhD was case study. A

case study refers to an in-depth inquiry of a “*phenomenon within its real-life context*” (Yin, 2003). I selected case study design because it is suitable for studying complex social processes or phenomena and it recognizes that contextual conditions are relevant to understanding the phenomenon of interest (Yin, 2003). These reasons made the case study design suitable to my PhD because healthcare priority-setting processes are context-dependent social processes (Hauck et al., 2004, Martin and Singer, 2003, Coulter and Ham, 2000). In essence, the case study approach allowed me to engage with real-life Kenyan policy actors to explore their realities of the policy process, implementation, and institutionalization of explicit healthcare priority-setting processes. Furthermore, I selected case study because it is suitable for examining a phenomenon that has not been previously examined, or alternatively, has been examined limitedly within a particular context (Yin, 2003). This was relevant to my PhD given the limited number of studies examining macro-level healthcare priority-setting processes in Kenya.

Specifically, I conducted three holistic single-case studies. A holistic single-case study design involves an in-depth inquiry of a single phenomenon of interest which forms the case or unit of analysis (Yin, 2003). One of the key rationales for conducting a holistic single case study is the limited observation of a phenomenon of interest as was the case with macro-level healthcare priority-setting processes in Kenya. The three holistic single cases were related to the three sub-studies of this PhD namely: a) the gazettement of the HBPAP policy idea; b) HBPAP’s healthcare priority-setting process for health benefits package development; and c) institutionalization of HTA Kenya.

Each holistic single case was guided by a different theory or conceptual framework. The first holistic single case of the HBPAP policy was guided by Kingdon’s Multiple Streams theory to generate an explanation of how and why the policy idea on HBPAP was gazetted. The second holistic single case of HBPAP’s healthcare priority-setting process was guided by the adapted

Barasa et al., framework to describe and qualitatively evaluate the process. The third and final holistic single case of institutionalization of HTA was guided by the conceptual framework developed in Chapter 4 to identify factors that were influencing the institutionalization of HTA in Kenya. The findings of each of these holistic single cases are provided in Chapters 6-8. A synthesis of these findings generated relevant policy implications on factors that influenced the policy process, implementation, and institutionalization of explicit healthcare priority-setting at the macro-level in Kenya as shown in Chapter 9.

### 5.2.5 Time horizon

Time horizon refers to the duration of time over which the phenomenon of interest is investigated (Saunders et al., 2019). In terms of time horizon, this study was longitudinal as I examined retrospectively over time the policy process, implementation, and institutionalization of explicit healthcare priority-setting at the macro-level in Kenya.

### 5.2.6 Data collection and data analysis

Data collection and data analysis are the innermost features of the “research onion” framework. I discuss each of these features separately below.

#### 5.2.6.1 *Data collection*

Data collection refers to the process of accessing and collecting appropriate data from data sources (Saunders et al., 2019). The following subsections outline how I accessed and collected data from my data sources.

##### 5.2.6.1.1 *Ethical considerations*

Since my study involved primary data collection from human subjects, I applied and received ethical approval from the Ethics Committee of the London School of Hygiene and Tropical Medicine (LSHTM)- Reference Number: - 25640 (Appendix 3). I also obtained local research ethics approval from the Kenya Medical Research Institute Scientific and Ethics Review Unit

(KEMRI-SERU), Nairobi, Kenya- Reference Number: - KEMRI/SERU/CGMR-C/185/4018 (Appendix 4). KEMRI is a state corporation tasked with conducting and ensuring that health research in Kenya adheres to key ethical and scientific principles (Kenya Medical Research Institute, 2019). Furthermore, I obtained a research license from the National Commission for Science, Technology, and Innovation as required by the Science and Technology Innovation Act. Lastly, I completed LSHTM's online Research Ethics training to ensure that I understood the ethical principles of research (Appendix 5).

#### 5.2.6.1.2 Sampling strategy and study population

I used purposive and snow-balling techniques to sample study participants. Purposive sampling refers to “*the deliberate choice of a participant due to the qualities the participant possesses*” (Etikan et al., 2016) with the aim of optimizing collection of “*information-rich data*” (Ritchie et al., 2013, Sandelowski, 1995). The qualities that a participant possesses may include their socio-demographic features, knowledge and/ or experience. These qualities enable researchers to conduct in-depth inquiry thereby generating thick descriptions that lead to a better understanding of the phenomenon of interest (Etikan et al., 2016, Ritchie et al., 2013).

For my study, I purposively selected participants with known involvement in the cases under inquiry as they were likely to have greater knowledge and/or experience of the cases than participants with no known involvement. *For sub-study 1*, the purposive criterion was the participant's known involvement in the policy process for developing and gazetting the HBPAP policy idea. *For sub-study 2*, the purposive criterion was the participant's known involvement in HBPAP's healthcare priority-setting process as a HBPAP member. *For sub-study 3*, the purposive criterion was the participant's known involvement in activities related to institutionalization of HTA in Kenya.

A participant's known involvement was determined in the following ways. Firstly, through publication of their names in publicly available official documents such as gazette notices. Secondly, through my involvement in activities related to healthcare priority-setting processes such as providing administrative support to HBPAP (during its second year of tenure) and participating in a HTA training workshop. Lastly, through guidance from my supervisor- Professor Edwine Barasa- who was not only a HBPAP member but also an active policy actor with several years of policy engagement at the national level in Kenya. My involvement and that of my supervisor Professor Edwine Barasa facilitated access to study participants. The close involvement of a researcher in the phenomenon of inquiry has been shown to increase access to study participants and data (Walsham, 2006).

The purposively selected participants were subsequently asked to nominate other actors who were actively involved in the respective study cases through snowballing technique which aids in accessing hard-to-reach elites where power and trust are necessary for access (Atkinson and Flint, 2001). Snowballing was suitable for this study since stakeholders who are involved in national level processes are considered political and technical elites given that the national level is the highest political office for the health sector and is responsible for providing technical support to the national and sub-national levels in Kenya. Given their position and mandates, access to some of these stakeholders was only made possible through email or telephone introduction by other study participants.

Sampling of the study participants stopped at the point of data saturation- where no new information was emerging from the in-depth interviews with the addition of new participants (Ritchie et al., 2013, Saunders et al., 2018). The final sample of participants included in each sub-study is provided in Table 5.2. I do not provide any demographic information to avoid deductive disclosure of participants and to protect the participant's anonymity and confidentiality given the small sample size and the sensitive nature of healthcare priority-

setting and resource allocation decisions. Deductive disclosure of participants can occur when rich descriptions of study participants are provided in qualitative studies which not only undermines the participants' anonymity and confidentiality, but also exposes them to harmful effects (Kaiser, 2009).

Table 5.2: List of participants

<b>Sub-study 1: What led to the gazettelement of the HBPAP policy idea in Kenya?</b>	
<b>Category</b>	<b>Number</b>
Development Partners	n=7
Local Research Organizations	n=3
Ministry of Health	n=8
Semi- Autonomous Government Agencies	n=2
<b>Total</b>	<b>n=20</b>
<b>Sub-study 2: To what extent did HBPAP's healthcare priority-setting process meet the procedural and outcome conditions of a good healthcare priority-setting process, and why?</b>	
Development partners	n=3
HBPAP members	n=9
Local Academic and Research organizations	n=2
Ministry of Health	n=4
Semi-autonomous Government Agencies	n=2
<b>Total</b>	<b>n=20</b>
<b>Sub-study 3: What were the factors influencing the institutionalization of HTA in Kenya?</b>	
Development partners	n=6
Local Academic and Research Organizations	n=6
Ministry of Health	n=8
Semi-Autonomous Government Agencies	n=10
<b>Total</b>	<b>n=30</b>



#### 5.2.6.1.3 Data collection

I collected data through in-depth interviews and document reviews between July 2021 and April 2022.

##### **A. In-depth interviews**

For the interviews, I developed a semi-structured topic guide (Appendix 6) from the key elements of the study's conceptual and theoretical frameworks. A semi-structured topic guide was appropriate for this study as it allowed core topics to be discussed thereby optimizing the interview time especially when the time was limited. However, it also allowed for flexibility in the sequencing and phrasing of the questions. Lastly, as important to a study seeking respondent perceptions and views, it enabled exploration of new topics beyond those outlined in the topic guide but related to the phenomenon under inquiry (Jamshed, 2014, Ritchie et al., 2013, Turner III, 2010).

The topic guide contained questions pertaining to the three sub-studies. The rationale behind using a single topic guide was the knowledge that some of the participants could answer questions for more than one sub-study given their involvement in macro-level healthcare priority-setting processes. This led to an overlap of study participants across the three sub-studies (for example 14 participants answered questions for sub-study 1 and 2; 6 participants answered questions for sub-study 2 and 3; and 6, 14, and 24 participants answered questions for only sub study 1, 2, and 3 respectively. The final number of respondents interviewed for each sub study was 20, 20, and 30 respectively). *For sub-study 1*, the topic guide elicited participant's views on the problem(s) associated with healthcare priority-setting processes and health benefits packages of relevance to HBPAP's mandates. The interview guide also elicited participants' views on potential policy solutions that were considered, the political context surrounding the policy idea on HBPAP; and lastly, the policy windows and policy entrepreneurs that led to the gazettelement of the HBPAP policy. *For sub-study 2*, the topic guide

elicited participants' views on the procedural and outcome conditions of the healthcare priority-setting process conducted by HBPAP. Lastly, *for sub-study 3*, the topic guide elicited participants' views on factors influencing institutionalization of HTA in Kenya.

After developing the semi-structured topic guide, I requested a group of health policy and systems researchers to comment on the appropriateness of the questions to the cases under interrogation. Then, I piloted the topic guide with a few participants who had previously been involved in macro-level processes as this group was similar to the final sample included in my study. These participants were not part of the final sample population because they did not meet the purposive criterion of being involved in the cases of interest to this PhD. The aim of the pilot was three-fold: - to test the clarity of the questions, to identify any glaring omissions, and to test my interviewing technique. I used the feedback obtained from the health policy and systems researchers as well as the pilot study to improve the guide's content validity by rewording and rephrasing the questions. Content validity of a tool in qualitative research refers to the suitability of a tool's questions to the phenomenon under inquiry (Saunders et al., 2019). I also used the feedback obtained from the pilot to improve my interviewing technique by avoiding leading questions and listening attentively.

After the pilot testing, I invited study participants to engage in the in-depth interviews via telephone and email. None of them declined to participate. Before the interviews, each participant reviewed the study's information sheet (Appendix 7) and provided informed consent (Appendix 8). Their participation was therefore voluntary. I conducted the interviews via face-face or zoom videoconferencing at a time that was convenient to the participant. Each interview was conducted in English, audio-recorded with an encrypted audio-recorder and, lasted between 25 and 80 minutes. I took fieldnotes during the in-depth interviews to summarize discussion points when participants requested for the tape recorder to be switched off given the perceived sensitivity of the information they were about to share. I also took

fieldnotes as aids for critical reflection of emerging themes, and to note areas that needed further questioning.

Because the in-depth interviews were conducted during the Covid-19 pandemic, participants and I observed proper precautionary measures during face-face interviews. These measures included wearing of masks, sanitization, physical distancing, and use of well-ventilated rooms. Zoom videoconferencing offered an alternative approach for conducting the interviews when lockdowns were imposed in Kenya due to the Covid-19 pandemic. However, data collection through zoom videoconferencing was challenging for two reasons. Firstly, internet instability led to intermittent loss of connection which interrupted recording potentially leading to loss of data. I mitigated against this loss by repeating questions to participants and by asking participants to repeat their responses. Secondly, zoom videoconferencing was less personal than face-face interviews which may have potentially undermined rapport and the collection of thick data.

During in-depth interviews, I protected a participant's anonymity and confidentiality by not collecting any personal data such as name, gender, or position held. Instead, I assigned a numerical code to each participant's audio-file as an identifier. In addition, during interviews, I did not disclose to the current participant which other participants had been interviewed.

### ***B. Document reviews***

In this study, I reviewed various documents as shown in Table 5.3. Documents are forms of secondary data as they include data that have been collected and made available by other sources rather than by the researchers (Saunders et al., 2019, Bowen, 2009). Documentary data can be in the form of text or non-text data. Examples of text data include an organization's database, internal correspondence/communications (e.g., emails, formal letters, memos, minutes) and, publications (e.g., reports, magazines, newspapers) (Saunders et al., 2019). On

the other hand, non-text data include media accounts, audio or audio-visual recordings, and images (e.g., photographs and web images) (Saunders et al., 2019).

Table 5.3: A list of the documents that were reviewed across the three sub-studies

<b>Types of documents</b>	<b>Examples (in electronic format)</b>
Campaign manifesto	<ul style="list-style-type: none"> <li>• Transforming Kenya- Securing Kenya’s prosperity 2013-2017</li> <li>• Jubilee Manifesto 2017- Continuing Kenya’s Transformation together</li> </ul>
Government documents (national policy documents, laws, and bills)	<ul style="list-style-type: none"> <li>• 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> Drafts of the Kenya Health Financing Strategy 2015-2030</li> <li>• Second Medium-Term Plan 2013-2017 Transforming Kenya: Pathway to devolution, socio-economic development, equity, and national unity</li> <li>• Sessional Paper No 2 on National Social Health Insurance in Kenya</li> <li>• Health Act 2017</li> <li>• Kenya Health Policy 2014-2030</li> <li>• Cabinet Memorandum 2018- Roadmap to attain Universal Health Coverage in Kenya</li> <li>• Gazette notice Vol. CXX- No.69</li> </ul>
HBPAP documents	<ul style="list-style-type: none"> <li>• Procedural documents- attendance sheets and memos</li> <li>• HBPAP reports and annexes</li> <li>• HBPAP presentations</li> </ul>
Semi-autonomous Government Agencies’ documents	<ul style="list-style-type: none"> <li>• Report on National Health Insurance Fund Strategic Review and Market Assessment of Prepaid Health Schemes</li> <li>• NHIF reforms panel report</li> </ul>
Local Academic and Research Organizations	<ul style="list-style-type: none"> <li>• Published empirical studies by academic and research organisations</li> <li>• Reports on stakeholder engagement workshops</li> <li>• PowerPoint presentations made during stakeholder workshops</li> <li>• Reports on Health Technology Assessment capacity in Kenya</li> </ul>

Development Partner reports and presentations	<ul style="list-style-type: none"> <li>• Report on stakeholder analysis to support design and finalization of health financing strategy for Kenya</li> <li>• World Health Organization meeting- Towards UHC in Kenya: issues, options, and guiding principles for the way forward</li> <li>• World Bank Report on Moving towards UHC in Kenya</li> <li>• Health Benefits Package Advisory Panel Study visit to Thailand</li> <li>• Japan International Cooperation Agency Loan policy action on Health Technology Assessment</li> <li>• Mission report on National Health Insurance Fund Health Financing Reforms Experts Panel visit to Thailand on UHC and Health Technology Assessment</li> <li>• Report on the Stakeholder analysis to support design and finalization of the Health Financing Strategy for Kenya</li> </ul>
Media reports	<ul style="list-style-type: none"> <li>• Web media e.g., Development Partners’ Websites and MOH websites</li> <li>• News media e.g., Online newspaper reports</li> <li>• Social media e.g., Twitter</li> </ul>

I identified documentary data in the following ways. Firstly, through the study participants who shared with me the documents and/ or recommended media platforms where I could find additional information. The availability of documents from study participants and organizational media platforms strengthened the authenticity of the data retrieved. Secondly, I searched online for websites and social media accounts of organizations that were known to be involved in national level processes within the health sector in Kenya as well as recognized media houses in Kenya. Thirdly, I was aware of the existence of some of the documents because I had provided support to HBPAP, and I had participated in a HTA workshop. Lastly, I was informed of the existence of some of the documents by one of my supervisors- Professor Edwine Barasa- who has been involved as a policy actor at the national level in Kenya.

I included documents in this study for the following reasons. Firstly, documents provide a good data source for retrieving accounts of past events (Althubaiti, 2016, Bowen, 2009). This was important since my study involved interviews of cases that had occurred several months to years ago from the point of data collection. These interviews were prone to recall bias which refers to participants' inability to remember past experiences accurately (Althubaiti, 2016). However, by combining interviews and document reviews, I minimized the methodological shortcoming of recall bias that was associated with the interviews. Combining different data collection methods builds trustworthiness in study findings by overcoming methodological shortcomings of individual data collection methods (Shenton, 2004, Long and Johnson, 2000).

Secondly, by reviewing documents, I was able to identify supplementary information on actors, context, and procedures that were relevant to the 3 study objectives but had not been identified by the study participants. This information is presented as excerpts and images in the findings' sections of Chapters 6-8. Furthermore, I used the supplementary information obtained from the documents to develop additional questions and prompts for the interviews. This is a recognized benefit of including document reviews in qualitative studies (Bowen, 2009).

Lastly, I included documents to triangulate findings from interviews (and vice versa) since I collected and analyzed data concurrently. The inclusion of documentary data in a study supports researchers to verify findings obtained from other sources (Bowen, 2009). For example, by reviewing the social media accounts and websites of organizations involved in macro-level healthcare priority-setting processes in Kenya, I obtained text and non-text data such as images that corroborated participants' reports which strengthened the credibility of the study findings. These images and excerpts are provided as findings in Chapters 6-8. The identification of similar findings from different data collection methods examining the same phenomenon of interest increases the credibility or trustworthiness of the findings (Saunders et al., 2019).

#### 5.2.6.1.4 Data management

##### ***A. Data transcription***

I sent all the audio-recordings for transcription to a professional transcription agency approved by KEMRI in Kenya. The transcription agency signed a confidentiality clause on how to store and delete the data once transcription was completed. During transcription, all personally identifying information provided subconsciously by participants were redacted (or de-identified or de-labelled) to maintain participant's anonymity and confidentiality. Each transcript had a unique numerical code that was assigned to each audio-file during data collection. I reviewed each transcript for transcription accuracy by comparing it to the respective audio-file.

##### ***B. Data storage***

*For data collected through interviews*, I transferred all audio-recordings to an encrypted and password protected laptop to prevent loss and unauthorized access. Similarly, I stored transcripts of the audio-recordings in the laptop. I expanded all fieldnotes onto Microsoft Word immediately after the interviews to avoid data loss through forgetfulness. All file names for audio-recordings, transcripts, and fieldnotes contained a code that captured the data collection method, number, date, and time. For example, IDI\_001\_09082021\_0900. This was done to maintain participant's confidentiality and to facilitate easier storage and retrieval.

*For documentary data*, I downloaded electronic versions of documents from emails sent by participants and from websites of recognized organizations that are involved in macro-level processes within Kenya's health sector. I used the copy and paste function to transfer text data from media sources onto Microsoft word documents to facilitate easier retrieval and storage. In addition, I downloaded images obtained from social media directly onto my laptop.

I stored all the data obtained in this study in a password protected folder to prevent unauthorized access. I placed this folder in One drive to allow automatic backup of the data thereby preventing accidental losses. The data will be stored for a minimum of 10 years after the completion of the study in keeping with LSHTM's data storage and retention policy.

### ***C. Data classification and sharing***

This was guided by the LSHTM Data classification and Handling Policy. In this study, data collected through in-depth interviews and HBPAP's procedural documents were classified as confidential as disclosure could upset individuals involved. These data were therefore only accessible to the student and her supervisory team. However, some of the de-identified data have been made available in the form of quotes during submission of the manuscripts to academic journals, submission of this thesis, and presentations in scientific conferences. Future requests for access to primary qualitative data by people other than the study team will be submitted to the data governance committee in LSHTM for advice. The interview topic guide was classified as public since it was developed from existing conceptual and theoretical frameworks. It is therefore publicly accessible as an appendix in this thesis (Appendix 6).

### ***D. Data disposal***

All audio-files were destroyed once transcripts were verified as true reflections of them. All transcripts, electronic fieldnotes, and electronic documents will be disposed through secure data wiping or erasure 10 years after the completion of the study. These data disposal strategies are in keeping with the LSHTM data storage and retention policy.

#### ***5.2.6.2 Data analysis***

Data analysis refers to the process of systematically processing collected data to convert it from its raw form to useful information (Saunders et al., 2019). In qualitative research, data analysis involves condensing, categorizing, and synthesizing large volumes of text and non-text data



into meaningful themes that answer a study's research question(s) (Saunders et al., 2019, Ritchie et al., 2013). This is achieved through conceptualization which refers to the process of forming concepts or ideas that reflect the substantive meaning underpinning the text or non-text data (Saunders et al., 2019, Ritchie et al., 2013).

In this PhD, I condensed, categorized, and interpreted iteratively text and non-text data from interviews and documents using thematic analysis. Thematic analysis refers to the process of “*systematically identifying, organizing, and offering insight into patterns of meaning (themes) across a data set*” (Braun and Clarke, 2012). I chose thematic analysis because it provides a flexible approach for identifying patterns across data. To facilitate the process of analysis, I uploaded all text and non-text data- that is, transcripts, electronic fieldnotes, electronic documents and images- to NVIVO software.

I used the 6-step approach for thematic analysis described by Braun and Clarke to identify themes across these data sources (Braun and Clarke, 2006) in analyzing data for each of the three holistic single-case studies. *In Step 1*, I immersed myself in the data through reading and re-reading to familiarize myself with the contents of each data source. *In Step 2*, I identified and coded data using a deductive approach. A deductive approach refers to the use of concepts from a theory or a conceptual framework to conduct, organize, and support data analysis (Saunders et al., 2019). I chose a deductive approach as it would enable the reader to judge the trustworthiness of the study findings and conclusions for themselves based on the theories and/or conceptual frameworks employed during data analysis (Collins and Stockton, 2018, Gilson et al., 2012). For sub-study 1, I identified and coded data based on the concepts outlined in Kingdon's multiple streams theory namely problems, policy solutions, politics, policy windows, and policy entrepreneurs. For sub-study 2, I identified and coded data on each of the procedural and outcome conditions outlined in the adapted Barasa et al., framework. For sub-study 3, I identified and coded data on each of the factors outlined in the conceptual framework

on factors influencing institutionalization of HTA. *In Stage 3*, I generated a list of themes by identifying recurrent and meaningful patterns within the coded data that were of relevance to the objective of each case study. *In Stage 4*, I verified the quality of the themes by sharing the list of themes and the coded data extracts with my supervisors who checked whether the themes reflected the patterns of meaning in the coded data. At this stage, I checked for similarity or recurrence of themes across interviews with different participants thus achieving data source triangulation. I also checked for similarity or recurrence of themes between interviews and documents thus achieving method triangulation. Once the themes were considered coherent, I moved into *Step 5* where I applied the approved themes across the entire data set. Each theme addressed an aspect that was relevant to the research objective under consideration. In this step, I extracted quotes, excerpts and images that supported the approved themes. I took careful consideration to ensure that the quotes did not contain unique contextual or socio-demographic information that could lead to the identification of the participant giving the statement. *In Step 6*, I synthesized the themes logically and meaningfully by each study objective. At this stage, I conducted member checks of the synthesized findings with a few study participants. I summarized the key findings in a PowerPoint presentation and allowed the study participants to comment on whether the findings reflected their experience of the cases. The member checks were done via face-face or via zoom videoconferencing based on the participant's availability. The participants agreed that these findings were credible. I used the key findings of each single-case study to generate a study report in the format of a journal manuscript as presented in Chapters 6 to 8. In this 6<sup>th</sup> step, the theoretical and conceptual frameworks applied in each study objective facilitated transferability of the study findings and conclusions to other studies that had applied similar conceptual and theoretical frameworks as shown in the discussion sections of Chapters 6-8.

### *5.2.6.3 Reflexivity*

Reflexivity refers to the awareness of the potential influence of one's characteristics, beliefs and/or personal and professional experiences on the study in terms of data collection, analysis, and interpretation of findings (Berger, 2015). In this study, my academic and professional experiences influenced the study in the following ways. Firstly, my academic training in medicine and health systems influenced my interest in the study topic of healthcare priority setting as well as the choice of qualitative methods for data collection respectively. Secondly, my professional experience as a district manager exposed me to meso-level healthcare priority-setting processes which also influenced my interest in understanding healthcare priority-setting processes at other levels of the health system. Thirdly, my role as a health systems researcher working on several health financing projects in KEMRI-Wellcome trust stimulated my interest in understanding healthcare priority-setting. This role also allowed me to participate in several policy engagement processes at the national level. This participation included providing support to the HBPAP during its second year of tenure as well as participating in a HTA workshop. This engagement enabled me to interact in a professional capacity with several participants included in the study. This interaction was crucial as it led to easier access to study participants and documents required for this study. Fourthly, while I reference literature published by one of my advisors, she had no role in influencing the choice of literature or interpretation of study results as presented in this thesis. Lastly, one of my supervisors, Professor Edwine Barasa, was not only a HBPAP member but also an active policy actor with several years of policy engagement at the national level in Kenya. His involvement enabled me to have easier access to relevant study participants (through introductions) and documents required for this study.

#### *5.2.6.4 Strategies for building rigour*

To build trustworthiness in my study findings, I employed the following strategies. Firstly, I triangulated data sources by interviewing participants from different organizations to identify different perspectives about the cases under inquiry. Interviewing multiple stakeholders helps to build trustworthiness in the study findings by triangulating findings from multiple data sources hence reducing the risk of bias associated with using one data source (Shenton, 2004, Long and Johnson, 2000). For example, individual interviews are prone to social desirability bias which refers to the tendency of a participant to provide answers that they think are appropriate or favourable (Bergen and Labonté, 2020, Althubaiti, 2016, Grimm, 2010). I minimized the risk of social desirability bias by building rapport with the study participants and by interviewing multiple stakeholders from multiple organizations.

Secondly, I triangulated study methods by collecting data using more than one data collection method, that is, by combining interviews and documents. Triangulation of study methods helps to overcome methodological shortcomings or limitations of individual study methods thus building trustworthiness in the study findings (Shenton, 2004, Long and Johnson, 2000). For example, interviews are prone to recall bias which refers to a participant's inability to remember past experiences accurately (Althubaiti, 2016). Since my study involved interviewing people about cases that had occurred several months to years in the past, it was prone to recall bias. To minimize the methodological shortcoming of recall bias associated with the long recall duration of the interviews, I supplemented interviews with document reviews which have been shown to provide a good data source for retrieving accounts of past events (Althubaiti, 2016, Bowen, 2009).

Thirdly, I held monthly peer debriefing sessions with all my supervisors (2 of whom had not previously been involved in macro-level priority-setting processes in Kenya) during data collection and analysis. Peer debriefing allows a researcher to discuss his/her methods,

findings, and conclusions with colleagues thereby building credibility in the study by challenging the researcher's assumptions and/ or stimulating the researcher to consider and explore other possible explanations and perspectives (Shenton, 2004, Long and Johnson, 2000). In this PhD study, the peer debriefing sessions were important in mitigating against bias that may have otherwise been introduced during data collection and analysis by my previous involvement and that of Professor Edwine Barasa in policy engagement at the national level in Kenya. During the peer debriefing sessions, we discussed the interview topic guide and, emerging codes and themes. These discussions helped me to address any preconceptions I may have had about the study cases which enabled the findings to be more grounded in the data.

Lastly, I conducted member checks which allow study respondents to validate the findings upon completion of data collection (Long and Johnson, 2000). I summarized the study findings in a PowerPoint presentation and allowed a few study participants (based on their availability) to comment on whether the findings reflected their experience of the cases. The participants agreed that the findings were credible.

### 5.3 Methodological limitations

There were several risks or limitations in this study. Firstly, there was a risk of recall bias. This case study involved a retrospective account of a policy process and healthcare priority-setting process that began several years ago. It was therefore likely that participants had limited recall of the events under inquiry. I minimized the effect of recall bias by introducing the study prior to the interview and by conducting document and media reviews which have been shown to be effective in retrieving accounts of past events (Althubaiti, 2016, Bowen, 2009).

Secondly, there was a risk of social desirability bias in which respondents provide responses that they perceive would be acceptable as opposed to what truly took place. In this study, I minimized the risk of social desirability bias by building rapport with the study participants,

by providing participants with a clear description of the study and its aims, and by triangulating data through multiple data collection methods and sources (Bergen and Labonté, 2020).

Lastly, it is likely that my participation and that of one of my supervisors-Prof Edwine Barasa in policy engagement processes at the macro-level in Kenya may have introduced researcher bias during data collection and analysis. However, I minimized this risk by triangulating data sources, by conducting member checks, and by holding peer debriefing sessions with the supervisory team (2 of whom had not previously been involved in priority-setting processes in Kenya) to ensure that the study findings were based on the data collected.

## 5.4 Chapter summary

In this chapter, I have outlined the methodology employed to answer the three sub questions for this PhD study. I conducted three holistic single-case studies to address these questions. The case studies were related to: - a) the gazettelement of the HBPAP policy idea; b) HBPAP's healthcare priority-setting process for health benefits package development; and c) institutionalization of HTA Kenya. I collected data through in-depth interviews and document reviews. I analysed the data thematically. Both data collection and data analysis were informed by Kingdon's theory, the Barasa et al., framework, and my framework (based on the findings of the scoping literature review in Chapter 4) as appropriate to the case studies. The findings of these analyses are presented in Chapters 6-8 of this thesis. I concluded this chapter by highlighting the limitations of the methodology employed in this PhD and the measures I used to minimize them.

## CHAPTER 6: WHY WAS THE POLICY IDEA ON THE HEALTH BENEFITS PACKAGE ADVISORY PANEL GAZETTED IN KENYA? A RETROSPECTIVE POLICY ANALYSIS

In this chapter, I present the results of the first sub-study of this PhD in the format of a journal ready manuscript. The aim of this sub-study was to examine the policy process that led to the gazettelement of the HBPAP policy idea. Using Kingdon's multiple streams theory, this chapter explains how and why the HBPAP policy was gazetted in Kenya.

## RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

### SECTION A – Student Details

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<b>Thesis Title</b>	A critical examination of the policy process, implementation, and institutionalization of explicit healthcare priority-setting at the macro-level in Kenya		
<b>Supervisors</b>	Professor Anna Vassall, Professor Lucy Gilson, and Professor Edwine Barasa		

If the Research Paper has previously been published, please complete Section B, if not please move to Section C.

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Where is the work intended to be published?	International Journal of Health Policy and Management
Please list the paper's authors in the intended authorship order:	Rahab Mbau, Anna Vassall, Lucy Gilson, Edwine Barasa
Stage of publication	<b>SubmittedSubmitted</b>

### **SECTION D – Multi-authored work**

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I was responsible for conceiving and designing the study; data collection; data analysis and interpretation; and drafting and critical revision of these chapters. My supervisors were involved in the critical revision and final approval of the manuscript.
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### **SECTION E**

<b>Student Signature</b>	Rahab Mbau
<b>Date</b>	22 <sup>nd</sup> December 2022

<b>Supervisor Signature</b>	Anna Vassall
<b>Date</b>	22 <sup>nd</sup> December 2022

## Abstract

### **Background**

In 2018, Kenya's Ministry of Health gazetted the Health Benefits Package Advisory Panel (HBPAP) to develop a benefits package for its Universal Health Coverage (UHC) programme using an explicit healthcare priority-setting process. In this study, we examine the policy process that led to the gazettelement of the HBPAP.

### **Methods**

We conducted a case study based on semi-structured interviews with 20 national-level participants and, document reviews. We analyzed the data thematically using Kingdon's Multiple Streams Theory.

### **Results**

We found that the problem stream was characterized by fragmented and implicit healthcare priority-setting processes that had resulted in unaffordable, unsustainable, and wasteful health benefits packages. A potential policy solution for these problems was the creation of an independent expert panel that would use an explicit and evidence-based healthcare priority-setting process to develop an affordable and sustainable benefits package. The political stream was characterized by the re-election of the government and the appointment of a new Cabinet Secretary for Health. Coupling of the three streams occurred during a policy window that was created by the political prioritization of UHC by the newly re-elected government. Policy entrepreneurs (health economists, health financing experts, health policy analysts and health systems experts) leveraged this policy window to push for the establishment of an independent expert panel as a policy solution for the issues in the problem stream. They employed strategies such as forming networks, framing, marshalling evidence and utilizing political connections to push for this policy solution.

## Conclusions

Applying Kingdon's theory in this study was valuable in assisting explanation of why the HBPAP policy idea was gazetted. It demonstrated the crucial role of policy entrepreneurs and the strategies they employed to couple the three streams during a favourable policy window. This study contributes to the body of literature on healthcare priority-setting processes with an unusual analysis focused on a key procedural policy for such processes.

## Background

The world has set global targets to achieve universal health coverage (UHC) by 2030 as part of the sustainable development goals (United Nations Development Program, 2017). Under UHC, anyone in need can obtain good-quality essential health services such as health promotion, disease prevention, diagnosis, treatment, rehabilitation, and palliation with no financial difficulties (World Health Assembly 58, 2005). The attainment of UHC is constrained by the resources available in every country (irrespective of income level) which are insufficient to meet the cost of providing all effective health services (World Health Organization, 2014, World Health Organization, 2013, World Health Organization, 2010, Bobadilla et al., 1994).

In addition to resource scarcity, it is estimated that approximately 20-40% of health sector spending is wasted through inefficient allocation of resources across health services (World Health Organization, 2010). This wastage has partly been attributed to implicit healthcare priority-setting processes which are driven by historical patterns and stakeholder interests (Glassman and Chalkidou, 2012, World Health Organization, 2010). Healthcare priority-setting refers to the process of making decisions on how to allocate resources across competing uses (Coulter and Ham, 2000, McKneally et al., 1997). Healthcare priority-setting processes can be implicit or explicit. While implicit processes are ad hoc and unsystematic, explicit

healthcare priority-setting processes are deliberative, evidence-based, inclusive, and systematic (Chalkidou et al., 2016).

Resource constraints and continued wastage have generated interest in explicit healthcare priority-setting processes to inform UHC-related decisions (Chalkidou et al., 2016, World Health Organization, 2014, World Health Assembly, 2014). Introducing an explicit healthcare priority-setting process into a system is an intrinsically political act given actors' interests in what processes and criteria should be followed to allocate resources as well as actors' involvement, roles, and responsibilities in the healthcare priority-setting process (Smith et al., 2014, Hauck et al., 2004, Ham and Glenn, 2003). However, the political process (policy formulation process) through which countries come to adopt explicit healthcare priority-setting processes largely remains unanalysed (Smith et al., 2016, Smith et al., 2014).

On June 8th, 2018, the Ministry of Health (MOH) in Kenya- a lower-middle income country in East Africa- gazetted a new policy on the constitution of a Health Benefits Package Advisory Panel (HBPAP) (The Kenya Gazette, 2018). HBPAP, a committee of 15 members (1 chairman and 14 members) and 2 joint secretaries, was introduced as a mechanism for conducting an explicit healthcare priority-setting process for health benefits package development in Kenya (The Kenya Gazette, 2018). A health benefits package outlines a specific set of health services for a defined population to be purchased from pooled resources (Glassman et al., 2017, Glassman et al., 2016, Bobadilla et al., 1994).

The policy on HBPAP was a procedural policy as it sought to influence how and by whom the healthcare priority-setting process for health benefits package development was conducted at the national level in Kenya. A procedural policy refers to any course of action that changes how and by whom processes or functions of an organization or government are conducted (Howlett, 2017, Commonwealth of Learning, 2012). Using Kingdon's Multiple Streams

Theory, we conducted this study to examine the policy process that led to the gazettelement of the HBPAP policy idea in Kenya.

## Methods section

### Study design

We used a case-study approach to conduct a retrospective policy analysis of the political process that led to the gazettelement of the policy idea on HBPAP. The case in this enquiry was the gazettelement of the HBPAP policy idea. The case study method allowed detailed inquiry into the dynamics around the case. We used an interpretive epistemological approach to draw on participants' perspectives and contextual factors (Klein and Myers, 1999, Walsham, 1995) to provide a rich explanation of why the HBPAP policy idea was gazetted.

### Study setting

This study was conducted at the national level in Kenya where HBPAP was established. Kenya's governance structure is devolved with administrative, fiscal, and political functions divided amongst 1 national and 47 semi-independent county governments (The Republic of Kenya, 2010). Health is devolved between the national and county governments. At the national level, the MOH is the highest political office for the health sector. Its mandates include formulating health policies, building capacity, providing technical assistance, and overseeing service delivery in tertiary public referral healthcare facilities (The Republic of Kenya, 2010).

Resources for Kenya's health sector come from three main sources namely public (tax and public health insurance), private (household out-of-pocket payments and voluntary health insurance) and donors. In 2019, these sources contributed 46%, 35.5%, and 18.5% of the total health expenditure respectively (World Health Organization, 2019). Purchasing, which refers to the transfer of pooled resources to healthcare providers for the provision of health services (World Health Organization, 2010), is done through three models. The first model is the

integrated public model where the MOH purchases services from tertiary public referral hospitals while the County Departments of Health purchase services from county public healthcare facilities namely community units, primary care facilities (dispensaries and health centres) and secondary referral facilities (primary care and secondary care hospitals). The second model is the public contract model where the National Health Insurance Fund (NHIF) - a state corporation- purchases services from both public and private (for-profit and not-for-profit) healthcare facilities. Lastly, the third model is the private contract model where private health insurers purchase services from private healthcare facilities (Mbau et al., 2018, Munge et al., 2015). This study considered the integrated public model and the public contract models.

### Theoretical framework

In this study, we used Kingdon's Multiple Streams Theory (Figure 1) given its demonstrable conceptual and empirical validity in explaining agenda-setting and other policy formulation stages through its broad application in multiple sectors, multiple levels of governance, and multiple countries (Jones et al., 2016, Nikolaos, 2007). Agenda-setting refers to the process through which issues and potential policy solutions earn policymakers' attention leading to policy formulation (Kingdon, 1993).

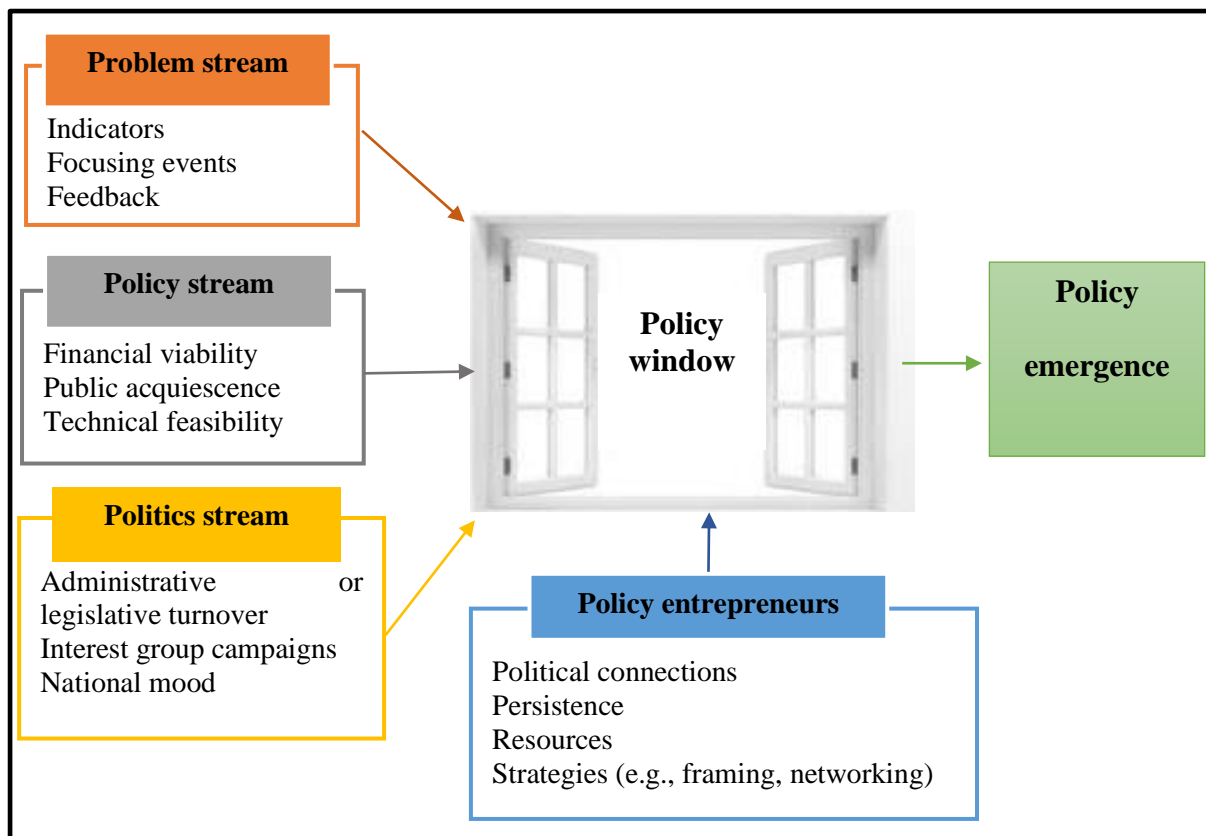


Figure 1: Kingdon's Multiple Streams Theory (Kingdon, 1993, Kingdon, 1984)

The three streams in Kingdon's theory are problem, policy, and politics. The problem stream refers to situations that deviate from what is considered normal or unrealized needs that require improvement through public (government) efforts (Kingdon, 1993). Problems become visible through indicators (measures of the level or severity of a problem), focusing events (unexpected occurrences such as crises or disasters that highlight a problem) and, feedback (information given back on the performance of similar policies and programs) (Kingdon, 1993, Kingdon, 1984).

The policy stream refers to potential solutions for addressing the problems (Kingdon, 1993, Kingdon, 1984). Policy solutions are developed by policy communities composed of individuals who are interested in, and seek to influence a specific policy area (Kingdon, 1993). Since policy communities often develop numerous policy solutions, several factors influence which solution might be considered for adoption by policymakers. These factors include

technical feasibility (whether the proposed solution works), public acquiescence (whether the mass public or attentive publics- individuals who are better informed and keenly interested in a particular issue than the general public- find the proposed solution acceptable) and, financial viability (whether the proposed solution has acceptable cost implications given the existing budget) (Kingdon, 1993).

The politics stream refers to the broader political context surrounding the policy under consideration. This stream is characterized by factors such as administrative or legislative turnover (changes in administration or legislation arising from campaigns, elections or nominations), national mood (the publics' or elected government officials' orientation towards issues) and, interest group pressure (demands for action by groups such as civil societies) (Kingdon, 1984, Kingdon, 1993).

The successful emergence of a policy follows coupling of the problem, policy, and politics streams. Coupling refers to the matching of a potential policy solution to an identified problem within favorable political conditions (Kingdon, 1993, Kingdon, 1984). Coupling occurs during a 'policy window', defined as a fleeting window of opportunity that expands or contracts the space for policymaking (Kingdon, 1993, Kingdon, 1984). A policy window opens due to compelling events in the problem or politics stream. Given the short nature of policy windows, timing is crucial: policy entrepreneurs must recognize them and act by introducing their preferred policy proposals when the political environment is receptive to change (Kingdon, 1993, Kingdon, 1984).

Policy entrepreneurs are actors within policy communities who are committed to engendering support for their preferred policy solutions from the public and policymakers (Kingdon, 1993, Kingdon, 1984). They can be found inside or outside of government (Kingdon, 1993, Kingdon, 1984). The ability of policy entrepreneurs to achieve policy influence is determined by their



access to key policymakers. It is also determined by their persistence and willingness to invest resources (e.g., time, money, technical skills) into the process. Policy entrepreneurs can also influence policy by employing strategies such as:- a) framing (the structuring and presentation of information on problems or policy solutions to generate specific views, meanings, or perceptions (Kingdon, 1993, Kingdon, 1984)); b) collecting evidence (Mintrom and Vergari, 1996, Mintrom, 2019); and, c) networking (engaging other relevant actors within policy communities to strengthen their likelihood of generating policy changes (Mintrom and Vergari, 1996, Mintrom, 2019)).

We used Kingdon's theory to inform: - a) questions asked during data collection, b) codes and themes generated during data analysis and, c) synthesis of the findings about the political process that led to the gazettelement of the HBPAP policy idea.

## Data collection

We collected data through interviews and, document and media reviews between July and September 2021.

### *In-depth interviews*

We selected participants for in-depth interviews through purposive sampling. The purposive criterion was the participant's known involvement in the political process for introducing the HBPAP policy. Participants were invited to the study via telephone and email- none declined participation. Prior to the interviews, participants reviewed the study's information sheet and provided informed consent. The interviews were conducted via face-face at the participant's place of work or via zoom videoconferencing.

All interviews were conducted in English and recorded using an encrypted audio-recorder. The interviews lasted between 45 and 80 mins. We used a semi-structured topic guide developed from the study's theoretical framework to elicit participant's views on the problems associated

with healthcare priority-setting processes for health benefits packages as relevant to HBPAP’s main mandate. The interview guide also elicited participants’ views on alternative policy ideas that were considered alongside HBPAP; the political context surrounding the policy idea on HBPAP; and lastly, the policy windows and policy entrepreneurs that led to the gazette of the HBPAP policy idea. We took fieldnotes during the interviews to summarize discussion points when participants requested for the tape recorder to be switched off. We also used the fieldnotes as aids for critical reflection of emerging themes.

We interviewed 20 participants (Table 1). No new participants were included after data saturation- the point at which there was no new information obtained from conducting additional interviews. We do not disclose participants’ demographic information to preserve their confidentiality and anonymity.

Table 1: List of participants

<b>Category</b>	<b>Number</b>
Donor-supported technocrats	n=7
Local Researchers	n=3
Ministry of Health (MOH) technocrats	n=8
Semi- Autonomous Government Agencies’ technocrats	n=2
<b>Total</b>	<b>20</b>

Document reviews

We reviewed the documents outlined in Table 2 to supplement the interviews. These documents were identified by the study participants and from online searches.

Table 2: Documents reviewed in the study

Types of documents	Examples (in electronic format)
Government documents (national policy documents, laws, and bills)	<ul style="list-style-type: none"> <li>• 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> Drafts of the Kenya Health Financing Strategy 2015-2030</li> <li>• Second Medium-Term Plan 2013-2017 Transforming Kenya: Pathway to devolution, socio-economic development, equity, and national unity</li> <li>• Sessional Paper No 2 on National Social Health Insurance in Kenya</li> <li>• Health Act 2017</li> <li>• Kenya Health Policy 2014-2030</li> <li>• Cabinet Memorandum 2018- Roadmap to attain Universal Health Coverage in Kenya</li> <li>• Gazette notices</li> </ul>
Semi-autonomous Government Agencies' documents	<ul style="list-style-type: none"> <li>• Report on National Health Insurance Fund Strategic Review and Market Assessment of Prepaid Health Schemes</li> </ul>
Local research organizations' documents	<ul style="list-style-type: none"> <li>• Published empirical studies, policy briefs, and reports</li> </ul>
Campaign manifesto	<ul style="list-style-type: none"> <li>• Transforming Kenya- Securing Kenya's prosperity 2013-2017</li> <li>• Jubilee Manifesto 2017- Continuing Kenya's Transformation together</li> </ul>
Development Partner reports and presentations	<ul style="list-style-type: none"> <li>• Report on stakeholder analysis to support design and finalization of health financing strategy for Kenya</li> <li>• World Health Organization meeting- Towards UHC in Kenya: issues, options, and guiding principles for the way forward</li> <li>• World Bank Report on Moving towards UHC in Kenya</li> </ul>
Media reports	<ul style="list-style-type: none"> <li>• News media e.g., Online newspaper reports</li> <li>• Web media e.g., Ministry of Health web portals and Development Partners web portals</li> <li>• Social media e.g., Twitter</li> </ul>

## Data analysis

Audio recorded data were transcribed verbatim into Microsoft Word. We reviewed each transcript for transcription accuracy against the respective audio-file and cleaned where necessary. We transferred fieldnotes to Microsoft word documents to prevent loss of data through forgetfulness. Each fieldnote was linked to the respective interview through dates and numbers. We then uploaded the transcripts and electronic documents to NVIVO software to facilitate thematic analysis using the Braun and Clarke approach (Braun and Clarke, 2006).

In phase 1, we immersed ourselves in the data to engender familiarization. In phase 2, we coded data with information on the problems, policy solutions, politics, policy windows and policy entrepreneurs. In phase 3, we generated a list of themes by grouping related codes. In phase 4, we checked for coherence between the themes and coded data extracts. In phase 5, we applied the approved themes across the data sources. In phase 6, we produced a synthesis report on why the HBPAP policy idea was gazetted. This report was revised and approved by all authors.

## Findings

In this section, we discuss the events in the policy process that led to the gazettelement of the HBPAP policy idea based on interviews with study participants and, document and media reviews. This policy process began in 2010 when issues emerged in the problem streams to 2018 when the HBPAP policy idea was gazetted. We start by describing the actors involved in the process followed by a discussion of the problem, policy, and politics streams. Lastly, we describe how policy entrepreneurs utilized a policy window to couple the three streams leading to the gazettelement of the HBPAP policy.

## Policy Actors

The policy process that led to the gazetting of the HBPAP policy idea did not occur in public spaces with societal actors. Instead, it occurred in closed-door meetings involving technical

and political actors, though the attentive publics consisting of national and county stakeholders in the health financing intergovernmental coordinating committee also had some influence (Table 3). Technical actors (technocrats) played key roles in defining the problem and policy streams. Political actors shaped the political stream by prioritizing UHC, whilst the attentive publics were consulted during the development of potential policy solutions as discussed below.

In the period of focus, the political actors included President Uhuru Kenyatta who was the holder of the highest political office in Kenya and, Dr. Cleopa Mailu and Mrs. Sicily Kariuki who were the Cabinet Secretaries for Health (analogous to Ministers for Health) or the holders of the highest political office in the MOH. Technical actors include health economists, health financing experts, health policy analysts, and health systems experts from various organizational bases. The MOH technocrats are civil servants with technical training and expertise in developing policies and supporting MOH’s functions. They have a long history of working with donor-supported Kenyan technical advisors. The donors include multilateral agencies such as World Bank and bilateral agencies such as United States Agency for International Development, Japan International Cooperation Agency, and German Agency for International Cooperation. MOH technocrats also have a long history of working with local researchers producing relevant health financing research. The NHIF, a semi-autonomous government agency, is the largest public health insurer, purchasing services from public and private healthcare facilities. The private health sector comprises both for-profit and not-for-profit healthcare providers.

Table 3: Actors and their roles in the emergence of the policy idea on HBPAP

<b>Actor</b>	<b>Type of actor</b>	<b>Role</b>
President Uhuru Kenyatta	Political	<ul style="list-style-type: none"> <li>Served as Kenya’s president from 2013</li> </ul>

		<ul style="list-style-type: none"> <li>• Declared UHC as one of his big 4 presidential agenda for his 2<sup>nd</sup> term (2017-2022)</li> <li>• Appointed Dr. Cleopa Mailu and Mrs. Sicily Kariuki as the Cabinet Secretaries for Health in 2015 and 2018 respectively</li> </ul>
Dr. Cleopa Mailu	Political	<ul style="list-style-type: none"> <li>• Served as the Cabinet Secretary for Health between 2015 and 2017</li> <li>• Formed the 2015 Technical Working Group (TWG) to develop Kenya's health financing strategy</li> </ul>
Mrs. Sicily Kariuki	Political	<ul style="list-style-type: none"> <li>• Served as the Cabinet Secretary for Health from January 2018</li> <li>• Mandated to implement the Presidential Agenda on UHC</li> <li>• Gazetted HBPAP in June 2018, and appointed its members</li> </ul>
UHC coordination department in the MOH	Technical	<ul style="list-style-type: none"> <li>• Formed by Mrs. Sicily Kariuki to formulate and implement UHC reforms</li> <li>• Developed the terms of reference for HBPAP</li> </ul>
MOH Technocrats	Technical	<ul style="list-style-type: none"> <li>• Developed and implemented health financing and UHC reforms.</li> <li>• Were part of the 2015 TWG that identified health financing problems in Kenya and proposed potential policy solutions.</li> </ul>
Local Researchers	Technical	<ul style="list-style-type: none"> <li>• Provided technical support and research evidence for health financing and UHC reforms.</li> <li>• Were part of the 2015 TWG that identified health financing problems in Kenya and proposed potential policy solutions.</li> </ul>

Donor-supported Kenyan technical advisors	Technical	<ul style="list-style-type: none"> <li>• Provided technical support for health financing and UHC reforms.</li> <li>• Were part of the 2015 TWG that identified health financing problems in Kenya and proposed potential policy solutions.</li> </ul>
NHIF technocrats	Technical	<ul style="list-style-type: none"> <li>• Were part of the 2015 TWG that identified health financing problems in Kenya and proposed potential policy solutions.</li> </ul>
Private health sector (Christian Health Association of Kenya, Kenya Health Federation) technocrats	Technical	<ul style="list-style-type: none"> <li>• Were part of the 2015 TWG that identified health financing problems in Kenya and proposed potential policy solutions.</li> </ul>
Intergovernmental coordinating committee	Technical	<ul style="list-style-type: none"> <li>• Consisted of national and county-level stakeholders who were consulted during the development of the health financing strategy.</li> </ul>

### The problem stream: Fragmented and implicit healthcare priority-setting processes and, unaffordable, unsustainable, and wasteful benefits packages

Technical actors directly involved in health financing and UHC reforms since 2015 had similar views about the problems facing existing healthcare priority-setting processes for health benefits package development in Kenya. These technical actors agreed that healthcare priority-setting processes were fragmented and implicit (non-transparent, non-inclusive, and non-evidence based) based on the evidence obtained from situation analyses of Kenya's health financing architecture regarding revenue pooling, pooling, and purchasing arrangements. This situation analysis was conducted by the technocrats using guidelines and tools such as the health financing progress matrix and guidance on conducting a situation analysis of health

financing for universal coverage respectively (Republic of Kenya, 2018, Ministry of Health, 2017, Ministry of Health, 2016, Technical Working Group, 2015).

The healthcare priority-setting processes were fragmented because they were conducted by different priority-setting bodies (Table 4). Since 2010, this fragmentation had led to the introduction of multiple health benefits packages with different service entitlements for different population groups (Figure 2).

Table 4: Priority-setting bodies that develop benefits packages for Kenya’s public health sector (Ministry of Health, 2017, Ministry of Health, 2016, Technical Working Group, 2015)

<b>Priority-setting body</b>	<b>Type of benefits package</b>	<b>Purchaser</b>
Directorate of policy and planning	Kenya Essential Package for Health	MOH & County Departments of Health
National Medicines and Therapeutics Committee	Kenya Essential Medicines List	MOH & County Departments of Health
Division of Vaccines and Immunization	Kenya Expanded Programme on Immunization	MOH & County Departments of Health
NHIF	<ul style="list-style-type: none"> <li>• National Scheme benefit package</li> <li>• Civil Servants and other Enhanced medical scheme benefit package</li> <li>• Health Insurance Subsidy Program for the poor, elderly, and people with severe disabilities</li> <li>• Health Insurance Subsidy Program for orphans and vulnerable children</li> <li>• Free maternity Program</li> <li>• Insurance program for secondary schools</li> </ul>	NHIF
County Departments of Health	County specific health benefit packages	County Departments of Health



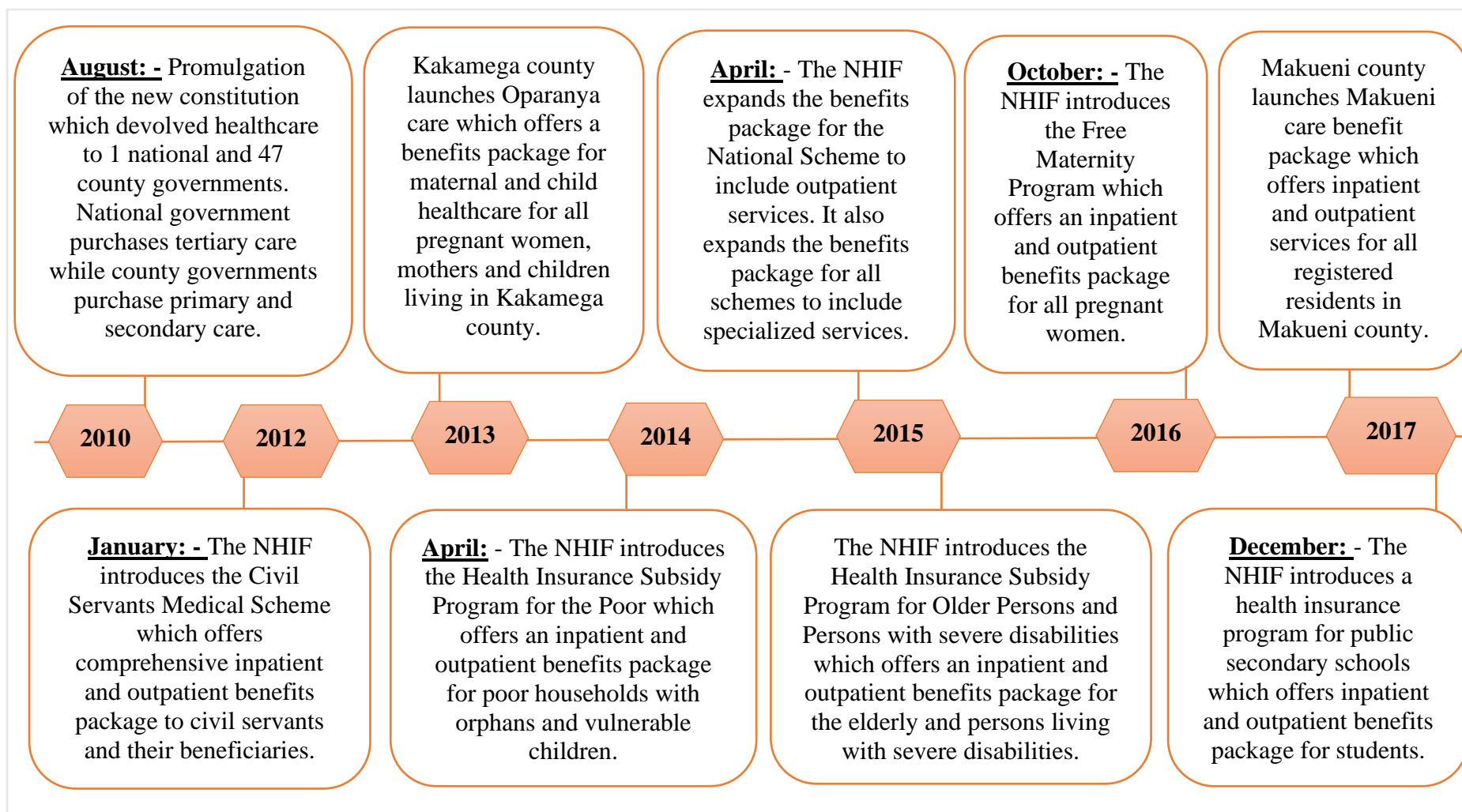


Figure 2: A timeline showing introduction of multiple health benefits packages by different purchasers in Kenya's public health sector

The existing healthcare priority-setting processes were also non-transparent and non-inclusive due to poor stakeholder involvement.

*'Decisions on which services Kenyans can access are very fragmented and made in silos such that only those involved in those processes are aware what processes are used. We just hear that some new drugs or vaccines have been introduced, but how did they get there? What processes did NHIF use to introduce its benefits packages? It is like a black box in decision-making'* Participant 3, MOH technocrat

Lastly, the healthcare priority-setting processes were non-evidence based given the inadequate use of explicit priority-setting criteria such as cost-effectiveness, feasibility, and affordability. Instead, these processes were driven by historical patterns of resource allocation and stakeholder interests. Participants reported that according to the situation analyses, the lack of evidence-based healthcare priority-setting processes had led to broad and poorly defined benefits packages that were wasteful, unaffordable, and unsustainable. This was concerning given the chronic underfunding of Kenya's health sector (Ministry of Health, 2017, Ministry of Health, 2016, Technical Working Group, 2015).

*'The situation analysis showed us that the process of developing the multiple benefit packages was not guided by any systematic or evidence-based process. The process was neither transparent nor inclusive. The symptoms of that broken system were benefit packages that were not affordable or sustainable.'* Participant 1, local researcher

While there were indicators and feedback from situation analyses highlighting the problem stream, there were no focusing events that suddenly highlighted these issues in Kenya.

## The policy stream: - Establishment of an independent expert panel as a potential policy solution

The technical actors directly involved in health financing and UHC reforms since 2015 recognized that addressing the problems facing existing healthcare priority-setting processes would enable Kenya to progress towards UHC. This recognition was based on other countries' experience of attaining UHC such as Thailand (Republic of Kenya, 2018, Ministry of Health, 2017, Ministry of Health, 2016, Technical Working Group, 2015). These technocrats recommended several policy ideas as potential solutions to the problems. One such policy idea was the establishment of a single funding pool to consolidate revenue across the different purchasers thereby reducing fragmentation. However, this proposal was wrought with feasibility concerns due to stakeholder interests and lack of a framework for consolidating the pools (Ministry of Health, 2017, Ministry of Health, 2016, Technical Working Group, 2015).

Another policy idea recommended by these technocrats was the establishment of an independent expert panel to harmonize the healthcare priority-setting process for health benefits package development across all purchasers thus reducing fragmentation. This panel would define a basic health benefits package for all purchasers in Kenya by using an explicit and evidence-based approach (Republic of Kenya, 2018, Ministry of Health, 2017, Ministry of Health, 2016, Technical Working Group, 2015).

*'When we were writing the health financing strategy in 2015, there was a suggestion that we needed an independent panel of experts to develop a harmonized benefit package using an independent, explicit, evidenced, and inclusive process'* Participant 2, Donor-supported technocrat

According to the study participants, majority of the technocrats supported the policy idea of establishing an independent expert panel. However, study participants reported that the NHIF

and some MOH technocrats had opposed this policy idea because they considered development of health benefits packages as one of their organization's mandates.

*'The contestation was whether the package should be developed by an independent expert panel, the MOH, or NHIF. There were those MOH officials who insisted that the MOH should be the one to propose a benefit package. Then, from a historical perspective, NHIF has been defining services. Divorcing benefits from its roles was very thorny.'* Participant 5, Donor-supported technocrat

Given this contestation, the technocrats compared the policy idea of establishing an independent expert panel to the policy idea of having the MOH and other purchasers become the main priority-setting bodies for designing the basic health benefits package (Table 5). These comparisons were made in consultation with attentive publics namely national and county stakeholders through the health financing intergovernmental coordinating committee. From this comparison, there was acquiescence from the attentive publics for the policy idea of establishing an independent expert panel for health benefits package development. The country also had the technical expertise to build a dedicated team for the panel. However, the administrative and operational costs of managing a panel were thought to be prohibitive thus undermining its financial viability.

*'The panel was a great shift towards systematic priority-setting for our country. It was uniquely designed to ensure that the process of setting priorities was open and transparent which was different from what was being done in the past.'* Participant 3, MOH technocrat

Table 5: Comparison of policy ideas (Ministry of Health, 2016, Technical Working Group, 2015)

<b>Priority-setting body responsible for designing the essential health benefits package</b>	<b>Pros</b>	<b>Cons</b>	<b>Implications</b>
MOH	<ul style="list-style-type: none"> <li>a) Assures harmonization and standardization of benefits</li> </ul>	<ul style="list-style-type: none"> <li>a) Difficulty in managing stakeholders' interests</li> <li>b) bureaucracies</li> </ul>	<ul style="list-style-type: none"> <li>a) necessitates legislation and regulation</li> <li>b) necessitates governance and operations structures</li> </ul>
Independent expert body or a health benefits expert committee (Advisory body composed of epidemiologists, health economists, health professionals, statisticians, health insurers, consumer organizations and experts in health technology assessment)	<ul style="list-style-type: none"> <li>a) less bureaucracies</li> <li>b) faster stakeholders buy-in</li> <li>c) dedicated and committed team</li> <li>d) standardization of the package across different purchasers</li> </ul>	<ul style="list-style-type: none"> <li>a) administrative and operational costs</li> </ul>	<ul style="list-style-type: none"> <li>a) necessitates legislation and regulation</li> </ul>
Other Purchasers	<ul style="list-style-type: none"> <li>a) understand the market risk</li> <li>b) less bureaucracy in decision-making</li> <li>c) may enhance creativity and innovation due to competition</li> </ul>	<ul style="list-style-type: none"> <li>a) conflict of interest</li> <li>b) enforcing regulation will be difficult</li> </ul>	<ul style="list-style-type: none"> <li>a) necessitates regulation and legislation</li> </ul>

### The politics stream: Changing political landscape

The political landscape of the period between 2010 when fragmentation of healthcare priority-setting processes for benefits packages began (Figure 2) to 2018 when the HBPAP policy idea was gazetted, was characterized by changes in national mood and, administrative and legislative turnover.

### *National mood*

In 2010, Kenya promulgated a new constitution that was approved by 67% of Kenyan voters (Macharia and Obulutsa, 2010). This new constitution recognized health as a basic human right. It also recognized that every Kenyan had a right to the highest standard of affordable healthcare (The Republic of Kenya, 2010). The recognition of these health-related rights in Kenya's supreme law represented national interest in health. This national interest further generated technical actors' interest in defining a basic package of health services to enable access to healthcare as outlined in the constitution.

*'The 2010 constitution led us to this very clear realization that there needs to be a lot of effort in trying to determine and ensure provision of a set of services that are crucial to the people. This discussion led to the whole concept of the basic benefits package.'*

Participant 8, MOH technocrat

The national mood was ultimately shaped by the political prioritization of UHC. In 2017, President Uhuru Kenyatta declared UHC as one of the four pillars for socio-economic development (Figure 3). The president's declaration on UHC was a symbolic act of the leading political party's standpoint on matters related to health which created a positive national mood for UHC that influenced health system stakeholders.

*'The president declared that he would like Kenya to attain UHC during this tenure. This very high-level policy statement cascaded to the Cabinet Secretary and the technocrats at the ministry who had to look for different ways of translating that directive into action'* Participant 5, MOH technocrat



Figure 3: The President’s declaration on UHC (The Executive Office of the President, 2017)

### *Administrative and legislative turnover*

In 2010, the biggest legislative turnover took place in Kenya when the new constitution was promulgated. This led to the devolution of revenue collection, pooling, and purchasing of health services between 1 national and 47 county governments. As seen in the problem stream (Table 4 and Figure 2), this contributed to the fragmentation of healthcare priority-setting processes as these organizations had different processes for developing benefits packages.

*‘It was really with devolution that fragmentation in the health sector became more evident. There were 47 county government pools and 1 national pool each responsible for health service delivery at different levels’* Participant 2, MOH technocrat

Several administrative changes within the MOH and the Office of the President shaped the political context for the policy and problem streams. In 2013, President Uhuru Kenyatta was successfully elected as the first president under the new constitution. Given his interest in affordable healthcare, he introduced several reforms such as user-fee removal in primary healthcare facilities and free maternity care in all public hospitals. While these reforms were meant to increase access to care, they inadvertently contributed to fragmentation of benefits

packages in the country. It was also unclear what priority-setting processes had been used to inform these new benefits.

*'Following the first term of Jubilee, we had waiver of user fees, Linda Mama for pregnant women to access ante-natal and maternity services and the health insurance subsidy program. However, it was paradoxical that we did not know how these decisions were arrived at'* Participant 1, Technocrat from Semi-autonomous government agency

In 2015, President Uhuru Kenyatta appointed Dr. Cleopa Mailu as the new Cabinet Secretary for Health. Dr. Mailu established the 2015 multi-stakeholder TWG to develop a health financing strategy for Kenya. This TWG consisted of technocrats from different organizations (Table 3) who identified the issues outlined in the problems stream and, who also recommended potential policy solutions for the identified problems.

In 2017, Mr. Uhuru Kenyatta was re-elected as the president for a second term. He declared UHC as one of his main agenda which influenced the national mood towards UHC reforms. In January 2018, President Uhuru Kenyatta reshuffled his cabinet and appointed a new Cabinet Secretary for Health, Mrs. Sicily Kariuki, who then established a UHC coordination department to formulate and implement UHC.

*'In early 2018, the new cabinet secretary identified a small group of people within the ministry who were going to help her deliver UHC. Then she went ahead and created a department for them'* Participant 3, MOH technocrat

## Emergence of a policy window, coupling of the streams, and the role of policy entrepreneurs

Despite being initially proposed in 2015, the policy idea of establishing an independent expert panel was not adopted because of unfavourable political conditions.



*'In 2015, we came up with the idea of an independent panel that would be designing and reviewing the benefits package every two years. But at that point, it was not taken forward because there was no political momentum'* Participant 6, Donor-supported technocrat

However, in 2017, there was a shift in the political momentum when President Uhuru Kenyatta politically prioritized UHC as one of his four main agenda. The prioritization of UHC created a policy window that a group of technocrats, turned policy entrepreneurs, seized to advocate for policies that would help the President achieve his ambition. This group of technocrats had been directly involved in defining the problem and policy streams since 2015. One of their policy recommendations was an independent expert panel to develop a basic health benefits package.

*'In December 2017, the President indicated that UHC was one of his Big Four Agenda in his second term. That was a water shed moment because it opened a window that had not existed before for us to push for proposals for health financing reforms that had been on-going for the last decade'* Participant 5, MOH technocrat

Recognizing their shared individual and organizational ideologies and interests in health financing and UHC reforms, the small group of technocrats turned policy entrepreneurs had deliberately engaged and interacted with each other in a network since 2015. In these networks, the policy entrepreneurs utilized their technical expertise and professional experience to develop policy ideas for UHC and health financing reforms, including the policy idea of an independent expert panel for health benefits package development. They outlined these policy ideas in presentations, health financing strategies and cabinet memoranda.

*'We had informal discussions with some MOH officials and development partners where we were discussing what could be done in terms of health reforms. We developed*

*PowerPoints and draft cabinet memo to lobby for change.* Participant 3, local researcher

In April 2018, some MOH officials, who were part of the network of policy entrepreneurs, took advantage of an impromptu meeting with Mrs. Sicily Kariuki to highlight potential policy ideas for achieving UHC. This meeting occurred in Washington DC where Mrs. Sicily Kariuki had attended the World Bank-International Monetary Fund Spring Meeting while the MOH officials had attended a Joint Learning Network meeting. Among the policy ideas presented to the Cabinet Secretary, was the idea of establishing an independent expert panel for health benefits package development.

*'An opportunity appeared when they [MOH Officials] were in Washington DC for a meeting and the Cabinet Secretary came in requesting for a meeting on UHC. They presented the cabinet memo to her, and this is what convinced the Cabinet Secretary to establish the panel to change how services were being purchased within the country in the journey towards UHC'* Participant 6, MOH technocrat

The network of policy entrepreneurs also employed framing of the problem and policy streams (Table 6) as a strategy to elicit support from the policymakers. Some of these framings rode on the President's promise for UHC and the Cabinet Secretary's mandate to implement the President's Agenda on UHC. To strengthen these frames, the policy entrepreneurs drew on the evidence obtained from the situation analyses. They also drew on international evidence to demonstrate that countries such as Thailand had successfully introduced independent experts panels for healthcare priority-setting for health benefits package development (Republic of Kenya, 2018).

Table 6: Frames used by policy entrepreneurs to elicit policymakers' support

<b>Framing of the fragmentation of priority-setting processes and benefits packages</b>	
<b>Frame</b>	<b>Examples of illustrative quotes</b>
Source of inefficiency	<i>'Fragmentation of priority-setting processes and of benefit packages increased inefficiencies in the health system through resource leakages'</i> (Document excerpt).
A bottle neck in UHC implementation	<i>'One of the biggest challenges in the implementation of UHC was the lack of a standard health benefits package'</i> Participant 8, MOH technocrat
<b>Framing of the independent experts panel</b>	
<b>Frame</b>	<b>Examples of illustrative quotes</b>
A way of harmonizing fragmented priority-setting processes	<i>'Since the priority-setting mechanisms were very fragmented and siloed, we needed a mechanism for bringing all these together to have a uniform way of doing things. This would be achieved through an independent panel'</i> Participant 1, MOH technocrat
A strategy for operationalizing and fulfilling the presidential agenda on UHC	<i>'To operationalize UHC within Kenya, we showed that there was a need to define a health benefits package. The panel would define this benefits package therefore offer an instrument to realize the UHC objective'</i> Participant 4, Donor-supported technocrat
A strategy for developing a health benefit package transparently and accountably.	<i>'A health benefits authority should be established with a structured process for priority-setting to explicitly define a package of services in a transparent and accountable manner'</i> Document excerpt
A mechanism for strategic use of funds and maximization of health outcomes	<i>'The panel was a process to ensure that priorities are set, and the available resources are used strategically to get the maximum outcome for a larger population'</i> Participant 3, local researcher
A mechanism for defining a fiscally sustainable benefits package	<i>'The panel was going to methodologically define one explicit benefits package that the government was going to commit to'</i>

	<i>provide by considering what services the government could afford’ Participant 7, Donor-supported technocrat</i>
A process that enhances the responsiveness of the benefits package to population health needs	<i>‘There was a need to define explicitly what essential benefits Kenyans would access under UHC while being cognizant of health as a constitutional right, our socio-economic reality and major causes of disease burden in the country. The best way to do this was to set up an independent expert panel’ Participant 4, MOH technocrat</i>
An inclusive platform that is owned and led by the people	<i>‘It was very important to have an inclusive team that represents different sectors for stakeholder buy-in. We wanted it to be a process that was driven and owned by the people and not the ministry. It was a way to get more people on the table to contribute’ Participant 7, MOH technocrat</i>
A process that guarantees independence and is insulated from influence by internal (bureaucratic) and external actor interests	<i>‘The panel was going to be an independent body of highly technical people responsible for developing the health benefits package. Its independence would ensure there was no influence from the Ministry or NHIF on how the process is done’ Participant 2, MOH technocrat</i>

The policy entrepreneurs also utilized the new political access to Mrs. Sicily Kariuki, which was created during the Washington meeting, to continue lobbying for the creation of an independent expert panel. Their persistence and persuasive framing paid off when, on the 8<sup>th</sup> of June, Mrs. Sicily Kariuki gazetted the HBPAP policy idea and appointed its members (Figure 4) (The Kenya Gazette, 2018). Mrs. Sicily Kariuki worked closely with the technocrats in the UHC coordination department and the policy entrepreneurs to develop the substantive content of the policy namely HBPAP’s roles, composition, and mandates.

*‘Through both formal and informal meetings, we were able to inform the Cabinet Secretary on what it would take to truly attain UHC. It is those discussions that led her*

to gazette the panel which consisted of experts drawn from the entire sector' Participant  
5, MOH technocrat

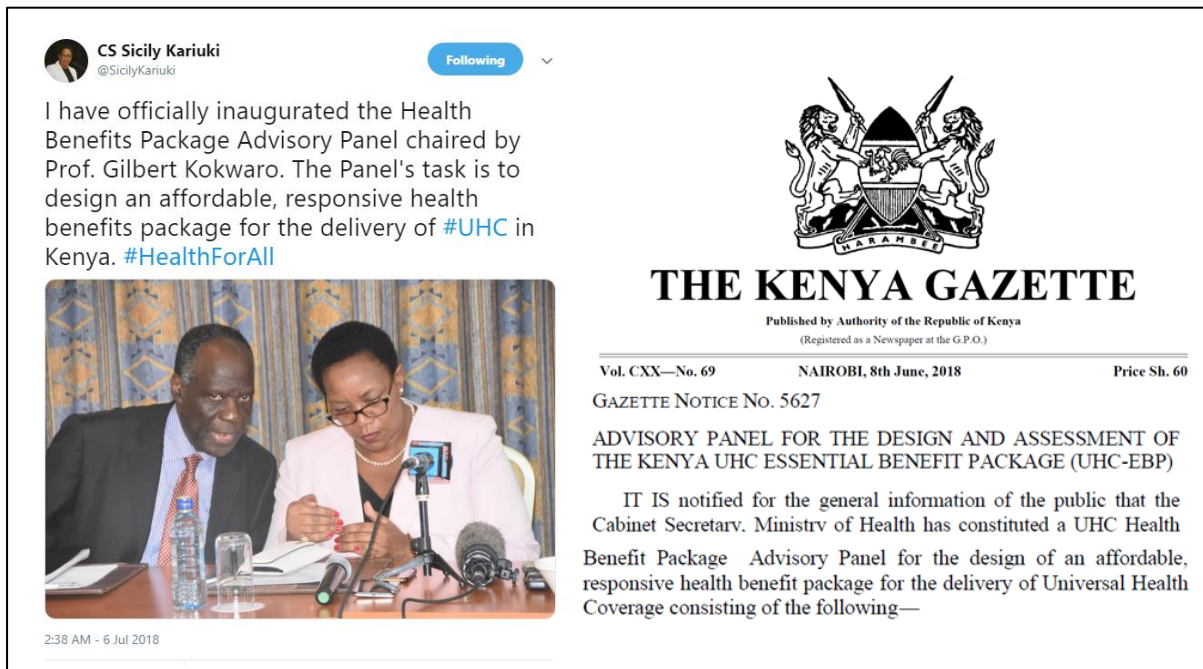


Figure 4: Gazettement of the HBPAP policy

## Discussion

In this study, we used Kingdon's multiple streams theory to examine the policy process that led to the gazettement of the HBPAP policy idea in Kenya. The HBPAP policy is an example of a procedural policy (Howlett, 2017, Commonwealth of Learning, 2012) as it sought to change how and by whom the healthcare priority-setting process for health benefits package development would be conducted in Kenya. Consistent with Kingdon's theory, the HBPAP policy idea was gazetted following the timely action of a network of policy entrepreneurs who matched the HBPAP policy idea to the identified problems of fragmented and implicit priority-setting processes and, unaffordable, unsustainable, and wasteful benefits packages when a policy window opened in the political stream. We discuss the significance of these findings against international literature.

In this case study, a policy window opened spontaneously in the political stream following the re-election of the president and the appointment of a new minister for health who were committed to UHC. Administrative changes open policy windows by creating the political impetus required for consideration of policy proposals. For example, in California, the election of Arnold Schwarzenegger, an ardent supporter of health and fitness activities, as a governor opened a critical policy window for tobacco control policies (Blackman, 2005). In the Wallonia- Brussels Federation in Belgium, the election of a new government in 2004 and the appointment of a doctor to oversee preventive medicine, an uncommon occurrence, created a policy window for the adoption of a hearing screening program for newborns (Vos et al., 2014). Lastly, in Canada, the appointment of a new cabinet minister created a policy window that led to the approval of the national health insurance policy (Blankenau, 2001).

This case study demonstrates the crucial role of policy entrepreneurs in coupling the streams during a policy window. To achieve this, policy entrepreneurs in our case study employed several strategies. Firstly, the policy entrepreneurs were adequately prepared with evidence of the issues in the problem stream and evidence of the viability of potential policy solutions. These were based on situation analyses and other countries' experiences respectively. The availability of these evidence strengthened policymakers' recognition of the problem and acceptance of the policy solutions. Similar findings have been reported in a Canadian healthcare centre where policy entrepreneurs demonstrated that Program Budgeting and Marginal analysis had been successfully introduced as an approach for healthcare priority-setting in other contexts which strengthened its acquiescence by stakeholders (Smith et al., 2016). Therefore, policy entrepreneurs who are adequately prepared with evidence on the problem and policy streams can effectively influence policy change (Mintrom, 2019, Abiola et al., 2013).

Secondly, recognizing common interests, the group of Kenyan technocrats who came to act as policy entrepreneurs deliberately engaged and interacted with each other in a network. For policy entrepreneurs, networks offer multiple benefits. For example, networks increase available resources (Gunn, 2017, Mintrom, 2019). In our case study, the network of policy entrepreneurs increased the technical and professional expertise required to support the development of the HBPAP policy. Similarly, in Lebanon, academic researchers built a network of policy entrepreneurs with civil society organisations, non-governmental organisations, and the media which increased their resources for advocacy campaigns for the tobacco control policy (Nakkash et al., 2018). Networks also build alliances of policy supporters thereby increasing the prominence of policy entrepreneurs in the policymaking environment (Mintrom and Vergari, 1996, Gunn, 2017). In our study, the network led to a greater coalition of supporters for the problem and policy streams from the MOH, Development partners, and Research organizations. Similarly, the United Nations Women, an international policy entrepreneur, worked collectively with other actors from government and non-governmental agencies to generate greater political support for the problem of violence against women (Mintrom and True, 2022).

Thirdly, policy entrepreneurs in our study used framing to draw more support from policymakers. Framing raises the political profile of a problem or policy solution by evoking policymakers' views and judgements which enables the problem or policy to ascend to the policymakers' agenda (Benford and Snow, 2000, Mintrom, 2019, Kingdon, 1993). Framing can be achieved by strategically linking ideologically congruent frames about a problem or policy solution with wider political and socio-economic ideologies or commitments at stakeholder, sub-national, national and/ or international level (Gunn, 2017, Benford and Snow, 2000). In our study, policy entrepreneurs used framing to strategically link the problem and policy streams to the national commitment for UHC thereby increasing the political priority of

these streams. In India, policy entrepreneurs linked maternal health to the millennium development goals thereby raising policymakers' attention (Shiffman and Ved, 2007). In India, policy entrepreneurs also framed health insurance policy as a social protection mechanism leading to the adoption of India's largest publicly funded health insurance program (Shroff et al., 2015). In Nepal, policy entrepreneurs bridged gender-based violence with the national concerns over human rights thereby generating approval from the Prime Minister's office (Colombini et al., 2016). Globally, policy entrepreneurs have linked cervical cancer to non-communicable diseases thus increasing the global priority for this disease (Parkhurst and Vulimiri, 2013). Lastly, the United Nations Women linked violence against women to the Covid-19 pandemic lockdown restrictions thereby elevating the global priority for this problem (Mintrom and True, 2022).

Lastly, policy entrepreneurs in our study utilized their proximal access to the Cabinet secretary to lobby for their preferred policy solution which enabled them to influence the policy process. Similarly, in Lebanon, policy entrepreneurs leveraged their political connections to lobby for tobacco control policies (Nakkash et al., 2018). Literature shows that the proximity of a policy entrepreneur to policymakers impacts on their activities and/ or effectiveness in bringing about policy changes (Gunn, 2017, Mintrom and Norman, 2009).

## Limitations

In this study, recall bias is a potential limitation given the retrospective nature of the study. However, by including document and media reviews, which are important historical accounts of past events (Bowen, 2009), we minimized this bias. Another potential limitation is social desirability bias whereby participants alter responses in the belief that these would make the responses more acceptable. However, by triangulating data sources and methods, we strengthened the trustworthiness of the findings. Lastly, the involvement of one of the authors



in previous policy formulation processes in Kenya may have biased the interviews and analysis, but this was mitigated through document and media reviews, and peer debriefing sessions among the authors who were not involved in these processes.

## Conclusions

Applying Kingdon's theory in this study was valuable in assisting explanation of the policy process that led to the gazettelement of the procedural policy on HBPAP. Technocrats from different organizational bases (Ministry of Health, Local research organizations, Development partners, National Health Insurance Fund and Private Sector) played key roles in defining the problem and policy streams. Political actors such as the President and the Cabinet Secretary for Health shaped the national mood in the political stream by prioritizing UHC. Attentive publics such the health financing intergovernmental coordinating committee were consulted during the development of potential policy solutions. A group of technocrats, turned policy entrepreneurs, played a crucial role in coupling the problem, policy, and political streams during a policy window that was created by the political prioritization of UHC. To achieve coupling, these policy entrepreneurs employed strategies such as working in networks; persuasive framing of problems and policy proposals; utilizing political connections; and marshalling of evidence on problems and policy streams. These insights can be useful to other countries seeking to introduce procedural policies on healthcare priority-setting processes for health benefits package development. This study also offers useful insights to local and international academic communities on the suitability of policy analysis theories in examining political processes for formulating procedural policies for healthcare priority-setting processes which remain limited.

## CHAPTER 7: A QUALITATIVE EVALUATION OF PRIORITY-SETTING BY THE HEALTH BENEFITS PACKAGE ADVISORY PANEL

In this chapter, I present the results of the second sub-study of this PhD in the format of a journal manuscript. The aim of this sub-study was to describe and qualitatively evaluate the healthcare priority-setting process conducted by HBPAP against the normative procedural and outcome conditions of a good healthcare priority-setting process as outlined in the Barasa et al., framework.

## RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

### SECTION A – Student Details

<b>Student ID Number</b>	LSH1902955	<b>Title</b>	Dr
<b>First Name(s)</b>	Rahab		
<b>Surname/Family Name</b>	Mbau		
<b>Thesis Title</b>	A critical examination of the policy process, implementation, and institutionalization of explicit healthcare priority-setting at the macro-level in Kenya		
<b>Supervisors</b>	Professor. Anna Vassall, Professor Lucy Gilson, and Professor Edwine Barasa		

If the Research Paper has previously been published, please complete Section B, if not please move to Section C.

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Where was the work published?	<b>Health Policy and Planning</b>		
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**A qualitative evaluation of priority-setting by the Health Benefits Package Advisory Panel in Kenya**

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**SECTION E**

<b>Student Signature</b>	Rahab Mbau
<b>Date</b>	22 <sup>nd</sup> December 2022

<b>Supervisor Signature</b>	Anna Vassall
<b>Date</b>	22 <sup>nd</sup> December 2022

# A qualitative evaluation of priority-setting by the Health Benefits Package Advisory Panel in Kenya

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## Abstract

Kenya's Ministry of Health established the Health Benefits Package Advisory Panel (HB PAP) in 2018 to develop a benefits package for universal health coverage. This study evaluated HB PAP's process for developing the benefits package against the normative procedural (acceptable way of doing things) and outcome (acceptable consequences) conditions of an ideal healthcare priority-setting process as outlined in the study's conceptual framework. We conducted a qualitative case study using in-depth interviews with national-level respondents ( $n = 20$ ) and document reviews. Data were analysed using a thematic approach. HB PAP's process partially fulfilled the procedural and outcome conditions of the study's evaluative framework. Concerning the procedural conditions, transparency and publicity were partially met and were limited by the lack of publication of HB PAP's report. While HB PAP used explicit and evidence-based priority-setting criteria, challenges included lack of primary data and local cost-effectiveness threshold, weak health information systems, short timelines, and political interference. While a wide range of stakeholders were engaged, this was limited by short timelines and inadequate financial resources. Empowerment of non-HB PAP members was limited by their inadequate technical knowledge and experience in priority-setting. Finally, appeals and revisions were limited by short timelines and lack of implementation of the proposed benefits package. Concerning the outcome conditions, stakeholder understanding was limited by the technical nature of the process and short timelines, while stakeholder acceptance and satisfaction were limited by lack of transparency. HB PAP's benefits package was not implemented due to stakeholder interests and opposition. Priority-setting processes for benefits package development in Kenya could be improved by publicizing the outcome of the process, allocating adequate time and financial resources, strengthening health information systems, generating local evidence, and enhancing stakeholder awareness and engagement to increase their empowerment, understanding and acceptance of the process. Managing politics and stakeholder interests is key in enhancing the success of priority-setting processes.

**Keywords:** Qualitative evaluation, macro (national) level, healthcare priority-setting process, Health Benefits Package Advisory Panel, Kenya

## Introduction

Healthcare priority-setting refers to the process of making decisions regarding allocation of resources among programmes, services and patient groups competing for scarce resources (Mckneally *et al.*, 1997). It occurs at all levels of the health system namely the micro (provider-patient); meso [sub-national or organizational (e.g., hospital)] and macro (national) levels (Mckneally *et al.*, 1997). Health-care priority-setting can be done implicitly or explicitly (Chalkidou *et al.*, 2016). Implicit priority-setting processes are *ad hoc* and non-transparent, while explicit priority-setting processes are systematic, transparent, inclusive, and driven by evidence, social values and deliberation among relevant stakeholders (Chalkidou *et al.*, 2016).

Health system resource constraints and wastage have led to growing demands for countries to adopt explicit priority-setting processes to inform universal health coverage (UHC) (World Health Organization, 2014; Chalkidou *et al.*, 2016). UHC means ensuring that everyone in need can obtain good-quality promotive, preventive, diagnostic, curative, palliative, and rehabilitative health services without financial troubles (World Health Organization, 2010). Explicit priority-setting processes can inform UHC decisions such as development of a health benefits package—a set of defined health services for a specified population that are funded from pooled resources (Bobadilla *et al.*, 1994; Glassman *et al.*, 2017).

As countries adopt explicit priority-setting processes, there is an accompanying demand to evaluate them

### Key messages

- Evaluation of healthcare priority-setting processes highlights what happens in practice and provides opportunities for improvement where actual practice does not align with normative procedural or outcome conditions.
- HBPAP's priority-setting process for health benefits package development partially fulfilled the normative procedural and outcome conditions due to internal and external limitations.
- Priority-setting processes for health benefits package development in Kenya could be improved by publicizing the out-come of the process, allocating adequate time and financial resources, strengthening health information systems, generating local evidence, enhancing stakeholder awareness and engagement, and managing politics and stakeholder interests.

(Smith *et al.*, 2012). This demand is driven by the public's interest in decision-makers demonstrating the fairness, legitimacy, accountability, and transparency of healthcare priority-setting processes, given the complexity and distributive conflicts associated with allocating scarce resources across competing uses (Ham and Coulter, 2001; Martin and Singer, 2003). Evaluation refers to the systematic collection and analysis of data to determine the merit of a process, policy, or program (Smith *et al.*, 2012).

Evaluation of healthcare priority-setting processes can be guided by normative conditions drawn from two philosophies—proceduralism and consequentialism (Coulter and Ham, 2000). Proceduralism judges whether a health-care priority-setting process follows acceptable ways of doing things, while consequentialism judges whether a healthcare priority-setting process leads to acceptable outcomes (Jan, 2014). A good healthcare priority-setting process fulfils the normative procedural and/or outcome conditions. Evaluation of healthcare priority-setting processes highlights what happens in practice and provides opportunities for improvement where actual practice does not align with normative procedural or outcome conditions (Smith *et al.*, 2012).

Globally, empirical studies on evaluation of healthcare priority-setting processes remain limited (Martin and Singer, 2003; Smith *et al.*, 2012). This gap is wider for macro level processes and low- and middle-income countries (LMICs). A literature review on evaluation of priority-setting processes in the health sector conducted in 2015 identified 27 empirical studies, of which only 5 and 7 covered the macro level and LMICs, respectively (Barasa *et al.*, 2015). Given this gap, evaluating how well priority-setting processes are conducted at the macro level in LMICs is, therefore, a substantially relevant health systems research question.

In Kenya, a lower-middle-income country, studies on evaluation of healthcare priority-setting processes at the macro level remain limited. Recent publications include a multi-country study on evaluation of macro level priority-setting for COVID-19 preparedness plans (Kapiriri *et al.*, 2021) and priority-setting for non-communicable diseases (Wanjau *et al.*, 2021). Previous studies have largely been conducted at the meso level, namely hospital level (Barasa *et al.*, 2017) and county level (Bukachi *et al.*, 2014; Nyandieka *et al.*, 2015; Waitthaka *et al.*, 2018b).

As part of the UHC reforms, Kenya's Ministry of Health (MOH) established the Health Benefits Package Advisory Panel (HBPAP) in 2018 to develop a benefits package for UHC using an explicit priority-setting process. This study seeks to contribute to the literature on evaluation of macro level priority-setting processes by describing and qualitatively evaluating the extent to which the priority-setting process conducted by HBPAP fulfilled the key elements of an ideal healthcare priority-setting process.

## Methods

### Study setting

Kenya's governance structure is devolved with 1 national government and 47 semi-independent county governments. In the health sector, the national government has policy and regulatory roles, while county governments oversee service provision (The Republic of Kenya, 2010). Kenya's health sector is financed from three major sources namely the government, households and donors which accounted for 46%, 35.5% and 18.5% of the total health expenditure in 2019, respectively (World Health Organization, 2019).

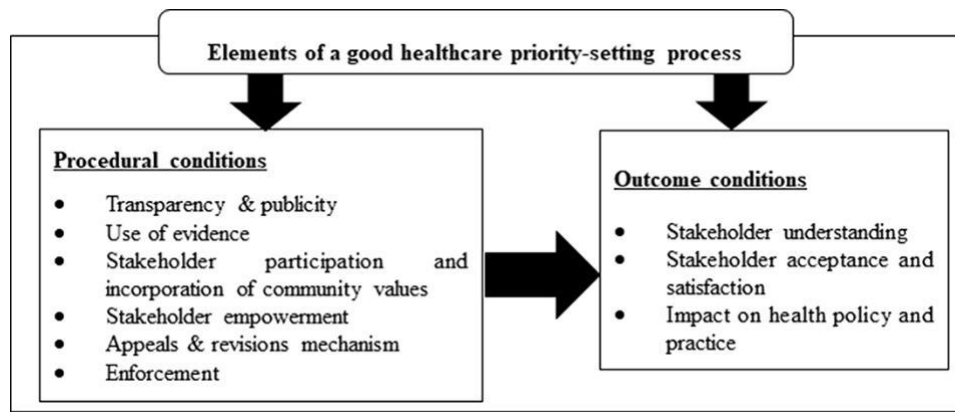
In the public health sector, purchasing, which refers to the transfer of pooled funds to healthcare providers for health service delivery (World Health Organization, 2010), is done by the following purchasing organizations. The MOH purchases services from national referral hospitals using global budgets derived from national government revenue. The county governments purchase services from county public hospitals and primary healthcare facilities using line-item budgets derived from the county revenue fund. Finally, the National Health Insurance Fund (NHIF) purchases services from public healthcare facilities using capitation, case-based payments, fee-for-service, and rebates derived from premium contributions from its members (Mbau *et al.*, 2018; 2020). The NHIF is the largest health insurer in Kenya covering ~17.8% of the population (Ministry of Health, 2018a). In 2018, the Kenyan government identified UHC as one of its four key aspirational development agenda and planned to roll it out as a 12-month pilot in four counties in 2019 before a progressive nationwide scale-up across all counties starting from 2020.

### Study design

We used a qualitative case study approach to explore people's perspectives and experiences of the priority-setting process given that priority-setting is a context-dependent social process (Coulter and Ham, 2000; Martin and Singer, 2003). The case in this enquiry was the priority-setting process for health benefits package development conducted by HBPAP within the MOH in Kenya.

### Conceptual framework

We adapted the Barasa *et al.*'s conceptual framework (Figure 1) to describe and qualitatively evaluate the extent to which HBPAP's priority-setting process fulfilled the key conditions of a good priority-setting process. We chose this framework because it is based on a synthesis of empirical and conceptual literature on normative procedural and outcome conditions that stakeholders across countries of different income levels considered essential for a good, fair, legitimate, socially justifiable, or successful priority-setting process at the macro and meso levels of the health system



**Figure 1.** Framework for evaluating healthcare priority-setting processes, adapted from (Barasa et al., 2015)

**Table 1.** List of participants

Category	Subcategory	Number	
HBPAP participants	HBPAP members	<i>n</i>	9
Non-HBPAP participants	MOH	<i>n</i>	4
	Academic and research organizations	<i>n</i>	2
	Public health sector agencies	<i>n</i>	2
	Development partners	<i>n</i>	3
<b>Total</b>		<i>n</i>	<b>20</b>

(Barasa et al., 2015). We also chose this framework because it drew on concepts from theoretical literature on deliberative democracy and procedural justice which spanned beyond the health sector (Barasa et al., 2015).

According to Barasa et al., the procedural conditions of a good priority-setting process include transparency, use of evidence, stakeholder participation and incorporation of community values, stakeholder empowerment, revisions and appeals mechanism and enforcement. The outcome conditions include stakeholder understanding, stakeholder acceptance and satisfaction and impact on health policy and practice (Barasa et al., 2015). The definitions of these conditions are provided in [Supplementary Material](#). We used this framework to develop the study’s interview topic guide and to guide data analysis.

**Study population and sampling strategy**

We sampled study participants through purposive and snowballing techniques. The aim was to generate a deep understanding of the experience of priority-setting through engaging information-rich participants rather than interviewing a representative sample of every stakeholder involved in the process (Sandelowski, 1995). The purposive criterion was a participant’s involvement in HBPAP’s priority-setting process as a HBPAP member. HBPAP members were then asked to nominate other stakeholders who were involved in the priority-setting process, aiding access to hard-to-reach elites. Sampling was stopped at the point of data saturation. A total of 20 stakeholders (Table 1) were interviewed. None of the participants’ demographic information is provided to maintain confidentiality and anonymity.

**Table 2.** List of reviewed documents

Types of documents	Examples (all available in electronic versions)
Government documents	(1) Gazette notice Vol. CXX- No.69 (2) Kenya Health Policy 2014–2030 (3) Draft UHC report (4) Policy brief on the harmonized benefits package (5) Online media reports on MOH web portals
HBPAP documents	(1) Procedural documents—attendance sheets and memos (2) HBPAP reports and annexes (3) HBPAP presentations
Semi-autonomous government agencies documents	(1) NHIF reforms panel report

**Data collection methods**

We collected data through in-depth interviews, document reviews and field notes between October and December 2021.

**In-depth interviews**

We contacted participants via telephone and email to request their participation; none declined. Before the interview, each participant reviewed the research information sheet and gave informed consent. The interviews were conducted via face–face in the participant’s office or via Zoom videoconferencing. Each interview was conducted in English, audio-recorded with an encrypted recorder and lasted approximately 1 h. For the interviews, we used a semi-structured topic guide that was informed by the key elements of the study’s conceptual framework.

**Document reviews**

We identified documents with potentially relevant information on HBPAP’s priority-setting process (Table 2) from interview participants and online media platforms.

**Field notes**

We took handwritten field notes during interviews to record audio information when participants requested for the tape

recorder to be switched off. We also used field notes as aids for critical reflection of emerging themes and refinement of the topic guide. After the interviews, we transferred the field notes to Microsoft word documents to prevent loss of data through forgetfulness. Each field note was linked to the respective interview through dates and numbers.

### Data analysis

All audio files were transcribed verbatim by a transcription agency. We reviewed all transcripts for transcription accuracy by comparing them to the audio files and cleaning them where necessary. All transcripts, field notes, and electronic documents were uploaded to NVIVO Pro software QSR International, Burlington, Massachusetts for effective organization during data analysis. We used the Braun and Clarke six-step approach to analyse the data thematically (Braun and Clarke, 2006).

In Step 1, we familiarized ourselves with the data through immersion. In Step 2, we generated a list of codes related to the elements of the study's conceptual framework. In Step 3, we developed themes by identifying patterns between codes and grouping similar codes together. In Step 4, we checked for coherence between the list of themes and the coded data extracts. In Step 5, we applied the approved themes across the data. In Step 6, we produced a synthesis of the findings related to the evaluation of HBPAP's priority-setting process and linked these findings to broader empirical literature. These findings were reviewed and approved by all authors.

### Trustworthiness

We built trustworthiness in the study findings by using different methods of data collection (method triangulation), interviewing multiple participants to identify multiple perspectives (data source triangulation), iterative questioning through rephrasing of questions and use of probes and holding peer debriefing sessions with the study team.

### Reflexivity

All authors have participated in priority-setting processes across different LMICs. Specifically, two authors have participated in previous priority-setting processes in Kenya which influenced their interest in the study topic and methodology including sampling of participants, data collection methods and data analysis.

## Findings

### Description of HBPAP's priority-setting process

HBPAP was appointed by the Cabinet Secretary for Health (equivalent to Minister for Health) on 8 June 2018. It consisted of HBPAP members who were experts with different technical backgrounds and experience in priority-setting such as

health financing and health systems experts, epidemiologists, clinicians, actuaries, and county government representatives. HBPAP was formed to, among others (Table 3), develop a benefits package for UHC using an explicit priority-setting process within 60 days (The Kenya Gazette, 2018). This UHC health benefits package would be funded by the Government of Kenya and purchased through the NHIF (Ministry of Health, 2018a). The health benefits package would be piloted in four counties before being implemented nationally across all 47 counties.

To develop the benefits package, HBPAP identified 10 priority-setting criteria using a nominal group technique—a structured approach that involves collective deliberation and consensus. Table 4 outlines these criteria, their definition, and how they were operationalized.

Next, HBPAP started with a long list of health services that was drawn from existing benefit packages in the health sector, namely the Kenya Essential Package for Health that was offered in public healthcare facilities and the NHIF's general scheme benefits package. HBPAP then invited nominations for additional services from a wide range of health systems stakeholders. HBPAP prioritized the list and conducted assessments and appraisal of services using the 10 priority-setting criteria. Assessments relied on published literature and secondary data because of short timelines and limited primary data. Services that met the priority-setting criteria following appraisal were included in the benefits package that was submitted as a proposal to the MOH for final decision-making. Figure 2 outlines HBPAP's priority-setting process.

### Evaluation of HBPAP's priority-setting process

Overall, HBPAP's priority-setting process partially fulfilled the normative procedural and outcome conditions specified by the study's conceptual framework. This partial fulfilment was due to several limitations as described further below.

### Procedural conditions

#### Fairly transparent but less publicly available information on HBPAP's priority-setting process

The composition, roles, and responsibilities of HBPAP were transparent and publicly available through a Government Gazette Notice (The Kenya Gazette, 2018). According to the Notice, HBPAP was constituted as an advisory body for the MOH. It consisted of 1 chairman, 14 members, and 2 joint secretaries. The roles and responsibilities of HBPAP and non-HBPAP members in the priority-setting process (Table 5) were transparent to those involved. These were explicitly outlined in HBPAP's Internal Procedures Manual (Ministry of Health, 2018b). However, the Manual was only accessible to HBPAP members and MOH officials which undermined its public availability.

HBPAP's priority-setting process was transparent. Transparency was achieved through generation and use of priority-setting criteria to inform selection of services for the health benefits package and involvement of stakeholders in the different steps of the priority-setting process. Transparency was also achieved through development of a detailed report on the process which made each step of the priority-setting process clear, replicable, and auditable.

*'The panel ensured that every stage of the process was open in compliance with the constitutional dispensation*

**Table 3.** HBPAP's roles and responsibilities as assigned by the MOH (The Kenya Gazette, 2018)

- (1) Develop criteria for assessing and appraising health technologies.
- (2) Develop an evidence-based health benefits package for Kenyans.
- (3) Propose provider payment methods and rates for the health benefits package.
- (4) Define a framework for institutionalizing health technology assessment in Kenya.



**Table 4.** The 10 priority-setting criteria for assessing and appraising services (Ministry of Health, 2018b)

Criteria	Definition	Data sources and operationalization
Effectiveness and safety	The service improves health status and is safe for use	Clinical guidelines and pathways
Burden of disease	The service addresses disease conditions that affect many Kenyans	Nationally representative surveys, burden of disease data from the Institute for Health Metrics Evaluation , routine data from Health Management Information Systems
Severity of disease	The service addresses the most debilitating illnesses in Kenya	Disability weights from burden of disease studies
Catastrophic health expenditure	Coverage of the service reduces the risk of poverty associated with an individual's access to that service	Nationally representative surveys and analyses
Cost-effectiveness	The service offers the best possible use of available resources to improve health status	Cost-effectiveness databases—Tuft Cost-Effectiveness Analysis, Disease Control Priorities 3 and World Health Organization—Choosing Interventions that are Cost-Effective
Affordability	Kenya has the financial resources to cover the costs associated with the provision of the service.	Budget impact analysis using expenditure and cost data from secondary sources
Feasibility: health workforce requirements	Kenya has the human resource capacity required to provide the service	Kenya health workforce report data and information from professional regulatory bodies
Feasibility: Service and health products and medical technology requirements	Kenya has other health technologies required to support provision of the service	Service readiness surveys
Equity	Provision of the service addresses disparities in access and utilization of needed health services	Benefit incidence analysis of services
Congruence with existing priorities	The service aligns with the priorities identified in the constitution and health sector policies	Document reviews of MOH policies

*that gives Kenyans a right to access and demand information. The panel also wanted to win the confidence of all stakeholders so that the ownership of the document was acquired ab initio until the end'* HBPAP participant 4

While HBPAP's priority-setting process was transparent, publicity around it was limited by the failure to publish HBPAP's report which had outlined explicitly the methodology used to design the health benefits package.

*'The report was to enable the government to decide on what to roll out as a benefits package for UHC and what to communicate to the public. However, the government did not adopt the report, so it has never been made public'* Development partner, participant 2

There was also lack of transparency and publicity of the final decision-making process in which the senior political leadership consisting of the President, the Cabinet Secretary for Health, and officials from the Ministry of Finance made the final decision on the implementation of HBPAP's proposed health benefits package.

*'There was no transparency in the final decision-making about whether or not to implement the benefits package that we had developed. We, therefore, do not know how the decision was made and what factors were considered'* HBPAP participant 1

### Adequate identification but limited application of priority-setting criteria

HBPAP identified commonly used priority-setting criteria (Table 4) from peer-reviewed literature, organizational

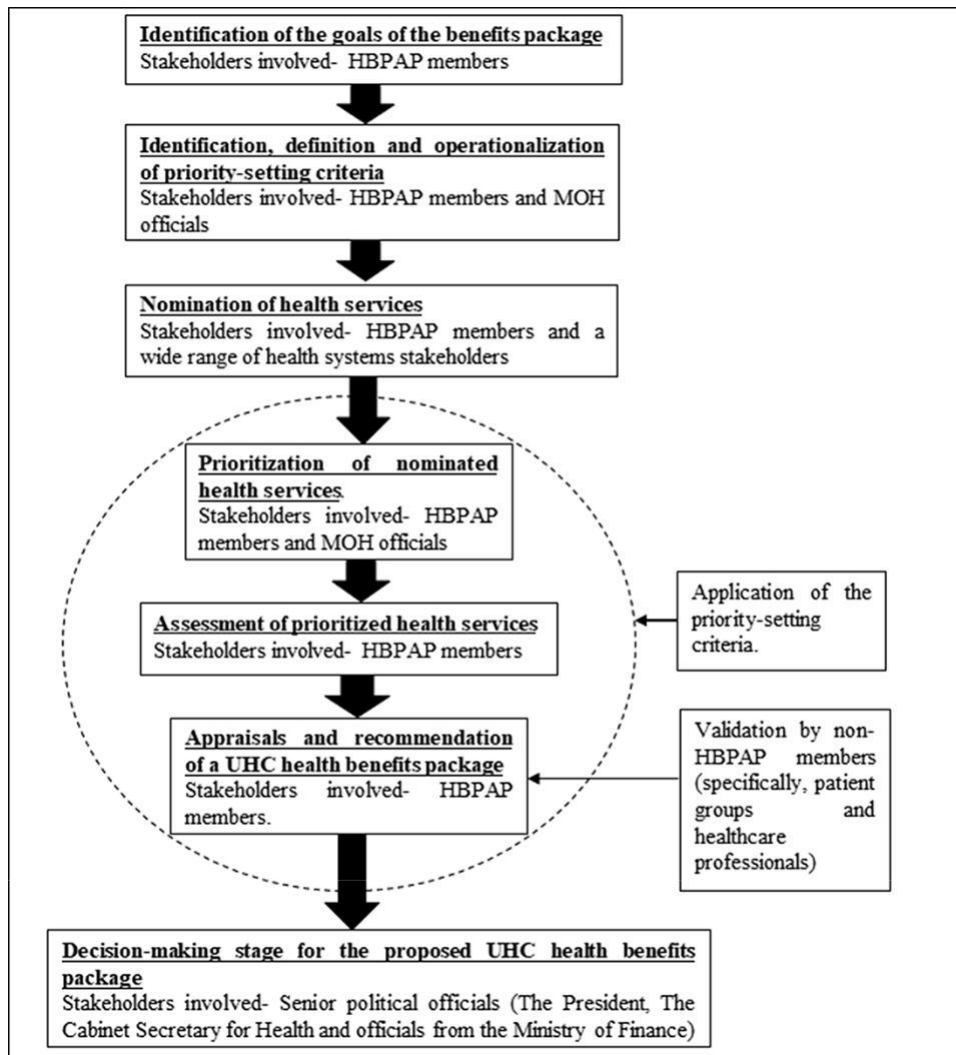
Websites, and national health policy documents (Ministry of Health, 2018b). However, the application of the criteria was undermined by limited quality of evidence (missing and/or outdated evidence) on the criteria due to inadequate availability of good-quality local primary or published data and inadequate health information systems. The application of the cost-effectiveness criterion was undermined by the lack of local cost-effectiveness threshold. Furthermore, the 60-day timeline was considered too short to allow application of the criteria across all nominated services. Finally, political interference overruled technical evidence in the final decision-making phase.

*'We had a time crunch. We only had 60 days...We could not intensively subject every service to the 10 criteria'* HBPAP participant 7

*'The criteria were very important to us from a technical and political perspective because this was a political and technical process. We had to tell technocrats and politicians why we were including A and not B and the criteria were majorly our point of argument but somehow politics took the larger pie of that cake in the final stage.'* HBPAP participant 6

### Adequate participation of stakeholders and incorporation of community values

There was good participation by HBPAP members in the priority-setting process as shown by their good attendance and contribution during meetings. In addition, a wide range of non-HBPAP stakeholders participated in the priority-setting process. Broadly, they included MOH technocrats and bureaucrats, health professional associations and unions, public and private health sector agencies, civil



**Figure 2.** HBPAP's healthcare priority-setting process for health benefits package development. Source: authors, based on participants' reports and document reviews

**Table 5.** Roles and responsibilities of HBPAP and non-HBPAP members (Ministry of Health, 2018b)

Category of stakehold-	Roles and responsibilities in the priority-setting process
HBPAP members	(1)Identify, define and operationalize the priority-setting criteria (2)Assess and appraise nominated services (3)Propose a health benefits package
Non-HBPAP members	(1)Nominate services (2)Advise on the priority-setting criteria and proposed health benefits package
Senior political leadership (The President, the Cabinet Secretary for Health and senior officials from the Ministry of Finance)	(1)Advise on the proposed benefits package (2)Make the final decision on the implementation of the proposed health benefits package

national government. Stakeholder participation was through stakeholder engagement forums that were financially and administratively supported by development partners and semi-autonomous government agencies. Stakeholder participation was important for incorporating stakeholder values and preferences and fulfilling the constitutional principles of procedural justice of public participation, right to information, accountability, and transparency (Ministry of Health, 2018b).

*'The panel consulted different stakeholders in their process of work so that it was not just their views but the views of the whole sector'* MOH participant 1

While HBPAP had tried to be as inclusive as possible, participants reported that some stakeholders, such as informal sector workers and international non-governmental organizations supporting disease-specific programmes, had been left out of the priority-setting process. They also reported that MOH bureaucrats should have been assigned more roles in

society organizations, development partners, and middle and senior political leaders from the four pilot counties and the

the process to increase their level of ownership and acceptance of HBPAP's priority-setting process and proposed health benefits package.

*'The Heads of Departments within the MOH were not extensively engaged in the process...That was a major pitfall because ownership by the MOH was not there. They just looked at the report as HBPAP's report. They didn't seem to accept it'* HBPAP participant 5

According to participants and the documents reviewed, extensive stakeholder participation and consideration of other shared community values were limited by the lack of a budget for HBPAP's operational costs and the 60-day timeline.

*'They tried; they met with different groups, but they had 60 days. What can you do in 60 days? 60 days was a very short time'* Development partner, participant 3

### **Adequate empowerment of HBPAP members but limited empowerment of non-HBPAP members**

HBPAP members were empowered to participate in the priority-setting process through (1) their appointment into HBPAP via a legal gazette notice, (2) HBPAP's semi-autonomous nature that provided them with the decision space to conduct the priority-setting process, (3) their technical expertise and professional experience in priority-setting processes, (4) the positive organizational culture within HBPAP which was characterized by strong and supportive leadership, commitment and mutual respect among members, and (5) political goodwill from the senior political leadership who not only appointed them but also dedicated time to engage with them.

*'There was support from the leadership to have this completed. The former Cabinet Secretary spent hours in the boardroom with the panel discussing the benefit package. There was also support and engagement from the President which pushed the panel through'* MOH participant 2

However, HBPAP members' empowerment was undermined by the lack of allocation of office space and financial resources which limited their operational activities such as stakeholder engagement forums. Their empowerment was also undermined by the 60-day timeline which limited the extent to which HBPAP members could meaningfully employ their technical expertise.

*'Time was a very scarce resource. In future, it would be good to allocate more time so that the panel can work well without rushing through the process'* HBPAP participant 9

Non-HBPAP members were empowered to participate in the priority-setting process through stakeholder engagement forums. HBPAP held different engagement forums for different stakeholders to minimize dominance of certain groups of stakeholders over others. However, empowerment of non-HBPAP members was limited by the inherently technical nature of the priority-setting process. Consequently, non-HBPAP members with technical expertise and prior experience in priority-setting were more empowered to contribute and influence the process than those without.

*'Stakeholders' technical knowhow influenced their participation. Donors in health financing had technical capacity to participate in the process but majority did not have health systems experience hence did not fully engage with the process'* HBPAP participant 6

### **Limited appeals and revisions mechanism**

Non-HBPAP members could challenge or provide feedback on the decisions made by HBPAP through stakeholder engagement forums or HBPAP's official email account. However, this feedback process was limited by the 60-day timeline for the priority-setting process. There was also no formal mechanism to revise and appeal the final decision of the priority-setting process because the senior political leadership did not adopt the proposed health benefits package.

*'An appeals or revision process did not occur because it was not clear what the package was. It must be clear what the package is for people to appeal or revise it. However, because the MOH decided to go another way, there was nothing to appeal'* HBPAP participant 1

### **Adequate availability and application of enforcement measures**

HBPAP's Internal Procedures Manual provided a good mechanism for ensuring that HBPAP's priority-setting process adhered to the key principles of explicit priority-setting. The manual covered: (1) meeting and decision-making procedures including code of conduct (impartiality and objectivity); (2) communication and stakeholder engagement strategies; (3) terms of reference such as membership, key roles and responsibilities, deliverables and reporting lines within and outside of HBPAP; (4) affirmation of commitment to HBPAP's activities and deliverables; and (5) conflict-of-interest statement which outlined the types, declaration, and management of conflicts of interest. Enforcement was also achieved through oversight and leadership provided by the HBPAP's Chairman and the Cabinet Secretary for Health. These leaders ensured that HBPAP's priority-setting process adhered to the principles outlined in the Internal Procedures Manual such as transparency and participation.

*'The Cabinet Secretary would always tell us, "You must bring the people along in the process"'* HBPAP participant 7

### **Outcome conditions**

#### **Adequate understanding of the priority-setting process by HBPAP members but limited understanding by non-HBPAP members**

HBPAP participants reported that participating in the priority-setting process for health benefits package development had deepened their understanding of the meaning of and need for priority-setting as well as how to conduct priority-setting explicitly.

*'It oriented me to the importance of explicit priority-setting which offers a clear path to follow as opposed to the usual ad hoc planning where you want to put everything in one basket'* HBPAP participant 5

Some non-HBPAP participants reported learning substantially by participating in HBPAP's priority-setting process and equated the learning to a crash course in healthcare financing. However, others reported that they did not understand the process or how it was conducted. They attributed this to their lack of technical knowledge or professional experience in priority-setting and the 60-day timeline that was too short to enable deep sensitization and education of non-HBPAP members.

*'In the meetings, people were getting confused and surprised. The panel tried to explain their work, but the limitation was time'* MOH participant 3

### **Adequate stakeholder acceptance and satisfaction with HBPAP's roles, composition, and process, but poor acceptance and satisfaction with the final decision-making stage**

Concerning HBPAP's roles, responsibilities and composition, participants reported that majority of HBPAP and non-HBPAP members were satisfied with these. These members felt that HBPAP consisted of experts with impeccable credentials who could competently develop a health benefits package for Kenya.

*'External stakeholders were happy with the fact that there was a panel. They looked at the mix of people who were there and their professional accolades. They knew this was a team that would do them good'*. HBPAP participant 3

However, participants reported that a few stakeholders such as some MOH bureaucrats and parastatals rejected and were dissatisfied with HBPAP's roles and responsibilities because they felt that their roles had been usurped and/or their experience in designing health benefits packages overlooked. This lack of acceptance limited HBPAP's access to official government documents and knowledge of the decisions being made at the senior political level.

*'The team based at the Ministry has this understanding that nothing can succeed without them. Some felt that this is something they could do, and they did not need anybody from elsewhere to come and do it. Externally, there were stakeholders who felt they should have been the ones to lead the process'* HBPAP participant 7

Concerning HBPAP's priority-setting process and proposed health benefits package, participants reported that many HBPAP and non-HBPAP members accepted and were satisfied with these. Participants felt that despite time and other resource constraints, HBPAP and non-HBPAP members were adequately involved in a transparent and auditable process that had led to the creation of a scientifically sound benefits package that met the needs of the people.

*'Everybody that interacted with the panel was very happy with this process and what came out of it'* HBPAP participant 2

However, some HBPAP and non-HBPAP participants criticized HBPAP's priority-setting process for being overly

academic or technical which undermined stakeholder understanding and acceptance of the priority-setting process. It also undermined incorporation of political views when setting priorities.

*'One of the panel's biggest deficiencies was lack of consideration of the political aspect of the process. This was more of a political than a technical process. The panel should have factored in what was politically feasible because this was not an academic exercise but an exercise to inform actual policy.'*

Development partner, participant 1

Concerning the final decision-making process by senior political leadership, HBPAP and non-HBPAP participants expressed their dissatisfaction and poor acceptance due to lack of transparency and consideration of scientific considerations. Participants were also dissatisfied with the lack of publication of HBPAP's report that detailed the proposed health benefits package given the time, expertise, and financial resources that went into developing it. Finally, participants were dissatisfied with the lack of implementation of HBPAP's proposed health benefits package as this undermined service coverage towards UHC.

*'Let me explain the disillusionment. The Panel's creation was a once in a lifetime moment. The panel had a window of opportunity to change how things were done in the health system. However, that window was squandered. Everyone could have done better to support the Panel. How long will it take to recreate that window? When will this ever happen again?'* Development partner, participant 3

### **Limited impact of HBPAP's priority-setting process on health policy and practice**

The outputs of HBPAP's priority-setting process were a proposed health benefits package and policy recommendations to support health system improvement towards UHC, including proposals for the institutionalization of evidence-based priority-setting processes (Ministry of Health, 2018b). However, the proposed health benefits package was not implemented in the UHC pilot due to several reasons.

First, the senior political leadership changed the UHC model from a health insurance model to a user-fee removal model. This change was thought to be due to concerns about the affordability of HBPAP's proposed health benefits package. The change to a user-fee removal model was, however, incompatible with the specification of health services and the design of payment methods such as capitation and case-based payments of the proposed health benefits package. In the user-fee removal model, no user fees would be charged in public hospitals in the four pilot counties. Instead, the public hospitals would be reimbursed for services offered using line-item budgets which outline costs of health system inputs as opposed to explicitly defined health services.

*'The pilot design changed to user-fee removal. The NHIF was no longer responsible for purchasing the UHC benefit package which made it difficult to operationalize the benefit package. The package and its provider payments were designed for a purchaser like NHIF.'* HBPAP participant 1

Second, participants reported that stakeholders' interests and opposition prevented implementation of the proposed health

benefits package. For example, NHIF opposed HBPAP's new health benefits package because it had its own benefits packages. The NHIF felt that HBPAP had usurped its role for benefits package design. However, senior MOH policymakers felt that the NHIF benefits packages were unaffordable and unsustainable. Private healthcare providers opposed HBPAP's new health benefits package because it would mean revenue loss from loss of contracts under the government's proposed implementation plan. Some development partners supporting health financing functions in Kenya opposed HBPAP's proposed benefits package because they held different opinions on the type of benefits package that should be implemented. Finally, some MOH bureaucrats and NHIF officials opposed HBPAP's priority-setting process because they felt that they had not been adequately involved.

*'What happened to the Panel's benefit package was policy capture. The benefit package was not implemented because of interests from different stakeholders which overshadowed the process.'* HBPAP participant 8

Despite the lack of implementation of HBPAP's proposed health benefits package in the UHC pilot, HBPAP's proposed recommendations for health system improvement had influenced several policy reforms. For example, the MOH combined HBPAP's proposed health benefits package with elements of other existing benefits packages such as the NHIF's benefits packages and the MOH's Kenya Essential Package for Health to develop a harmonized benefits package for nationwide implementation towards UHC.

*'There has been some impact of the panel's report. The ministry used the report to develop a Harmonized Benefits Package which is a blend of the package proposed by the panel and other existing packages such as Supa Cover, Linda Mama, Civil Servants among others'* MOH participant 1

In response to HBPAP's recommendation to institutionalize explicit priority-setting through health technology assessment (HTA), the MOH has appointed a focal point for HTA and developed a framework for institutionalizing HTA in Kenya. The MOH has also established a Medicines Affordability Pricing Advisory Committee to use HTA to inform pricing of pharmaceutical products and a HTA Technical Working Group to support development of a strategy for HTA.

*'One of the annexes in our report is the draft framework for institutionalizing health technology assessment in Kenya. It was a step for the MOH to put in place a systematic process for developing a benefit package because our life was temporary'* HBPAP participant 4

## Discussion

This case study qualitatively evaluated the extent to which HBPAP's priority-setting process for health benefits package development fulfilled the normative procedural and outcome conditions of a good priority-setting process as set out by

Barasa et al. (Barasa et al., 2015). The findings indicate that HBPAP's priority-setting process partially fulfilled these conditions. This case study offers the following lessons.

While the Barasa et al.'s framework recognizes the interconnection between procedural and outcome conditions, this study further shows the presence of interconnections between specific elements within the procedural and outcome conditions. These interconnections mean that the fulfilment of one element is likely to influence fulfilment of the other. For example, stakeholder participation in HBPAP's priority-setting process (procedural condition) influenced the extent of transparency and incorporation of community values (procedural conditions) as well as stakeholder understanding, acceptance and satisfaction (outcome conditions). Similar findings have been reported in macro level priority-setting processes in Uganda (Kapiriri and Be Larose, 2019), UK, New Zealand, Australia and Canada (Mitton et al., 2006) and meso level priority-setting processes in Kenya (Bukachi et al., 2014; Waithaka et al., 2018b) and Zambia (Tuba et al., 2010). Lack of transparency in the final decision-making stage in HBPAP's priority-setting process (procedural condition) undermined stakeholder acceptance and satisfaction (outcome condition). Comparable findings have been made in macro level priority-setting processes in Korea (Ahn et al., 2012). Finally, limited stakeholder acceptance and satisfaction (outcome conditions) with HBPAP's roles and proposed health benefits package undermined the impact of HBPAP's process on policy and practice (outcome condition).

This study also showed that partial fulfilment of the procedural and outcome conditions could be attributed to factors internal to the priority-setting process such as HBPAP's multidisciplinary and multi-stakeholder composition, HBPAP members' technical expertise, finances and time allocated for the process, and availability of internal procedures manual. These findings are supported by international literature. For example, the multi-stakeholder composition of priority-setting bodies influenced stakeholder participation and inclusiveness in macro level priority-setting processes in Australia (Whitty and Littlejohns, 2015). The technical expertise of the members of priority-setting bodies influenced their extent of participation and empowerment as well as the extent of external stakeholders' acceptance and satisfaction with macro level priority-setting processes in Australia, UK, New Zealand, and Canada (Mitton et al., 2006). Limited allocation of financial resources influenced external stakeholder involvement in meso level priority-setting processes in Kenya (Nyandieka et al., 2015; Waithaka et al., 2018b), Zambia (Zulu et al., 2014), and Tanzania (Maluka et al., 2010a; 2010b) and macro level priority-setting processes in Australia (Whitty and Littlejohns, 2015). Limited allocation of time for the priority-setting process influenced stakeholder understanding in Canada (Gibson et al., 2006), and use of evidence and stakeholder participation in Kenya (Nyandieka et al., 2015; Waithaka et al., 2018b) and Tanzania (Maluka et al., 2010b). Finally, the availability of manuals and guidelines influenced enforcement and degree of transparency and evidential requirements in macro level priority-setting processes in Australia (Whitty and Littlejohns, 2015) and UK (Mitton et al., 2006) and meso level processes in Kenya (Barasa et al., 2017).

Our study further showed that partial fulfilment of the procedural and outcome conditions could be attributed to

factors external to the priority-setting process, such as legal instruments (gazette notice, the constitution, and national policy documents), quality of evidence for priority-setting criteria and external stakeholders' technical expertise or experience in priority-setting. These findings are supported by international literature. For example, legal instruments influenced legitimacy, transparency, stakeholder participation, use of evidence, and availability of appeals, revisions and enforcement mechanisms in macro level priority-setting processes in Australia (Whitty and Littlejohns, 2015), Germany (Kieslich and Littlejohns, 2012) and Chile (Charvel *et al.*, 2018), as well as meso level priority-setting processes across countries of different income levels (Waithaka *et al.*, 2018a). Limited quality of evidence undermined use of criteria in macro level priority-setting processes in the UK, Australia, and Canada (Mitton *et al.*, 2006) and meso level priority-setting processes in Kenya (Waithaka *et al.*, 2018b) and Tanzania (Maluka *et al.*, 2010a; 2010b). External stakeholders' technical expertise and experience in priority-setting influenced their level of participation in priority-setting processes in Kenya (Wanjau *et al.*, 2021), UK (Robinson *et al.*, 2012), and Tanzania (Maluka *et al.*, 2010a).

This study also highlighted the political nature of priority-setting processes and the undermining influence of politics on a priority-setting process. Despite HBPAP establishing an explicit priority-setting process, political interference and stakeholder interests undermined transparency of the decision-making process, use of evidence, stakeholder acceptance and satisfaction with the roles and process, and impact of HBPAP's recommendations on health policy and practice. Priority-setting processes are inherently political given conflicting opinions on what procedures and evidence should be followed, who should be involved, and what roles they should play (Ham and Glenn, 2003). Existing literature shows that clarity and acceptance of roles influenced stakeholder participation at the meso level in Kenya (Barasa *et al.*, 2017). Political interference and donor interests influenced final decision-making in macro level priority-setting processes in Kenya (Wanjau *et al.*, 2021), Uganda (Kipiriri *et al.*, 2007) and meso level priority-setting processes in Kenya (Bukachi *et al.*, 2014; Waithaka *et al.*, 2018b), Tanzania (Maluka *et al.*, 2010b), and Zambia (Tuba *et al.*, 2010). Similarly, private sector interests (e.g., pharmaceutical industries) have also influenced final decision-making in macro level priority-setting processes in Australia (Mitton *et al.*, 2006) and Korea (Ahn *et al.*, 2012).

Given these findings, several strategies may be put in place to strengthen the priority-setting process for health benefits package development in Kenya. Publicity and transparency of the process can be increased through publication of reports using contextually appropriate modes of communication. Allocation of adequate time and financial resources can facilitate wider stakeholder involvement, identification of stakeholder preferences, and application of criteria. Improvement of health information systems and generation of local empirical studies and contextualized thresholds can improve quality and use of criteria. Stakeholder training and continuous involvement in priority-setting processes can empower them and increase their understanding and acceptance of the process. Finally, managing politics and stakeholder interests can enhance the success of priority-setting processes. This includes, for instance, mapping stakeholders and their interests and actively engaging them to

obtain negotiated buy-in for the process. It also includes establishing clear procedural and decision-making frameworks that explicitly demarcate stakeholders' roles, responsibilities, and powers to minimize political interference in decision-making.

Our study shows that the Barasa *et al.*'s framework offered a simple yet adequate approach for not only describing but also evaluating HBPAP's priority-setting process, considering the normative conditions of a good healthcare priority-setting process. While the framework recognizes the interconnection between procedural and outcome conditions, our study further highlights the presence of interconnections between specific elements within procedural and outcome conditions. In addition, by exploring why procedural and outcome conditions were partially met, our study identified internal and external factors that influenced the extent to which HBPAP met these normative conditions. Future researchers seeking to apply the Barasa *et al.*'s framework to evaluate healthcare priority-setting processes should not only explore interconnections within and across procedural and outcome conditions but also explore internal and external factors that might influence the extent to which the priority-setting body fulfils these conditions.

## Study limitations

This case study involved a retrospective account of a process conducted over 2 years ago which may have led to recall bias. However, this was mitigated through document reviews which are effective in retrieving accounts of past events (Bowen, 2009). The study respondents may have provided answers that they perceived as desirable leading to social desirability bias, but this was mitigated through triangulation of data using document reviews (Bergen and Labonté, 2020). With snow-ball sampling, it is possible that HBPAP members selected participants with similar views, but this was mitigated through document reviews. While not all stakeholders involved in HBPAP's priority-setting process were interviewed, document reviews make it unlikely that conducting more interviews would have led to greater depth in the findings. Finally, participation by some of the authors in previous priority-setting processes in Kenya may have biased the interviews and analysis, but this was mitigated through document reviews and peer debriefing sessions.

## Conclusion

This case study describes and qualitatively evaluates HBPAP's priority-setting process for health benefits package development, thus contributing to existing literature on evaluation of macro level priority-setting processes in LMICs. It demonstrates the value of evaluating existing priority-setting processes against the key conditions of an ideal priority-setting process as outlined in empirically and theoretically informed evaluative frameworks. It also demonstrates the interconnectedness of the elements within and across the procedural and outcome conditions. While a priority-setting process may be structured to be explicit and systematic, its procedural and outcome conditions may be partially fulfilled due to internal and external factors. Areas of partial fulfilment provide possible opportunities for strengthening the process. Importantly, priority-setting processes are inherently political;

thus, managing politics and stakeholder interests is key in enhancing the success of priority-setting processes.

## Supplementary data

Supplementary data are available at *Health Policy and Planning* online.

## Data availability

The data underlying this article cannot be shared publicly due to ethical reasons. As such, we wish to maintain the anonymity and confidentiality of all participants involved in the study. The data will only be shared on reasonable request to the corresponding author.

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## Author's contribution statement

R.M. and E.B. contributed to the conception or design of the work. R.M. contributed to data collection. R.M., K.O., A.V., L.G. and E. B. contributed to data analysis and interpretation. R. M. contributed to drafting the article. R.M., K.O., A.V., L.G. and E.B. contributed to critical revision of the article; R.M., K.O., A.V., L.G. and E.B. contributed to final approval of the version to be submitted.

## Reflexivity

The authors include four females and one male and span multiple levels of seniority from PhD fellow to associate and full professors. Two of the authors are health economists while three are health systems experts. All authors have extensive experience in health systems research in examining health financing arrangements and health policies in LMICs in sub-Saharan Africa and Asia.

**Ethical approval.** Ethical approval for this study was obtained from the London School of Hygiene and Tropical Medicine Ethics Committee (Reference Number: 25 640) and the Kenya Medical Research Institute Scientific and Ethics Review Unit, Nairobi, Kenya (Reference Number: KEMRI/SERU/CGMR-C/185/4018).

**Conflict of interest statement.** The authors declare no conflict of interest. Although the co-author Lucy Gilson is a section editor of the journal, there was no involvement with the peer review process for this article.

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## CHAPTER 8: FACTORS INFLUENCING THE INSTITUTIONALIZATION OF HEALTH TECHNOLOGY ASSESSMENT IN KENYA.

In this chapter, I present the results of the third sub-study of this PhD in the format of a journal ready manuscript. The aim of this sub-study was to identify factors that were influencing institutionalization of HTA in Kenya. Using the conceptual framework presented in Chapter 4, I present findings on factors that were supporting and/ or undermining institutionalization of HTA in Kenya.

## RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

### SECTION A – Student Details

<b>Student ID Number</b>	LSH1902955	<b>Title</b>	Dr
<b>First Name(s)</b>	RAHAB		
<b>Surname/Family Name</b>	MBAU		
<b>Thesis Title</b>	A critical examination of the policy process, implementation, and institutionalization of explicit healthcare priority-setting at the macro-level in Kenya		
<b>Supervisors</b>	Professor. Anna Vassall, Professor Lucy Gilson, and Professor Edwine Barasa		

If the Research Paper has previously been published, please complete Section B, if not please move to Section C.

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### **SECTION C – Prepared for publication, but not yet published**

Where is the work intended to be published?	BMC Health Services Research
Please list the paper's authors in the intended authorship order:	Rahab Mbau, Anna Vassall, Lucy Gilson, Edwine Barasa
Stage of publication	<b>Submitted</b>

### **SECTION D – Multi-authored work**

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I was responsible for conceiving and designing the study; data collection; data analysis and interpretation; and drafting and critical revision of these chapters. My supervisors were involved in the critical revision and final approval of the manuscript.
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### **SECTION E**

<b>Student Signature</b>	Rahab Mbau
<b>Date</b>	22 <sup>nd</sup> December 2022

<b>Supervisor Signature</b>	Anna Vassall
<b>Date</b>	22 <sup>nd</sup> December 2022

## Abstract

### **Background**

There is a global interest in institutionalizing health technology assessment (HTA) as an approach for explicit healthcare priority-setting. Institutionalization of HTA refers to the process of conducting and utilizing HTA as a normative practice for guiding resource allocation decisions within the health system. In this study, we aimed to examine factors influencing the institutionalization of HTA in Kenya.

### **Methods**

We conducted a qualitative case study using document reviews and in-depth interviews with 30 participants involved in the HTA institutionalization process. We used a thematic approach to analyze the data.

### **Results**

We found that institutionalization of HTA in Kenya was being supported by factors such as establishment of organizational structures for HTA; availability of legal frameworks and policies on HTA; increasing availability of awareness creation and capacity-building initiatives for HTA; policymakers' interests in universal health coverage and optimal allocation of resources; technocrats' interests in evidence-based processes; presence of international collaboration for HTA; and lastly, involvement of bilateral agencies. On the other hand, institutionalization of HTA was being undermined by limited availability of skilled human resources, financial resources, and information resources for HTA; lack of HTA guidelines and decision-making frameworks; limited HTA awareness among subnational stakeholders; and industries' interests in safeguarding their revenue.

### **Conclusions**

Kenya's Ministry of Health can facilitate institutionalization of HTA by adopting a systemic approach that involves: - a) introducing long-term capacity-building initiatives to strengthen human and technical capacity for HTA; b) earmarking national health budgets to ensure adequate financial resources for HTA; c) introducing a cost database and promoting timely data collection to ensure availability of data for HTA; d) developing context specific HTA guidelines and decision-making frameworks to facilitate HTA processes; e) conducting wider advocacy to strengthen HTA awareness among subnational stakeholders; and f) managing stakeholders' interests to minimize opposition to institutionalization of HTA.

**Key words:** - health technology assessment, institutionalization, Kenya

## Background

Health systems resource constraints and continued resource wastage have led to growing interest in explicit healthcare priority-setting processes to inform universal health coverage (UHC)-related decisions (Chalkidou et al., 2016, World Health Organization, 2014). Explicit healthcare priority-setting processes are deliberative, evidence-based, inclusive, systematic, and transparent processes for informing resource allocation decisions (Chalkidou et al., 2016). An example of an explicit healthcare priority-setting approach is health technology assessment (HTA). HTA is “*a multidisciplinary process that uses explicit methods to determine the value of a health technology to inform decision-making towards an equitable, efficient and high-quality health system*” (O'Rourke et al., 2020). A health technology refers to any intervention that can promote health; prevent, diagnose, or treat disease; prolong lives; or inform health service delivery. Examples include diagnostic tests, medicines, vaccines, procedures (medical and surgical), policies, and programs (O'Rourke et al., 2020, World Health Assembly, 2007). With the ever-growing demand for health technologies arising from UHC commitments, advancements in scientific knowledge, larger older population groups and rising burden of

communicable and non-communicable diseases, the need for HTA to inform explicit healthcare priority-setting becomes more crucial as health systems budgets remain limited (Norheim, 2015, Evans and Palu, 2016, World Health Assembly, 2014). Integrating HTA into healthcare priority-setting processes is a good governance measure that strengthens health systems by promoting transparency, inclusivity, and accountability in decision-making through systematic, deliberative, and inclusive processes (World Health Organization, 2011). HTA also promotes good governance by providing policymakers with an efficient means of allocating resources thus promoting sustainability in resource limited health systems striving to achieve UHC (World Health Assembly, 2014).

The impact and sustainability of HTA as an approach for explicit priority-setting in healthcare is dependent on its institutionalization (Bertram et al., 2021a, World Health Organization, 2001). Institutionalization of HTA refers to conducting and utilizing HTA as a normative practice for guiding healthcare priority-setting processes (World Health Organization, 2001). This requires development of institutional and organizational structures and processes that produce and utilize HTA in decision-making (Bertram et al., 2021a, World Health Organization, 2001). In countries where HTA has been institutionalized, it is routinely conducted as a way of informing health policy decisions on:- a) development and revision of health benefits packages for pharmaceutical and non-pharmaceutical products; b) development of clinical guidelines; c) market authorization of health technologies; and, d) pricing and reimbursement regulations for health technologies (Bertram et al., 2021a, World Health Organization, 2011, World Health Organization, 2001).

There are more high- and upper-middle-income countries that have institutionalized HTA as an explicit approach for healthcare priority-setting than low and lower-middle-income countries particularly in Sub Sahara Africa (Hollingworth et al., 2021, Chalkidou et al., 2017). Literature shows that institutionalization of HTA is affected by factors that may be context or

country-specific (Suharlim et al., 2022, Kaló et al., 2016, Rajan et al., 2011). Examining and identifying which country-specific factors are influencing institutionalization of HTA is important as it enables policymakers and technocrats to introduce appropriate measures to address them (Suharlim et al., 2022, Kaló et al., 2016, Rajan et al., 2011). However, studies examining factors that influence institutionalization of HTA in low and lower-middle income countries remain limited (Mbau et al., Submitted, 2023). We conducted the following study in Kenya to identify factors influencing institutionalization of HTA in this context.

## Methods

### Study design

We conducted a qualitative case study with the case as institutionalization of HTA in Kenya.

### Conceptual framework

We used a conceptual framework developed from a scoping review of empirical literature on factors influencing institutionalization of HTA across countries of different income levels globally (Mbau et al., Submitted, 2023). We identified five sets of factors that influenced a country's capacity to conduct and utilize HTA as a way of allocating resources in the health sector. These factors included: -a) organizational resources for HTA; b) legal frameworks, policies, and guidelines for HTA; c) learning and advocacy for HTA; d) stakeholder-related factors; and e) collaborative support for HTA. These factors were complexly interlinked as presented in the conceptual framework on Figure 1. This interlinkage meant that the factors could influence each other. We utilized this framework to develop questions for our data collection tool, to generate themes during data analysis, and to synthesize findings from the data.

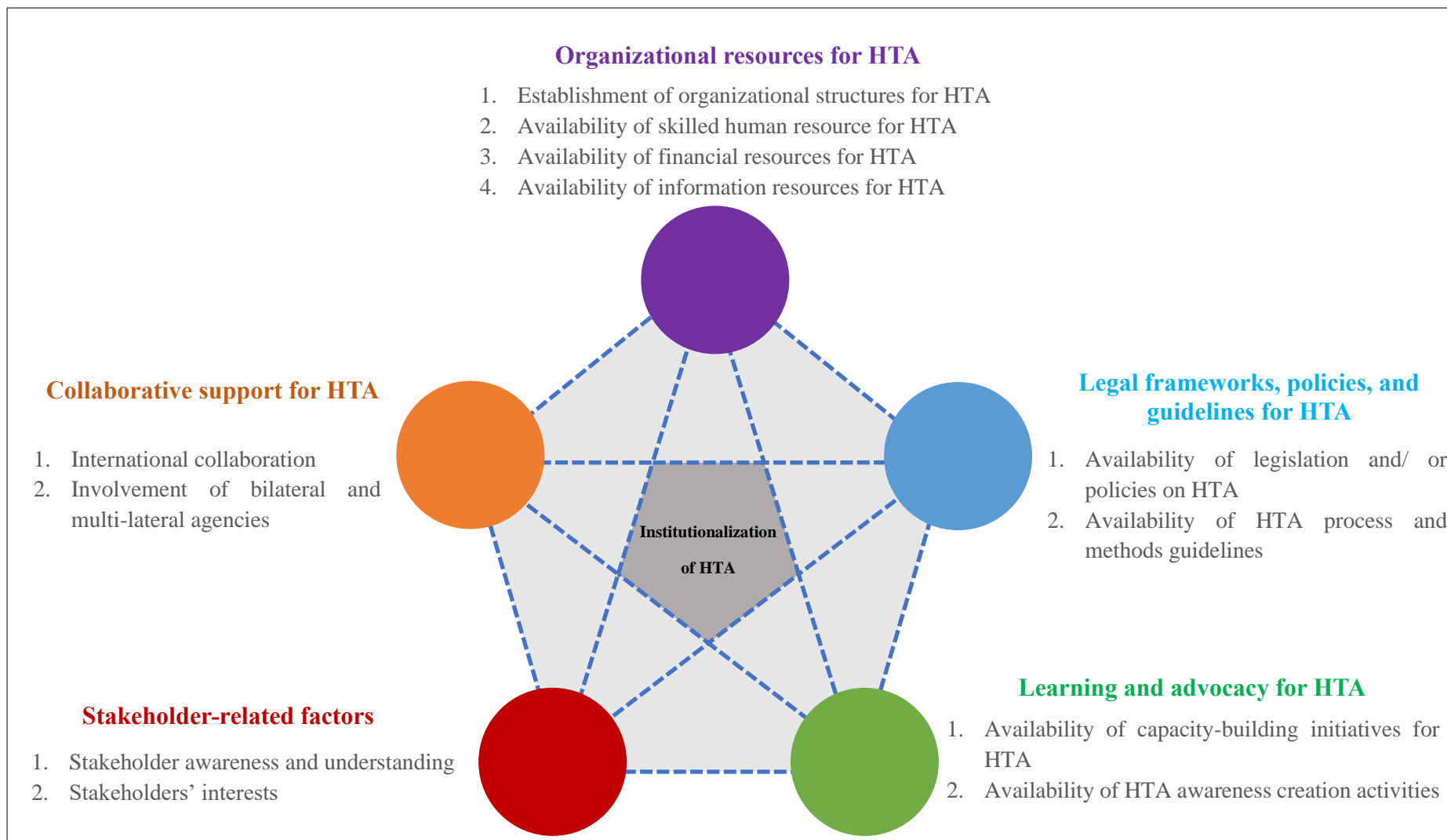


Figure 1: A conceptual framework on factors influencing institutionalization of HTA



## Study setting

Kenya is a lower-middle income country in Sub Sahara Africa with a population of approximately 53.8 million people (The World Bank, 2022). It has a devolved governance system with administrative, fiscal and political roles split among one national and forty seven county governments (The Republic of Kenya, 2010). Within the national government, the Ministry of Health (MOH) is responsible for building capacity, developing health policies, overseeing service delivery in national referral healthcare facilities, and providing technical assistance (The Republic of Kenya, 2010). Within the county governments, the County Departments of Health are responsible for implementing national health policies and overseeing service delivery in county healthcare facilities such as primary healthcare facilities (community units, dispensaries and health centres) and secondary healthcare facilities (primary and secondary referral hospitals) (The Republic of Kenya, 2010).

## Study population and sampling strategy

We used purposive and snowballing techniques to sample participants. The aim was to obtain rich descriptions of the case study by involving knowledge-rich participants. The purposive criterion was a participant's known involvement in activities related to the institutionalization of HTA in Kenya. The purposively selected participants were subsequently asked to identify other participants who were active in the HTA institutionalization space. We stopped sampling at saturation, that is, when no new information was emerging from additional interviews (Saunders et al., 2018). We interviewed 30 stakeholders (Table 1). We do not provide any demographic information to preserve the anonymity and confidentiality of the study participants.

Table 1: List of participants

<b>Category</b>	<b>Number</b>
Development Partners	n=6
Local Research organizations	n=6
Ministry of Health (MOH)	n=8
Semi- Autonomous Government Agencies	n=10
<b>Total</b>	<b>30</b>

## Data collection methods

We used in-depth interviews and document reviews to collect data between January and April 2022.

### In-depth interviews

We requested participants to engage in the study via telephone or email- none refused participation. Participants reviewed the study’s information sheet and provided informed consent. We conducted interviews directly via face-face or remotely via zoom videoconferencing at a time of convenience to the participant. Interviews were guided by a semi-structured interview guide, and they lasted between 25 and 80 minutes. All interviews were recorded using an encrypted audio recorder.

We also took fieldnotes during interviews to identify points that needed further clarification and to summarize emerging themes. We linked each fieldnote to the respective interview using the same identifier. Following the interviews, fieldnotes were transferred to Microsoft word to prevent data loss.

### Document reviews

We reviewed various documents as shown in Table 2. These documents included organizational and media reports with relevant information on institutionalization of HTA. We

identified these documents from study participants, online searches, and two members of the study team who had previously been involved in HTA-related activities in Kenya. We conducted interviews and document reviews simultaneously to enable triangulation of data from each of these data sources.

Table 2: List of documents reviewed

<b>Types of documents</b>	<b>Examples</b>
Government documents (national policies and laws)	<ul style="list-style-type: none"> <li>• Health Act 2017</li> <li>• Health Products and Technologies Supply Chain Strategy 2020-2025</li> <li>• Kenya Health Policy 2014-2030</li> <li>• Kenya Health Sector Strategic and Investment Plan 2013-2017</li> <li>• Drafts of the Kenya Health Financing Strategy 2015-2030</li> </ul>
Local Research Organizations' documents	<ul style="list-style-type: none"> <li>• Reports on stakeholder engagement workshops</li> <li>• PowerPoint presentations made during stakeholder workshops</li> <li>• Reports on HTA capacity in Kenya</li> </ul>
Health Benefits Package Advisory Panel's (HBPAP) documents	<ul style="list-style-type: none"> <li>• Final Report of the Universal Health Coverage Health Benefits Package Advisory Panel Report on the study visit by the Health Benefits Package Advisory Panel to Thailand on HTA</li> <li>• HBPAP reports and annexes</li> <li>• HBPAP PowerPoint presentations</li> </ul>
Development partners' reports	<ul style="list-style-type: none"> <li>• Mission report on Health Benefits Package Advisory Panel Study visit to Thailand</li> <li>• Japan International Cooperation Agency Loan policy action on HTA</li> <li>• Mission report on National Hospital Insurance Fund Health Financing Reforms Experts Panel visit to Thailand on UHC and HTA</li> </ul>
Media reports	<ul style="list-style-type: none"> <li>• Web media e.g., Development Partners websites and MOH websites</li> <li>• News media e.g., Online newspaper reports</li> </ul>

- |  |  |
|--|--|
|  | <ul style="list-style-type: none"><li>• Social media e.g., Twitter</li></ul> |
|--|--|

## Data analysis

We transcribed all audio-files verbatim. We then verified the quality of transcription by comparing each transcript to the respective audio-file. We uploaded all transcripts, field notes and electronic documents to NVIVO Pro software (QSR International, Massachusetts) for effective organization during data analysis. We analyzed the data thematically using the Braun and Clarke 6-step approach (Braun and Clarke, 2006). Firstly, we immersed ourselves in the data through reading and re-reading. Secondly, we developed a list of codes deductively based on the concepts outlined in the study's conceptual framework. Thirdly, we grouped similar codes into themes. Fourthly, we checked for coherence between the themes and the coded data extracts. Fifthly, we applied the approved themes across the data by extracting quotes, excerpts and images that matched them. Lastly, we synthesized the findings and linked the discussion of these findings to existing literature.

## Results

The data shows that Kenya has embarked on institutionalizing HTA. Several factors were influencing this journey as discussed below.

### Limited availability of organizational resources for HTA

#### *Establishment of organizational structures for HTA*

Since 2018, the MOH has established new organizational structures to conduct and utilize HTA, and to oversee implementation of HTA. This followed the Government's prioritization of UHC in 2017 (The Executive Office of the President, 2017). These organizational structures included the Health Benefits Package Advisory Panel (HB PAP), a HTA focal point, the

Medicines Affordability Pricing Advisory Committee (MAPAC), and a HTA technical working group.

HBPAP, a semi-independent panel, was established in 2018 to develop an essential and affordable health benefits package for UHC (The Kenya Gazette, 2018). HBPAP used a HTA approach to develop a health benefits package for UHC. HBPAP also developed a draft framework for institutionalizing HTA in Kenya (Health Benefits Package Advisory Panel, 2020).

*‘The establishment of the Panel [HBPAP] was the first attempt to set up a government driven HTA system where they recognized the use of HTA mechanism in decision-making’* MOH official 5

A focal point for HTA was created within the MOH in 2020. It was tasked with overseeing and coordinating HTA institutionalization activities within the country. According to participants, the HTA focal point has overseen several HTA capacity-building and advocacy creation activities.

*‘We applaud the ministry for creating a HTA office. This office has been responsible for helping stakeholders walk the journey towards implementing HTA’* Participant 8, Semi-autonomous government agency

MAPAC was established in 2021 to promote access, availability, and affordability of pharmaceutical products. To this end, MAPAC aims to use HTA to promote transparency of the healthcare priority-setting processes for medicines. MAPAC also aims to use HTA to regulate and negotiate pricing of medical products towards making them affordable (Medicines Affordability Pricing Advisory Committee, 2021).

*'MAPAC was inaugurated to develop strategic interventions to bring down healthcare costs. One of the strategic interventions the group has identified is HTA which can promote price transparency and visibility to everybody'* Participant 1, Semi-autonomous government agency

Lastly, a HTA technical working group was established in 2021 to develop a HTA strategy for Kenya. This technical working group is an 18-member team comprising of technocrats from:- a) the MOH such as the Department of Health Policy, Research and Development, Department of Health Products and Technology, Department of Health Financing, and UHC secretariat; b) Semi-autonomous government agencies such as Pharmacy and Poisons Board and Kenya Medical Supplies Agency; and c) local research organizations such as KEMRI-Wellcome Trust (Ministry of Health, 2021a).

In addition to the creation of new organizational structures for HTA, participants reported that the existence of multiple organizations involved in the regulation, procurement, and purchasing of health technologies offered an opportunity to institutionalize HTA across these functions. Examples of these organizations included: - a) the Pharmacy and Poisons Board which regulates health technologies by ensuring they are of good quality to be efficacious and safe; b) the Kenya Medical Supplies Agency which procures health technologies for government-owned healthcare facilities; and c) purchasers such as the national government, the county government, and the National Health Insurance Fund which purchase health technologies for government-owned healthcare facilities.

*'We have institutions in strategic positions that deal with regulation, procurement and purchasing. Their presence provides a very good opportunity for introducing HTA as a priority-setting mechanism for their functions'* Participant 4, Semi-autonomous government agency

### *Limited availability of skilled human resource for HTA*

In Kenya, the number of human resources with the technical skills to conduct HTA remain limited. A landscape analysis on HTA capacity in Kenya showed that more than 65% of health sector organizations had less than 5 individuals with formal training in HTA-related subjects such as health economics, mathematical modelling, statistics, evidence synthesis, and epidemiology (Barasa et al., 2021). In addition, the analysis showed that more than 70% of health sector organizations had less than 5 individuals with practical experience in conducting systematic reviews or meta-analyses, cost-effectiveness analysis, and budget impact analysis (Barasa et al., 2021).

*‘We do not have many people with the technical skills required to conduct HTA. The country is still in its infancy stages with regards to skills in evidence synthesis and economic evaluation. This inadequate local capacity is a barrier towards HTA’*

Participant 9, Semi-autonomous government agency

### *Limited financial resources for HTA*

The Government of Kenya has historically underfunded research. For example, less than 1% of the government’s health budget is allocated to research which accounts for less than 30% of the resources required (Ministry of Health, 2020a). As a result, more than 70% of funding for research is obtained from external sources such as donors (Ministry of Health, 2020a). Given the limited funding, participants reported that the MOH could not meet the costs of conducting HTA which undermined institutionalization of HTA in Kenya.

*‘The lack of financial resources is a big stumbling block for institutionalization of HTA. At the moment, a lot of research activities are donor funded’* Participant 2, local research organization

### *Limited availability of information resources for HTA*

Limited availability of information resources for HTA was reported as another factor limiting institutionalization of HTA in Kenya. Participants reported that despite improvements in Kenya's health management information system, completeness, and timeliness of data reporting at the facility, county, and national levels were still limited. They also reported that data on costs were not routinely reported, and databases across purchasers were poorly linked. All these factors undermined the availability and quality of data which limited the capacity to conduct HTA.

*'HTA processes are data hungry. For example, we need a database of costs to conduct economic evaluation and budget impact analysis. However, we do not have such a database'* Participant 10, Semi-autonomous government agency

### *Availability of legal frameworks and policies, but limited availability of guidelines for HTA*

#### *Availability of legal frameworks and policies on HTA*

Legislation and policies on HTA exist in Kenya. These documents recognize various organizational and institutional aspects on institutionalization of HTA as shown in Table 3. According to participants, the establishment of organizational structures for HTA was partly a fulfilment of these legislation and policies.

*'We are already seeing HTA in action within the current life of the Kenya Health Policy with the establishment of the panel [HBPAP] and MAPAC'* Development Partner 1



Table 3: Laws and policies on HTA

Examples of laws or policies	Aspects of HTA institutionalization recognized in the document
Health Act 2017 (Republic of Kenya, 2017)	<ul style="list-style-type: none"> <li>• Recognizes the role of HTA in: -               <ul style="list-style-type: none"> <li>✓ supporting financing decisions towards UHC</li> <li>✓ Regulation (e.g., market approval) of health technologies following assessment by a technically competent organization</li> </ul> </li> <li>• Recognizes priority-setting criteria for use in HTA namely safety and effectiveness</li> </ul>
Kenya Health Policy 2012- 2030 (Ministry of Health, 2012)	<ul style="list-style-type: none"> <li>• Recognizes the need for: -               <ul style="list-style-type: none"> <li>✓ A national HTA mechanism for assessing new health technologies</li> <li>✓ A national framework for regulating health technologies</li> </ul> </li> <li>• Recognizes priority-setting criteria for use in HTA namely quality, safety, efficacy/ effectiveness, and affordability</li> </ul>
Health Sector Strategic and Investment Plan 2013-2017 (Ministry of Health, 2013)	<ul style="list-style-type: none"> <li>• Recognizes: -               <ul style="list-style-type: none"> <li>✓ the establishment of a national HTA mechanism for health technologies and a national framework for regulation of health products as priorities</li> <li>✓ the priority-setting criteria for use in HTA such as clinical-effectiveness, quality, safety, cost-effectiveness and, ethical and cultural considerations</li> <li>✓ the role of HTA in developing essential medicines list and clinical guidelines</li> </ul> </li> </ul>
UHC policy 2020-2030 (Ministry of Health, 2020c)	<ul style="list-style-type: none"> <li>• Recognizes: -               <ul style="list-style-type: none"> <li>✓ the role of HTA in guiding investment decisions on health technologies and promoting their rational use</li> </ul> </li> </ul>
Kenya Health Financing Strategy 2020-2030 (Ministry of Health, 2020b)	<ul style="list-style-type: none"> <li>• Recognizes: -               <ul style="list-style-type: none"> <li>✓ The need to create a Health Benefits and Tariffs Authority to host national study and research functions on HTA</li> <li>✓ the role of HTA in informing investments on new health technologies and revising the UHC health benefits package</li> </ul> </li> </ul>

<p>Health Products and Technology Supply Chain Strategy (Ministry of Health, 2020a)</p>	<ul style="list-style-type: none"> <li>• Recognizes the need for: - <ul style="list-style-type: none"> <li>✓ a HTA policy to support management (e.g., pricing and market authorization) of health products and technologies</li> <li>✓ a national roadmap for institutionalization of HTA</li> <li>✓ building HTA capacity at national government agencies and county governments involved in health products and technology supply chain</li> <li>✓ increased involvement of stakeholders in the HTA process at the national and county government to create demand and use of HTA</li> <li>✓ surveys to assess use of HTA in pricing and market authorization of health products and technologies</li> </ul> </li> </ul>
<p>Strategy for HTA in the Kenyan Health Sector (Ministry of Health, 2021b)</p>	<ul style="list-style-type: none"> <li>• Recognizes: - <ul style="list-style-type: none"> <li>✓ The mandate of HTA in developing, revising, or updating the essential medicines list, essential medical devices list, benefit package for UHC, and the national vaccines list</li> <li>✓ The mandate of HTA in price negotiation for medical devices, medicines, and vaccines</li> <li>✓ The organizations whose decisions will be informed by HTA namely the Kenya Medical Supplies agency, the National Health Insurance Fund and, the MOH</li> <li>✓ The organizational and institutional architecture for HTA in Kenya including their roles and professional composition to support the HTA functions of topic nomination, topic selection, assessment, appraisal, and decision-making.</li> <li>✓ The priority-setting criteria for topic selection in HTA namely effectiveness and safety, burden of disease, severity of disease, equity, catastrophic health expenditure, congruence with existing priorities, health workforce requirements and service, health commodities, and technologies requirements</li> </ul> </li> </ul>

	<p>✓ The priority-setting criteria for assessment stage namely cost-effectiveness analysis and budget impact analysis.</p>
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While policies highlighting institutional and organizational arrangements for HTA exist in Kenya, they do not explicitly indicate sources and amounts of funding to be allocated for HTA-related activities. According to participants and document reviews, all organizational and institutional arrangements for HTA need to be explicitly defined and legislated to support institutionalization of HTA (Ministry of Health, 2021b).

*‘To institutionalize the proposed HTA process, it is proposed that a HTA policy be developed, and the requirement for HTA in benefit package decision-making be enshrined in the law. This could be in the form of an amendment to the Health Act’*

Document excerpt (Ministry of Health, 2021b)

### *Lack of HTA guidelines and decision-making frameworks*

Kenya lacks standardized process and methods guidelines as well as decision-making frameworks for HTA. For example, there were no process guidelines that would inform which rules and procedures would guide the different stages (nomination, selection, assessment, appraisal and decision-making) of the HTA process. There were also no methods guidelines or tools to inform choice of costing perspective and discount rates, or to measure quality adjusted life years. Lastly, there were no decision-making frameworks such as cost-effectiveness threshold to inform decision-making. The lack of HTA guidelines and decision-making frameworks undermined the country’s capacity to conduct and utilize HTA.

*‘We do not have a cost-effectiveness threshold or a quality adjusted life year set for Kenya. We must develop these tools if we are to use HTA routinely for decision-making’*

Participant 1, local research organization

## Increasing availability of learning and advocacy for HTA

### *Increasing availability of HTA capacity-building initiatives*

Several short-term HTA training workshops and courses have been conducted in Kenya since 2018 (KEMRI-Wellcome Trust, 2019, Ministry of Health, 2018). These capacity-building initiatives were targeted at HTA users such as national and county-level policymakers and, HTA doers such as academics and researchers in local universities, research centres, and semi-autonomous government agencies. Approximately 150 HTA doers and users across the health system have been trained on cost-effectiveness analysis and systematic evidence synthesis. According to study participants, these capacity-building initiatives not only built technical capacity but also raised individual and organizational awareness and understanding of the value of HTA in healthcare priority-setting. The initiatives have also helped to build a network of champions for HTA.

*'We have had several workshops which are good for building technical capacity. They also sensitize people to understand the value of HTA. In turn, these people are getting other key stakeholders within the organizations to appreciate what HTA is about.'*

Participant 7, Semi-autonomous government agency

A local research organization has also created a mailing list for sending monthly HTA newsletters. These newsletters aim to promote continuous dissemination of HTA knowledge to HTA doers and users.

*'Every month, we send out a newsletter with interesting topics related to HTA such as economic evaluations, HTA-related conferences, or any forthcoming trainings. We do this to keep HTA relevant on people's minds.'* Participant 3, local research organization

Despite the increasing availability of short-term capacity-building initiatives, long-term capacity-building initiatives such as undergraduate and postgraduate training in HTA remain

limited. This undermined the availability of skilled human resource for HTA. Study participants therefore called for the introduction of HTA-related courses at undergraduate and postgraduate level in public and private universities to strengthen individual and organizational capacity for HTA.

*‘We need more HTA courses in our universities. Their curriculum should be structured to ensure that aspects of health economics and research methodologies such as data analysis and evidence synthesis are captured’* Participant 5, local research organization

### *Increasing availability of advocacy and awareness creation for HTA*

There have been several advocacy and awareness creation initiatives for HTA in Kenya such as study tours, advocacy meetings, and stakeholder engagement workshops. For example, Kenyan stakeholders namely the Parliamentary Health Committee, the Senate Health committee, the MOH, the County Governments, Academics, HBPAP, and the National Health Insurance Fund Health Financing Experts Panel have gone on study tours to Thailand to learn about UHC and the role of HTA in UHC- related decisions (Figure 2).

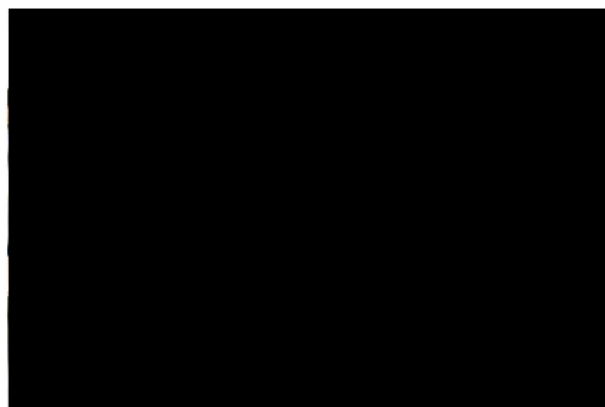


Figure 2: A study tour to Thailand by Kenyan Delegates (HITAP, 2019c)

High-level policy advocacy meetings for HTA have also been held in Kenya with participants including Thai Government officials and Kenyan stakeholders from the Council of Governors,

MOH and National Treasury. There have also been stakeholder engagement workshops for HTA involving policymakers from the MOH and semi-autonomous government agencies. These advocacy meetings and stakeholder engagement workshops were aimed at raising awareness among key policy and decisionmakers on the definition of HTA, its role in healthcare priority-setting processes and policy decisions, and its value in generating budget savings through price negotiations (HITAP, 2019b, HITAP, 2018, KEMRI-Wellcome Trust, 2018).

The study tours, high-level policy meetings, and workshops have increased HTA awareness among key policy and decision-makers in government and semi-autonomous government agencies. A landscape assessment of HTA awareness among major health sector agencies at the national level in Kenya showed that over 60% of the respondents indicated that the leadership of these agencies were aware of HTA and were willing to support development of HTA within their organizations by allocating resources (Ministry of Health, 2021b).

## Stakeholder-related factors

### *Varying stakeholders' interests towards HTA*

#### *Policymakers' interests in UHC and optimal allocation of resources*

Participants reported that policymakers' interest in achieving UHC and the accompanying need to define a publicly funded health benefits package for the UHC programme drove their support for explicit and evidence-based approaches such as HTA. In addition, policymakers' interests in allocating scarce health system resources optimally generated further interest in HTA as a tool for informing resource allocation decisions. This need intensified during the Covid-19 pandemic which exposed the inability of Kenya's health system to meet increased healthcare needs. Consequently, MOH policymakers requested local research organizations to

conduct HTA to inform government's resource allocation decisions during the Covid-19 pandemic.

*'COVID not only highlighted but also amplified the gaps in our health system in terms of lack of finances, human resources, infrastructure, and medicines. The ministry's decisions on what to prioritize during the pandemic had to be made systematically using evidence and HTA provided that. It is one of the positive things that Covid did for us'*

MOH official 4

#### *Technocrats' interests in evidence-based resource allocation processes*

Participants reported that technocrats supported institutionalization of HTA given their interests in evidence-based resource allocation processes. These technocrats included Kenyan health economists and health systems experts within the MOH, local academic and research organizations, and development partners. Technocrats supported HTA as they believed it would provide an evidence-based approach for improving affordability, sustainability, and equitable distribution of health benefits packages in Kenya. They were also responsible for recommending various institutional and organizational arrangements for HTA as presented in the health policies outlined in Table 3.

*'Health economists and other specialists who sat in committees at the national level were instrumental in designing the content of those policies which catapulted the agenda for transforming the health system through evidence-based processes such as HTA'* MOH official 7

#### *Industries' interests in safeguarding their revenue*

In Kenya, lack of price regulation of health technologies has resulted in importer mark-ups ranging between 54%-256% and 133%-748% for generic and originator products respectively (Medicines Affordability Pricing Advisory Committee, 2021). While this generated higher

profits for industries and other associated organizations, it led to unaffordability and inequitable access to health technologies. The MOH, through MAPAC, is seeking to use HTA to regulate pricing of health technologies to enable equitable and affordable access. However, according to participants and media reports (Figure 3), this was likely to reduce the profit margins for industries and importers of health technologies leading to resistance to institutionalization of HTA.

*'One barrier will be industries that have been benefitting from the lack of HTA. If we introduce HTA, then they are not going to benefit from the lack of transparency and they are likely to resist'* Participant 1, Semi-autonomous government agency

ARTICLE

## Reference Pricing Likely To Be Detrimental To Drugmakers' Revenues In Kenya

Fitch Solutions / Pharma & Healthcare / Kenya / Fri 08 Nov, 2019

Figure 3: Illustrative media reports on industries' interests (Fitch Solutions, 2019)

### *Limited HTA awareness among officials in county governments and health facilities*

Despite growing awareness of HTA among policymakers at the national level, study participants reported that awareness of HTA and its value in policymaking was still low among policy and decision-makers at the county government and hospital levels. These stakeholders were important given Kenya's devolved health system structure. Their limited awareness was therefore undermining institutionalization of HTA in Kenya. Participants called for greater inclusion of sub-national stakeholders in training and advocacy initiatives to support



institutionalization of HTA through greater stakeholder awareness, acceptability, and ownership.

*‘For institutionalization of HTA to take place, we need everyone to buy into HTA starting from the policymakers at the ministry to the frontline workers. For this to work countrywide, counties must be involved. There is need for further sensitization’*

Participant 4, Semi-autonomous government agency

## Collaborative support for HTA

### *Presence of international collaboration for HTA*

International collaboration for HTA in Kenya occurred through a bilateral agreement between Kenya and Thailand. In February 2019, Kenya and Thailand’s ministries of health signed a bilateral memorandum of understanding on Health Collaboration (Figure 4) to support institutionalization of HTA in Kenya (HITAP, 2019a). As part of this memorandum, the Thai Government- through the Health Intervention and Technology Assessment Program (HITAP) - has provided Kenya’s MOH with technical assistance to develop the HTA institutionalization framework, to build individual and organizational technical capacity for HTA, and to conduct HTA pilot studies of priority to the country. The Thai government has also provided scholarships for HTA at Masters and Doctor of Philosophy level in an effort to promote Kenya’s technical capacity for HTA (HITAP, 2019a).

*‘The Kenyan government in partnership with the Thai government are working to do a technical transfer between the two countries showing goodwill bilaterally’* MOH

official 3



Figure 4: Signing of the bilateral collaboration between Kenya and Thailand (HITAP, 2019a)

International collaboration for HTA in Kenya also occurred through global health networks such as the International Decision Support Initiative (iDSI). iDSI aims to support low and middle-income countries to reform their healthcare priority setting processes. Since 2019, the iDSI has financially supported several HTA workshops with the aim of building organizational capacity for HTA.

*'In terms of international efforts, the iDSI has been working with its local partner in Kenya to build capacity for HTA through workshops.'* Participant 6, local research organization

#### *Involvement of a bilateral agency*

The Japan International Cooperation Agency (JICA)- a bilateral agency- has offered Kenya a conditional grant to support institutionalization of HTA (Ministry of Health, 2019). The disbursements of this conditional grant were tied to specific HTA institutionalization deliverables such as the development of a strategy for HTA institutionalization and capacity building (Ministry of Health, 2019). These loan conditions incentivized Kenya's MOH to conduct capacity-building workshops and to develop a strategic framework for institutionalizing HTA.

*'JICA is financing HTA institutionalization efforts in Kenya'* Participant 4,  
Development partner

## Discussion

In this paper, we set out to examine the factors that were influencing institutionalization of HTA in Kenya. The key insights derived from this study include the following.

The first key insight is that Kenya's journey towards institutionalizing HTA is being supported by factors such as: - a) establishment of organizational structures; b) availability of legal frameworks and policies; c) increasing availability of awareness creation and capacity-building initiatives; d) policymakers' interests in UHC and optimal allocation of resources; e) technocrats' interests in evidence-based processes; f) presence of international collaboration for HTA; and g) involvement of bilateral agencies. The supportive influence of these factors on institutionalization of HTA has been reported in other settings. For example, the establishment of organizational structure(s) expanded the capacity of countries such as Canada (Battista et al., 2009) and the United Kingdom (Raftery and Powell, 2013) to conduct and utilize HTA. *Secondly*, the availability of legislation and policies on HTA in Denmark (Sigmund and Kristensen, 2009), Germany (Perleth et al., 2009), Philippines (Sharma et al., 2021), and Thailand (Teerawattananon et al., 2009) supported institutionalization by defining institutional and organization arrangements for HTA. *Thirdly*, the availability of awareness creation activities increased the visibility of the value of HTA to health systems stakeholders in Spain (Sampietro-Colom et al., 2009) while the availability of short and long-term capacity-building initiatives in Thailand strengthened the human resource capacity for HTA (Leelahavarong et al., 2019, Teerawattananon et al., 2009). *Fourthly*, government's interest in UHC and efficient allocation of resources promoted development of HTA in Netherlands (Chinitz, 2004, Bos, 2000). *Fifthly*, technocrats interests' in the use of HTA to improve health system performance supported institutionalization of HTA in Mexico (Gómez-Dantés and

Frenk, 2009). *Sixthly*, international collaboration through iDSI contributed to increased HTA awareness creation and capacity-building initiatives in Indonesia (Sharma et al., 2020), Ghana (Addo et al., 2020), and South Africa (MacQuilkan et al., 2018). *Lastly*, involvement of bilateral agencies such as the World Health Organization and the World Bank supported funding of HTA projects and capacity-building initiatives in China (Chen et al., 2009) and Indonesia (Sharma et al., 2020).

The second key insight is that several factors were undermining Kenya's journey towards institutionalizing HTA namely: - a) limited availability of organizational resources such as skilled human resources, financial resources, and information resources for HTA; b) lack of HTA guidelines and decision-making frameworks; c) limited HTA awareness among policy and decision-makers at the subnational level- that is, county governments and health facilities; and d) industries' interests in safeguarding their revenue. The limiting influence of these factors on institutionalization of HTA has been reported in other settings. For example, limited availability of skilled human resource for HTA undermined capacity to conduct HTA in India (Jain et al., 2014), Iran (Arab-Zozani et al., 2020), South Africa (Mueller, 2020), and Tanzania (Surgey et al., 2019). *Secondly*, limited availability of financial resources undermined institutionalization of HTA in Iran (Mohtasham et al., 2016), South Africa (Mueller, 2020) and Tanzania (Surgey et al., 2019). *Thirdly*, limited availability and completeness of data for HTA undermined institutionalization of HTA in several high, middle and low-income countries globally (World Health Organization, 2015, Rajan et al., 2011). *Fourthly*, the lack or limited availability of contextually relevant process and methodological guidelines, and decision tools has undermined utilization of HTA in Sub Saharan countries (Hollingworth et al., 2021). *Fifthly*, the limited awareness of HTA, its concepts and relevance among policy and decision-makers in Malaysia (Sivalal, 2009) and South Africa (Mueller, 2020) undermined institutionalization of HTA. *Lastly*, manufacturers' interests in safeguarding pricing of their

health technologies undermined institutionalization of HTA in the United States of America (Callahan, 2012, Luce and Cohen, 2009).

The third key insight is that factors influencing institutionalization of HTA in Kenya were interlinked. These interlinkages have also been identified in other studies. For example, international collaboration for HTA increased the availability of HTA awareness creation and capacity-building activities in Kenya. Countries involved in international collaborative networks across Europe and Asia also reported similar findings (Liu et al., 2020, Banta et al., 2009). Secondly, policymakers' interests in defining a health benefits package for UHC and regulating pricing of health technologies led to the creation of organizational structures for HTA in Kenya. Similar findings have also been reported in several high and upper-middle-income countries in Asia (Pwee, 2009, Leelahavarong et al., 2019) and Europe (Chinitz, 2004, Bos, 2000) where policymakers had similar interests. Thirdly, availability of legislation and policies on HTA partly led to the creation of organizational structures for HTA in Kenya. Several high-income countries in Europe with legislation and policies on HTA reported similar findings (Banta et al., 2009). Fourthly, technocrats' interests in HTA influenced development of policies on HTA in Kenya. Similarly, technocrats in several high- and middle-income countries in Asia (Sivalal, 2009, Hisashige, 2009) developed policies on HTA due to their interests in HTA. Lastly, the limited availability of long-term capacity-building initiatives undermined the availability of skilled human resource for HTA in Kenya. Similar findings have been reported in other countries globally with limited availability of long-term capacity-building initiatives (Mueller, 2020, Jaramillo et al., 2016, Babigumira et al., 2016, World Health Organization, 2015).

The fourth key insight is that the study findings offer important policy implications on how the MOH can nurture and sustain the institutionalization process in Kenya. This can be achieved through a systemic approach that addresses the current limitations in Kenya's capacity to

conduct and utilize HTA. In this systemic approach, the MOH should earmark funds from the national health budget to ensure adequate availability of financial resources for HTA. The MOH should introduce a cost database, promote timely data collection through trainings and incentives to strengthen data resources for HTA, and create a monitoring and evaluation process for these types of data. The MOH should introduce undergraduate and postgraduate training in HTA to ensure availability of skilled human resource for HTA. The MOH should develop contextually relevant process and methods guidelines and decision tools for HTA to facilitate HTA processes. The MOH should conduct wider advocacy to increase HTA awareness among national and sub-national stakeholders. The MOH should manage stakeholders' interests through sensitization and persuasive framing of the value of institutionalizing HTA to minimize opposition. Lastly, the MOH should strengthen international collaborations through south-south collaborations to facilitate the institutionalization process.

The last key insight is that, by applying the conceptual framework outlined in this study, we demonstrated its empirical utility in identifying factors that were influencing institutionalization of HTA in Kenya. This framework can therefore be adopted or adapted by future researchers who aim to examine factors influencing institutionalization of HTA in other contexts.

## Limitations

A potential limitation of this study is social desirability bias whereby participants alter responses in the belief that this would make the responses more acceptable. However, by triangulating data sources and methods, we strengthened the trustworthiness of the findings. It is also possible that the previous involvement of 2 of the authors in HTA-related processes in Kenya may have biased the interviews and analysis. However, we mitigated against this bias

by reviewing documents to corroborate the findings and by holding peer debriefing sessions as a study team to ensure that findings were based on collected data.

## Conclusion

Examining factors that influence institutionalization of HTA is substantially relevant in low and middle-income countries where institutionalization of HTA remains limited. In this study, we used a conceptual framework based on five sets of factors that were identified from a scoping review on factors influencing institutionalization of HTA across countries of different income levels. By applying this conceptual framework, we were able to identify factors that were supporting and limiting institutionalization of HTA in Kenya. These findings offer useful policy implications that policymakers within the MOH can implement to facilitate progress towards institutionalization of HTA in Kenya. Researchers seeking to examine factors influencing institutionalization of HTA in other contexts can also adopt or adapt this framework.

## CHAPTER 9: DISCUSSION, POLICY & RESEARCH IMPLICATIONS, AND CONCLUSIONS

### 9.1 Introduction

This marks the final chapter of this PhD study. Here, I bring together findings from the results chapters to highlight key insights on what influenced the policy process, implementation, and institutionalization of explicit healthcare priority-setting at the macro-level in Kenya. I also outline policy implications of the findings, strengths and limitations of the study, areas for future research studies followed by a conclusion.

### 9.2 Examination of the policy process for the HBPAP policy

Understanding how and why new healthcare priority-setting processes are introduced in a health system is important. However, as indicated by several authors (Smith et al., 2016, Smith et al., 2014) and findings in Chapter 3 of this thesis, such studies remain limited. For the first sub-study of this PhD, I examined the policy process that led to the gazettelement of the HBPAP policy.

The HBPAP policy represented a procedural policy as it sought to change how and by whom the healthcare priority-setting process for health benefits package development was conducted in Kenya. A procedural policy changes how and by whom processes or functions of an organization or government are conducted (Howlett, 2017, Commonwealth of Learning, 2012). Using Kingdom's multiple streams theory, I examined how and why the HBPAP procedural policy idea was gazetted in Kenya. A summary of the key findings from this analysis is presented in Figure 9.1.



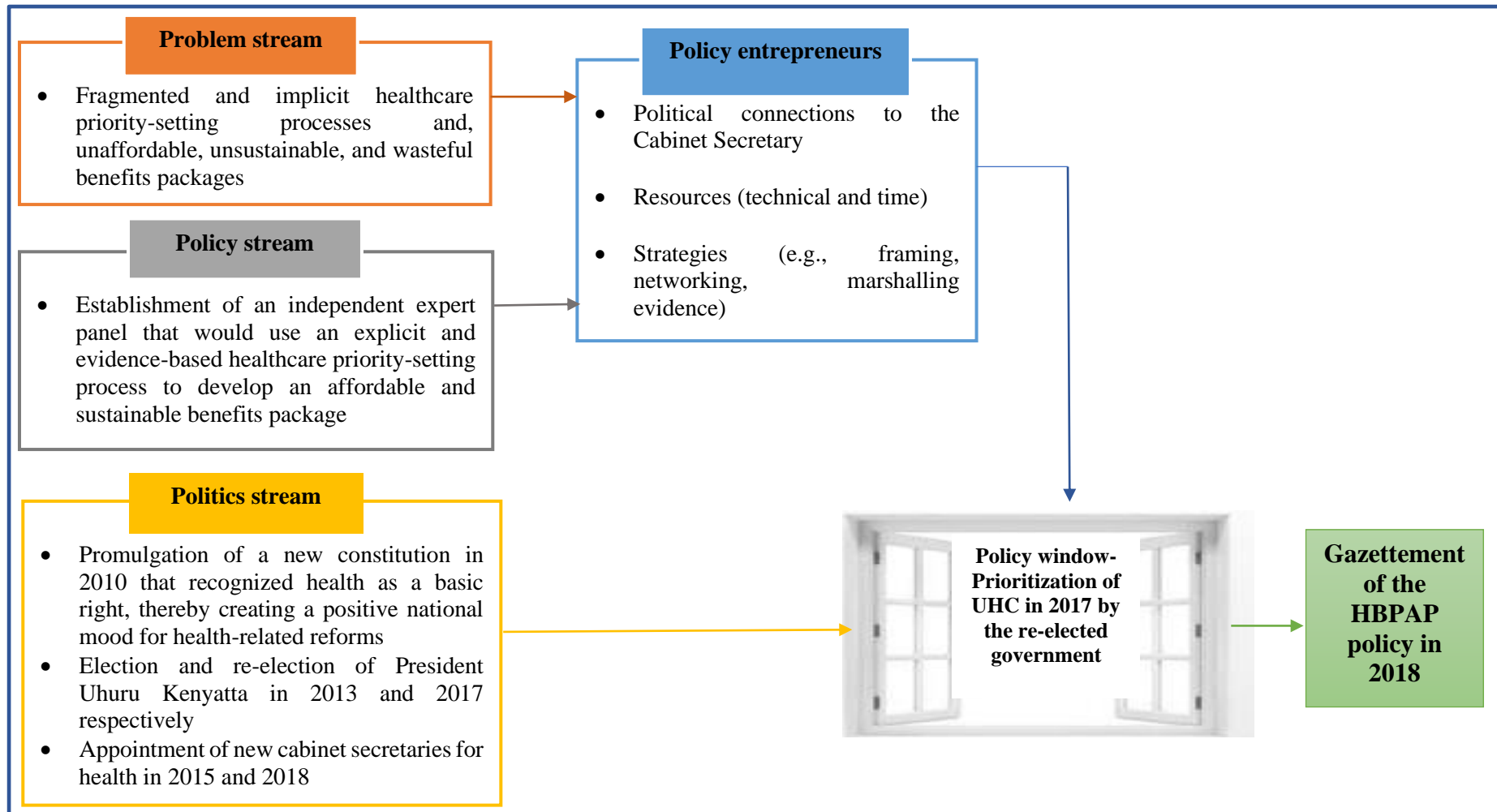


Figure 9.1: Illustration of the policy process that led to the gazettement of the HBPAP policy using Kingdon's multiple streams theory

This case study offered the following insights, most of which are in alignment with Kingdon's multiple streams theory (Kingdon, 1984, Kingdon, 1993).

Firstly, it showed that issues in the problem stream - that is, the fragmented and implicit healthcare priority-setting processes and, unaffordable, unsustainable, and wasteful health benefits packages in Kenya- became visible through indicators and feedback from situational analyses of Kenya's health financing architecture. These indicators and feedback highlighted unrealized needs that required improvement through government action. As Kingdon's theory states, issues in the problem stream become visible through indicators, feedback and/ or focusing events (Kingdon, 1984, Kingdon, 1993).

Secondly, Kingdon's theory states that policy solutions are developed by policy communities with an interest in influencing a specific policy area (Kingdon, 1993), and this case study showed that potential policy solutions were identified by a policy community consisting of technocrats who shared individual and organizational ideologies and interests in strengthening health financing and UHC reforms in Kenya. These technocrats were Kenyan health economists, health financing experts, health policy analysts, and health systems experts from the MOH, Development partners, and local research organizations. In Kenya's case, these technocrats were also responsible for identifying issues in the problem stream.

Thirdly, this study showed that the viability of the potential policy solution of establishing an independent expert panel was strengthened by the availability of technical experts for the panel, and the presence of public acquiescence from "attentive publics" in the inter-governmental coordinating committee. "Attentive publics" refer to individuals who are better informed and keenly interested in a particular issue than the general public (Kingdon, 1993). This finding was in keeping with Kingdon's theory which posits that the viability of a potential policy

solution is influenced by factors such as technical feasibility, public acquiescence, and financial viability (Kingdon, 1993).

Fourthly, this case study showed that a policy window opened in the politics stream following the political prioritization of UHC by the re-elected government. The opening of this policy window increased policymakers' receptiveness to UHC-related reforms including reforms on healthcare priority-setting processes. This finding aligned with Kingdon's theory which indicates that a policy window can open either in the policy or politics stream and that it influences the subjects that policymakers pay attention to (Kingdon, 1993, Kingdon, 1984).

Fifthly, consistent with Kingdon's theory which postulates that successful policymaking follows timely recognition of a policy window and employment of multiple strategies by policy entrepreneurs (Kingdon, 1993, Kingdon, 1984), this case study showed that the gazettement of the HBPAP policy idea followed the timely recognition of the policy window and the use of multiple strategies by policy entrepreneurs in Kenya. To begin with, these entrepreneurs worked collaboratively in a technocratic network given their shared interests and ideologies in healthcare financing and UHC reforms. When a policy window opened in the politics stream, these technocratic policy entrepreneurs employed the following strategies to influence the policy process: - a) they marshalled evidence to highlight issues and solutions in the problem and policy streams respectively; b) they utilized political connections to advocate for their preferred policy solutions; and c) they used persuasive framing to raise the political profile of issues and solutions in the problem and policy streams respectively by strategically linking these to the government's commitment to UHC.

Lastly, however, while Kingdon's theory argues that the three streams progress independently before coupling occurs during a policy window, this study shows otherwise. In this study, the problem and policy streams progressed simultaneously since the technocrats involved in

identifying the problems were the same ones involved in developing policy solutions to these problems. As Nikolaos, 2007 and Moloughney, 2012 note from empirical applications and critical reviews of Kingdon's theory, the three streams may not always flow independently (Moloughney, 2012, Nikolaos, 2007)

The application of Kingdon's multiple streams theory in this case study gave visibility to the policy process that led to the gazettelement of the HBPAP policy idea. It highlighted the important role played by technocrats in the gazettelement of the HBPAP procedural policy. These technocrats not only identified issues in the problem stream but also developed potential policy solutions and acted as policy entrepreneurs when a policy window opened in the politics stream. Kingdon's theory not only offered a structured approach for examining the policy process but also increased the analytical value of the examination by explaining how and why the HBPAP procedural policy was successfully formulated and introduced in Kenya. Practitioners and researchers can therefore utilize this theory to strengthen their analysis and understanding of the policy process for procedural policies on healthcare priority-setting.

### 9.3 A qualitative evaluation of HBPAP's healthcare priority-setting process

Following the gazettelement of the HBPAP policy in June 2018, HBPAP had 60 days to develop a health benefits package for UHC using an explicit healthcare priority-setting process. For the second sub-study of this PhD, I described and qualitatively evaluated the healthcare priority-setting process for health benefits package conducted by HBPAP. As indicated in Chapter 1 of this thesis, evaluating the quality of existing healthcare priority-setting processes is of growing interest due to the publics' demand in decisionmakers' demonstrating the fairness, legitimacy, accountability, and transparency of healthcare priority-setting processes given the complexity and distributive conflicts of allocating scarce resources across competing uses (Smith et al., 2012, Martin and Singer, 2003, Ham and Coulter, 2001). However, as shown in Chapter 3 of

this thesis, studies that evaluate healthcare priority-setting processes at the macro-level remain limited.

I described and qualitatively evaluated HBPAP's healthcare priority-setting process against the normative procedural and outcome conditions of a "good" healthcare priority-setting process as outlined in the Barasa et al., evaluative framework (Barasa et al., 2015). As indicated in Chapter 5 *subsection 5.2.2.2* of this thesis, the Barasa et al., framework incorporates procedural and/ or outcome conditions from the Accountability for Reasonableness Framework which makes a healthcare priority-setting process fair and legitimate, and the Sibbald et al., framework which makes a healthcare priority-setting process successful (Barasa et al., 2015). It also reflects values from the Social Values Framework which make a healthcare priority-setting process socially justifiable (Barasa et al., 2015). Therefore, a "good" healthcare priority-setting process is technically and procedurally fair, legitimate, successful, and socially justifiable.

This case study showed that HBPAP's healthcare priority-setting process fulfilled partially the procedural and outcome conditions outlined in the Barasa et al., framework. This partial fulfilment was due to both internal (within HBPAP) and external (outside HBPAP) factors as discussed below. *Firstly*, HBPAP achieved transparency by: - a) using criteria to inform its decisions; b) involving non-HBPAP members (health system stakeholders) in the process; and c) outlining openly all its procedures, criteria, and decisions in the HBPAP report. HBPAP was motivated to attain transparency given the mandate outlined in external legal documents such as the gazette notice and the constitution. However, while HBPAP's process was transparent, the final decision-making stage by the senior political leadership was not since the leadership did not openly and publicly disclose what informed the final decisions. In addition, the senior political leadership failed to publish HBPAP's report which undermined publicity of HBPAP's process. These findings reflected partial fulfilment of the procedural condition on transparency

and publicity which requires all aspects of the healthcare priority-setting process to be open and publicly available (Barasa et al., 2015).

*Secondly*, HBPAP identified a list of 10 criteria to inform decisions in the priority-setting process (See Table 4, Chapter 8). These criteria included technical criteria (e.g., effectiveness and safety, burden of disease, severity of disease, catastrophic health expenditures, cost-effectiveness, affordability, and feasibility) and social values (e.g., congruence with existing policies and equity). HBPAP's application of these criteria was however undermined internally by the short timeline and, externally by the poor availability of data, lack of thresholds, and dominance of policymakers' interests in the final decision-making stage. According to these findings, HBPAP's priority-setting process fulfilled partially the procedural condition on use of evidence which requires application of criteria in the priority-setting process and associated resource allocation decisions (Barasa et al., 2015).

*Thirdly*, HBPAP involved a broad range of non-HBPAP members in the priority-setting process and captured their values through stakeholder engagement forums. HBPAP's involvement of non-HBPAP members was internally motivated by the need to achieve transparency and externally motivated by the need to fulfil the constitutional requirement for public participation in public processes. However, certain groups of stakeholders such as members of the public and non-governmental organizations were not involved. The extensive involvement of non-HBPAP members was undermined internally by the limited availability of funds and short timelines. As a result, HBPAP's priority-setting process fulfilled partially the procedural condition on stakeholder participation and incorporation of community values which requires involvement of relevant health systems stakeholders and consideration of their values in the priority-setting process (Barasa et al., 2015).

*Fourthly*, HBPAP members were empowered internally by: - a) the semi-autonomous nature of the panel; b) positive organizational culture characterized by commitment, respect, and supportive leadership; and c) their technical and professional expertise in healthcare priority-setting. To empower non-HBPAP members, HBPAP held different stakeholder engagement forums for different groups of non-HBPAP members to minimize dominance of one group over others. However, non-HBPAP members were disempowered by their limited technical and professional experience in healthcare priority-setting which undermined their contribution during the priority-setting process. These findings reflected partial fulfilment of the procedural condition on stakeholder empowerment which requires stakeholders to have the power participate and contribute meaningfully to the priority-setting process (Barasa et al., 2015).

*Fifthly*, HBPAP allowed non-HBPAP members to challenge its procedures and decisions through emails and questions during stakeholder engagement forums. However, the appeals and revision mechanisms were undermined internally by the short timelines and the lack of transparency in the final decision-making stage. Consequently, HBPAP's priority-setting process fulfilled partially the procedural condition on revision and appeals which requires the priority-setting process to have a mechanism for challenging and changing decisions (Barasa et al., 2015).

*Sixthly*, enforcement within HBPAP was achieved internally through the internal procedures' manual and through oversight and leadership by the HBPAP chairman. Externally, enforcement was achieved through leadership and oversight by the Cabinet Secretary for Health. HBPAP's priority-setting process therefore fulfilled the procedural condition on enforcement which requires priority-setting processes to have mechanisms for ensuring adherence to the other procedural conditions (Barasa et al., 2015).

*Seventhly*, this case study showed that HBPAP members had developed a greater understanding of healthcare priority-setting by participating in the process. However, understanding among non-HBPAP members was limited internally by short timelines that prevented deep sensitization of these stakeholders and externally by non-HBPAP members' limited knowledge and experience in healthcare priority-setting. Thus HBPAP's priority-setting process fulfilled partially the outcome condition on stakeholder understanding which requires stakeholders involved in the healthcare priority-setting process to demonstrate greater understanding of the structure, rationales, and decisions of the priority-setting process (Barasa et al., 2015).

*Eighthly*, HBPAP's process was associated with varying levels of stakeholder acceptance and satisfaction. For example, while many non-HBPAP members accepted and were satisfied with HBPAP's roles, responsibilities, process, and proposed benefits package, a few stakeholders from the MOH and NHIF rejected HBPAP's roles and responsibilities citing them as usurping their own roles in health benefits package design. In addition, all stakeholders were dissatisfied with the final decision-making process by the senior political leadership because these leaders neither indicated what informed the final decision nor published the HBPAP report. Therefore, HBPAP's priority-setting process only partially fulfilled the outcome condition on stakeholder acceptance and satisfaction which requires stakeholders involved in the priority-setting processes to show approval and contentment with the priority-setting process and associated decisions (Barasa et al., 2015).

*Lastly*, HBPAP's healthcare priority-setting process had limited impact on health policy and practice due to the failure to implement HBPAP's proposed health benefits package. It, therefore, only partially fulfilled the outcome condition of the Barasa et al., framework which requires the healthcare priority-setting process to result in changes in priorities, policies, or distribution of resources (Barasa et al., 2015). The failure to implement the proposed package was attributed to several external factors such as changes in the UHC model made by the senior



political leadership, policy capture by some stakeholders’ interests, and opposition from other stakeholders. For example, NHIF and some development partners opposed HBPAP’s proposed health benefits package because they had their own benefits package proposals while private healthcare providers opposed HBPAP’s proposal because they wanted to protect their revenue since HBPAP’s benefit package would only be implemented in public healthcare facilities.

The internal and external factors that influenced the extent to which HBPAP’s healthcare priority-setting process fulfilled the normative procedural and outcome conditions of a “good” healthcare priority-setting process are summarized in Table 9.1. Some of these factors were supportive while others were prohibitive. The influence of these factors on HBPAP’s healthcare priority-setting process lends credence to the bounded rationality theory- outlined in Chapter 2 *subsection 2.2.1.2* of this thesis. This theory recognizes that individual factors (such as cognitive factors) and organizational factors (such as institutional requirements and goals, and availability of information resources) create bounds that limit rationality during decision-making processes (Jones, 1999, Simon, 1995). In HBPAP’s case, the internal and external factors created bounds that limited fulfilment of the normative procedural and outcome conditions.

Table 9.1: Factors that influenced HBPAP’s healthcare priority-setting process

	<b>Internal factors</b>	<b>External factors</b>
<b>Supportive</b>	<ul style="list-style-type: none"> <li>• HBPAP members’ technical expertise and/ or experience in healthcare priority-setting</li> <li>• Organizational culture (respect and commitment)</li> <li>• Availability of internal procedures manual</li> </ul>	<ul style="list-style-type: none"> <li>• Laws or constitutional requirements</li> <li>• Leadership and oversight by the Cabinet Secretary for Health</li> </ul>

	<ul style="list-style-type: none"> <li>• Leadership and oversight by the HBPAP chairman</li> </ul>	
<b>Prohibitive</b>	<ul style="list-style-type: none"> <li>• Short timelines</li> <li>• Limited financial resources for HBPAP’s operational activities</li> </ul>	<ul style="list-style-type: none"> <li>• Limited data quality and availability</li> <li>• Limited technical expertise and/ or experience in healthcare priority-setting among external stakeholders’</li> <li>• Stakeholders’ interests</li> </ul>

This case study advances our knowledge of the quality of the healthcare priority-setting process conducted by HBPAP in terms of the fulfilment of normative procedural and outcome conditions of a technically and procedurally “good” healthcare priority-setting process. This case study shows that HBPAP implemented some “good” procedural practices with the aim of conducting an explicit, evidence-based, transparent, and inclusive healthcare priority-setting process. These procedural practices included use of evidence, stakeholder involvement, stakeholder empowerment, development of a report, appeals and revision, and enforcement. These practices reflected an HTA process which, as indicated in Chapter 2 of this thesis, offers a formal, structured, transparent, and inclusive process to explicitly ascertain whether resources will be allocated to a health technology based on its value (O'Rourke et al., 2020). However, fulfilment of HBPAP’s “good” procedural practices was undermined by various internal and external factors which also undermined fulfilment of the outcome conditions.

## 9.4 Identification of factors influencing institutionalization of HTA in Kenya

Post HBPAP, Kenya embarked on a journey to institutionalize HTA as an approach for explicit healthcare priority-setting in Kenya. Institutionalization of HTA refers to the process of

conducting and utilizing HTA as a normative practice for guiding decisions on allocation of resources among competing uses within the health system (World Health Organization, 2001). The need to establish long-term mechanisms for healthcare priority-setting such as HTA is well recognized as countries pursue UHC (Chalkidou et al., 2016, World Health Assembly, 2014). Institutionalization of HTA remains limited in low and lower-middle income countries (Hollingworth et al., 2021, Chalkidou et al., 2017). As shown in Chapter 4 of this thesis, studies that examine factors that influence institutionalization of HTA in LMICs also remain limited. For the third sub-study of this PhD, I aimed to identify factors that were influencing institutionalization of HTA in Kenya using the conceptual framework provided in Chapter 4. This framework was developed from a synthesis of empirical studies on factors influencing institutionalization of HTA across countries of different income levels.

This case study offered the following key insights regarding factors that both enabled and constrained the process of institutionalizing HTA in Kenya. Firstly, Kenya's MOH has established multiple organizational structures to conduct, utilize and/or oversee HTA. These organizations include the HTA focal point, the Medicines Affordability Pricing Advisory Committee and, the HTA technical working group. Despite the availability of organizational structures for HTA, Kenya lacks adequate resources for HTA in terms of finances, data, and skilled human resources. For example, Kenya's government has chronically underfunded research which led to insufficient funds to support the HTA process. Kenya also lacked a cost database, and its health information system was incomplete which undermined availability of data for HTA. Lastly, the number of people with the technical skills for HTA such as health economics and evidence synthesis were limited. Based on the framework's condition on availability of organizational resources for HTA, Kenya has organizational structures for HTA but lacks other organizational resources which both enabled and constrained the process of institutionalizing HTA. As seen in Chapter 4, the limited availability of organizational

resources undermined institutionalization of HTA in other LMICs globally (World Health Organization, 2015, Babigumira et al., 2016, Rajan et al., 2011).

Secondly, Kenya has legislation and policies on institutional and organizational arrangements for HTA which outlined: - a) the need for organizational structures for HTA; b) role of HTA in healthcare priority-setting; and c) examples of priority-setting criteria to be used in the HTA process. These legislation and policies led to the establishment of the organizational structures for HTA identified above. However, Kenya lacks process and methods guidelines for HTA such as quality adjusted life year set and a cost-effectiveness threshold which undermined the country's capacity to conduct and utilize HTA. Based on the framework's condition on availability of legal frameworks, policies, and guidelines for HTA, the availability of legal frameworks and policies for HTA in Kenya supported institutionalization of HTA but the lack of process and decision frameworks undermined it. As shown in Chapter 4, the supportive influence of the availability of legal frameworks and policies on HTA has been reported in several HICs globally (Banta et al., 2009, Banta and Almeida, 2009, Shemer et al., 2009) while the undermining influence of limited availability of HTA process and methods guidelines has been reported in LMICs globally (Hollingworth et al., 2021, Babigumira et al., 2016).

Thirdly, several short-term capacity-building and awareness creation initiatives for HTA have been conducted in Kenya. These initiatives included workshops, courses, study visits, and high-level policy meetings. However, the availability of long-term training for HTA such as undergraduate and postgraduate training was limited which undermined Kenya's pool of skilled human resource for HTA. Based on the framework's condition on learning and advocacy for HTA, there was increasing availability of HTA capacity-building and awareness creation activities which helped to raise HTA awareness and capacity for some HTA users and doers particularly at the national-level.

Fourthly, the extent of awareness and understanding of the value of HTA varies across Kenyan stakeholders which influenced the institutionalization process. For example, while HTA awareness and understanding were higher among national level policymakers in Kenya, it remained limited among stakeholders at the subnational level. Subnational level stakeholders play a vital role in resource allocation given Kenya's devolved health system structure. This case study also showed that stakeholders' interests had varying influence on the institutionalization of HTA in Kenya. On one hand, policymakers', and technocrats' interests in optimal allocation of resources and evidence-informed resource allocation processes led to the establishment of organizational structures for HTA and development of HTA policies respectively. On the other hand, industries' interests in safeguarding their profit margins undermined the institutionalization of HTA in Kenya. Based on the framework's condition on stakeholder-related factors, Kenyan stakeholders expressed varying levels of awareness and interest which both supported and hindered institutionalization of HTA. As seen in Chapter 4, similar findings have been reported in other countries globally. For example, while policymakers' and technocrats' interests supported institutionalization of HTA in several high and upper-middle income countries globally (Liu et al., 2020, Rajan et al., 2011, Banta et al., 2009), industries' interests undermined institutionalization of HTA in other high and middle-income countries (Callahan, 2012, Banta, 2003, Jaramillo et al., 2016). Limited stakeholder awareness undermined institutionalization of HTA in several countries irrespective of their income level (World Health Organization, 2015, Babigumira et al., 2016).

Lastly, Kenya has received collaborative support for HTA from various organizations. For example, Kenya entered into a bilateral agreement with Thailand which led to the provision of capacity-building and awareness creation activities in Kenya. Other collaborations have occurred through iDSI (a global health network) and JICA (a bilateral agency) which also led to capacity-building and awareness creation for HTA in Kenya. Collaborative support for HTA

through JICA also led to the development of a policy framework for institutionalizing HTA in Kenya. Based on the framework's condition on collaborative support for HTA, Kenya has received adequate collaborative support which has supported institutionalization of HTA. Similar findings have been reported across countries of all income levels globally where international collaboration supported institutionalization of HTA through capacity-building and awareness creation (Liu et al., 2020, MacQuilkan et al., 2018, Banta et al., 2009, Banta, 2009, Sivalal, 2009).

This case study increases our knowledge of factors that both enabled and constrained the process of institutionalizing HTA in Kenya. It shows that factors supporting institutionalization of HTA included: - establishment of organizational structures for HTA; availability of legal frameworks and policies on HTA; increasing availability of awareness creation and short-term capacity-building initiatives for HTA; policymakers' interests in UHC and optimal allocation of resources; technocrats' interests in evidence-based processes; presence of international collaboration for HTA; and lastly, involvement of bilateral agencies. On the other hand, factors undermining institutionalization of HTA in Kenya included: - limited availability of financial, information and skilled human resources; lack of HTA guidelines and decision-making frameworks; limited HTA awareness among subnational stakeholders; limited availability of long-term capacity building activities; and industries' interests in safeguarding their revenue.

The factors identified in this case study were linked. For example, legal frameworks and policymakers' interests led to the establishment of organizational structures for HTA. Technocrats' interests led to the development of policies on HTA. Short-term capacity-building and awareness creation activities enhanced stakeholders' awareness and understanding. International collaboration led not only to increasing availability of HTA capacity-building and awareness creation activities but also to development of strategies for HTA. These complex linkages are summarized in Figure 9.2.

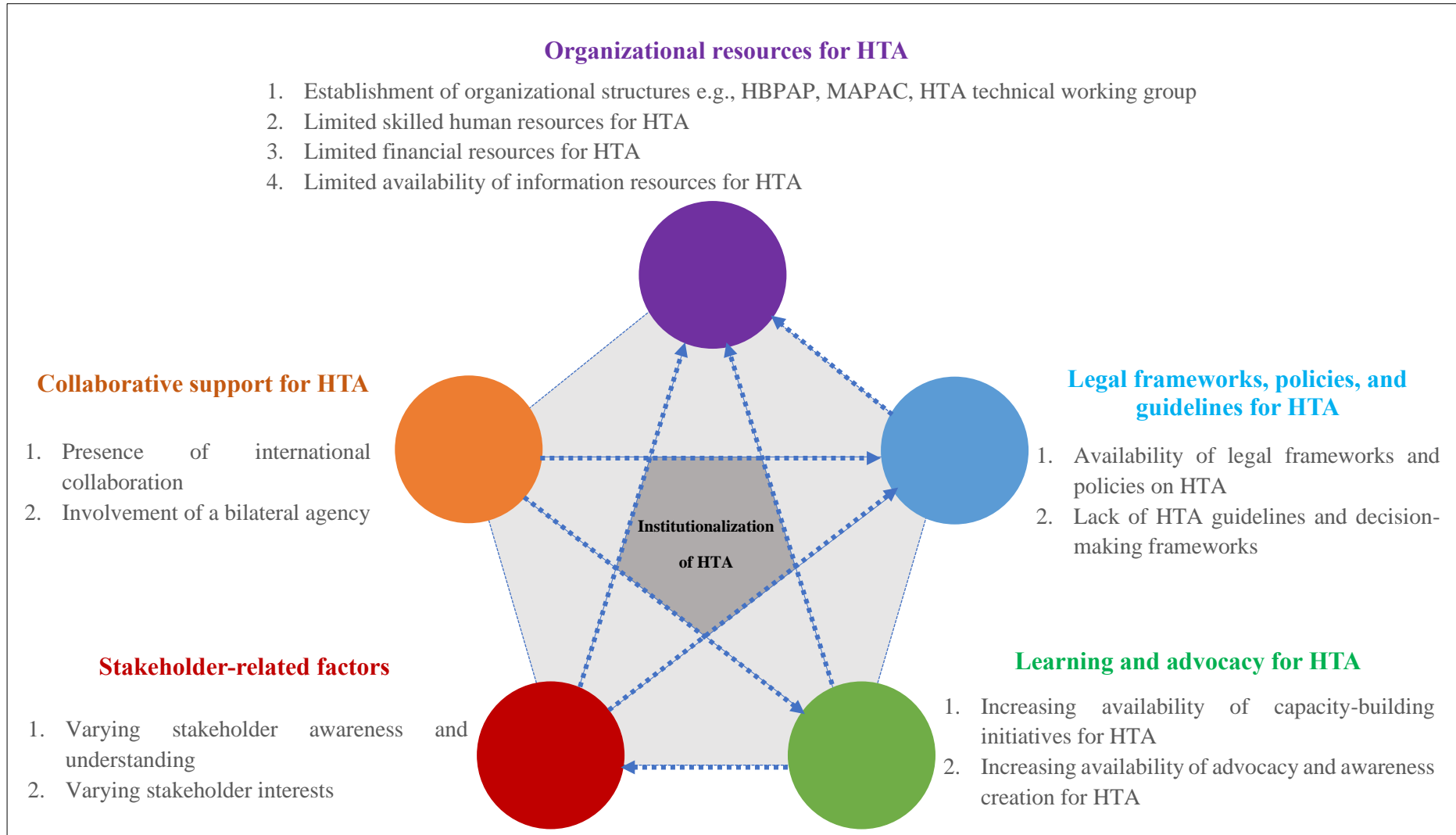


Figure 9.2: Factors influencing institutionalization of HTA in Kenya

## 9.5 Cross-cutting theme - The influence of stakeholders' interests

A common factor that influenced the policy process, implementation, and institutionalization of explicit healthcare priority-setting processes in Kenya was stakeholders' interests. Table 9.2 summarises the key stakeholders and interests that impacted on the process of *developing* the HBPAP policy, as discussed further below.

Table 9.2: Policy actors and their key interests in HBPAP as a policy idea

Type of actor	Examples	Interests
<b>Political actors</b>	President Uhuru Kenya	<ul style="list-style-type: none"> <li>Attaining UHC during his tenure</li> </ul>
	Cabinet Secretaries for Health (equivalent to Ministers for Health)	<ul style="list-style-type: none"> <li>Fulfilling the president's directive on UHC</li> </ul>
<b>Technocrats</b>	Kenyan health economists, health financing experts, health policy analysts, and health systems experts from the MOH, Development partners, and local research organizations	<ul style="list-style-type: none"> <li>Strengthening health financing and implementing UHC reforms in Kenya</li> </ul>
<b>Payers</b>	National Health Insurance Fund (NHIF)	<ul style="list-style-type: none"> <li>Protecting their role in health benefits package development</li> </ul>
<b>Bureaucrats</b>	MOH departments and divisions	<ul style="list-style-type: none"> <li>Protecting their role in health benefits package development</li> </ul>

To begin with, technocrats' interests in health financing and UHC reforms led them to deliberately engage and interact with each other in a network from 2015. In this network, the



technocrats conducted situational analyses of Kenya's health financing architecture which helped them to identify the problem of fragmented and implicit healthcare priority-setting, and unaffordable, unsustainable, and wasteful benefit packages. After identifying these problems, the technocrats developed potential solutions. One such solution was the establishment of an independent experts' panel to conduct an explicit healthcare priority-setting process for health benefits package development. While this policy solution received public acquiescence from "attentive publics" in the intergovernmental coordinating community, it faced opposition from a few policy actors namely the NHIF and a few MOH bureaucrats whose main interest was to safeguard their mandates of developing health benefits packages.

When President Uhuru Kenyatta declared UHC as one of his key interests, technocrats leveraged this window of opportunity to advocate for the establishment of the independent expert panel. To this end, technocrats utilized persuasive framing to align the issues and solutions in the problem and policy streams respectively to policymakers' interest in attaining UHC. The technocrats presented these persuasive arguments directly to the Cabinet Secretary who was interested in fulfilling the president's directive on UHC. The President's and the Cabinet Secretary's interest in UHC led them to be receptive to the technocrats' policy solution, eventually leading to the gazettelement of the HBPAP policy and, in turn, the establishment of HBPAP- a panel of experts tasked with developing an explicit health benefits package using an explicit healthcare priority-setting process. The success of the Kenyan technocrats in promoting the gazettelement of the HBPAP policy lends credence to the "*theory of collective action*" which posits that groups with shared interests or common objectives have better cohesion which allows them to effectively lobby for their preferred policies (Hauck and Smith, 2015).

Regarding the healthcare priority-setting process conducted by HBPAP, the interests of the stakeholders outlined in Table 9.3 influenced the *outcome* conditions of the process.

Table 9.3: Actors and their key interests in HBPAP’s priority-setting process

<b>Type of actor</b>	<b>Examples</b>	<b>Interests</b>
<b>Political actors</b>	President Uhuru Kenya, Cabinet Secretary for Health, and Officials from Ministry of Finance	<ul style="list-style-type: none"> <li>• Affordability of implementing the priority-setting decision</li> </ul>
<b>Technocrats</b>	Kenyan health economists, health financing experts, health policy analysts, and health systems experts from the MOH, Development partners, and local research organizations	<ul style="list-style-type: none"> <li>• Develop a health benefits package using an explicit healthcare priority-setting process</li> </ul>
<b>Payers</b>	NHIF	<ul style="list-style-type: none"> <li>• Protect their role in health benefits package development</li> </ul>
<b>Bureaucrats</b>	MOH departments and divisions	<ul style="list-style-type: none"> <li>• Protect their role in health benefits package development</li> </ul>
<b>Private sector organizations</b>	Private healthcare providers	<ul style="list-style-type: none"> <li>• Protect their revenue and profits</li> </ul>

From the outset, HBPAP’s main interest was to develop a health benefits package using an explicit healthcare priority-setting process. To this end, HBPAP implemented “good” procedural practices by using evidence, involving stakeholders, outlining explicitly its process in the HBPAP report, and by allowing stakeholders to challenge its decisions. However, in the final decision-making stage, the health benefits package that was proposed by HBPAP was not implemented due to stakeholders’ interests. For example, the NHIF and some MOH

bureaucrats opposed the proposed health benefits package because of their interests in preserving their historical mandates of health benefits package development. Private healthcare providers opposed the proposed benefits package because of their interest in protecting their revenue. If implemented, the proposed benefits package would have only been provided by public healthcare facilities leading to revenue losses for the private healthcare providers. Lastly, senior policymakers changed the UHC model from a health insurance model to a user-fee removal model which was incompatible with the proposed health benefits package. This change was attributed to policymakers' interest in maintaining affordability of implementing resource allocation decisions.

These findings highlighted the political nature of HBPAP's healthcare priority-setting process, reflecting theoretical and wider empirical literature that recognize the intrinsically political nature of healthcare priority-setting processes for health benefits packages. According to these literature, the political nature of these processes is due to conflicting stakeholders' interests about:- a) what processes and criteria should be followed; b) which stakeholders should be involved; c) what roles and responsibilities stakeholders should fulfil; and d) impact of implementing proposed health benefits packages (Bump and Chang, 2017, Smith et al., 2014, Hauck et al., 2004, Ham and Glenn, 2003, Coulter and Ham, 2000).

Lastly, the interests of the stakeholders outlined in Table 9.4 influenced the process of *institutionalizing* HTA in Kenya.

Table 9.4: Actors and their key interests in institutionalization of HTA

Type of actor	Examples	Interests
<b>Political actors</b>	MOH policymakers	<ul style="list-style-type: none"> <li>UHC and optimal allocation of resources</li> </ul>
<b>Technocrats</b>	Kenyan health economists and health systems experts within the	<ul style="list-style-type: none"> <li>Evidence-based resource allocation processes</li> </ul>

	MOH, local academic and research organizations, and development partners	
<b>Private sector organizations</b>	Industries and importers of health technologies	<ul style="list-style-type: none"> <li>• Protecting their revenue and profits</li> </ul>

Policymakers within the MOH were interested in achieving UHC and in defining a health benefits package for the UHC programme. Recognizing the scarcity of resources in Kenya’s health system, these policymakers developed an interest in utilizing explicit and evidence-based processes to enable optimal allocation of resources towards UHC. These interests drove the MOH policymakers to support HTA. Technocrats’ interests in evidence-based resource allocation processes also led them to support HTA as it offered an evidence-based process for improving resource allocation towards affordability, sustainability, and equitable distribution of health benefits packages in Kenya. These interests also led the technocrats to develop institutional and organizational arrangements for HTA as outlined in Kenyan health policies on HTA. However, while technocrats’ and policymakers’ interests’ supported institutionalization of HTA, interests of private sector organizations such as industries and importers of health technologies did not. These organizations were more interested in safeguarding their revenue, and so opposed the institutionalization of HTA in Kenya.

The influence of stakeholders’ interests across the three case studies on the policy process, implementation, and institutionalization of explicit healthcare priority-setting in Kenya reported here highlight the political and complex nature of these processes. Drawing from Smith et al., who recognize the central influence of politics in priority-setting, practitioners and advocates of explicit healthcare priority-setting processes should, therefore: - a) identify existing stakeholder interests; b) explore how and which interests would be affected; and c)

assess how stakeholders would respond to these processes (Smith et al., 2014). In so doing, practitioners and advocates can develop strategies to strengthen the influence in these processes of those stakeholders with interests that are supportive of explicit healthcare priority-setting.

## 9.6 Policy implications

Efforts to improve existing healthcare priority-setting processes should be based on empirical findings (Kapiriri and Martin, 2007, Martin and Singer, 2003, Ham and Glenn, 2003). It is argued that empirical findings facilitate policy learning by highlighting what happens in practice which then informs strategies to address gaps identified in practice (Ham and Glenn, 2003). Based on the findings of what happened in practice, this PhD offers important policy implications for practitioners and researchers involved in formulating, implementing, and institutionalizing explicit healthcare priority-setting processes at the macro-level in Kenya and other countries considering similar procedural policies.

Concerning the policy process for formulating policy ideas on explicit healthcare priority-setting processes, proponents of these policy ideas should not only examine which policymakers may be most supportive of the ideas but also identify synergies of interest that could be explored to facilitate uptake of these policy ideas in the health system. Uptake of these policy ideas can be enhanced by raising their political profile through strategies such as persuasive framing, marshalling evidence, and use of political connections.

Concerning HBPAP's healthcare priority-setting process for health benefits package development, MOH policymakers can put in place several strategies to manage the internal and external factors that undermined HBPAP's fulfilment of the normative procedural and outcome conditions. These strategies may include: - a) availing reports on the priority-setting process using relevant communication platforms to promote transparency and publicity; b) allocation of adequate time for the priority-setting process to enable adequate application of evidence,

adequate stakeholder involvement, and functional appeals and revision; c) allocation of adequate financial resources to enable wider stakeholder involvement and, generation of local empirical studies; d) strengthening of health information systems to enable availability of good quality data; e) development of explicit and systematic process and methods guidelines as arbitration mechanisms for managing and regulating conflicting criteria, values, and interests; f) continuous involvement of external stakeholders in healthcare priority-setting processes to strengthen their knowledge and experience; g) development of explicit conditions for appeals and revisions and establishment of functional internal and external mechanisms for appeals and revisions; and g) development of clear decision-making frameworks that outline which stakeholders are involved and which criteria are considered to promote transparency, justification of decisions, and minimization of stakeholder influence in the decision-making stage.

Concerning factors influencing institutionalization of HTA as an approach for explicit healthcare priority-setting in Kenya, MOH policymakers can adopt a systemic approach given the breadth of limitations identified across the factors outlined in the study's conceptual framework. In this systemic approach, the MOH should:- a) earmark funds from the national health budget to ensure adequate availability of financial resources for HTA; b) establish a database for costs and other relevant data required for HTA processes; c) introduce undergraduate and postgraduate training in courses relevant to HTA to increase availability of skilled human resources; d) develop contextually relevant process and methods guidelines and decision tools for HTA to facilitate HTA processes; e) conduct wider advocacy to increase HTA awareness among national and sub-national stakeholders; f) manage stakeholders' interests through sensitization and persuasive framing of the value of institutionalizing HTA to minimize opposition; and g) strengthen international collaborations through south-south collaborations to facilitate the institutionalization process.

## 9.7 Strengths of the PhD study

This PhD study has several strengths. Firstly, it demonstrates the analytic value of applying a policy analysis theory such as Kingdon's Multiple Streams Theory to a procedural policy for healthcare priority-setting processes such as HBPAP. By applying this theory, I was able to explain how and why the HBPAP policy idea was gazetted in Kenya. In this way, this PhD contributes to the limited body of literature that applies policy analysis theories to examine the policy process of introducing procedural policies for healthcare priority-setting. It also demonstrates the adaptability of Kingdon's theory in examining different types of policy processes.

Secondly, this is the first study to evaluate HBPAP's healthcare priority-setting process for health benefits package development in Kenya. As shown in Chapter 3 of this PhD, studies that evaluate healthcare priority-setting processes at the macro-level remain limited particularly in low and middle-income countries. By evaluating HBPAP's healthcare priority-setting processes, I identified "good" practices that HBPAP had put in place which can be adopted in future healthcare priority-setting processes. I also identified internal and external factors that both supported and undermined HBPAP's fulfilment of "good" procedural practices as well as outcome conditions. These findings generated useful policy implications that can be used to improve future healthcare priority-setting processes in Kenya.

Lastly, I utilized a conceptual framework on factors influencing institutionalization of HTA that I developed from a synthesis of existing empirical literature from countries of different income levels. This framework provides a structured way of systematically identifying and discussing factors that may influence institutionalization of HTA. By applying it in this PhD, I tested its usability in terms of ease of comprehension and application within the local context. Future researchers can utilize this conceptual framework to conduct similar studies in their local contexts. They can also improve or modify the framework based on the findings from

their studies. The factors identified in the conceptual framework can also be used by researchers and policymakers to inform development of roadmaps to support institutionalization of HTA in their contexts.

## 9.8 Limitations of the PhD study

This PhD study may suffer from the following limitations. Recall bias is a potential limitation given that this study involved a retrospective account of three processes namely policy process for HBPAP policy, HBPAP's healthcare priority-setting process, and institutionalization of HTA which began several years ago. However, I minimized this bias by including document and media reviews which are known to be important historical accounts of past events (Bowen, 2009).

Another potential limitation is social desirability bias whereby participants alter responses in the belief that these would make the responses more acceptable. However, I minimized this bias by triangulating data sources (interviewing different participants to obtain different perspectives) and methods (using different methods of data collection).

Thirdly, it is possible that by asking purposively selected participants to select additional participants through snowball sampling, this may have identified participants with similar views leading to biased findings. However, by triangulating data sources (interviewing different participants to obtain different perspectives) and by triangulating data methods (using different methods of data collection such as media and document reviews), I minimized this risk.

Lastly, my involvement and that of one of my supervisors (EB) in previous healthcare priority-setting processes in Kenya may have biased the interviews and analysis. However, I minimized this risk through extensive document and media reviews, and by holding peer debriefing sessions with the supervisory team to ensure that the study findings were founded on the data collected.



## 9.9 Recommendations for further research

There are four issues that emerged from this PhD that may require further investigation. Firstly, analyses of policy processes for developing procedural policies on healthcare priority-setting remain limited in low and middle-income countries. Such analyses can draw on any of the theories and conceptual frameworks outlined in Chapter 2 of this thesis. Conducting such analyses will enable not only identification of actor and contextual influences but also reflection and comparison of patterns of influence across these contexts thus building on this literature.

Secondly, future studies on evaluation of healthcare priority-setting processes should explore internal and external factors that might explain how and why these processes fulfil (or fail to fulfil) the procedural and outcome conditions of a “good” healthcare priority-setting process. Furthermore, these studies should explore stakeholders’ views on the importance and acceptability of the internal and external factors identified in this PhD. This could widen the range of factors that practitioners and researchers consider while conducting or evaluating healthcare priority-setting processes respectively particularly in low and middle-income countries where such processes remain limited. Such studies could also allow comparison of factors influencing implementation of similar healthcare priority-setting processes with other countries.

Thirdly, there is need to explore stakeholders’ views on the five sets of factors that were outlined in the conceptual framework on factors influencing institutionalization of HTA. Specifically, studies could investigate the acceptability, suitability, and completeness of these factors or the framework to different contexts. This could also enable cross-country comparisons of institutionalization experiences.

Lastly, this PhD has shown that stakeholders can influence the policy process, implementation, and institutionalization of explicit healthcare priority-setting processes. Future studies should therefore consider conducting stakeholder analysis to explore and map out how stakeholders' level of interest and power influenced the policy process, implementation, and institutionalization of explicit healthcare priority-setting processes in the context of interest.

## 9.10 Conclusion

This PhD examined the policy process, implementation, and institutionalization of explicit healthcare priority-setting processes at the macro-level in Kenya. This is a substantively relevant research and policy question as such literature remains limited in low- and middle-income countries. The main conclusions from this PhD study include the following.

The use of Kingdon's multiple streams theory to examine the policy process for the HBPAP policy provided a useful analytical lens which deepened my understanding of the problem, policy solutions, and political forces that influenced how and why the HBPAP policy was formulated and gazetted. It also highlighted the critical role played by technocrats not only in identifying the issues and solutions in the problem and policy streams respectively but also in coupling the three streams when a policy window opened in the politics stream. This analysis also showed that strategies such as persuasive framing, marshalling evidence, and political connections can be used to increase the political profile of a procedural policy hence facilitate its adoption.

The evaluation of the implementation of HBPAP's healthcare priority-setting process against the normative procedural and outcome conditions of a "good" healthcare priority-setting process, highlighted internal and external factors that both supported and undermined the quality of the process. HBPAP implemented some "good" procedural practices with the aim of conducting an explicit, evidence-based, transparent, and inclusive healthcare priority-setting

process. These procedural practices included use of evidence, stakeholder involvement, stakeholder empowerment, development of a report, appeals and revision, and enforcement. These practices were supported by internal factors such as: - HBPAP members' technical expertise and experience in healthcare priority-setting, positive organizational culture characterized by respect and commitment, availability of internal procedures manual, and leadership and oversight by the HBPAP chairman. They were also supported by external factors such as laws, and leadership and oversight by the Cabinet Secretary for Health. However, these "good" practices were undermined by internal factors such as limited availability of funds and short timelines, and external factors such as: - poor data quality and availability, limited technical expertise and experience in healthcare priority-setting among external stakeholders, and stakeholders' interests. This analysis shows that to implement a 'good" healthcare priority-setting process for health benefits package development, policymakers should maintain supportive internal and external factors, and introduce strategies to address prohibitive internal and external factors.

The use of the conceptual framework on factors influencing the institutionalization of HTA showed that several factors supported and undermined the institutionalization of HTA in Kenya. Among the supportive factors were the establishment of organizational structures for HTA; availability of legal frameworks and policies on HTA; increasing availability of awareness creation and short-term capacity-building initiatives for HTA; policymakers' interests in universal health coverage and optimal allocation of resources; technocrats' interests in evidence-based processes; presence of international collaboration for HTA; and lastly, involvement of bilateral agencies. On the other hand, prohibitive factors included: - limited availability of financial, information and skilled human resources; lack of HTA guidelines and decision-making frameworks; limited HTA awareness among subnational stakeholders; and

industries' interests in safeguarding their revenue. To institutionalize HTA in Kenya, policymakers need a systemic approach that addresses current limitations.

Importantly, this PhD study shows that the policy process, implementation, and institutionalization of explicit healthcare priority-setting at the macro-level in Kenya occurred in political environments characterized by multiple and conflicting stakeholders' interests which supported and/ or undermined these processes. Regarding the policy process, alignment of policymakers' and technocrats' interests led to the development and gazettement of the procedural policy on HBPAP. Regarding implementation of HBPAP's healthcare priority-setting process, policymakers' interests undermined fulfilment of the outcome condition on impact on policy and practice due to the failure to implement HBPAP's proposed health benefits package. Lastly, regarding institutionalization of HTA, while policymakers' and technocrats' interests supported the institutionalization process through establishment of organizational structures and development of policies on HTA, industries' interests undermined the process through opposition. Based on this knowledge, practitioners and advocates of explicit healthcare priority-setting processes should identify stakeholders' interests, explore how and which interests would be affected, assess how stakeholders would respond to these processes, and develop appropriate strategies to manage stakeholders' interests. In so doing, practitioners and advocates may create supportive environments for introducing, implementing, and institutionalizing explicit healthcare priority-setting processes.

In conclusion, explicit healthcare priority-setting processes are integral aspects of purchasing and benefits package design as countries seek to achieve UHC in an efficient, equitable and sustainable manner. Therefore, the importance of examining factors that influence the policy process, implementation, and institutionalization of explicit healthcare priority-setting processes at the macro-level cannot be overstated. Such examinations will not only highlight

what happens in practice, but also provide opportunities to develop strategies to improve what happens in practice.

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## APPENDICES

### Appendix 1: Articles included in the scoping review on policy processes and evaluation of healthcare priority-setting processes

	<b>Author and year of publication</b>	<b>Country</b>	<b>Data collection methods</b>	<b>Study objective</b>	<b>Conceptual framework/ evaluative criteria</b>
1.	(Ahn et al., 2012)	Korea	Document reviews and interviews	To examine the contribution of social values in healthcare priority-setting in Korea.	Social values framework
2.	(Charlton, 2019)	United Kingdom (UK)	Document reviews and interviews	To analyze the fairness of NICE's approach to decision-making	Accountability for Reasonableness
3.	(Charvel et al., 2018)	Brazil, Costa Rica, Chile, and Mexico.	Document review	To assess the extent to which each country's priority-setting, as instituted in the legal instruments, is fair and justifiable.	Accountability for Reasonableness and the Social Values framework.
4.	(Cleemput et al., 2012)	Austria, Belgium, France, Netherlands, and Sweden	Document reviews and interviews	To evaluate the extent to which each country's drug reimbursement system fulfils the conditions of the Accountability for reasonableness framework.	Accountability for reasonableness
5.	(Essue and Kapiriri, 2018)	Uganda	Document review and interviews	To assess the extent to which the healthcare priority-setting process for non-communicable diseases was successful	Kapiriri and Martin's framework
6.	(Greß et al., 2005)	Germany, Switzerland, and UK	Document review	To evaluate the procedures and criteria for determining benefits and the	Legitimacy



				legitimacy of this process in Germany, Switzerland, and UK.	
7.	(Greenberg et al., 2009)	Israel	Document reviews	To examine the legitimacy and fairness of the process for updating the National List of Health Services in Israel	Accountability for reasonableness
8.	(Jansson, 2007)	Sweden	Document and interviews	To describe and analyze the priority-setting process for new pharmaceutical products.	Accountability for reasonableness
9.	(Kapiriri et al., 2007)	Canada, Norway, and Uganda	Interviews	To describe and evaluate healthcare priority-setting processes in Ontario-Canada, Norway, and Uganda	Accountability for reasonableness
10.	(Kapiriri et al., 2021)	Algeria, Angola, Burkina Faso, Cameroon, Cape Verde, Chad, Democratic Republic of the Congo, Ethiopia, Ghana, Kenya, Mali, Mozambique, Niger, Nigeria Rwanda, South Africa, Uganda, and Zambia	Document reviews	To evaluate the degree to which national COVID-19 preparedness and response plans adhered to quality indicators of successful priority setting	Kapiriri and Martin's framework
11.	(Kapiriri and Be LaRose, 2019)	Uganda	Document reviews and interviews	To understand how priorities and resource allocation occur during disease outbreaks.	Kapiriri and Martin's framework for evaluating priority-setting

12.	(Kieslich, 2012)	Germany	Case study	To describe the priority-setting structures in Germany	Social Values Framework
13.	(Littlejohns et al., 2012)	UK	Document review	To describe the arrangements and role of social values in priority-setting in England and Wales.	Social Values Framework
14.	(Mitton et al., 2006)	Australia, Canada, New Zealand, and UK	Interviews	To evaluate the fairness of four internationally established centralized drug review processes using accountability for reasonableness	Accountability for reasonableness
15.	(Mohamadi et al., 2020)	Iran	Document reviews and observations	To analyze policymaking process of the Health Insurance Benefit Package in Iran.	Kingdon's multiple streams theory
16.	(Mori and Kaale, 2012)	Tanzania	Interviews and document reviews	To describe and evaluate the priority-setting process for a new anti-malarial drug	Accountability for reasonableness
17.	(Mostafavi et al., 2016)	Iran	Document reviews and interviews	To examine the role of health priority-setting in Iran	Social Values Framework
18.	(Rumbold et al., 2017b)	UK	Case study	To analyze the decision-making process of NICE	Rawl's conception of reasonableness
19.	(Sabik and Lie, 2008)	Denmark, Israel, Netherlands, New Zealand, Norway, Sweden, UK, and the state of Oregon in the US.	Document review	To review explicit priority-setting efforts in eight countries	Triple criteria- public participation, principles, and effect on policy and practice
20.	(Tantivess et al., 2012)	Thailand	Document reviews and personal communication	To review the experience of applying values in the formulation of a health	Social Values Framework

				benefits package in a publicly funded insurance scheme	
21.	(Wallace and Kafiriri, 2019)	Uganda	Document reviews and interviews	To describe and evaluate the healthcare priority-setting process for maternal, new-born and child health	Kafiriri and Martin's conceptual framework
22.	(Wallace and Kafiriri, 2017)	Uganda	Document reviews and interviews	To describe and evaluate the healthcare priority-setting process for vaccines	Kafiriri and Martin conceptual framework
23.	(Whitty and Littlejohns, 2015)	Australia	Document review	To describe the role of social values in priority setting related to health technology assessment processes and decision-making in Australia.	Social Values Framework
24.	(Youngkong et al., 2012)	Thailand	Participant observation	To describe and evaluate the application of multicriteria decision analysis in the universal health coverage benefit scheme in Thailand	Accountability for reasonableness

**Appendix 2: Articles included in the scoping review on factors influencing institutionalization of HTA**

	<b>Author and year of publication</b>	<b>Country (ies)</b>	<b>Data collection methods</b>	<b>Study objective</b>
1.	(Addo et al., 2020)	Ghana	Interviews	To identify the knowledge, role, and perception of HTA among decision-makers and researchers in Ghana
2.	(Arab-Zozani et al., 2020)	Iran	Document reviews	To describe the history of HTA in Iran
3.	(Babigumira et al., 2016)	Afghanistan, Bangladesh, Democratic Republic of Congo, Dominican Republic, Ethiopia, Jordan, Kenya, Namibia, Rwanda, South Africa, Swaziland, Vietnam	Mixed methods-survey and interviews	To examine the challenges of using performing and using HTA across several low- and middle-income countries
4.	(Banta, 2003)	Netherlands, Sweden, United States of America (USA), United Kingdom (UK)	Historical analysis	To describe the development of HTA in Netherlands, Sweden, UK, and USA
5.	(Banta, 2009)	Argentina, Brazil, Chile, Cost Rica, Colombia, Cuba, Mexico, Panama, Paraguay, Peru, Trinidad and Tobago, & Uruguay	Historical analysis	To describe the development of HTA in the Caribbean and the Latin America
6.	(Banta et al., 2009)	Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia,	Historical analysis	To provide a summary of the experiences with health technology assessment at the European level

		Netherlands, Norway, Poland, Scotland, Spain, Sweden, Switzerland, UK,		
7.	(Banta and Almeida, 2009)	Brazil	Authors' experiences and document review	To describe current and historical activities towards the development of HTA in Brazil.
8.	(Banta and Oortwijn, 2009)	Netherlands	Individuals' experiences and, documents and media reviews	To describe the history of HTA in Netherlands
9.	(Battista et al., 2009)	Canada	Historical analysis	To document the history of HTA in Canada
10.	(Bos, 2000)	Netherlands	Historical analysis	To describe HTA development in the Netherlands
11.	(Callahan, 2012)	USA	Case study	To demonstrate the intertwining of ethics and politics in the implementation of HTA in the USA
12.	(Carlsson, 2004)	Sweden	Historical analysis	To describe HTA development in Sweden
13.	(Chen et al., 2009)	China	Authors' experience.	To review HTA development in China

			Literature review, website searches	
14.	(Chinitz, 2004)	Denmark, France, Sweden, and UK,	Political analysis	To examine HTA in Denmark, France, Sweden, and UK from a political science perspective
15.	(Ciani et al., 2012)	Italy	Interviews and document reviews	To review the state of HTA in Italy based on central and regional initiatives
16.	(Cleemput and Van Wilder, 2009)	Belgium	Document reviews (legal documents and reports)	To provide an overview of HTA in Belgium
17.	(Corabian et al., 2005)	Romania	Stakeholder discussions	To document the experience of a HTA mentorship program in Romania
18.	(Csanádi et al., 2019a)	Ukraine	Survey	To assess the status of HTA implementation in Ukraine
19.	(Csanádi et al., 2019b)	Hungary	Interviews	To demonstrate the influence of institutional context on HTA development in Hungary.
20.	(Danguole, 2009)	Lithuania	Historical analysis	To describe development of HTA structures in Lithuania

21.	(Darawsheh and Germeni, 2019)	Kuwait	Interviews	To explore barriers and facilitators to implementing HTA in Kuwait
22.	(Dilmaç et al., 2012)	Turkey	Document review	To share the experience of the process of institutionalizing HTA in Turkey
23.	(Doaee et al., 2012)	Iran	Document review and observations	To describe the establishment of HTA in Iran
24.	(Downey et al., 2017)	India	Historical analysis	To report on the progress towards institutionalization of HTA in India
25.	(Drummond and Banta, 2009)	UK	Document reviews and personal experiences	To describe the development and present situation of HTA in the UK
26.	(Favaretti et al., 2009)	Italy	Historical analysis	To review the history of HTA in Italy.
27.	(Fleurette and Banta, 2000)	France	Historical analysis	To describe HTA development in France.
28.	(Fricke and Dauben, 2009)	Germany	Historical analysis	To describe HTA development in Germany.
29.	(Gibis et al., 2001)	Estonia	Workshop	To apply the Strength, Weakness, Opportunities and Threat (SWOT)

				framework to study HTA development in Estonia.
30.	(Gómez-Dantés and Frenk, 2009)	Mexico	Historical analysis	To examine the history of HTA in Mexico
31.	(Granados et al., 2000)	Spain	Historical analysis	To document HTA development in Spain
32.	(Gulácsi et al., 2009)	Hungary	Historical analysis	To describe the history, role and challenges facing HTA in Hungary.
33.	(Gulácsi et al., 2014)	Bulgaria, Czech Republic, Hungary, Poland, Romania	Historical analysis	To evaluate HTA developments in the field of HTA to date in 5 Central and Eastern European countries with a focus on its institutionalization, standardization of methodology, use of HTA in practice and capacity building
34.	(Hailey, 2009)	Australia	Document review	To describe the development and application of HTA in Australia
35.	(Hisashige, 2009)	Japan	Historical analysis	To document the history of HTA development in Japan
36.	(Hollingworth et al., 2019)	Ghana	Case study	To summarize key insights on HTA implementation in Ghana



37.	(Huic et al., 2017)	Croatia	Document reviews	To provide a history of HTA implementation in Croatia
38.	(Jaramillo et al., 2016)	Colombia	Interviews	To identify barriers and facilitators for HTA development in Colombia.
39.	(Jain et al., 2014)	India	Interviews	To explore stakeholders' knowledge, positions, and interests with regards to HTA in the Indian health system'
40.	(Jonsson and Banta, 1994)	Sweden	Historical analysis	To describe development of HTA in Sweden
41.	(Jonsson, 2009)	Sweden	Historical analysis	To describe development of HTA in Sweden
42.	(Jørgensen et al., 2000)	Denmark	Document reviews and interviews	To describe HTA development in Denmark
43.	(Kahveci et al., 2017)	Turkey	Document reviews	To identify changes leading to formalization of HTA
44.	(Kamae et al., 2020)	Japan	Document reviews and expert input	To document development of HTA in Japan and challenges facing it
45.	(Kim, 2009)	South Korea	Document review and personal communication	To analyze evolution of HTA in South Korea

46.	(Kim et al., 2021)	Bhutan, Kenya, Thailand, and Zambia	Discussion	To identify challenges towards institutionalization of HTA in Bhutan, Kenya, Thailand, and Zambia
47.	(Kuchenbecker and Polanczyk, 2012)	Brazil	Authors' experiences	To analyse HTA development in Brazil including challenges towards institutionalizing HTA.
48.	(Lavín et al., 2017)	Chile	Interviews	To describe beliefs of stakeholders with respect to HTA and its institutionalization in a sample of stakeholder representatives in Chile.
49.	(Lee et al., 2021)	Vietnam	Interviews	To evaluate progress towards development of HTA in HTA in Vietnam
50.	(Leelahavaring et al., 2019)	Thailand	Document reviews and authors experiences	To explore institutionalization of HTA in Thailand
51.	(Liaropoulos and Kaitelidou, 2000)	Greece	Historical analysis	To document history of HTA in Greece

52.	(Liu et al., 2020)	China, Japan and, South Korea	Case studies	To provide an overview of HTA development in China, Japan, and South Korea
53.	(Löblová, 2018a)	Czech Republic and Poland	Document analysis and interviews	To explore the mechanisms through which epistemic communities influence adoption of policies on HTA.
54.	(Löblová, 2018b)	Czech Republic	Interviews	To establish the interests and policy positions of key health policy stakeholders regarding the creation of a HTA agency in Czech Republic, and what considerations influenced them.
55.	(Luce and Cohen, 2009)	USA	Document reviews	To describe and explore the reasons for the current health technology assessment (HTA) landscape in the USA
56.	(MacQuilkan et al., 2018)	China, India, and South Africa	Case study	To identify problems and shareable insights on HTA by assessing and comparing HTA journeys in China, India, and South Africa
57.	(Menon and Stafinski, 2009)	Canada	Historical analysis	To describe HTA development in Canada over a period of 20 years

58.	(Mohtasham et al., 2016)	Iran	Interviews	To identify the barriers in the process of preparing, utilizing, and implementing HTA in Iran.
59.	(Mueller, 2020)	South Africa	Document review and survey	To investigate challenges facing implementation and utilization of HTA in South Africa
60.	(Németh et al., 2017)	Hungary	Document review and authors' experiences	To describe the process of implementing HTA in Hungary and the challenges facing it.
61.	(Olyaeemane sh et al., 2014)	Iran	Document reviews and questionnaire	To investigate challenges facing Iran's HTA system
62.	(Perleth et al., 2009)	Germany	Document reviews and personal experiences	To describe HTA development in Germany since the 1990s'
63.	(Raftery and Powell, 2013)	UK	Document review	To discuss UK's HTA programme
64.	(Pwee, 2009)	Singapore	Historical analysis	To describe HTA in Singapore
65.	(Rajan et al., 2011)	Argentina, Australia, Austria, Belgium, Bolivia, Brazil, Canada, Chile, Denmark, Ecuador, Finland, Germany, India, Iran, Ireland, Israel, Italy, Jordan,	Survey	To identify barriers, enablers, and motives for HTA establishment across countries of different income levels

		Lithuania, Malaysia, Mexico, Netherlands, New Zealand, Norway, Pakistan, Panama, Peru, Republic of Korea, Spain, Sweden, Switzerland, Thailand, UK, USA, and Venezuela,		
66.	(Roza et al., 2019)	Malaysia	Document review	To describe the evolution of HTA in Malaysia
67.	(Sampietro-Colom et al., 2009)	Spain	Survey	To describe the introduction and diffusion of HTA in Spain
68.	(Sharma et al., 2020)	Indonesia	Document reviews, observation, and stakeholder discussions	To identify conducive factors for the development of HTA in Indonesia
69.	(Shemer et al., 2009)	Israel	Historical analysis of authors' knowledge and published literature	To describe the history and present situation of HTA in Israel
70.	(Shi et al., 2017)	China	Document reviews, webpage searches and institutional survey	To review the status of HTA in China and analyse the challenges of HTA development in the context of health reform.

71.	(Sigmund and Kristensen, 2009)	Denmark	Document review	To describe the strategy, implementation, and development of HTA in Denmark
72.	(Sivalal, 2009)	Australia, Bangladesh, Bhutan, Brunei, Cambodia, Hong Kong, Korea, Laos, India, Indonesia, Iran, Taiwan, Malaysia, Maldives, Mongolia, Nepal, New Zealand, Philippines, Pakistan, Singapore, Sri Lanka, Thailand, Vietnam	Historical accounts and author's knowledge	To describe HTA development in the Asia pacific region
73.	(Surgey et al., 2019)	Tanzania	Situational analysis	To describe the journey of the introduction of HTA into decision-making processes using the National Essential Medicines List in Tanzania as a case study.
74.	(Tamir et al., 2008)	Israel	Historical analysis	To describe the evolution of HTA in Israel
75.	(Teerawattanon et al., 2009)	Thailand	Document review (domestic and international literature)	To review the development of HTA, including the socioeconomic context, outputs, and policy utilization in Thailand
76.	(Wild, 2009)	Austria	Historical analysis	To describe the implementation of HTA in Austria

77.	(World Health Organization, 2015)	Afghanistan, Albania, Armenia, Australia, Austria, Azerbaijan, Bangladesh, Barbados, Bahrain, Belarus, Belgium, Benin, Bhutan, Brazil, Bulgaria, Cambodia, Cameroon, Canada, Cape Verde, Central African Republic, China, Colombia, Comoros, Cost Rica, Cote d'Ivoire, Croatia, Cuba, Cyprus, Czech Republic, Denmark, Democratic Republic of Congo, Ecuador, Egypt, Eritrea, Estonia, Ethiopia, Fiji, Finland, Georgia, Germany, Ghana, Guatemala, Hungary, Iceland, India, Indonesia, Iran, Iraq, Italy, Jamaica, Japan, Jordan, Latvia, Lebanon, Libya, Lithuania, Luxembourg, Kazakhstan, Kenya, Kiribati, Korea, Laos, Macedonia, Madagascar, Mali, Malta, Maldives, Malaysia, Mexico, Micronesia, Moldova, Monaco, Montenegro, Mozambique, Nauru, Nepal, Netherlands, New Zealand, Norway, Peru, Philippines, Poland, Portugal, Qatar, Romania, Russian Federation, San Morino, Saint Vincent and Grenadines, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, Somalia, South Africa, Spain,	Survey	To measure capacity for HTA, governance of the HTA process and, utilization of HTA in WHO member states.
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		Sri Lanka, Sweden, Switzerland, Sudan, Syrian Arab Republic, Tanzania, Thailand, Timor-Leste, Trinidad and Tobago, Turkey, Tuvalu, UK, USA, Vietnam		
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## Appendix 3: - LSHTM Research ethics approval

### London School of Hygiene & Tropical Medicine

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#### Observational / Interventions Research Ethics Committee

Dr Rahab Mbatia  
LSHTM

11 June 2021

Dear Dr Rahab Mbatia

**Study Title:** Examining macro-level healthcare priority-setting practices for Universal Health Coverage by the Ministry of Health in Kenya.

LSHTM Ethics Ref: 25640

Thank you for responding to the Observational Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

#### Confirmation of ethical opinion

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

#### Conditions of the favourable opinion

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

#### Approved documents

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

Document Type	File Name	Date	Version
Other	Prof Edwine Barasa Ethics certificate	24/10/2019	1.0
Other	Prof Anna Vassal Ethics Certificate	07/11/2019	1.0
Other	Prof Kathryn Oliver Ethics Certificate	13/11/2019	1.0
Local Approval	KEMRI-SERU Approval	29/06/2020	1.0
Local Approval	Research_Permit_NACOSTI	20/08/2020	1.0
Other	Rahab Mbatia Ethics certificate LSHTM	22/08/2020	1.0
Investigator CV	Rahab Mbatia CV	27/03/2021	1.0
Investigator CV	Prof Kathryn Oliver CV	27/03/2021	1.0
Investigator CV	Prof Anna Vassall CV	27/03/2021	1.0
Investigator CV	Prof Edwine Barasa CV	27/03/2021	1.0
Protocol / Proposal	LSHTM Interview topic guide R Mbatia 2021	27/03/2021	1.0
Protocol / Proposal	LSHTM Data extraction table for document review R Mbatia 2021	27/03/2021	1.0
Information Sheet	LSHTM Participant Information Sheet R Mbatia 2021	27/03/2021	1.0
Information Sheet	LSHTM consent form R Mbatia 2021	27/03/2021	1.0
Advertisements	Email invitation for indepth interviews	27/03/2021	1.0
Covering Letter	Cover Letter LSHTM Ethics v1 9th June 2021	09/06/2021	1.0
Protocol / Proposal	LSHTM Protocol R Mbatia 2021 v2 9th June 2021	09/06/2021	2.0
Local Approval	KEMRI-WELL/COME TRUST Payment guidelines for stakeholders	09/06/2021	1.0

After ethical review

## Appendix 4: - KEMRI Research ethics approval



# KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840-00200, NAIROBI, Kenya  
Tel: (254) 2722541, 2713349, 0722-205901, 0733-400003, Fax: (254) (020) 2720030  
Email: [director@kemri.org](mailto:director@kemri.org), [info@kemri.org](mailto:info@kemri.org), Website: [www.kemri.org](http://www.kemri.org)

**KEMRI/RES/7/3/1**

**June 15, 2021**

**TO: RAHAB MBAU  
PRINCIPAL INVESTIGATOR**

**THROUGH THE DEPUTY DIRECTOR, CGMR-C  
KILIFI**

Dear Madam,

**RE: KEMRI/SERU/CGMR-C/185/4018 (REQUEST FOR ANNUAL RENEWAL):  
EXAMINING MACRO-LEVEL HEALTHCARE PRIORITY-SETTING  
PRACTICES FOR UNIVERSAL HEALTH COVERAGE BY THE MINISTRY OF  
HEALTH IN KENYA.**

Thank you for the continuing review report for the period **June 29, 2020, to May 12, 2021**.  
The Committee acknowledges receipt of the following documents:

- a) Current approved protocol and data collection tools.
- b) SERU approval letter.
- c) CRR form.

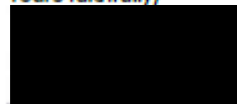
The Expedited Review Team noted that a protocol deviation form has been submitted as the request for annual renewal was done after the expiration date of the last approval. Measures taken to address deviation are adequate.

This is to inform you that the Expedited Review Team of the KEMRI Scientific and Ethics Review Unit (SERU) was of the informed opinion that the progress made during the reported period is satisfactory. The study has therefore been granted **approval** for continuation.

This approval is valid from **June 29, 2021**, through to **June 28, 2022**. Please note that authorization to conduct this study will automatically expire on **June 28, 2022**. If you plan to continue with data collection or analysis beyond this date, please submit an application for continuing approval to the SERU by **May 17, 2022**.

You are required to submit any proposed changes to this study to SERU for review and the changes should not be initiated until written approval from SERU is received. Please note that any unanticipated problems resulting from the implementation of this study should be brought to the attention of SERU and please, inform SERU when the study is completed or discontinued. You may continue with the study.

Yours faithfully,



**PROF. CHARLES OBONYO  
THE ACTING HEAD  
KEMRI SCIENTIFIC AND ETHICS REVIEW UNIT**

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In Search of Better Health

## Appendix 5: - LSHTM Research Ethics training certificate



**This is to certify that**  
**Rahab Mbau**

successfully completed the

**Research Ethics**

e-learning course

with a score of

90.00 %

Comprising of modules covering:

- Introduction to the History of Research Ethics
- Fundamental Ethical Principles, including:
  - Respect for persons
  - Beneficence
  - Justice
- Responsibilities of Research Ethics Committees
- Understanding Vulnerability
- Privacy and Confidentiality

On

August 22, 2020

Provided by

London School of Hygiene & Tropical Medicine

This course meets the requirements for protection of human subjects training required by individuals involved in the design and/or conduct of National Institutes of Health (NIH) funded human subjects research.

## Appendix 6: - Interview topic guide

**Study Title:** A critical examination of the policy process, implementation, and institutionalization of explicit healthcare priority-setting at the macro-level in Kenya.

<b>Interview number</b>	
<b>Date of interview</b>	
<b>Type of stakeholder</b>	

### Introduction

I am carrying out a study to understand what led to the establishment of the Health Benefits Package Advisory Panel (HBPAP) and how this panel carried out its work, as well as plans to institutionalize health technology assessment (HTA) as an explicit and systematic approach for healthcare priority-setting in Kenya.

#### **I will start by asking you questions about why HBPAP was gazetted**

1. What healthcare priority-setting problems led to the emergence of the policy idea on HBPAP given its main mandates?
  - Who identified these problems and how did they identify them?
2. Who was involved in developing the policy idea on HBPAP?
  - What alternative policy ideas did they consider alongside HBPAP?
3. How would you describe the political context surrounding the problems and the development of the policy idea on HBPAP?
  - What administrative or legislative changes influenced these streams?
4. What window (s) of opportunity(ies) led to the gazettement of HBPAP?
5. Which actor(s) were instrumental in advocating for HBPAP during the window of opportunity?

#### **I am now going to ask you questions about how HBPAP conducted its work**

1. How transparent was HBPAP's priority-setting process for developing the health benefits package?
  - *how was the process made public?*
  - *What factors influenced the level of transparency and publicity of HBPAP's priority-setting process?*
2. What evidence and criteria did HBPAP use in its process?
  - *What were the sources of these criteria and evidence?*
  - *What factors influenced the use of criteria and evidence?*
3. How were HBPAP members involved in the process for HBP development?
  - *What factors influenced their level of involvement?*
  - *What was their level of understanding and acceptance of this process?*
4. Which external stakeholders were involved in HBPAP's process for HBP development?
  - *How were they involved?*
  - *What factors influenced their level of involvement?*

- *What was their level of understanding and acceptance of this process?*
5. What mechanisms existed for stakeholders to review or challenge the recommendations and decisions made with regards to the health benefits package?
    - *How did these mechanisms work?*
    - *What factors influenced these appeals and revisions mechanisms?*
  6. What was the influence of HBPAP's process on health policy and allocation of resources in the health sector?
    - *What factors supported or hindered this influence?*
  7. What factors supported or hindered HBPAP's healthcare priority-setting process?

**I am now going to ask you questions about plans to institutionalize HTA in Kenya.**

1. What factors are influencing (supporting or hindering) institutionalization of HTA in Kenya? Probes-
  - *Availability of organizational resources? (e.g., human resources, financial resources, information resources)*
  - *Availability of legal frameworks, policies, and guidelines for HTA?*
  - *Availability of learning and advocacy for HTA (e.g., capacity building initiatives and HTA awareness creation activities)*
  - *Availability of collaborative support for HTA (e.g., international collaboration, involvement of bilateral and multi-lateral agencies)*
  - *Stakeholder-related factors such as stakeholders' interests and awareness*
2. What strategies can be put in place to support institutionalization of HTA in Kenya?

## Appendix 7: - Participant information sheet for in-depth interviews

**Study Title:** A critical examination of the policy process, implementation, and institutionalization of explicit healthcare priority-setting at the macro-level in Kenya.

**Lay title:** Examining how the Ministry of Health in Kenya introduces, conducts, and establishes processes for allocating resources for healthcare services as a norm at the national level in Kenya.

### *Introduction*

I would like to invite you to take part in a research study. Joining the study is entirely up to you. Before you decide, you need to understand why the research is being done and what it would involve. I will go through this information sheet with you and answer any questions you may have or clarify anything that may not be clear. Please feel free to talk to others about the study if you wish. Take time to decide whether to take part.

### *What is the purpose of this study?*

In this study, I want to understand how the Ministry of Health in Kenya introduces, conducts, and establishes processes for allocating resources for healthcare services as a norm at the national level in Kenya. I will use the Health Benefits Package Advisory Panel (henceforth the Panel) and Health Technology Assessment as examples.

### *Who is organising and funding the research?*

I am a PhD student at the London School of Hygiene and Tropical Medicine (LSHTM). This study is funded by Commonwealth Scholarship Commission in the UK. LSHTM has full responsibility for the project including looking after the information obtained during the study, using it properly, and monitoring the study.

### *Why have I been asked to take part?*

You have been invited to take part because you are in a good position to help me understand the process of resource allocation for health services conducted by the Ministry of Health due to your role and experience as a stakeholder at the national level.

### *Do I have to take part?*

No. It is up to you to decide to take part or not. If you don't want to take part, that is ok. There will be no negative repercussions for this. If you agree to take part, I will discuss with you how you will be involved in the study and then ask you to sign a consent form of which you will keep a copy.

### *What will I have to do if I take part?*

Once you provide consent, I will ask you questions and listen to your ideas and opinions on what led to the establishment of the Panel, how well the Panel conducted its functions and what factors are influencing institutionalization of this process in Kenya. The discussion will take about an hour, and it will be done via face-face or zoom videoconferencing at a place and time of your convenience. Only you and I will be present unless you indicate otherwise. If you chose face-face interviews, you and I will be required to adhere to Covid-19 risk mitigation strategies given the current global pandemic. These strategies include: - wearing of masks, regular handwashing/ sanitization, maintaining social distancing and being in an open and well-ventilated room. Approximately 50 stakeholders from the national level will be involved in the study. We wish to audio record and take notes of the discussions with your consent.

### *What are the possible risks or disadvantages to me of taking part?*

There are no physical risks to you. I acknowledge that your discussions, responses, and opinions with regards to how the Ministry makes decisions on allocation of resources may be confidential and sensitive. I will ensure that no personally identifying information will be collected or used in the study outputs.

Participants who choose to participate in virtual interviews via zoom videoconferencing will be compensated for internet bundles spent to attend the interview according to the KEMRI Wellcome Trust Research Program reimbursement policies. The reimbursement rates outlined in these policies indicate that for a virtual meeting lasting between 1-2hours, participants will be provided with a compensation of 250 Kenya shillings to purchase 1GB of data. There will be no compensation for face-face interviews as this will be held at a place and time of your convenience.

*Are there any advantages to me for taking part?*

There are no direct benefits to you. However, the information you provide will help our knowledge and understanding of this research area on how the Ministry of Health in Kenya makes choices and decisions on the allocation and distribution of resources for the health sector. This may help Kenyan policy makers to develop better policies towards improving resource allocation decisions at the national level.

*Can I change my mind about taking part?*

Yes. You can withdraw from the study at any time. You just need to tell me that you don't want to be in the study anymore without any negative implications. If you withdraw from the study, I will destroy all your tape-recorded interviews, but I may need to use the data collected on you up to your withdrawal.

*What will happen to information collected from me?*

All information collected through the interviews will be kept private: only the study team will have access to the audio-records. These audio-records will be destroyed immediately after they have been converted into written form (transcripts) in keeping with LSHTM policies. The data in the transcripts will be anonymised. This means that any information about you (e.g., your name, professional information etc) will be removed so that you cannot be recognised, and your data will have a code number instead. All the transcripts will be stored securely in password protected databases and destroyed within 10 years of the end of the study. Relevant quotes obtained from the information you provide will be used to write up publications in the form of thesis, scientific journals, presentations, and policy briefs so that other researchers and policy makers can learn from them.

*Where can you find out more about how your information is used?*

You can find out more about how we use your information: -

- At <https://www.lshtm.ac.uk/files/research-participant-privacy-notice.pdf>
- by asking one of the research team members
- by sending an email to [DPO@lshtm.ac.uk](mailto:DPO@lshtm.ac.uk)

*Who has reviewed this study?*

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by LSHTM Research Ethics Committee (Ref: 25640) and Kenya Medical Research Institute- Scientific and Ethics Research Unit (KEMRI- SERU) (Ref: KEMRI/SERU/CGMR-C/185/4018). SERU is a unit within KEMRI that ensures that all study

protocols involving human subjects adhere to scientific and ethical principles to protect the rights and welfare of human participants. SERU must agree that the research is important, relevant to Kenya and follows nationally and internationally agreed research guidelines.

*Further information and contact details*

Thank you for taking time to read this information sheet. If you think you will take part in the study, please read, and sign the consent form. If you would like any further information, please contact: -

Rahab Mbau, PhD candidate

Email address: [rahab.mbau@lshtm.ac.uk](mailto:rahab.mbau@lshtm.ac.uk). Tel +254 715 265839

If you have concerns about the study, you can contact LSHTM

Postal address: London School of Hygiene and Tropical Medicine, 15-17 Tavistock Place  
London WC1H 9SH, UK.



## Appendix 8: - Consent form for in-depth interviews

1 **Title of the project:** A critical examination of the policy process, implementation, and  
 2 institutionalization of explicit healthcare priority-setting at the macro-level in Kenya.

3 **Name of researcher:** Rahab Mbau

4

Statement	Please initial each box
I confirm that I have read and understood the information sheet dated.....(version.....) for the above named study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily.	
I understand that my consent is voluntary and that I am free to withdraw this consent at any time without giving any reason and without my legal rights being affected.	
I understand that the data about me or from me will not be shared via a public data repository or with other researchers and that I will not be identifiable from this information	
I give permission for you to record our discussion and transcribe the recording for data analysis	
I understand that the researcher may use anonymised quotes or descriptions in the research outputs (e.g., presentations and publications)	
I agree to take part in the above-named study	

5

6 Participant's signature..... Date.....

7

8 Researcher's signature..... Date.....