TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

CQ	Chloroquine
CIHR	Canadian Institute of Health Research
DHS	Demographic and Health Survey
ECs	Ethical Committees
EBM	Evidence-based medicine
EVIPNet	Evidence Informed Policy Network
EBP	Evidence-based practice
EBPM	Evidence-Based Policy Making
HPSR	Health Policy and Systems Research
ITNs	Insecticide Treatment Nets
IEC	Information, Education and Communication
IRS	Indoor residue spraying
IPTp	Intermittent Preventive Treatment for Malaria in Pregnancy
IPTp-SP	Intermittent Preventive Treatment in pregnancy with Sulfadoxine-pyremethamine
KT	Knowledge translation
KTPs	Knowledge Translation Platforms
LA	Lumefantrine-artemether
LMICs	Low- and Middle-Income Countries
MOH	Ministry of Health
NMCP	National Malaria Control Programme
ODPRN	Ontario Drug Policy Research Network
SP	Sulfadoxine-pyrimethamine
TUMS	Tehran University of Medical Sciences
WHO	World Health Organization

CHAPTER ONE

1.0 GENERAL INTRODUCTION

1.1 Introduction

Malaria remains one of the major causes of high morbidity and mortality in Africa despite global and national efforts to curb it.[1] In 2015, it was estimated that 214 million cases of malaria and 429 000 deaths due to the disease occurred globally, of which more than 90% were from the African region.[2] However, malaria mortality decreased in children under the age of five, from 723 000 in 2000 to 306 000 in 2015. The African region registered a huge decrease from an estimated 694 000 deaths to 292 000 deaths during that period. Malawi is one of the sub-Sahara African countries where malaria is endemic, mainly affecting children under the age of five and pregnant women. It is estimated that about six million cases are reported annually in Malawi, with 40% of all the hospitalization being children under the age of five years and 29% of all outpatients across all ages are due to malaria.[3] *Plasmodium falciparum* is the major parasite cause of malaria infection, contributing approximately 98% of all malaria infections, with the remaining 2% due to *Plasimodium ovale, Plasmodium malariae* and *Plasmodium vivax*. The primary vectors of *Plasmodium* parasites in Africa are mosquitoes belonging to the species *Anopheles gambiae* s.s., *An. Arabiensis and An. funestus.*[3]

For the past three decades, Malawi has made significant movement towards preventing and controlling malaria in the country. An organized approach in addressing the burden of malaria begun in 1984 when the first National Malaria Control Programme (NMCP) was established, with the mandate to develop the national malaria policy to guide and coordinate the implementation of malaria interventions.[4] Over the years the policy has undergone important transformation. The current policy vision is to eliminate malaria in the country, through the mission of reducing the malaria burden to a level of no public significance.[5] This policy is supported by various specific policies and guidelines, which take into consideration the local epidemiological and policy contexts, including: the Malaria Vector Control Strategy 2015-2019; National Malaria Monitoring and Evaluation Plan 2007-2011 (2007); National Malaria Treatment Guidelines (2007); National Malaria Communication Strategy (2009); Guidelines for Indoor Residual Spray (2008); Trainers Manual on Case Management (2007); Guidelines for the Management of Insecticide Treatment

Nets (ITNs) Program (2007); Guidelines for Health Surveillance Assistants for Delivery of Sulfadoxine-Pyrimethamine for Intermittent Preventive Treatment (2006); Malawi Health Policy (under review); guidelines on pharmacovigilance (under development); and Guidelines for malaria Rapid Diagnostic Testing (under development).[5] Collectively, these policies and guidelines speak to the need for intensified malaria control interventions in response to the continuing burden of the disease. These specific malaria control and treatment interventions are described below:

Health Promotion

Health promotion is the first primary prevention strategy for malaria in Malawi against both the vector and the parasite and done as part of Information, Education and Communication (IEC) strategy. The NMCP has made a substantial stride in providing public health awareness to the communities regardless of all forms of physical, terrain, cultural, religious and financial barriers. This is attributed to the intersectoral, community involvement and massive health promotion campaigns against malaria causes, transmission, prevention, symptoms and signs and prompt health seeking behaviour at all levels using any informal and formal population gatherings.[6]

Distribution and Usage of Long Lasting Insecticide Treated Nets (LLITNs)

The use of long lasting insecticide treated nets (LLINs) is another primary prevention strategy for malaria in Malawi especially in under five children and pregnant women, who are considered the most vulnerable populations.[7] Sleeping under LLINs is a proven method of preventing malaria. Evidence from research trials in Africa conducted before and until mid-1990s with support from the World Health Organization (WHO) has shown that "the lives of some 500,000 African children might be saved each year from malaria if the nets, treated with biodegradable pyrethroid insecticide, were widely and properly used".[8] The recent demographic and health survey in Malawi has revealed that 57% households own at least one LLIN, although only 24% have enough to cover each member of the household if one net is used by two people. The survey also revealed that more than 40% of children under five and pregnant women slept under a net two nights prior to the survey.[9] Although there has been an increase in net usage among children under the age of five from 39% in 2010 to 43% in 2015-16, and among pregnant women from

35% to 44% in the same period, this coverage does not reach the Abuja Declaration target of 60% by 2005, which was later changed to 80% by 2010.[9,10] This indicates the need for further efforts to be conducted.

Intermittent Preventive Treatment for Malaria in Pregnancy (IPTp)

Pregnant women are more susceptible to malaria compared to non-pregnant women and malaria can cause adverse pregnancy outcomes.[11] Intermittent preventive treatment for malaria in pregnancy (IPTp) is a primary preventive intervention against malaria parasite through chemoprophlaxis which is aimed at sustaining effective and potent anti-malarial blood level circulation during pregnancy.[12] In collaboration with the Reproductive Health Directorate (RHD) in the Ministry of Health (MOH), the NMCP has integrated IPTp intervention with a comprehensive antenatal care (ANC) package. Malawi's adapted policy on IPTp recommends the provision of at least three doses of Sulfadoxine-pyrimethamine (SP) during pregnancy.[13] The Demographic and Health Survey (DHS) has shown that 63% of women received two or more doses during their pregnancy two years prior to the survey, while only 30% reported to have received three or more doses,[9] which is also below the Abuja Declaration target of 60%.[14]

Indoor Residual Spraying (IRS)

Indoor residue spraying (IRS) is the application of a long acting insecticide on the interior walls of all houses and other shelters in a given area in order to kill the adult vector mosquitoes that land and rest on wall surfaces.[15] This is the latest and fourth primary malaria intervention to be adopted by the Malawi NMCP.[16] However, the rolling out of IRS has been very slow with only 5% of the households receiving IRS in the year preceding the survey.[9]

Malaria case management (MCM)

In the circumstances that the above primary preventive interventions are not fully implemented or have failed, transmission of malaria parasites continues, leading to an increase of malaria infections. When this happens, the NMCP policy emphasizes prompt diagnosis and treatment with lumefantrine-artemether (LA), an artemisin-based combination therapy (ACT), which has also been boosted by the introduction of malaria rapid diagnostic testing (MRDT) for quick

malaria diagnosis.[13] The DHS showed that 92% of children who reported of having fever two weeks prior to the survey were treated with LA.[9]

Tertiary Malaria management

Severe Malaria manifests clinically as normal malaria with at least a complication.[17] Malaria complications range from anaemia, cardiac failure, renal failure, liver failure, convulsions (cerebral malaria) as well as its sequelae leading to seizures, tropical spleen syndrome and death especially in under five children, to miscarriage (abortion), underweight neonates and death in pregnant mothers and neonates.[18] As a preventive measure, the NMCP in collaboration with Directorate of Clinical Services advocates for prompt effective treatment of uncomplicated malaria to prevent worsening into complications. If the severe form of malaria is reached, the recommended treatment is the administration of artesunate or quinine.[13]

In addition to these interventions the introduction of malaria vaccines is under exploration. The World Health Organization (WHO) announced the implementation of a malaria vaccine pilot programme in Ghana, Kenya, and Malawi commencing in 2018.[19] A vaccine candidate called RTS,S, also known as Mosquirix™, has shown great efficacy, safety, and tolerability during the Phase III trial,[20] hence the pilot studies assess its delivery feasibility in the real world setting.

The implementation of these interventions have contributed to the decrease of malaria prevalence in Malawi from 43% in 2010 to 33% in 2014.[21] But despite this achievement malaria remains a major health problem in Malawi that is ranked third in leading causes of mortality and disability in the country.[22]

1.2 Study rationale and significance

Development of malaria control policies requires a thorough understanding of critical issue that can potentially affect policy implementation. Malaria research can provide evidence that should play a very important role in policy development. While considerable research in malaria control and prevention is and has been conducted in Malawi, [23] there is a need to intensify on the utilisation of these research findings. One of the important areas to be considered in Malawi's health care is to focus on maximum utilisation of health research in malaria for policy

development. With the growing need for decision-makers to justify the basis of their decisions and be explicit, evidence for decision making becomes paramount.[24] In addition, a climate of increasing financial stringency makes it imperative to demonstrate that government investments in research are effective and providing value for money.[25] Evidence-based decisions are vital in the achievement of these policies through the improvement of leadership, management, and prudent resource allocation. There is also increasing recognition that investment in public health research needs to be justified by demonstrating its added value to the community. Furthermore, there is need to engage with stakeholder communities in illustrating the research process and the outcome of research and in demonstrating that research provides value to the community.

In Malawi, one of the challenges in public health is the lack of a systematic mechanism through which malaria research can be fully utilised for policy development. Unless research is commissioned by the government, individual researchers do not always know the pathway through which they can engage with the government and influence policy development. In addition, foreign researchers conduct malaria research in the country and present the findings externally, which in most cases is inaccessible to the ministry of health and guide decision making. Besides, if available, the findings may not be of much use because of little or no engagement with the NMCP, to incorporate their needs, in the research process. While some institutions or elements that promote health research in policy development exist, they remain fragmented and overwhelmed with all the health research in the country, offering little cohesive support.

This study aimed at developing a framework that promotes the utilisation of malaria research for policy development in Malawi. The framework will encourage the engagement of researchers and policymakers, and increase visibility and coordination of the existing elements promoting research utilisation for policy development with the focus on malaria. This should eventually lead to the development of evidence-based interventions to address the malaria burden, which is very critical to a resource limited country such as is the case in Malawi.

1.3 Study motivation

The evidence-based medicine approach, which focused initially on clinical decision-making, has more recently been extended to policy and management decisions, where it is sometimes referred to as 'evidence-based' or 'evidence-informed' policy making.[26-28] Increasingly, the use of global research evidence is being seen as a key component of policy making processes. Thus, it has been suggested widely that health goals are more likely to be achieved by policies that are informed by rigorous research evidence.[29] The evidence-informed policy-making approach suggests that research evidence from the evaluation of health care interventions, particularly evidence from systematic reviews of randomized controlled trials (RCTs), is the most robust form of evidence for informing policy decisions about the allocation of resources to services or programmes as well as decisions on how to deliver and finance these services.[26,30,31] However, there is still uncertainty on how research evidence is used by policy makers and on how best to ensure that available knowledge is translated into policies and actions. Knowledge translation, defined as the "exchange, synthesis, and effective communication of reliable and relevant research results"[32] is particularly pertinent in low- and middle-income countries (LMICs). These countries are known for their poverty stricken situations as they continue being faced with the problem of scarce resources as well as high disease burden.[33] Effective and affordable interventions are available for many of the health problems contributing to the disease burden in these countries but often these interventions are not implemented or are discarded in favour of less proven interventions. Despite the availability of evidence to support the effective interventions, it has not led to the automatic translation of research evidence into policy-making.[29,34,35] This has led to a growing attention being paid to knowledge translation in global health.[35-37] Studies suggest that the relationship between knowledge production (research that generates evidence) and knowledge translation is complex[38,39] with a multitude of factors operating at the individual, organizational, systems and contextual levels.[40]

The socio-economic impact of research has become a central concern of the government agencies funding research.[28] While there are many opposing views on the worth of assessing research on its ability to give a "return on investment"– the research community cannot ignore that the shift to a more accountable management of tax-payer's contributions will, inevitably,

result in more pressure on research funding accountability.[41] While some in the research community might resent what they regard as 'interference' from central government, it can be viewed as a positive sign that governments believe in the significance of research and, therefore, want to develop the best tools to help determine where best to invest.[28] Justification for funding has to be established through measuring the impact of the funded research efforts.

The routes and mechanisms through which research is communicated to places where it can make a difference are many and varied. The ways in which research is then used are also complex. For example, research may directly influence changes in policy, practices and behaviour. Research may also, in more subtle ways, change people's knowledge, understanding and attitudes towards social issues. Tracking these subtle changes is difficult, but is perhaps more important in the long run. Additional problems include: knowing *where* to look for research impacts, i.e. who are the research users?; knowing *when* to look for these impacts, i.e. how long is sufficient for research to take effect?; and knowing *how* to assess the specific contributions made by the research, i.e. was the research really the key factor in any changes observed?.[39]

As health care costs continue to rise, policy makers need to examine successful disease intervention approaches and to utilise research findings when allocating limited country's resources.

1.4 Research objectives

Overall objective:

To develop a framework for promoting the utilisation of malaria research for policy development in Malawi.

Specific objectives

The specific objectives were:

(a) To determine the type and amount of malaria research conducted in Malawi and its related source of funding from 1984 to 2016;

(b) To explore the influence of malaria research on malaria policy development and review the policy making process in Malawi;

(c) To assess the facilitating factors and barriers to malaria research utilisation for policy development in Malawi;

(d) To examine barriers to the implementation of malaria policies in Malawi.

(e) To develop a framework for the promotion of malaria research utilisation for policy development in Malawi;

1.5 PhD study conceptual framework

A conceptual framework is a map for the researcher that proposes relationships and links of various elements or concepts guiding the research process, with the purpose of providing a reference point for organised thinking and research focus for easy interpretation of the study.[42,43] Figure 1.1 presents the framework that illustrates the focus of this study. It highlights how the objectives are linked to the final product of the research. It also presents how the final product can complete the loop in identifying further research needs.

The initial step of the study was to establish the availability of malaria research conducted in Malawi when the first NMCP was established in 1984 to 2016 when this study was being conducted. This assessment led to the examination, through case studies, of how the research has contributed to malaria policy development and also learn about the policy making process in Malawi. In addition, the study sought to explore the existing facilitating factors and barriers to malaria research utilization for policy development in Malawi. Lessons from the case studies and the assessment of facilitating factors and barriers lead to the development of a contextual framework to promote utilisation of malaria research for policy development. The framework provides guidance to researchers if they wish to contribute to the policy process and for policymakers to seek for evidence during policy decision making. Development of evidence-based policies is a starting point for research utilization but the main impact should be the improvement of public health. Thus, a crucial stage rests on the implementation of these policies, which has always faced challenges restricting the realisation of policy intents.[44] This study further

examined some of the challenges during the implementation of malaria policies in Malawi. This will not only lead to development of strategies to address the challenges but generate knew knowledge to guide policy development and make policymakers understand that policy development and implementation are interactive processes.

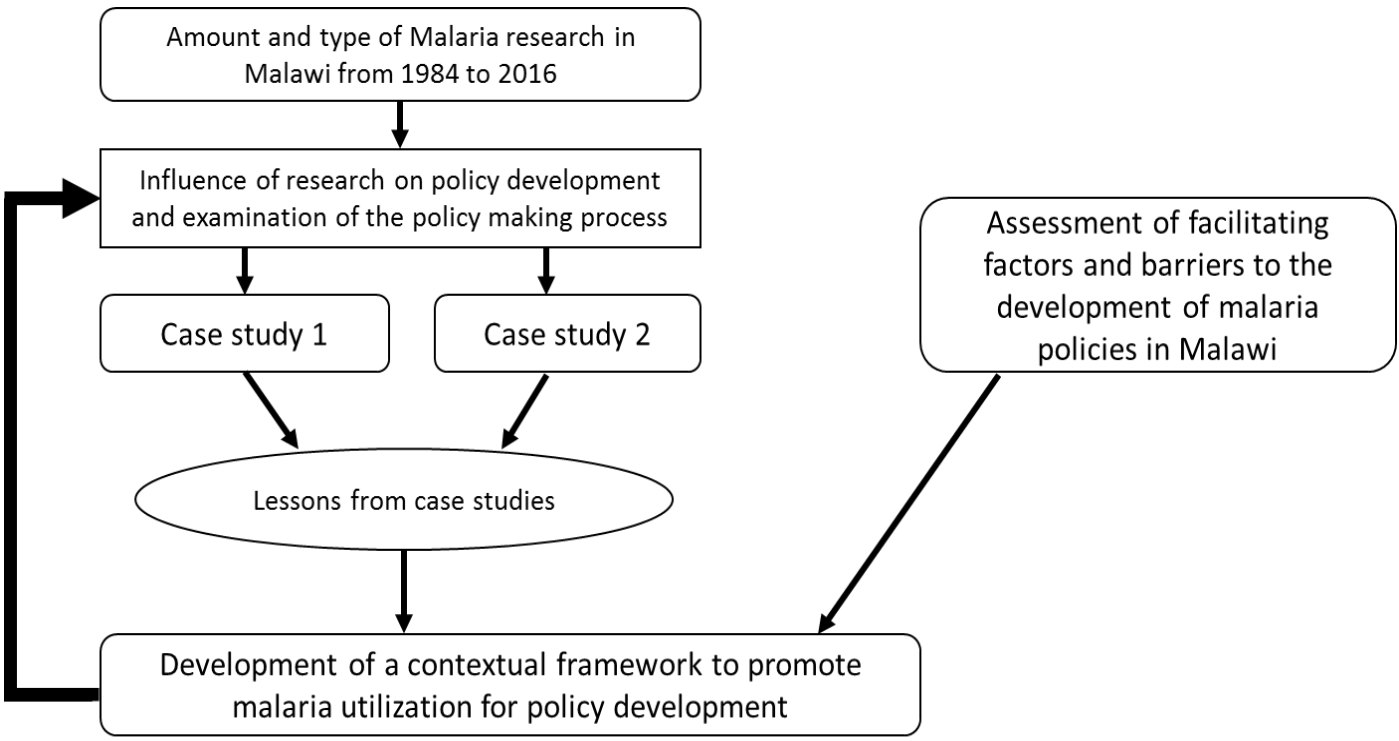

Figure 1.1: Study conceptual framework

1.6 Study setting and population

Setting

The study was conducted in Malawi, a landlocked country located in the South eastern region of Africa that is bordered by Zambia to the West, Mozambique to the South East and West, and Tanzania to the North East (Figure 1.2) and table 1.1 presents some basic demographic and health indicators.

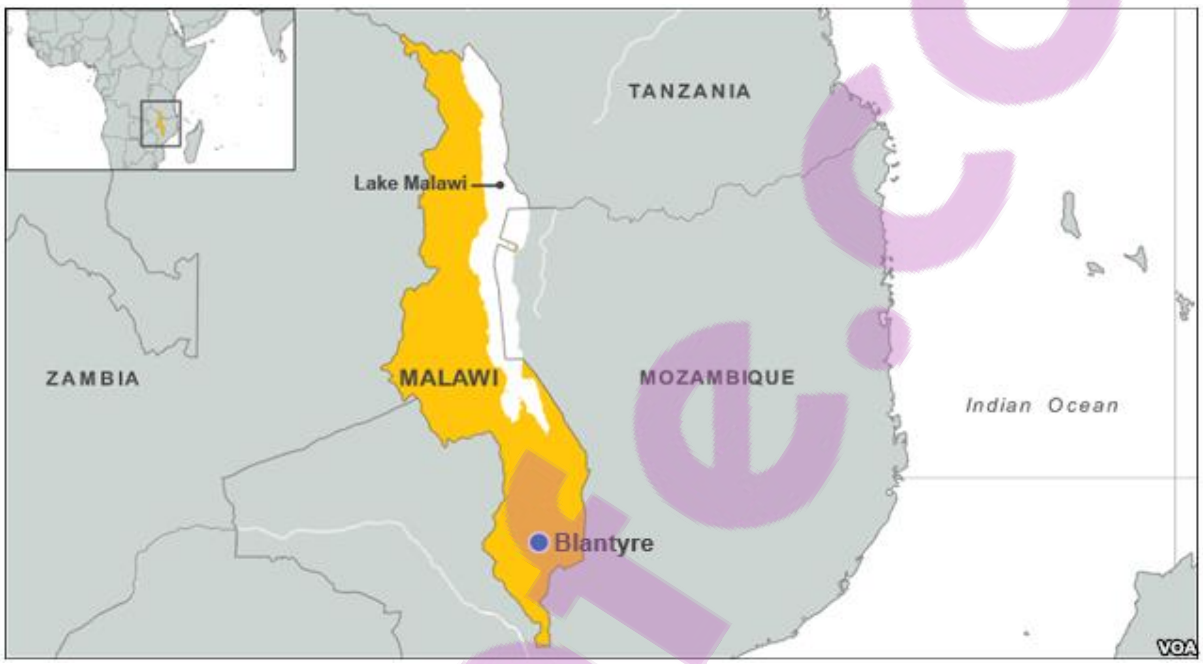

Figure 1.2: Map showing the location of Malawi

Table 1.1: Basic health and demographic indicators for Malawi

Indicators	Measure
Total land area	119,310 km^2
Total population	Projected at 17.3 million in 2017
Population density	188/km^2
Total fertility rate	4.4
Maternal mortality ratio	439/100,000
Infant mortality rate	42/1000
Under-five mortality rate	63/1000
HIV prevalence	8.8% (10.8% women, and 6.4% men)
Life expectancy at birth	55 years for both men and women

Sources: Malawi Demographic and Health Survey 2015-16[9], United States Agency for International Development. President's Malaria Initiative: Malawi Malaria Operational Plan. 2017[3]

Study population

The population targeted for this study comprised of policymakers in Ministry of Health, Programme managers at the NMCP, malaria researchers in various institutions in Malawi, and all the relevant stakeholders identified. Therefore, purposive sampling and snowballing techniques were used in identifying participants of this study.

1.7 Methods and study design

The study utilised mixed methods including both quantitative and qualitative based on the study objectives. The specific approaches included were systematic literature search, record review, case studies, and in-depth interviews with key informants. Table 1.2 presents an overview of the research methods based on the study objectives, which are described further below:

Table 1.2: Overview of the study methods

STUDY PHASE	STUDY OBJECTIVE	METHOD (S)
Phase I	To determine the type and amount of malaria research conducted in Malawi and its related source of funding from 1984 to 2016	• Systematic literature search • Record review
Phase II Case studies	To explore the influence of malaria research on malaria policy development and understand the policy making process in Malawi	• Systematic literature search • Record review • In-depth interviews
Phase III	To assess the facilitating factors and barriers to malaria research utilisation for policy development in Malawi	• Record review • In-depth interviews
Phase IV	To examine barriers to the implementation of malaria policies in Malawi	• In-depth interviews
Phase V	To develop a framework for promoting malaria research utilisation for policy development in Malawi	• Lessons from Phases II and III • Stakeholders' feedback

Phase I

Type and amount of malaria research in Malawi and its related source of funding from 1984 to 2016

A systematic literature search was conducted in the Medline/PubMed database for Malawian publications on primary research and an examination of records of approved malaria studies from two Ethical Committees (ECs) in Malawi. Bibliometric analysis was utilised to capture the affiliations of first and senior/last authors, funding acknowledgements, while titles, abstracts and accessed full text were examined for research type. This objective is presented in the publication of chapter 3.

Phase II

Examination of malaria research influence on policy development, and the understanding of the policy making process in Malawi;

Policy analysis case studies were conducted to describe the interaction of various stakeholders in policy formulation, and the influence of research on the development of a particular policy. A case study approach in policy analysis, by utilizing qualitative research in which key informants involved in the policy process change are identified and interviewed in-depth, yields rich findings as it incorporates an understanding of interaction of various players in the health systems.[29,45] Some people question the reliability and reproducibility of the qualitative research approach. However, this can be improved by using strict research protocol guidelines through audio recording, transcription, and presenting the in-depth data extract in the final reports.[46] It also has to be borne in mind that qualitative research does not focus on population generalization but instead it can help readers to understand the concepts behind the research and be able to apply such concepts in another setting depending on the nature of the particular study.[47] Hence, it is vital to provide contextual factors so that readers can make judgment as to whether transferability to other settings can be possible.[48]

Case studies as described by Yin[49] "are in-depth investigations of a single instance of a phenomenon in its real-life context". Utilising the case study approach by asking vital questions has revealed to significantly improve the study value.[50] The in-depth interviews that are mostly

recommended for this approach[29] adopt broad, open-ended questions, which focus on describing the process of change, including the wider socio-political perspective in which the policy change occurred. The case studies, therefore, adopted a phenomenology approach, which seeks to understand the issues of a particular topic based on the lived experience of the participants.[51] In this regard key informants involved in the policy development or change were purposefully identified to share their experiences during the change. Open-ended questions to prompt the discussion were posed, such as: *"Can you please describe the process by which the policy change occurred in Malawi?"*

The Grounded theory was mostly utilised in the analysis of the case studies.[52] This theory works on an induction approach which starts from a general position and through the constant interaction, of the researcher with the data, themes emerge and a specific position or a theory grounded in the data is generated.[53]

Position of the researcher in the policy analysis

One of the critical issues to highlight in the policy analysis process is the position of the researcher as it may affect the accessibility of the policy setting and the ability to conduct significant research.[54] Basically there are two positions whereby a researcher can either be an insider or outsider. An insider is usually someone who may be the researcher but also part of the policy process.[50] Being an insider means easy access and the ability to collect relevant issues pertaining to the case, and easily relate the findings to the policy environment during analysis. However, the main challenges of being an insider lie on inherent biasness in the approach of data collection, and sometimes respondents may not be open enough to respond to sensitive questions. On the other hand, an outsider comes externally to examine the policy process and is not affiliated to the policy making set up. The outsider will hold an upper hand in probing for sensitive issues by being curious.

The position of the researcher taken in this policy analysis is that of an outsider. It is therefore, assumed that the researcher collected rich data as the respondents spoke freely on controversial issues, and the analysis made was less biased since the researcher objectively touched on all relevant aspects affecting the policy process, whether good or bad.[50]

The identification of case studies was done purposively to examine both treatment and prevention policies. The policies examined reflected on the pioneer work done in Malawi. For example on treatment, Malawi was the first country in 1993 to switch from Chloroquine (CQ) to Sulfadoxine-pyremethamine (SP) in the treatment of uncomplicated malaria[55] and later in 2007 from SP to lumefantrine-artemether (LA), an artemisin based combination therapy (ACT).[16] While on prevention, the Intermittent Preventive Treatment during Pregnancy (IPTp) was selected because Malawi was also the first country in 1993 to adopt IPTp with SP.[13]

The case study on treatment was conducted to examine the role of research on the policy changes made while the case study on prevention was conducted to understand the policy change process in addition to the role played by research evidence.

The two case studies that are further described in chapters four and five are:

- Malaria research and its influence on anti-malarial drug policy in Malawi: A Case study
- Changing the Intermittent Preventive Treatment in pregnancy with Sulfadoxine-pyremethamine (IPTp-SP) policy in Malawi: A case study

Phase III

Assessment of facilitating factors and barriers to malaria research utilisation for policy development in Malawi

This phase adopted a similar methodological approach as described in Phase II. The main objective was to identify the existing factors or elements that support the promotion of Knowledge translation (KT) in Malawi and their barriers. These elements, therefore, form the critical elements of the developed framework.

Phase IV

The promotion of evidence-based policies is a critical step towards utilisation of research findings. However, if the policies are not well implemented the ultimate impact of research, which is the improvement of public health, is not attained then its purpose is not well served. In this phase, the research methodological approaches similar to ones used in Phase II were utilised in order to explore barriers to the implementation of malaria policies for purposes of providing

awareness to policy makers to view policy development and implementation as interactive processes.

Phase V

Development of a framework to promote malaria research utilisation for policy development in Malawi.

Development of the framework was based on the lessons from the case studies and findings from Phase III while being guided by literature of existing research-to-policy frameworks. A rigorous iterative approach with a sample of stakeholders was conducted for validation and applicabilty of the framework.

1.8 Thesis structure

The thesis is presented in nine chapters that include four peer-reviewed articles originating from this research work.

- ***Chapter one:*** Presents the introductory part of the study and it touches upon study rationale and motivation, study objectives, and an overview of research methods adopted in addressing each objective.
- ***Chapter two:*** Highlights the extensive literature that was reviewed and which guided this study. This includes literature on types of evidence, utilisation of evidence in policy development, understanding the policy development process, promotion of research evidence in policy development focusing on theories, models and frameworks, and further on policy implementation.
- ***Chapter three:*** Presents an original paper published in the *Malaria Journal.* It covers the type and amount of malaria research including its related sources of funding conducted in Malawi from 1984 to 2016.
- ***Chapter four***: Presents an original paper published in the *Health Research Policy and Systems Journal.* This is case study I that describes how malaria research conducted in Malawi was instrumental in changing the treatment policies for uncomplicated malaria.

- ***Chapter five***: Presents case study II, an original paper published in the *Malaria Journal* and it tackles the experiences of changing the IPTp-SP policy and the roles of various stakeholders during this process.
- ***Chapter six:*** Presents an original paper published in the *Malaria Journal* and it presents the factors or elements facilitating utilisation of malaria research in policy development and the barriers to this process
- ***Chapter seven:*** Presents some of the challenges to the implementation of malaria policies in Malawi. This chapter is in a format of a manuscript under review in the *Journal of Health Services Research.*
- ***Chapter eight:*** Presents the process of developing the framework to promote utilisation of malaria research for policy development in Malawi. This chapter is an original paper published in the *Health Research Policy and System Journal*.
- ***Chapter nine:*** Presents the overall general conclusion of the research, recommendations, and proposed areas of further research.

The references of a particular section are provided at the end of each chapter. The reference style used in chapters one, two, and nine is according to the Vancouver system accepted by the Faculty of Health Sciences, School of Health Sciences and Public Health at the University of Pretoria. The styles for chapters three, four, five, six, seven, and eight are according to the specifications prescribed by the journals to which the papers are published or are submitted for publication.

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CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

This chapter presents a review of literature based on the study objectives. The first section explores the meaning of evidence and the various types of research categories of health research that provide new knowledge and evidence for decision making, followed by a discussion on how evidence can be utilised in the process of policy making. This stage brings up the section of understanding the policy making process and how the various types of evidence can be used in this process, which also incorporates the challenges of utilising evidence in this process. The following section is a discussion about the promotion of evidence in policy development through the understanding of the roles of theories, models and frameworks. This discussion highlights examples of frameworks that guided the development of the research-to-policy framework in this study. Further recognition is made of the need to take into consideration the challenges of policy implementation, which hinder the realisation of policy objectives.

2.1.1 What constitutes evidence?

Understanding how evidence is defined is critical on how it is used for decision-making. The meaning of evidence is understood differently between researchers and non-researchers. Non-researchers broadly define evidence colloquially as "anything that establishes a fact or gives reason for believing in something.[1] This evidence can constitute professional or expert opinion and experiences, political judgement, habits and traditions, and values. Utilising this kind of evidence requires strict judgement because it is not gathered through rigorous means and the experiences may not be replicated. This should be of great concern when dealing with human life. On the other hand, researchers have a restrictive description of what constitutes evidence. They view evidence as information originating from explicit and systematic approaches that are universally accepted and replicable.[2] The credibility of scientific research evidence depends on the methodology tests while relevance applies to colloquial evidence.[3] Decision makers such as policy makers are more inclined to take into consideration colloquial evidence while challenged to practice evidence-based decision making which highly considers research evidence.

However, as the more acceptable research evidence is considered for decision-making, colloquial evidence can be assimilated into the picture by conducting multidisciplinary research. Proponents of scientific research evidence have further categorised evidence as either context-free or context-sensitive.[4] Context-free evidence originates from rigorous controlled scientific methods that reveal the universal truth or effectiveness of the issues under study while context-sensitive evidence is highly rooted in social science as it reveals the applicability of findings from context-free evidence.[3] Therefore, these two approaches of gathering scientific evidence should be viewed as complementary because context-free provides evidence on 'what works' while context-sensitive provides evidence on how 'what works' can be implemented in the real setting and this can include factors such as organizational capacity, socio-economical, and population dynamics.

2.1.2 Sources of evidence for health care – health research

Decision making and policy development for the improvement of public health needs to be supported by scientific evidence,[5] which is provided through health research. One of the most important aspects in the promotion of research utilisation for decision-making is understanding the various types of research since it will guide the strategies taken for its utilisation. Describing types of research has been confusing since it may come from different research backgrounds such as social science, biomedical, health economics.[6] Various definitions have been used showing inconsistency in the scientific world, creating confusion and hence affecting its credibility and how it is sought.[7] Evidence for decision making in health care can originate from primary or secondary health research.[8] Primary research, which is also referred to as original research, is concerned with the collection and analysis of primary data from tools such as experiments, interviews, surveys, and questionnaires.[8,9] On the other hand, secondary research, which is also called desk research, focuses on analysing and interpreting primary research findings. It involves the synthesis of existing two or more primary research to answer a specific topical question.[8,10] Review papers or articles can be written from secondary research and these can be in the form of a narrative review, systematic review, and meta-analysis.[8] A simple narrative review involves appraising and summarising existing literature on an existing topic to identify gaps and guide in conducting a primary research. This approach can be subjective and

lead to bias in order to support the researcher's position. A systematic review addresses most of the challenges encountered in the ordinary narrative review. A systematic review involves a definite, rigorous, and comprehensive approach in identifying and synthesising two or more primary research fitting an eligibility criteria that is pre-defined in order to answer a specific topical question. Meta-analyses combine and compare the findings of two or more primary quantitative research in order to assess the effectiveness of a particular intervention or type of treatment by using standardised statistical procedures.[11] Reviews have become popular for planning, decision making and policy development in health. With a growing body of primary research evidence, managers, policy makers, and health practitioners do not have the time and expertise to search for particular studies and yet interpret such findings, in addition to the fact that one study cannot provide the basis of a final decision,[12] hence systematic reviews and meta-analysis serve this purpose.

2.1.3 Categories of primary health research

Various approaches have been used to define and understand categories of primary research but in this review the categories adopted are best defined by Rohrig[8] with an addition of context-sensitive Health Policy and Systems Research (HPSR) that is explained by Remme.[6] Primary health research can be categorized into basic, clinical, epidemiological and HPSR. Basic research, which is sometimes called fundamental, pure, or curiosity-driven research, is experimental and theoretical in nature with no particular purpose of its application but rather to create new knowledge.[13] Basic research will include pharmacology, microbiology, biochemistry, physiology, and genetics investigations.[8] Clinical health research, which can either be interventional or observational, is a type of research that seeks to assess the effectiveness and safety of an intervention such as a drug, vaccine, and diagnostic tool in humans.[8,14] Usually the intervention would have been discovered during basic research. While epidemiological studies involve investigations on the distribution and patterns of health determinants and diseases in a given population with the purpose of understanding their dynamics and devising strategies for prevention and control.[15] Another type of context-sensitive primary research has evolved to understand and improve the delivery of health services in a country and it is called HPSR. HPSR seeks to generate new knowledge for improving the organisation of societies to achieve better

health by focusing on health systems.[16] The WHO defines health systems as "all organisations, people and actions whose primary intent is to promote, restore or maintain health".[17] The building blocks of a health system are illustrated in the WHO framework presented in Figure 2.1 below:

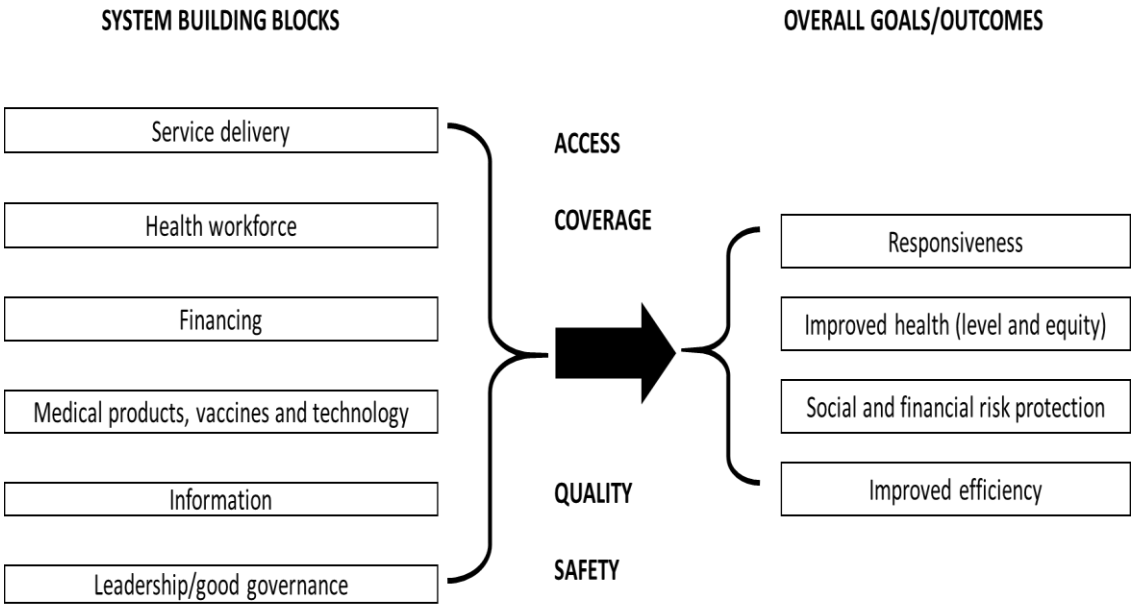

Figure 2.1: The six building blocks of a health system in a country (Reprinted from World Health Organization. Everybody's business--strengthening health systems to improve health outcomes: WHO's framework for action. 2007).

Therefore, HPSR will encompass any study on the six building blocks, assessment on accessibility, coverage, quality and safety of health services, and the evaluation on the achievement of outcomes and goals. A study assessing the outcomes of investing in new technology in comparison to improving the utilisation and delivery of health services to prevent deaths in under five children has revealed a shift in the focus to HPSR. The study found out that improving the technology potentially reduced 22% of deaths while improvement of health services delivery prevented 63% of deaths.[18] However, the same study also revealed that much of research funding support is towards developing new technologies rather than improving health delivery.

The responsibility of the government should be to focus on the improvement of health services delivery by showing political will and supporting HPSR, which can be categorised into operational, implementation, and health system as described by Remme *et al.*[6] The HPSR

domains have been differentiated according to how they are organised, address the research question, and their interaction with the health system although slight overlaps exist.

Operational research

This kind of research is mostly used by health care providers. Operational research tends to be context specific and address a specific local health problem hence its generalisation to other settings is not obvious although the approach taken can be replicated elsewhere. There may be problems that threaten a local disease control programme, hence it is characterised by a stern problem-solving emphasis and its significance for rapid uptake of the research findings. It is also characterised by the specific research designs such as descriptive and analytical, and the usage of mathematical models. The research questions may come from the routine monitoring and evaluation project activities.

Implementation research

This type of research is mainly used by managers of programs in scaling up an intervention. It provides a general strategy of intervention implementation for increased access to the target population. It is important to note that this type of research tries to promote an intervention whose efficacy has been proven by other research, therefore, it explores on innovative strategies for wider implementation. This type of research will complement the rolling out of a new policy. Therefore, some good policies may be developed from quality research but their impact may not be felt due to lack of evidence on how best to implement them. Hence, implementation research further addresses this challenge. Social science research methods such as qualitative research methods are often used and usually undertaken by research from various fields.

Health system research

This type of research is mainly used by policymakers for the improvement of the health system. Health system research will in general be focused on the health system and tends to move away from disease specific concerns, therefore, it will address issues of health financing, governance, and policy in order to solve problems of service delivery and increases the productivity and success of the health system. The type of research is multidisciplinary and case studies can be

used to answer context specific health system problems but it can also generate valuable lessons for other similar settings.

The three main categories of HPSR can be related to type of policies that come along with them. Legislative policies can emanate from health system research as they relate to the overall framework of the health system; and administrative policies may originate from implementation research as they focus on the running and the allocation of resources in the health system; while clinical policies arise from operational research that will seek for example alternative interventions to a treatment.[19] Hanney *et al.*[19] have acknowledged that research evidence is less utilised at the legislative policies and highly needed at the clinical policies. However, at the clinical policies, where research is highly needed, it is delayed to be converted for the improvement of patient care.[20]

Figure 3.1 and Table 3.1 (in Chapter 3) provide the categories of research type, their definitions and examples as used in this review.

2.1.4 Utilisation of research evidence during policy development

Research utilisation can come in various forms during the policy development process. Lavis *et al.* [21] explain that research can be; instrumental if the research findings have directly led to policy development; conceptual if research is gradually utilised as reference; and symbolic if the research evidence is used to support an already made decision.

However, utilisation of research is based mainly on three factors that need to be working efficiently and these include; availability of research itself which is vigorous and an appropriate knowledge base, regular dialogue between researchers and research users is very critical for research uptake, and the capacity of both the research and users in terms of experiences and qualifications that would enable them to carry out rigorous research and translate it in a form that is well understood to the users, while the users should be able to grasp and understand the findings from research.[22] In addition, understanding the policy making process is important as it helps the researchers in strategising on how research can influence the process.

2.1.5 The policy making process

A policy is a plan or a guide that can influence decision making for an organisation and can be broad if it articulates a wide direction, it can be more specific in a particular sector such as health, and it can also be operational for guiding decisions for a programme or project.[23] Policies can also be categorised as public policies if they affect the general population and these are mainly made by the government, or they can be private policies made by private organisations.[19] However, the process of policy formulation involves those in leadership to make the best choice among alternatives and it involves how the policies are instigated, framed, discussed, communicated, executed and evaluated.[24] This, hence, calls for thorough research analysis and consultations to make recommendations.[23] Lavis *et al.*[21] have described the main stages of policy development process and the role of research in each process, which include policy agenda setting, policy formulation, and policy implementation, while policy evaluation is an ongoing activity that feeds and guides the whole process.

The policy agenda setting involves the initial identification of the area to be addressed, which can be a health problem that has been identified through research and instrumental use of research is prominent at this stage.[19] Policy formulation follows next with the purpose of seeking an approach to solving the problem. At this stage, evidence is sought and examined for alternative options and a choice is made on the best option. This becomes the critical stage in research utilisation because the choice to be made affects the population hence the evidence needs to be of high quality and the intervention developed should be practical while taking into consideration contextual factors. Eventually when the formulated policy is put to practice, research can play an important role in validating the best way of implementation. It is also important to recognise that implementation of the policy might be accomplished by organizations other than those that formulated and adopted it hence, successful implementation depends on the involvement of these institutions in the policy development process.

Finally, policy evaluation pertains to providing evidence on how a policy is performing in achieving its objectives. What needs to be evaluated should be clear because some outcomes

can either be short or long term. In health policies, long term results such as reduced morbidity and mortality are the most important outcomes.[21]

It must be acknowledged that the policy making process is intricate[25] and hence understanding its challenges is crucial in promoting research for policy development. Various barriers to research utilisation range from institutional set up to individuals.[26] Haines *et al.*[20] listed potential barriers that may exist in the health care system, patients, practitioner, and the environments of practice, educational, social, and political to research utilisation. Madjedzadeh *et al.*[27] identified and grouped the barriers into four domains that need improvement to maximise research utilisation; improvement in the context, improvement in knowledge creation, improvement in knowledge transfer, and improvement in knowledge utilisation. Hennik, [28] conducted an assessment of barriers and strategies of using research to inform health policy in developing countries such as Malawi. The study indicated that there are common barriers which highlight the existing gap between researchers and policymakers. The specific barriers included the lack of appreciation by policy makers on the contribution of research to policy and program development, poor communication of research findings by researchers, research evidence not addressing the needs of the country, and the challenge within policymakers to seek and synthesize research findings. The best strategy to promote research uptake for policy formulation was revealed when policymakers were involved in the research process and harboured vested interests in the findings. This was clear for commissioned research but a challenge for non-commissioned research. This study has further informed the need of developing a framework to promote malaria research utilisation in policy development as proposed in the current study. It is clear that researchers conducting non-commissioned research find it challenging to contribute to policy because they do not know which policymakers to involve and where to present their findings, beyond academic circles, if they seek to influence policy.[28]

This is also worsened by externally funded research whose findings are unavailable to policymakers, since this kind of research may not be locally disseminated or address the local research needs. These barriers need tailor-made strategies to maximise on the benefits that research can provide in improving public health in developing countries.

2.1.6 The case for promoting research evidence in policy development

Research becomes meaningless if it does not provide the information required to influence decisions including those leading to establishment of essential interventions and/or leading to positive behaviour change. In order for research to be of high and acceptable value, the researcher should strive to ensure that the results and the recommendations presented lead to maximum utilisation for policy-decision-making and the subsequent translation of policies into practical solutions. This is how research can contribute to the desired health outcomes.[19] Therefore, promotion of research should be aimed at providing evidence for decision-making. However, the notion of evidence-based decision-making has at time been a paradox.[29] While there has been sufficient amount of clinical research showing empirical evidence, it has not always led to adoption of the new innovation.[30] The set-up of the health systems poses the main challenge of addressing health problems in developing countries. The weak health systems in LMICs made it difficult for these countries to address the Millennium Development Goals.[20,31] Research initiatives have been recognised to be critical in strengthening the health systems and improving the equitable distribution of scarce resources in these countries.[32] Such recognition should be the basis for supporting and utilising research for the improvement of health systems in the LMICs since they cannot afford to waste their resources on research that may not be utilised to enhance the lives of the citizens. However, despite the generation of research evidence, the disease burden in LMICs has remained relatively unchanged demonstrating a major gap between what is known and done,[33] a phenomenon known as the 'know-do-gap'.[34] This challenge of failing to use research evidence in addressing health disparities in LMICs through policies and practice prompted various organizations including the WHO to put this on their agenda, hence it is a mission of WHO to address the 'know-do' gap, by emphasising on the timely availability of quality evidence and promote its use for policy development and practice.[35] In addition to little funding spent on conducting research on diseases that mostly affect LMICs compared to diseases affecting developed countries, as acknowledged by WHO,[34] these LMICs, should maximise on the available evidence in order to improve the quality of life and avoid costs from interventions that may be implemented without proper evidence and cause harm.[36]

2.1.7 Evidence-based practice (EBP)

The notion of evidence-based practice has evolved from evidence-based medicine (EBM),[37] which is described as the "conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients".[38] With the observation that patients do not receive the best care despite large volumes of new knowledge and with the challenge faced by clinicians to keep up with this knowledge generation and synthesis, the concept of EBM was developed to address this gap.[39] The principles of applying EBM involve five steps which start with formulating answerable questions from converted information needs, then searching for the best evidence to provide answers to the questions, this evidence is then appraised critically for usefulness and validity. Once adopted the evidence is applied to the clinical practice followed by evaluation.[40]

The concept of EBM has progressively compelled non-clinical settings including the health policy to utilise research evidence in policy making.[41] This has urged policymakers to focus on using scientific evidence rather than political ideologies in policy making leading to a term called Evidence-Based Policy Making (EBPM).[42] The main focus of EBPM is to promote the availability of timely quality evidence and seek to facilitate communication between researchers and policymakers, which has been isolated to be a key factor.[43,44] One of the approaches advocated to promote this interaction is the usage of knowledge brokers pioneered by Jonathan Lomas and Foundation.[45] Knowledge brokers aim at promoting the interaction between researchers (producers) and policy makers (researcher users) so that they can have a mutual understanding by encouraging policy makers to be responsive to research output while researchers conduct research based on policy needs. In addition to this global recognition on the importance of EBPM in strengthening health systems and saving lives through scientific and technological advances, the WHO championed the establishment of Evidence Informed Policy Network (EVIPNet) with the African region being first to have such a network.[46,47] EVIPNet provides a forum for networking among countries by bringing together institutions promoting EBPM to share experiences and improve their initiatives, which has since led to the establishment of Knowledge Translation Platforms (KTPs) in Africa.[47] The promotion of research in policy development has been supported by theories, frameworks, and models.

2.1.8 Theories, frameworks, and models of research utilisation in policy development

Similar to EBM, theories, conceptual frameworks, frameworks and models have guided the promotion of research utilisation in policy development. Theories provide a way through which concepts are seen as mental images and provide description, prediction, and explanation on the relationship of the concepts.[48] The theories lead to the development of conceptual frameworks, sometimes called conceptual models, which integrate the concepts and their propositions into a more meaningful manner with the purpose of providing a structured reference point for organised thinking and interpretation. However, conceptual frameworks may change with arising new evidence that may challenge or strengthen them.[49] On the other hand, frameworks or models provide a more objective and precise narrow scope of interactions between the concepts, which are well defined with specific relationships in real world setting.[49]

The purpose of frameworks and models is to promote Knowledge Translation (KT) that is described as "the exchange, synthesis and ethically sound application of knowledge – within a complex system of interactions among researchers and users – to accelerate the capture of the benefits of research through improved health, more effective services and products, and a strengthened health care system".[50-52] The objective of KT goes beyond the dissemination of scientific information through publications as a primary form of spreading the research results. It involves all the stages of the research process (from knowledge creation to utilisation), interaction and engagement between the researcher and research users and other stakeholders for the purposes of addressing the gap between the available large quantities of research evidence and its usage,[53] and improving the lives of the general population.[50,54]

Examples of frameworks or models of research-to-policy in health

Utilisation of research has been promoted depending on who needs the research findings and for what purposes. Various models of research utilisation have been developed; however, the common drivers are based on the following four approaches summarized by Lavis *et al.*[55]

The push models

These models call upon the researchers to have their research work known to the users i.e. policy makers. This approach assumes that there is a linear process in which research will automatically be fed into policy development.[56] Therefore, for this approach to work, extensive research dissemination by the researchers needs to be done and reach out to the appropriate audience. Packaging of the research finding messages and the channels of communication are critical in this approach.

Pull models

These models rely on the demand from the users of research, the policy makers. It assumes that the policy makers will prioritise and seek for evidence or research to be conducted and use the finding for decision-making. Therefore, the users may be responsible for funding and commissioning of research. This approach works well with expertise of the users. If they are well knowledgeable the users will be able to critically evaluate evidence or comprehend how and when to use research evidence in making decisions.

Network and interaction models or exchange, integrated models

These models highlight the collaboration and interaction that may occur between researchers and users. The relationship can go beyond social so that there is mutual trust among the parties. Therefore, interpersonal contact is the recipe for knowledge exchange in this approach. For maximum research utilisation, the users are encouraged to be involved throughout the research process and have personal interest in the utilisation of research. In this way, research is also conducted with the best interests of policy needs and the findings from the research are likely to be accepted for decision making.

In some settings, there are independent individuals or organisations who act as knowledge brokers whose responsibility is to facilitate the usage of knowledge generated from research.

A systems model

In this approach, there can be a national or a regional-level institution that works to bridge the gap between knowledge generation and usage. The institution is responsible for knowledge generation and facilitating for its utilisation. The success of the institution is based on the following capacities: generative capacity in order to conduct research and provide evidence; disseminative capacity to contextualise and translate and disseminate the research findings; absorptive capacity in order to explore external knowledge and adapt it to the local situation; and responsive capacity in order to continuously explore and adapt for the improvement of the institution.[57] Institutions such as the Cochrane library are better examples of this model.[33]

There are various examples of models and frameworks that advocate the utilisation of research in policy development but those that are briefly discussed in this review and indeed from whose lessons shaped the development of the framework in this study were based on the facts that: they incorporate the stage of knowledge creation; they promote the interactive model; they consider the contextual factors in their application; and their focus is policy formulation and not clinical practice.

These frameworks and models include:

- The Canadian Institute of Health Research (CIHR) model of knowledge translation;
- The Knowledge-to-Action Process Framework;
- The Tehran University of Medical Sciences Knowledge Translation Cycle; and
- The Ontario Drug Policy Research Network.

Canadian Institute of Health Research (CIHR) model of knowledge translation

The CIHR is an institution that funds and accelerates knowledge translation in Canada[58] and has influenced the field of knowledge translation globally. The CIHR proposed and developed a global conceptual model for KT that can guide research utilisation, however it proposes that a more specific framework can be developed with more working details according to the context in which it will be used.[51] Through the contextualisation approach specific factors can be

considered to enable effective collaboration, and desired outcomes during each of the KT opportunities.[51]

The CIHR model constitutes six components that interact during the KT and these are: Definition of the research question and methods (KT1); conducting the research (KT2); Research publication (KT3); Contextualising the research findings to sociocultural norms (KT4); Decision making and action taken through the research findings (KT5); and Continuation of research based on the recommendations from impact of knowledge use (KT6).

The figure 2.2 below shows the relationship of these components during the KT process:

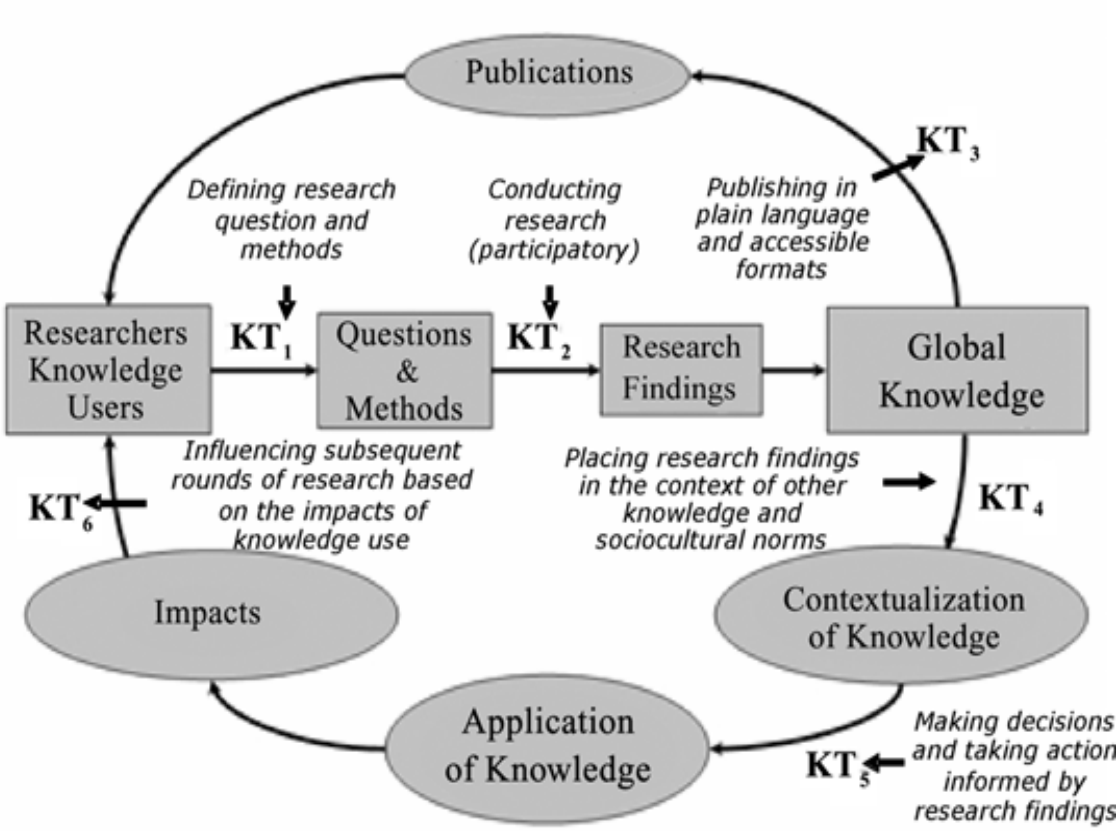

Figure 2.2: The CIHR model (Reprinted from Tetroe J. Knowledge translation at the Canadian Institutes of Health Research: A primer. FOCUS A Technical Brief from the National Centre for the Dissemination of Disability Research (NCDDR). 2007(18))

The Knowledge-to-Action Process Framework

Graham *et al*.[59] developed this conceptual framework to facilitate KT for many settings including policy development. The framework has two components that include the knowledge creation funnel and the action cycle. Each component has its own stages as the knowledge creation is made up of knowledge inquiry, synthesis, refinement and creation of knowledge tools, while the action cycle comprises seven phases that utilise the refined tools from the knowledge creation component. The framework acknowledges that the interactions are complex and dynamic and can occur sequentially or simultaneously with the knowledge creation phase influencing the action cycle at any given point. This framework is illustrated in Figure 2.3 below:

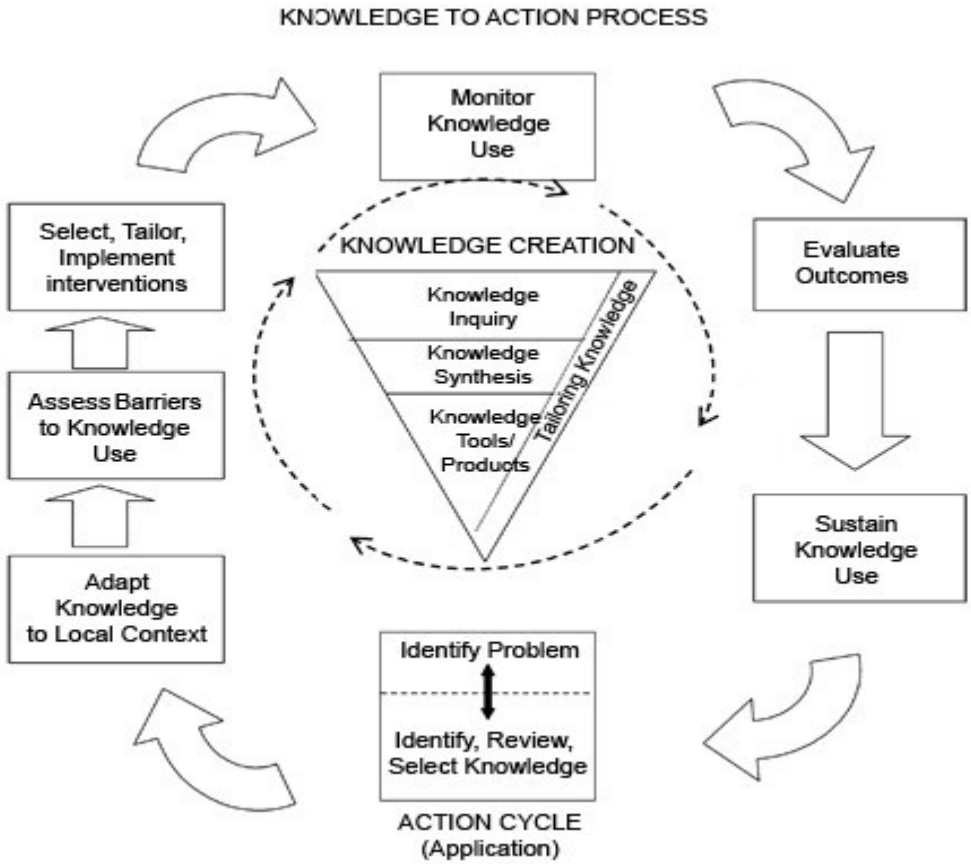

Figure 2.3: The Knowledge to Action Framework (reprinted from Graham ID, Logan J, Harrison MB, Straus SE, Tetroe J, Caswell W, et al. Lost in knowledge translation: time for a map? J.Contin.Educ.Health Prof. 2006; 26(1):13-24)

The Tehran University of Medical Sciences (TUMS) Knowledge Translation Cycle

Majdzadeh *et al*.[27] developed the TUMS knowledge translation cycle which provides a conceptual framework linking various elements for translating knowledge for research utilisation. The framework consists of five areas that include: knowledge creation, transfer, research utilisation, question transfer and the context of organisation as presented in Figure 2.4. The push side represents researchers who are in the field of knowledge creation and strive to have their findings utilised, while the pull sider representing the users of research such as policymakers who seek for research evidence during policy making. The two groups are linked during the exchange efforts of the knowledge created and transfer of research questions. It is at this stage that they can interact and share common views to maximise on research utilisation. However, the framework considers the need of assessing the contextual setting that would influence the interaction of the two parties. In addition, it is also important to assess the barriers to this interaction and devise strategies of addressing them.

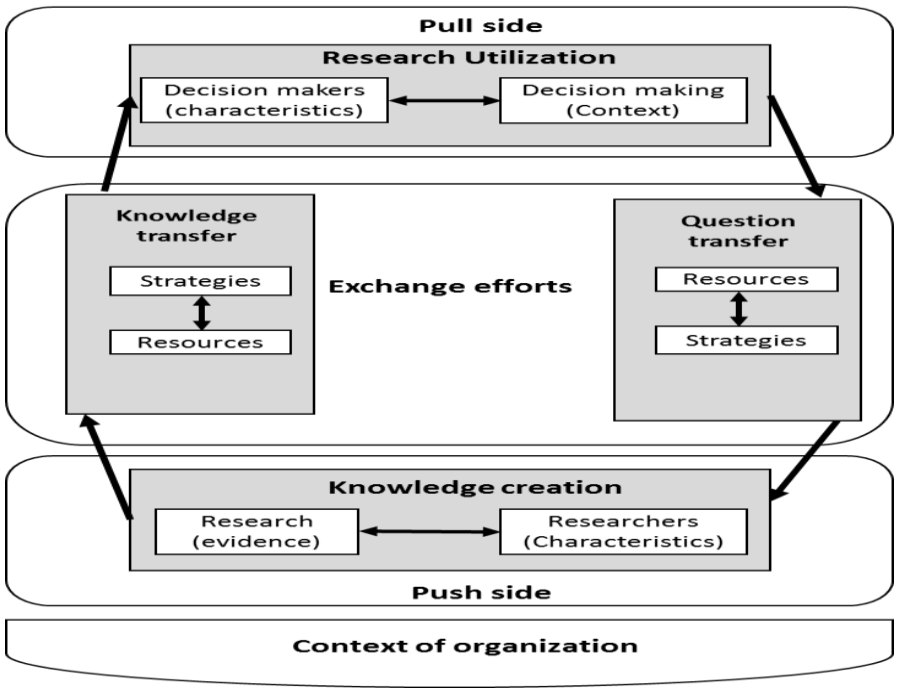

Figure 2.4: The TUMS knowledge translation cycle (Reprinted from Majdzadeh R, Sadighi J, Nejat S, Mahani AS, Gholami J. Knowledge translation for research utilization: design of a knowledge translation model at Tehran University of Medical Sciences. J.Contin.Educ.Health Prof. 2008; 28(4):270-277)

The Ontario Drug Policy Research Network

This is a detailed model for research utilisation as it highlights the relationship between the Ontario Public Drug Program (OPDP) and the Ontario Drug Policy Research Network (ODPRN).[60] This model was specifically created to facilitate the utilisation of commissioned research for purposes of drug policy changes. Therefore, the interaction between the research and policy institutions provides a rapid-response of research utilisation that delivers timely evidence for policy making. The emphasis is placed on the collaboration of researchers and policymakers in developing and refining the research questions, and regular updates to the policy makers on the research process. However, if there are no research needs by the policy makers, researchers continue conducting academic research, which may also later be utilised if needed. Figure 2.5 illustrates the organisational set up of the framework.

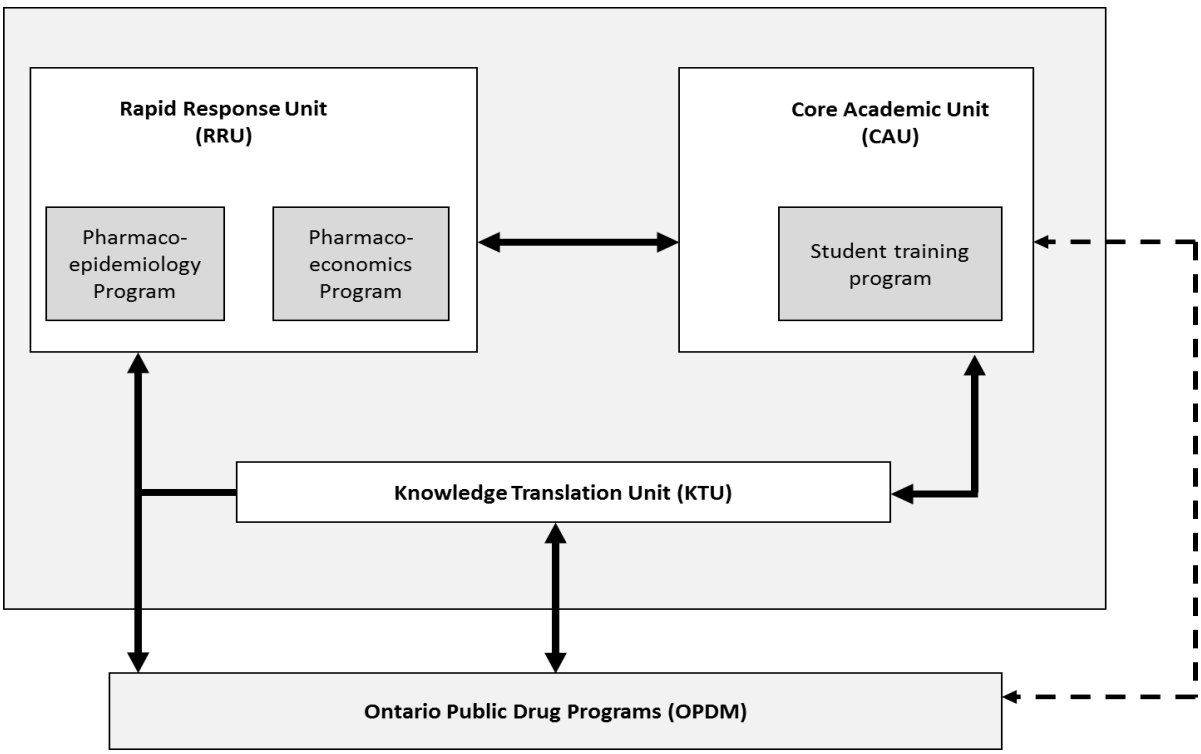

Figure 2.5: The ODPRN organisational framework (Reprinted from Khan S, Moore JE, Gomes T, Camacho X, Tran J, McAuley G, et al. The Ontario drug policy research network: bridging the gap between research and drug policy. Health Policy. 2014; 117(3):392-398)

The first three frameworks (the CIHR model, Knowledge to Action, and TUMS knowledge translation cycle) provide an overall conceptual picture of how the KT process should occur. As conceptual frameworks, they do not show specific elements such as individuals, institutions or highlighting roles and responsibilities of how to facilitate particular processes in the framework. For an effective KT process it is important to take into consideration the contextual factors and micro-perspective of individuals and institutions to support this process.[61] Therefore, further details showing comprehensive frameworks can augment these models. The ODPRN organisational framework is an example of a detailed framework highlight specific elements with their roles and responsibilities arranged in a particular setting to boost interaction for purposes of enhancing KT. This framework provides a practical perspective of how a contextual KT framework operates. Despite being a framework for commissioned research, it provides vital lessons on the interaction processes between researchers and policymakers through research question formulation and the involvement of policymakers throughout the research process, which facilitates the acceptability and utilisation of the research findings. It also provides room for capacity building for researchers to conduct academic research when there are no specific policy research needs.

These frameworks offer vital lessons for KT by revealing that the processes are intricate, non-linear, and can occur simultaneously. In addition, they highlight that the process of KT is not smooth since there are various factors influencing it and hence the need to consider contextual factors. All in all, it is very important that the process of KT in policy development be influenced by the constant interaction between researchers and policymakers beginning from the conceptualisation of research questions, throughout the research process so that the findings are embraced and accepted in the policy development process. By assessing barriers and facilitating factors to knowledge translation a detailed contextual framework can be developed. The assessment should highlight specific elements, their roles and responsibilities that should be arranged in a particular organisational structure to enhance their interaction, communication, partnerships, and prevent duplication of activities while striving to achieve KT.

Thus, from these lessons the proposed framework in this study aims at bringing together the explored elements of KT in order to promote the utilisation of malaria research in policy

development in Malawi. This contextual framework should enhance visibility of the existing elements of KT and hence offer guidance to researchers and knowledge users such as policymakers of where to begin from or whom to engage with in order to pursue KT of malaria research.

2.1.9 Policy implementation

The efforts of developing evidence-based policies are a foundation of improving public health. Further attention should be placed in the implementation of the policies. Therefore, the processes of policy development and implementation should be interactive. As much as research evidence for policy making is prerequisite, their implementation determines realisation of policy objectives and goals. Policies will stipulate what needs to be done and achieved through policy intents but implementation puts them to test, where a gap has been acknowledged to exist and a persistent problem to developing countries.[62] Considering that policies have been developed from tangible evidence, these challenges dwell on the delivery of health services due to weaker health systems instigating strategies of strengthening them.[63] It is therefore, ideal to understand the factors in the health system that can affect policy implementation as conceptualised by Van Horn.[64] The framework identifies eight elements that need to be taken into consideration during policy implementation and these include; resources, standards, communication, enforcement, characteristics of implementing agencies, the political situation, economic and social factors, and the disposition of implementers. These factors determine capability of the health system in implementing a particular policy, therefore, political will is crucial. However, the approach of implementing the policies is equally important. There are three main approaches, as described by Birkland[65], that explain the interaction between policymakers and implementers which will determine the success of achieving policy objectives. These approaches include: the top-down approach which assumes a linear sequence of events with policies made at central level and communicated down to implementers on the ground; and the reverse of the top-down as it adopts a bottom-up approach by taking into consideration the views of implementers, who having knowledge on the ground can change and adjust the way the policies are implemented. However, these two approaches have their own challenges, for example the top-down approach is authoritative requiring clear and effective communication and coordination, while in the

bottom-up approach the implementers assume power to change implementation of policies that may not reflect the purpose in which they were made. Owing to these challenges a third approach called 'A Third Generation of Implementation Research' was proposed, which is a network approach that attempts to merge the concerns of the two approaches. It attempts to create dialogue between policymakers and implementers early in the development of policy goals, outputs, and outcomes. Policy implementation should thus adopt the third approach just like in policy development, in addition it should receive as much attention as policy development as it extends the intentions of policy objectives.

2.2 Conclusion

This literature review was based on the objectives of the study. It has highlighted the various types of evidence from which decisions can be based, which includes both colloquial and scientific evidence. However, for decision making in public health and owing to the various economic challenges faced in developing countries, tangible scientific evidence should be the basis for decision making and policy development. This evidence can come from either primary research, which is conceived from the collection and analysis of primary data, or secondary research which analyses and summarises primary research to develop an overall picture of similar primary studies. Secondary research becomes convenient by summarising many studies and saves time for decision makers who may not have the time and expertise to synthesise scientific findings.

Utilising research evidence during policy development requires an understanding of the different steps in policy making that include agenda setting, policy formulation, and implementation with policy evaluation being an ongoing process. It is through this understanding that particular evidence can form the basis for decision making to move to the next step. In this process, evidence can be used instrumentally if it directly changes policy, conceptually if it is gradually used as a reference point, or symbolically if it supports an already made decision. However, all efforts should be made for scientific evidence to be the basis for health policy development.

Various approaches can be used to guide the utilisation of evidence in policy making and these include theories, conceptual frameworks, and actual frameworks or models. These strategies

aim at promoting knowledge translation and can focus on enhancing the interaction between researchers and users of evidence, who in this case are policymakers. The frameworks that advocate for researcher-to-policy maker relationship are interactive in nature and stipulate that to increase the chances of research utilisation, this collaboration should begin at the knowledge creation stage where common views are shared. The assessed conceptual models provide a general overview of how the process of KT should be conducted, however, contextual and specific frameworks can be developed to augment these concepts. The major lessons that these conceptual models provide when developing contextual frameworks include: assessing the barriers and promoting factors to knowledge translation within the environment and strategise; realisation that the processes occurring within the framework are non-linear but rather simultaneous; the emphasis should be to enhance collaboration between researchers and policymakers starting from knowledge creation; and knowledge brokers can take the responsibility of promoting this collaboration. Therefore, the proposed framework in this study aims at promoting malaria research utilisation for policy making in order to contribute to addressing the malaria burden in Malawi. The framework should identify and organise elements promoting KT and enhance their relationship and visibility. The framework should serve both commissioned and non-commissioned research. Individual researchers, conducting non-commissioned research, have always found it challenging to engage with policymakers and convey their research findings to contribute to policy. Therefore, this framework should bring awareness and provide channels of communication on how such researchers can relay their findings and contribute to policy formulation.

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CHAPTER THREE

Introduction

This chapter forms the initial stage in the development of the framework. The aim was to determine the scale of malaria research conducted in Malawi. The chapter, therefore, reveals the amount and type of malaria research conducted in Malawi from 1984 up to 2016, which forms a repository of evidence that should potentially be utilised in policy development.

3.0 MALARIA RESEARCH IN MALAWI FROM 1984 TO 2016: A LITERATURE REVIEW AND BIBLIOMETRIC ANALYSIS

Abstract

Background: Malaria research can play a vital role in addressing the malaria burden in Malawi. An organized approach in addressing malaria in Malawi started in 1984 by the establishment of the first National Malaria Control Programme and research was recognized to be significant. This study aimed to assess the type and amount of malaria research conducted in Malawi from 1984 to 2016 and its related source of funding.

Methods: A systematic literature search was conducted in the Medline/PubMed database for Malawian publications and approved malaria studies from two Ethical Committees were examined. Bibliometric analysis was utilized to capture the affiliations of first and senior/last authors, funding acknowledgements, while titles, abstracts and accessed full text were examined for research type.

Results: A total of 483 publications and 165 approved studies were analysed. Clinical and basic research in the fields of malaria in pregnancy 105 (21.5%), severe malaria 97 (20.1%) and vector and/or agent dynamics 69 (14.3%) dominated in the publications while morbidity 33 (20%), severe malaria 28 (17%) and Health Policy and Systems Research 24 (14.5%) dominated in the approved studies. In the publications, 146 (30%) first authors and 100 (21%) senior authors, and 88 (53.3%) principal investigators in approved studies were affiliated to Malawian-based institutions. Most researchers were affiliated to the Malawi-Liverpool Wellcome Trust, College of Medicine, Blantyre Malaria Project, Ministry of Health, and Malaria Alert Centre. The major malaria research funders were the National Institute for Health/ USA, Wellcome Trust and the

US Agency for International Development. Only three (2.5%) out of 118 journals publishing research on malaria in Malawi were from Africa and the *Malaria Journal*, with 76 (15.7%) publications, published most of the research from Malawi, followed by the *American Journal of Tropical Medicine and Hygiene* with 57 (11.8%) in comparison to only 13 (2.7%) published in the local *Malawi Medical Journal*.

Conclusions: Clinical and basic research, which is mostly funded externally, in the fields of malaria in pregnancy, severe malaria and vector and/or agent dynamics dominated, while health policy and system research was least supported. The quantity may reflect scientific research activity but the initial primary impact is contribution to policy development.

Keywords: Malaria research, Funding, Health policy, Malawi

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3.1 Background

Research is defined as an organized curiosity leading to a systematic enquiry, with the purpose of understanding the subject at hand and generating new knowledge. This definition has been applied in health research as the production of new knowledge using scientific methods to identify and tackle health problems [1]. Research can therefore play a vital role in health by understanding disease dynamics and discovering new interventions of treatment and prevention. Developed countries have made major strides and impacted enormously on the global health research arena with little contribution from developing countries. Due to contextual differences, challenges exist in the generalisation and applicability of health research findings to different settings, hence locally available evidence is critical [2]. Developing countries should also realise that only 5% of funding for global health research is devoted to address their research needs where 90% of health problems exist [3]. Health research has been identified to be critical in providing evidence for decision-making, leading to development of interventions addressing health problems in the world [2]. All efforts should thus be made for such research evidence, which is one step towards policy change [4], to be translated into policy and practice in order to attain the ultimate goal of improving public health. It is against this background that developing countries should invest and conduct robust health research and utilise it for policy development and planning to improve health systems and avert preventable health burdens [2, 5].

Malawi, as a resource-limited developing country, faces many health challenges requiring great attention. Malaria is ranked third on major disease burdens in Malawi [6] with an estimated four million cases occurring annually, mostly in pregnant women and children under 5 years old [7]. An organized approach in addressing the malaria burden in Malawi started in 1984 by the establishment of the first National Malaria Control Programme (NMCP) and the development of its national malaria control policy. One of the policy directions was to conduct viable research to guide the development of policies in malaria treatment, control and prevention [8]. This development was in line with the recommendation by the Commission on Health Research for development in developing countries in 1990 to increase

capacity of health research in developing countries [1]. It is imperative to assess whether these efforts have had any impact through the health research output in malaria as recommended by the Organization for Economic Cooperation and Development (OECD) in describing research activity for a country [9].

The aim of this study was to assess the malaria research output by mapping the type and amount of malaria research conducted in Malawi since 1984 when the first NMCP was established to 2016 when this study was conducted. The assessment also describes affiliations, level of collaborations and the sources of funding for malaria research in Malawi. This assessment also forms part of a larger study promoting malaria research utilisation in policy development that should eventually lead to the development of evidence-based interventions to address the malaria burden in Malawi. The research promotion will be instituted by the development of a contextual malaria research-to-policy framework. One of the initial steps in the development of this framework is to verify the availability of malaria research conducted in Malawi and create a malaria research repository.

3.2 Methods

An online systematic literature search was conducted for published primary research from Malawi and the examination of approved malaria studies by the two Ethical Committees (ECs) in Malawi, namely the National Health Sciences Research Committee (NHSRC) and the College of Medicine Research and Ethics Committee (COMREC).

3.2.1 Published literature

An online Medline/PubMed database search was conducted to capture malaria publications from Malawi since 1984–2016, with the latest search conducted on 9th January 2017. The Medline/PubMed, an online international database, was chosen as the only database searched because it freely provides access to over 5000 peer reviewed indexed journals which are periodically updated by the US National Library of Medicine and hence it is bound to capture a large number of viable research publications [10, 11]. The medical subject headings (MESH) tool was used by combining Boolean 'AND' of malaria and Malawi terms as follows: ('malaria' [MeSH Terms] OR 'malaria' [All Fields]) AND ('Malawi' [MeSH Terms] OR 'Malawi'

[All Fields]) AND (‘1984/01/01’ [PDAT]: ‘2016/12/31’ [PDAT]).

3.2.2 Inclusion and exclusion criteria

Primary malaria research conducted in Malawi was included in the review, and multi-country primary research that involved collection of primary data from Malawi. The study excluded commentaries, systematic reviews and meta-analyses, and research articles that only referenced malaria research conducted in Malawi. However, original studies from Malawi referenced and included in the systematic reviews and meta-analysis were sought and incorporated in the analysis.

3.2.3 Approved malaria studies

A list of approved malaria studies from the two ECs in Malawi, NHSRC and COMREC was obtained. The assumption was that all viable health research conducted in Malawi undergoes ethical approval and its records should be accessible at these ECs. The extraction of these studies required coverage from the periods when the ECs were established. The NHSRC, under the Research Unit in the Ministry of Health, was established in 1988 and mandated to review and clear all health research conducted in Malawi. However, with growing research demand, COMREC, under the College of Medicine (COM) in the University of Malawi, was established in 1996 and mandated to facilitate the review of proposals of faculty members and students of COM and Kamuzu College of Nursing, and their affiliates which include the Malawi-Liverpool Wellcome (MLW) Trust, Blantyre Malaria Project (BMP), Malaria Alert Centre (MAC), and Centre for Reproductive Health (CRH).

3.2.4 Analysis plan

Bibliometric analysis, which was limited to the quantitative indicator of research activity and extent of co-authorship, was utilized [12]. This study was purely descriptive by examining the amount, trends, institutional affiliations of first and last authors, types, and sources of funding for malaria research conducted in Malawi. In addition, various relationships of the variables were established through cross-tabulations.

The analysis focused on providing outputs of the following: (1) amount of malaria research conducted in Malawi from 1984 to 2016; (2) type of malaria research studies conducted in that period; (3) institutional affiliations of first and senior/last authors in addition to local and

international collaborations; and, (4) source of malaria research funding. The variables extracted from the publications and approved studies included years of publication and study approval, affiliations of the principal investigators (PIs), first and senior/last authors, and funding acknowledgements. Categorization of malaria research into various types was through inspection of the titles, abstracts and full papers, where possible. For the purposes of this review, the type of malaria research were first categorized into primary and secondary then the focus on primary research was later grouped into basic, epidemiological, clinical, and Health Policy and Systems Research (HPSR) (Fig. 3.1; Table 3.1). Analysis was further extended to areas of focus for malaria research, which included malaria in pregnancy, immunology, severe malaria, drug evaluation, morbidity, diagnosis, vector and/or agent dynamics, drug discovery, malaria vaccine, co-infections, HPSR, and prevention (research on long-lasting treated nets, indoor residual spraying, environmental sanitation, and personal protection). This categorization was done by two independent reviewers and differences were resolved on consensus and to measure the level of agreement a Cohen's kappa score of 0.83 was calculated using the GraphPad software [13].

The IBM Statistical Package for Social Sciences (SPSS) software version 20 was utilized for analysis, while other specific analyses and graphical outputs were also conducted in Microsoft Excel. Analysis of publications and ethically approved studies was conducted separately because studies may constitute larger studies from which specific publications may arise and that the names of the studies may not necessarily be the titles of publications.

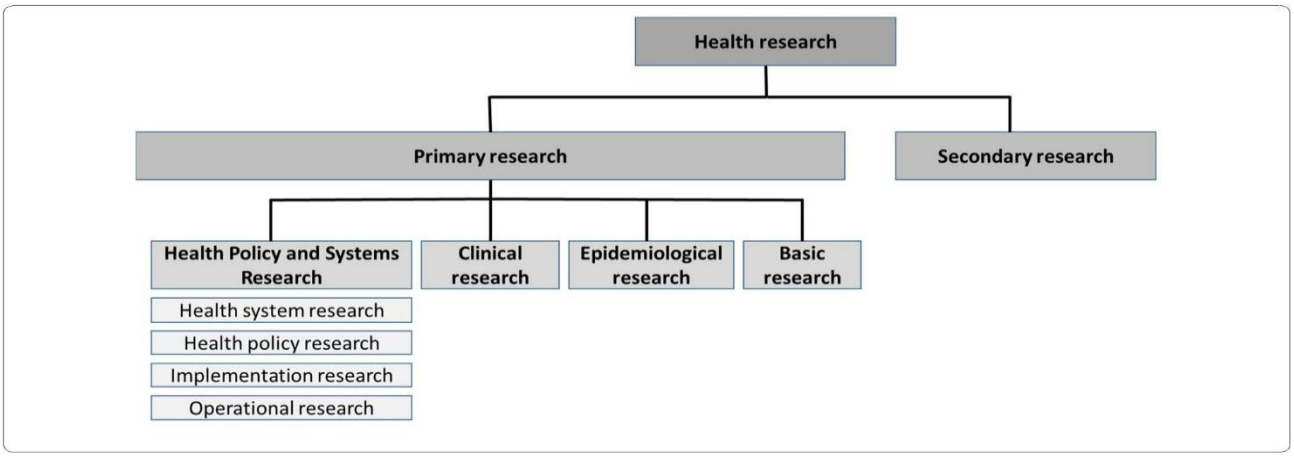

Figure 3.1: Categories of research used in the review

3.3 Results

A total of 747 potential publications were retrieved online while records of 165 approved studies were accessed from COMREC and NHSRC. After applying the inclusion and exclusion criteria to the publications, 483 publications were assessed for type and amount of malaria research from Malawi, of which 412 (85.3%) was research conducted in Malawi only and 71 (14.7%) was multi-country research which included Malawi. Furthermore, 410 publications and 37 approved studies were assessed for sources of malaria research funding (Fig. 3.2). However, records of approved studies in earlier years (from 1988 to 2005 from NHSRC, and from 1996 to 2005 from COMREC) were not available.

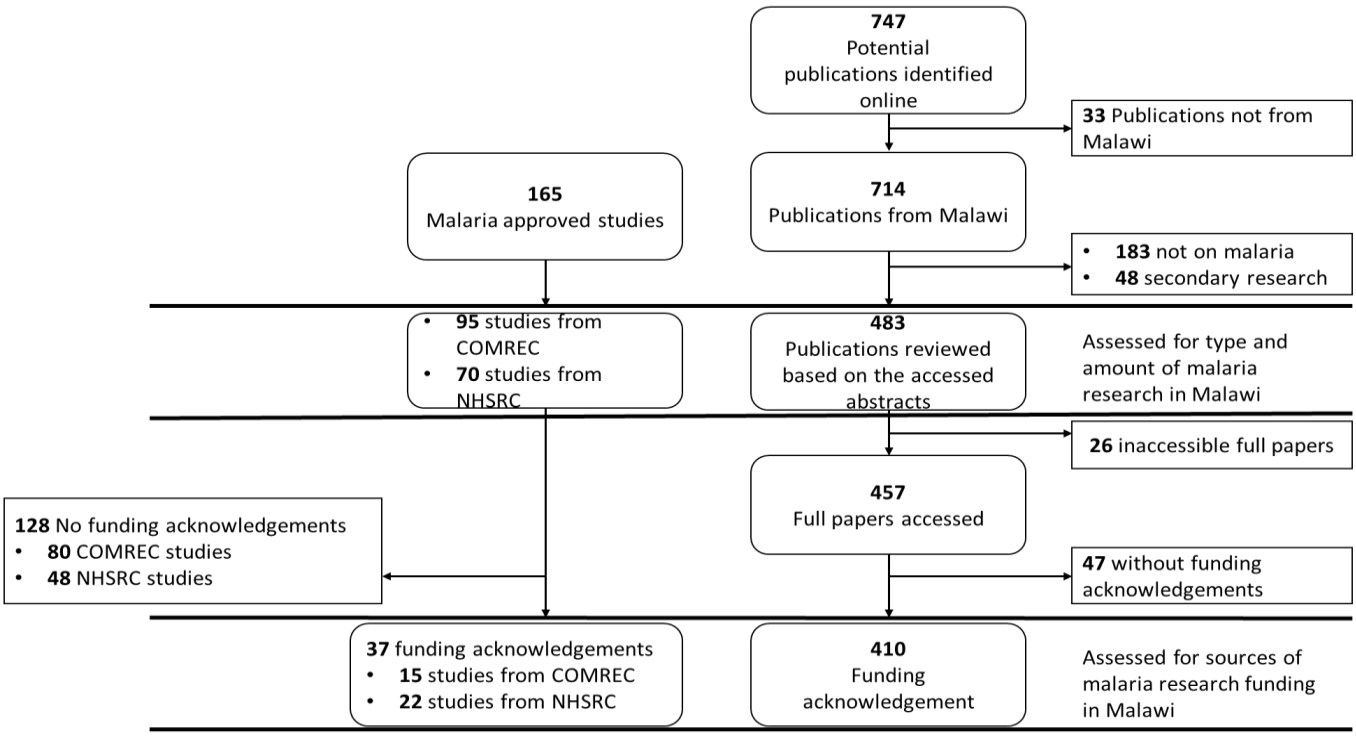

Figure 3.2: A flow chart of the selection process of studies and publication reviewed

3.3.1 Trend of malaria research since 1984

The number and trend of malaria publication records for each year are presented in Fig. 3.3. It is evident that there has been a slow increase in the number of malaria publications from 1984 to 2001 with exceptions in 1994 and 1996 and increasing steadily from 2002 to 2016. The lowest number of publications was in 1986 with only one (0.21%) publication while the highest number was in 2015 with 51 (10.6%) publications. However, there was an average of 15 publications per year.

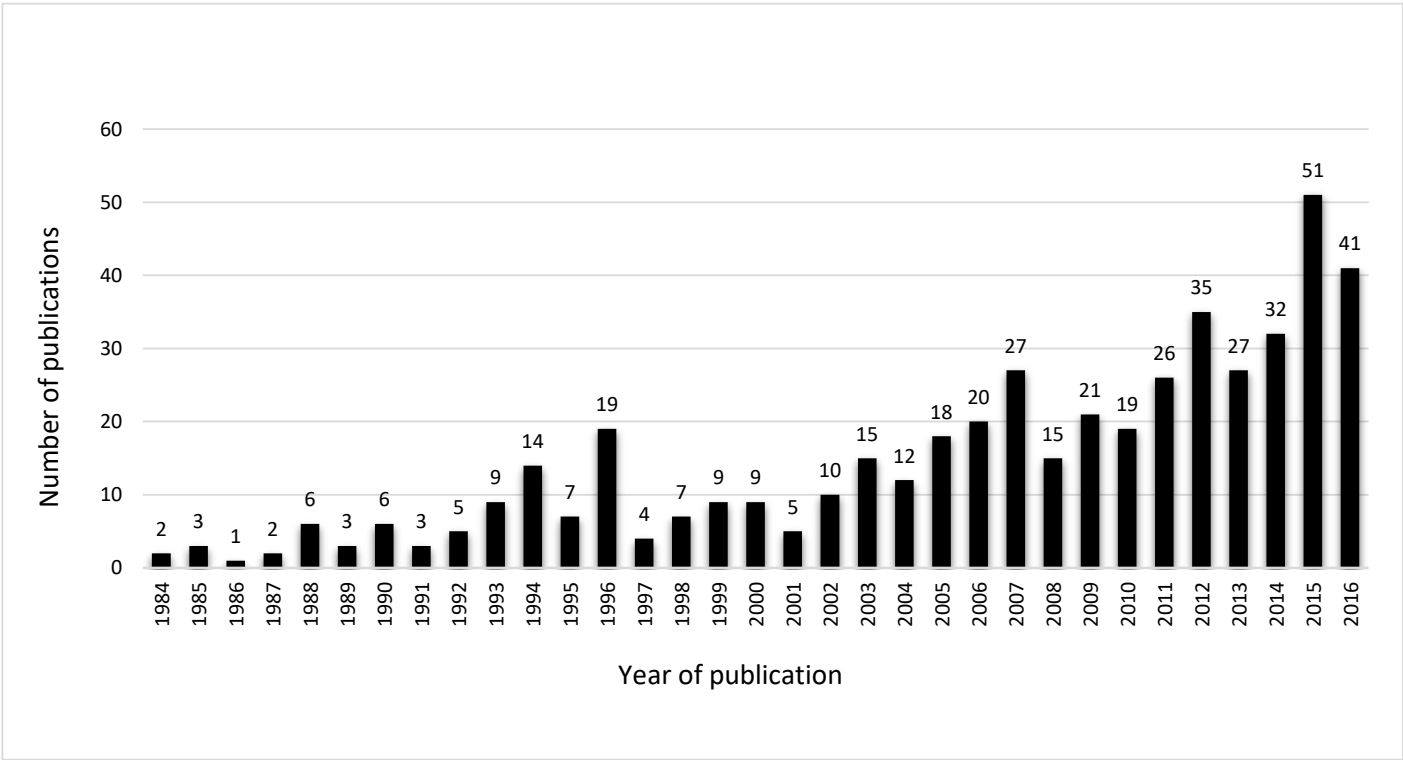

Figure 3.3: Trend of malaria publications in Malawi

Approved studies from ECs showed a steady increase with 2014 approving 27 studies and uniquely in 2007 when 21 studies were approved compared to the previous and later years until 2014 (Fig. 3.4).

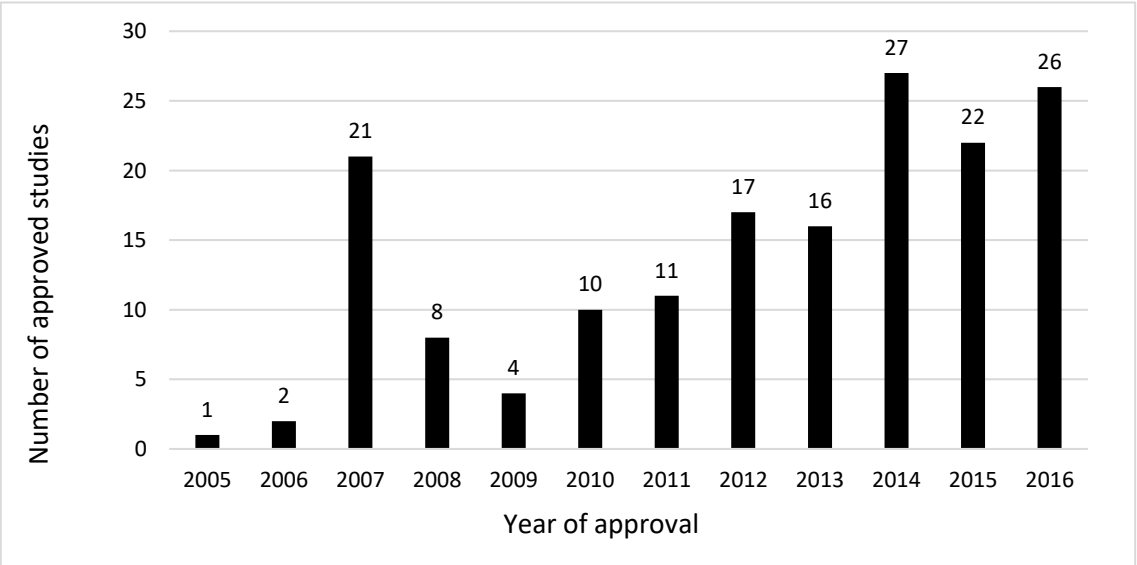

Figure 3.4: Trend of malaria approved studies in Malawi

3.3.2 Publishing journals for malaria research in Malawi

There were a total of 118 journals that published malaria research from Malawi with only three (2.5%) African journals, which included the *African Journal of Health Sciences* with one (0.2%), *African Health Sciences* with two (0.4%), and the *Malawi Medical Journal* with 13 (2.7%) publications. However, Fig. 3.5 shows journals with five (1%) or more publications. It shows that *Malaria Journal* registered the highest number of publications, contributing 76 (15.7%) publications, while the local *Malawi Medical Journal* contributed 13 (2.7%) publications.

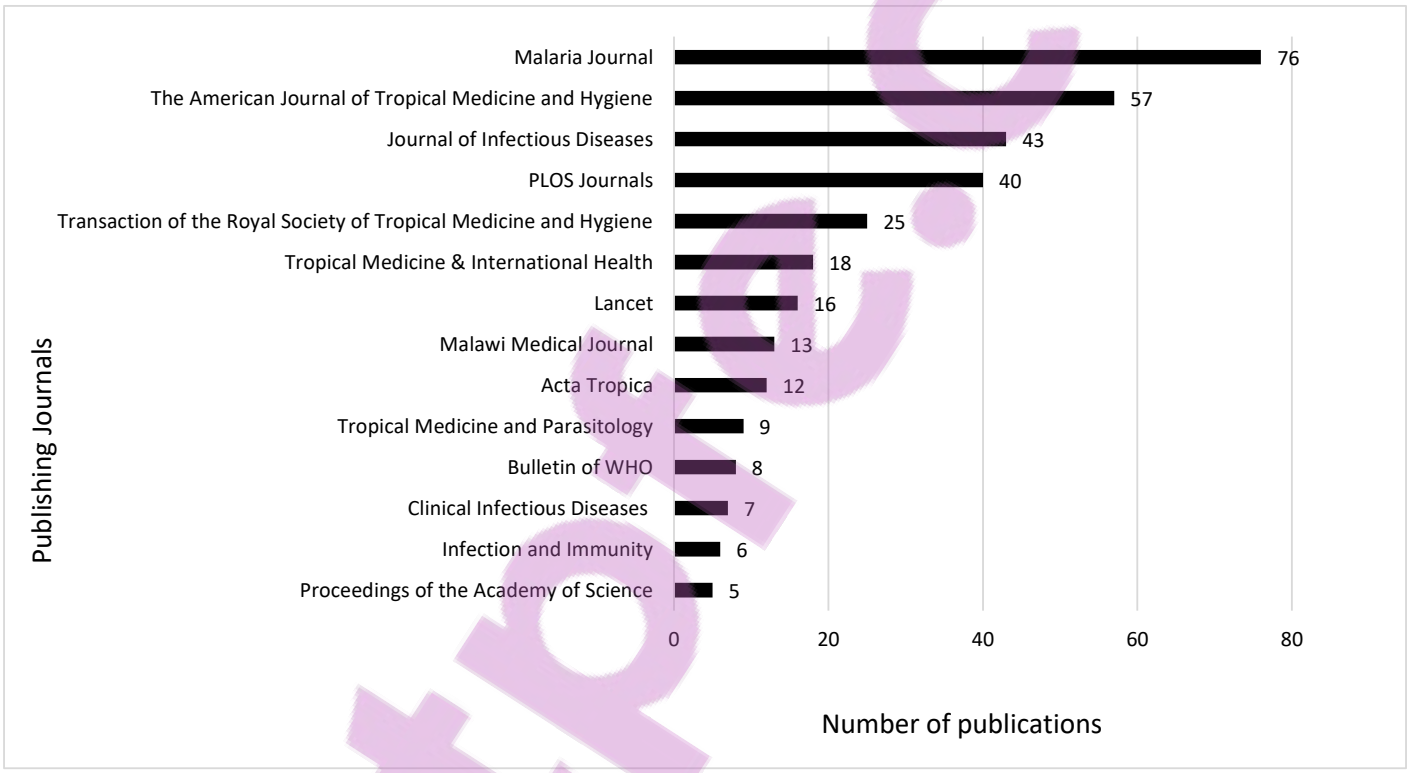

Figure 3.5: Journals publishing malaria research from Malawi

3.3.3 Types of research

Categorizing studies into specific types posed a challenge as many studies overlapped. However, this was overcome by the agreement of two independent reviewers on disagreed studies. The first categorization of type on malaria research was based on either research being basic, clinical, epidemiological, or HPSR. Both the publications and approved studies show that clinical research was dominant with 185 (38%) and 53 (32%), respectively (Fig. 3.6). Further categorization of HPSR publications (n=66), shows that 28 (43%) were health systems research, 14 (21%) were implementation research, while health policy and operation research had 12 (18%) publications each. The HPSR in the approved studies (n=39) shows that 18 (46%) were implementation, 13(33%) operational, six (16%) health systems, and two (5%) health policy research.

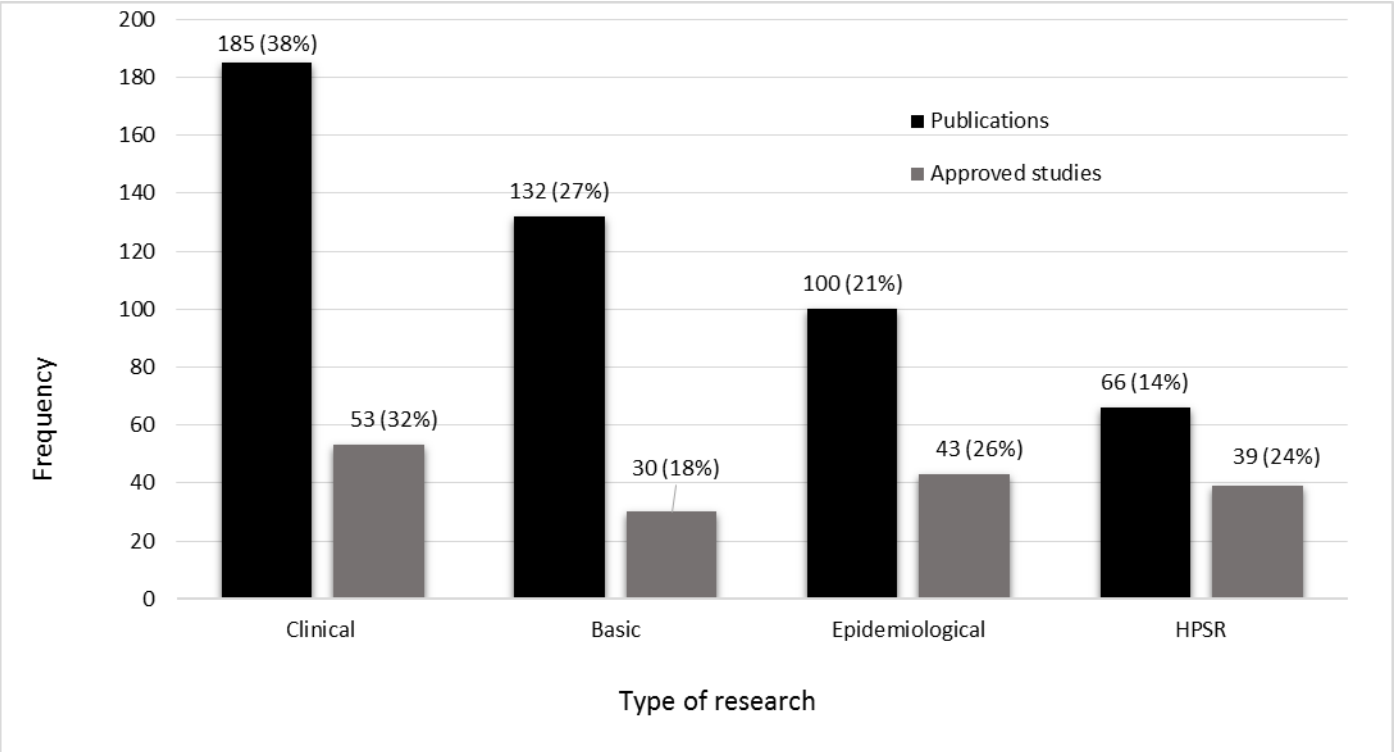

Figure 3.6: Type of malaria research conducted in Malawi

3.3.4 Focus areas for malaria research conducted in Malawi

Malaria research was also assessed in relation to areas of focus. It was shown that 105 (21.7%) publications were focused in the field of malaria in pregnancy and 97 (20.1%) in severe malaria with only one publication on malaria vaccine, while morbidity studies 33 (20%), severe malaria 28 (17%) and HPSR 24 (14.5%) dominated in the approved studies (Table 3.2).

Table 3.2: Areas of focus for malaria research in Malawi

Field of malaria research	**Number of publications**	**Approved studies**
Malaria in pregnancy	**105 (21.7%)**	15 (9.1%)
Severe malaria	**97 (20.1%)**	28 (17%)
Vector and/or agent dynamics	69 (14.3%)	16 (9.7%)
Morbidity	64 (13.3%)	**33 (20%)**
Drug evaluation	52 (10.8%)	20 (12.1%)
HPSR	38 (7.9%)	24 (14.5%)
Prevention	30 (6.2%)	14 (8.5%)
Diagnosis	20 (4.1%)	6 (3.6%)
Immunology	7 (1.4%)	3 (1.8%)
Malaria vaccine	1 (0.2%)	6 (3.6%)
Total	**483 (100%)**	**165 (100%)**

Forty-two publications were also reviewed in reference to co-infections. Thirty-three (79%) out of 42 publications were on HIV and AIDS and malaria co-infection, followed by four (2%) on nutritional problems; the 12 approved studies identified were on co-infection research of malaria and HIV and AIDS.

3.3.5 Affiliation of first and senior/last authors

Institutional affiliations of first and senior/last authors were assessed by examining whether they were affiliated to a Malawian or foreign institution. The results showed that 146 (30%) first authors out of 483 publications were affiliated to a Malawian institution. Forty-eight (32.8%) were affiliated to MLW followed by 31 (21.2%) at COM, University of Malawi (Table 3.3).

Table 3.3: Affiliations of first and senior authors in Malawi

Malawian institutions	**first authors**	**Senior authors**
Malawi-Liverpool Wellcome Trust	48 (32.8%)	30 (30%)
College of Medicine, University of Malawi	31 (21.2%)	20 (20%)
Ministry of Health	18 (12.3%)	20 (20%)
Malaria Alert Center	15 (10.3%)	8 (8%)
Chancellor College, University of Malawi	7 (4.8%)	2 (2%)
Queen Elizabeth Central Hospital	5 (3.4%)	-
Kamuzu Central Hospital	5 (3.4%)	-
Blantyre Malaria Project	5 (3.4%)	19 (19%)
St. Gabriel's Hospital	2 (1.4%)	-
International Eye Foundation	2 (1.4%)	-
Save the Children International	2 (1.4%)	-
Centre for Water, Sanitation, Health and Appropriate Technology Department	1 (0.7%)	-
Beit Cure International Hospital	1 (0.7%)	-
Centre for Social Research	1 (0.7%)	1 (1%)
Safe Motherhood Project and Blantyre Integrated Malaria Initiative	1 (0.7%)	-
Department of Pediatrics, University of Malawi	1 (0.7%)	-
Malamulo Hospital	1 (0.7%)	-
TOTAL	**146 (100%)**	**100 (100%)**

Upon further analysis of first authors affiliated to Malawian institutions compared to year of publications, there had been a slight increase with time. The exception was observed in 2007 and 2015 with 15 publications each with first authors in Malawian institutions (Fig. 3.7).

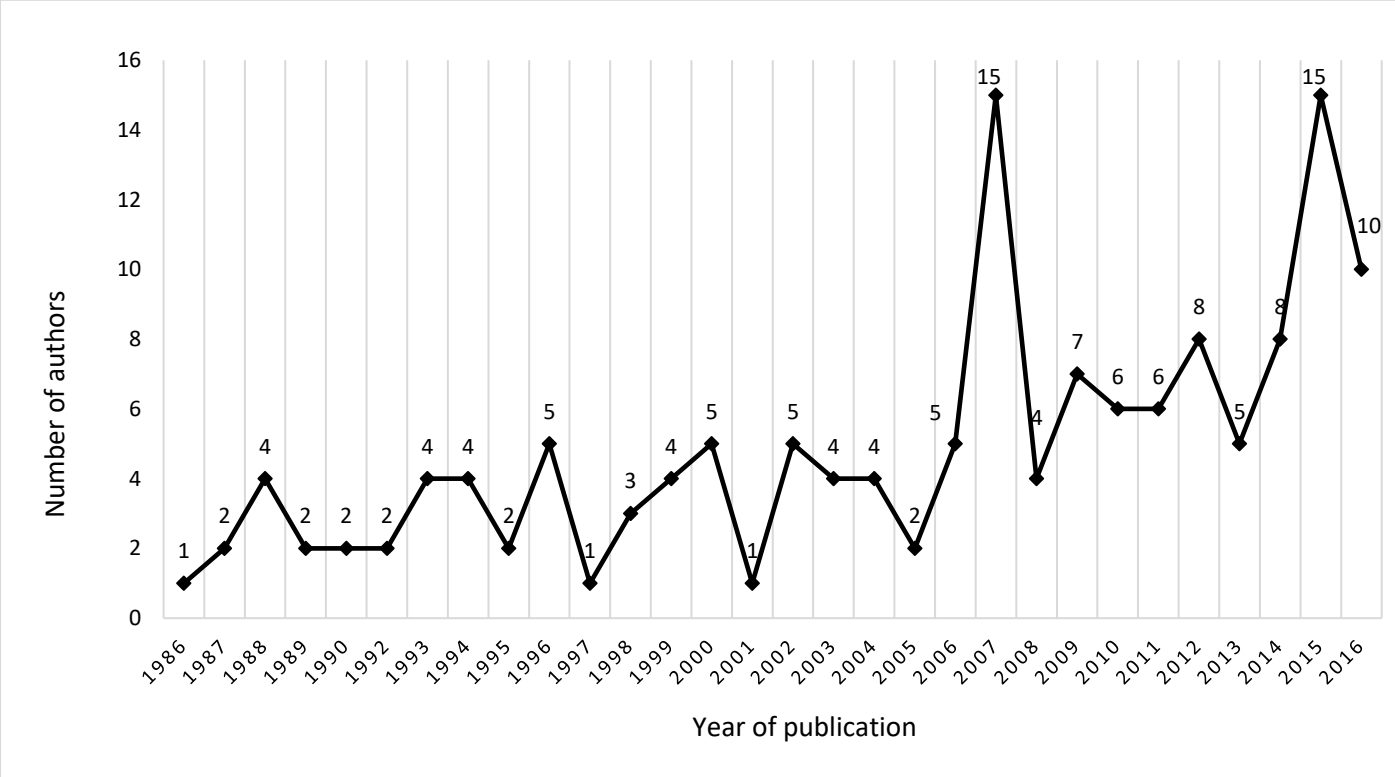

Figure 3.7: Number of first authors affiliated to Malawian institution with time

Senior authorship was assessed through examination of the last author, who is considered to be the supervisor or senior member of the team [14]. The results showed that 100 (21%) senior authors out of 483 publications were affiliated to an institution based in Malawi. Thirty (30%) were affiliated to MLW followed by 20 (20%) to COM and MOH each (Table 3).

In the 165 approved studies assessed 88(53.3%) PIs were affiliated to a Malawian institution, 16 (9.7%) to a foreign institution while the affiliation of 61 (37%) PIs was unknown as it was not indicated in the records. Table 4 shows that 20 (23%) PIs were affiliated to COM and 12 (14%) to MAC, BMP and UNC project each.

3.3.6 Collaboration

Collaboration was ascertained when there was an affiliation between a Malawian and a foreign institution as indicated in the authors' affiliations. Out of 483 publications, 350 (72%) showed a collaboration, while 120 (25%) indicated foreign institutions only and 13 (3%) were Malawian institutions only.

Collaboration in the approved studies was not established because only the institution of the PI was indicated in the records. However, it is a requirement that foreign institutions conducting research in the country should be affiliated to a local institution and incorporate local researchers for purposes of collaboration and capacity building.

3.3.7 Sources of malaria research funding in Malawi

Funding acknowledgements were assessed in the accessed full papers. One of the limitations was that only 457 (94.6%) full papers out of 483 publications included in the review could be retrieved. In addition, 410 (89.7%) out of 457 full papers acknowledged their source of funding (Fig. 3.2). There were several papers that acknowledged more than one funder and Fig. 3.8 only shows funding acknowledgments for a funder(s) in four (1%) or more publications. Similarly, details of approved studies from ECs were incomplete as only 37 (22.4%) out of 165 studies indicated their source of funding.

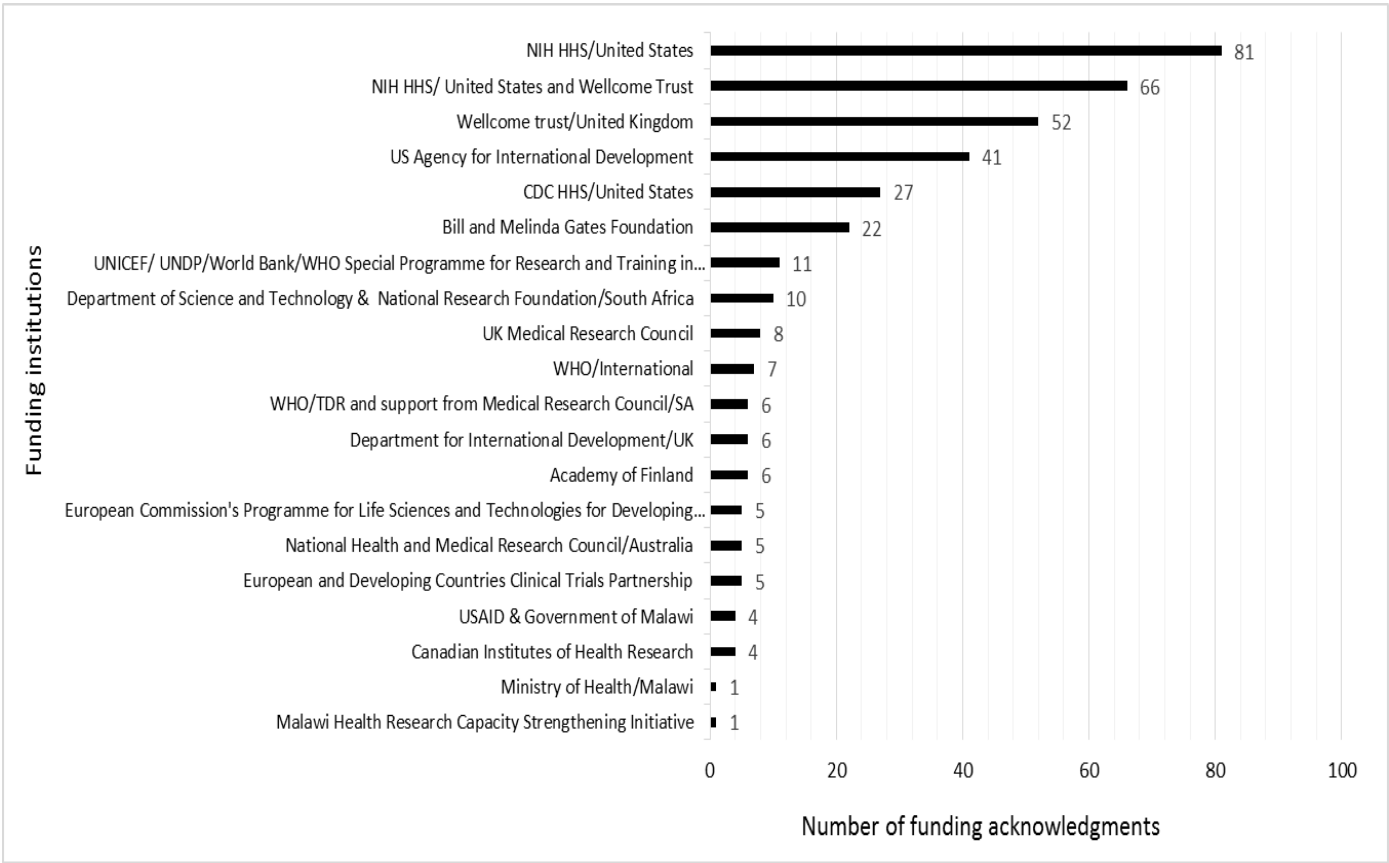

Figure 3.8: Malaria research funders in Malawi acknowledged in publications

The National Institute of Health, Health and Human Sciences (NIH HHS) was the highest funding institution with 81 (20%) funding acknowledgements, followed by co-funding institutions of NIH HHS and the Wellcome Trust, UK, with 66 (16%) funding acknowledgements. Funding acknowledgements from Malawian institutions were explored and four (1%) publications were jointly funded by USAID and the Government of Malawi, while the Malawi Ministry of Health and Malawi Health Research Capacity Strengthening Initiative funded one (0.2%) research each. It is of interest to note that five out of these studies funded by the Malawian institutions and those with partners are mainly contextual studies that seek to understand the morbidity, epidemiology, and implementation of interventions.

Thirty-seven (22.4%) of the ethically approved studies indicated their source of funding. Figure 3.9 shows analysis of approved studies from funding institutions that funded two or more studies (n=23). The Centre for Disease Control Health and Human Services (CDC HHS) funded six studies while the Malawian Ministry of Health funded three studies.

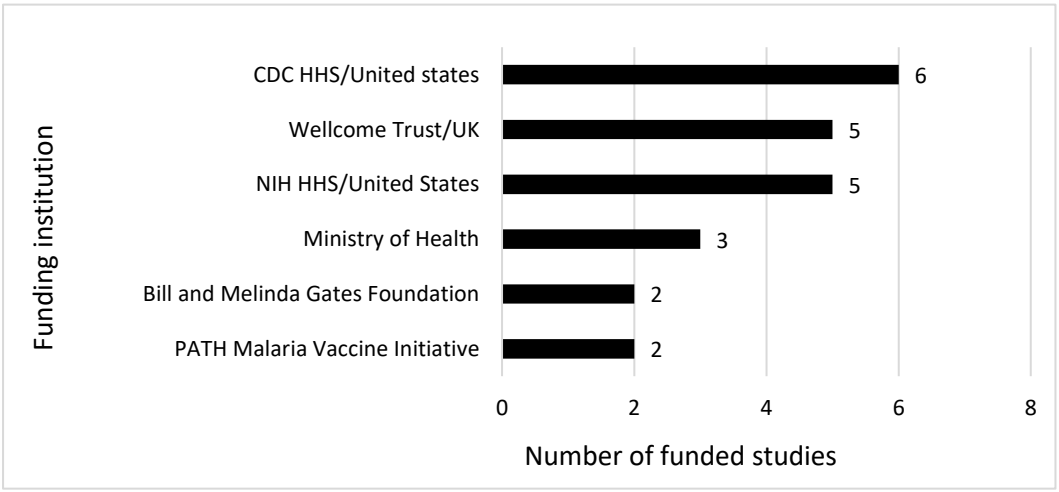

Figure 3.9: Malaria research funders in Malawi acknowledged in the approved studies

The analysis showed that clinical research was highly funded, with 154 (38%) out of 410 publication acknowledgments and 16 (43%) of approved studies, while 51 (12%) of publications and five (14%) of approved studies in HPSR were the least to be funded as acknowledged (Fig. 3.10).

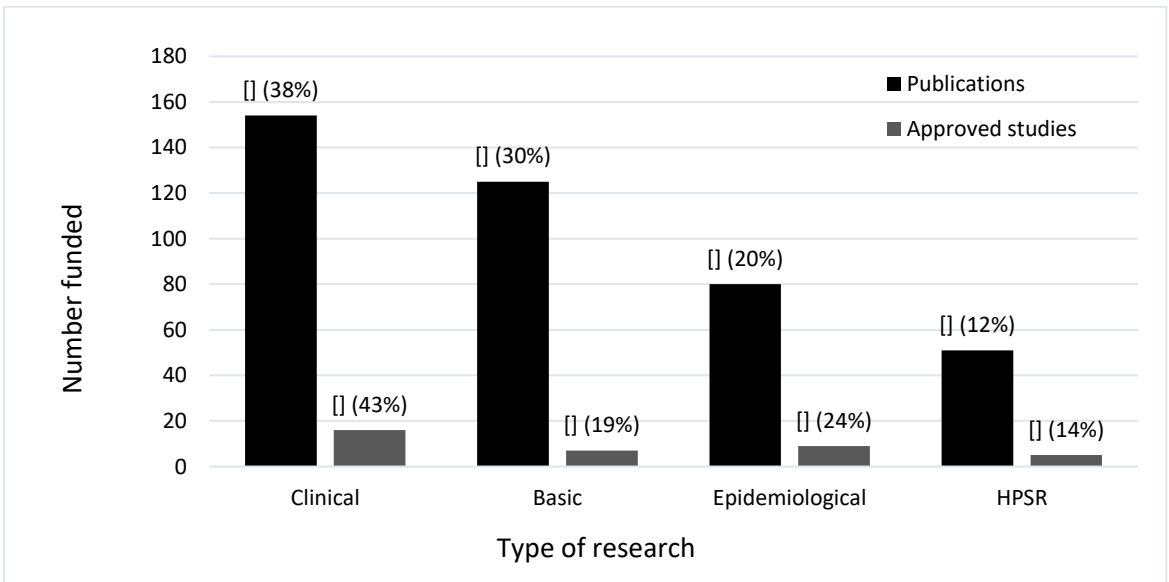

Figure 3.10: Most funded malaria research type in Malawi

3.4 Discussion

The review focused on assessing the type and amount of malaria research conducted in Malawi from 1984 to 2016 and its related source of funding. Bibliometric analysis was utilised to measure the number of publications from primary malaria research conducted in Malawi as a measure of scientific research activity. A total of 483 publications of primary malaria research originating from Malawi were online and 165 malaria approved studies from ECs. Malaria research activity in Malawi has steadily grown from two publications in 1984 to 51 in 2015 and 41 in 2016, and from one approved study in 2005 to 26 in 2016. This growth is linked to the research capacity in Malawi coinciding with the establishment of the COM in 1991 and its affiliates, such as the MAC, MLW and BMP. This has also shown that the majority of researchers are affiliated to these institutions as revealed in the assessment of first and senior/last authors. Other notable research institutions conducting malaria research in Malawi include the University of North Carolina (UNC) project, and the Ministry of Health. This rise in research activity contributed to Malawi being ranked eighth in the top African countries publishing malaria research between 1995 and 1997 [15]. Another important aspect revealed in this assessment was the level of collaboration. It is through collaboration that local capacity building can be strengthened although the level of involvement in the research is critical to ascertain this. The study has shown high collaboration, from publications, between one or more institutions in Malawi and one or more foreign institutions. It would have been ideal to establish the origins of authors and assess how many Malawian researchers were involved in the studies but ascertaining this based on names alone was a challenge (because last names may change through marriage, hence, being categorized differently) leading to underestimation or overestimation.

The type of research conducted in Malawi has shown that clinical and basic research are extensively conducted, with HPSR being the least supported. A similar review of research on infectious and non-infectious diseases in Malawi for the purposes of research gap analysis in the development of a national health research agenda revealed that clinical research was common while HPSR was the least [16]. The type of research reflects the research focus of COM and its affiliates in conducting clinical and basic research in malaria in pregnancy, severe malaria, and vector and/or agent dynamics. Similarly, these institutions will also acknowledge

their major funders, for example, BMP attracts funding from NIH, USA, and MLW attracts funding from the Wellcome Trust, UK, which has also been identified to be the UK largest funder of infectious disease research to countries with colonial ties and Malawi is ranked as the fourth highest beneficiary [17]. This high reliance on external support for research funding is also reflected in the amount of funding from external support for malaria control [18].

The quality of these publications was not assessed due to the large volumes handled. However, the fact that they were published in reputable journals signifies that they underwent thorough peer review and were checked for quality. Malaria research from Malawi was mainly published in international journals since only three African journals were identified in this study and these included the *African Journal of Health Sciences*, *African Health Sciences*, and the *Malawi Medical Journal*. The major publisher of malaria research from Malawi is *Malaria Journal*, followed by the *American Journal of Tropical Medicine and Hygiene* and of special interest was the local *Malawi Medical Journal* indexed in Medline with 13 (2.7%) publications. This should be a platform to encourage local researchers to publish in local and regional journals as they are easily accessible to local policymakers and have been shown to influence policy change more than European or American journals [19]. Local academic institutions should put equal weight on the basis for promotion to publications in these journals as long as they are indexed in reliable databases [11].

Funding acknowledgements from publications show that NIH, USA topped the list, followed by joint funding by NIH and Wellcome Trust. Funding acknowledgements may indicate support but do not show the exact amount of funds put into the research. Some funders partially support or provide infrastructure which may not be acknowledged. Funders may influence recognition to be acknowledged and keep records of publications they fund [20]. All in all, funders and policymakers are obliged to assess the quality and impact of their research investments and one of the approaches is to quantify the publication output, hence publishing should be a requirement for every funded research [21].

Of interest were the acknowledgements from Malawi, which showed joint funding by the USAID and the Government of Malawi in four publications, while the Ministry of Health and the Malawi Research Capacity Strengthening Initiative were acknowledged in one publication each. This shows high reliance on external funding and the challenge of local research funding availability. This can further be related to external support of clinical and basic research, which attracts more funding and is likely to be published [15]. The HPSR, which is the least supported in the publications, addresses issues that provide remedies to local health systems and likely influences practice and policy development as it is contextual [22]. This type of research need support from the government if it aims at improving the health system and policy implementation. The challenge also remains in its dissemination by publication because of the difficulty to be accepted in international journals [15]. However, as more local and regional journals, such as the *Malawi Medical Journal*, are being indexed in the Medline, this type of research should be encouraged for publication, undergo peer review and increase visibility and readability. Policies based on non-peer reviewed work usually raise concerns on the quality of evidence used, which may later have implications on quality of services [23]. Policymakers should be involved in the research process from the beginning and encourage collaboration with academicians, who should be responsible for publishing work as part of their promotion criteria.

As the HPSR is focused on improving the local health systems, the government should be responsible for providing funding for such research. Malawi is in the process of renewing the National Health Research Agenda, which outlines the country's research needs. This is a critical step that can be the foundation of resource mobilisation. Through its wider dissemination, external funding institutions can be compelled to align their research focus to local needs. In addition, the government should commit research funding as agreed in the Abuja Declaration, setting aside 2% of the health budget to research [24].

3.5 Limitation(s) of the study

The online search was only limited to the Medline/PubMed database, hence publications from Journals not indexed in this database may have been missed. However, all efforts were

made to search from reference sections of full articles that were accessed for potential articles missed out in the initial search. In addition, due to time and staff capacity the broad term of 'malaria' was used in the search with the assumption of capturing all malaria-related terms. However, this may have missed out other potential publications with terms not associated to malaria.

3.6 Conclusion

Viable malaria research has been conducted in Malawi since 1984 with clinical and basic research leading in both publications and funding. The major sources of funding for malaria research in Malawi come from NIH, USA, and the Wellcome Trust, UK, whose institutions, the BMP and MLW respectively, are affiliated to COM. The research focus of these institutions is reflected in the findings of this review, as clinical and basic research dominate in the fields of malaria in pregnancy, severe malaria and vector and/or agent dynamics. The least supported HPSR provides contextual evidence for the improvement of the health systems. As Malawi embarks on renewing the National Health and Research Agenda (NHRA), it is important that great attention is be placed on conducting HPSR, which will serve to understand the delivery of health services in Malawi and community dynamics in policy adoption during implementation. This, therefore, calls for government commitment to mobilise resources to support such research, which should also be encouraged for publication in local or regional journals indexed in major databases. Similarly, local malaria researchers should be aggressive in resource mobilisation, such as grant applications, in order to conduct research that addresses local needs, as stipulated in the NHRA.

The quantity of publications, which may reflect the scientific research activity of a country, does not alone reveal the primary impact of research [11], i.e., improvement of public health. One immediate way of assessing this is to examine how development of health policies has been informed by local research.

Abbreviations

BMP: Blantyre Malaria Project; CDC: Centre for Disease Control; CDC HHS: Centre for Disease Control Health and Human Services; COM: College of Medicine; COMREC: College of Medicine Research and Ethics Committee; CRH: Centre for Reproductive Health; ECs: Ethical Committees; HPSR: Health Policy and Systems Research; MAC: Malaria Alert Centre; MESH: Medical Subject Headings; MLW: Malawi-Liverpool Wellcome; NHSRC: National Health Sciences Research Committee; NIH HHS: National Institute of Health, Health and Human Sciences; NMCP: National Malaria Control Programme; OECD: Organization for Economic Co-operation and Development; UNC: University of North Carolina; USAID: US Agency for International Development.

Authors' contributions

CAM conceived and developed the idea, and prepared the manuscript. KP contributed to shaping the idea. CMM, HL, TdJ, and CH contributed their technical expertise in directing and critiquing of the manuscript. All authors read and approved the final manuscript.

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Competing interests

The authors declare that they have no competing interests.

Availability of data and materials

The data that support the findings of this study are available from the corresponding author upon request.

Ethics approval

Ethical clearance was obtained from the National Health Sciences Research Committee (Ref No. NHSR #1203) in Malawi and the Faculty of Health Sciences Research Ethics Committee at the University of Pretoria (Ref No. 146/2013).

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CHAPTER FOUR

Introduction

Chapter three revealed the various types of malaria research conducted in Malawi, between 1984 and 2016, demonstrating the availability of evidence for policy formulation. The next step was to examine how malaria research has influenced policy development in Malawi. Chapter four, therefore, explores how this evidence has influenced the development of local malaria policies in Malawi during 1984 to 2016.

4.0 MALARIA RESEARCH AND ITS INFLUENCE ON ANTI-MALARIAL DRUG POLICY IN MALAWI: A CASE STUDY

Abstract

Background: In 1993, Malawi changed its first-line anti-malarial treatment for uncomplicated malaria from chloroquine to sulfadoxine-pyrimethamine, and in 2007, it changed from sulfadoxine-pyrimethamine to lumefantrine-artemether. The change in 1993 raised concerns about whether it had occurred timely and potentially leading to early development of *Plasmodium falciparum* resistance to sulfadoxine-pyrimethamine. This case study examined evidence from Malawi in order to assess if the policy changes were justifiable and supported by evidence.

Methods: A systematic review of documents and published evidence between 1984 and 1993 when chloroquine was the first-line drug, and 1994 and 2007 when sulfadoxine-pyrimethamine was the first-line drug was conducted herein. The review was accompanied with key informant interviews.

Results: A total of 1287 publications related to malaria drug policy changes in sub-Saharan Africa were identified. Using the inclusion criteria, four articles from 1984 to 1993 and eight articles from 1994 to 2007 were reviewed. Between 1984 and 1993, three studies reported on chloroquine poor efficacy prompting policy change by WHO's recommendation. From 1994 to 2007, four studies conducted in the early years of policy change reported on high sulfadoxine-pyrimethamine efficacy of above 80%, retaining it as a first-line drug. Unpublished sentinel site

studies between 2005 and 2007 showed a reduced efficacy of sulfadoxine-pyrimethamine, influencing policy change to lumefantrine-artemether. The views of key informants indicate that the switch from chloroquine to sulfadoxine-pyrimethamine was justified based on local evidence despite unavailability of WHO's policy recommendations while the switch to lumefantrine-artemether was uncomplicated as the country was following the recommendations from WHO.

Conclusion: Ample evidence from Malawi influenced and justified the policy changes. Therefore, locally generated evidence is vital for decision making during policy change

Key words: malaria, anti-malarial drug policy, Chloroquine, Sulfadoxine-pyrimethamine, Lumefantrine-artemether, Malawi

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4.1 Background

Research is critical in providing information that can be used for decision making and policy change [1, 2]. For instance, the World Health Organization (WHO) emphasized the importance of evidence when developing policy recommendations on the use of Intermittent Preventive Treatment of malaria in pregnancy (IPTp) with Sulfadoxine-pyrimethamine (SP) after reviewing published evidence from various research findings in malaria-endemic regions, including Malawi [3]. On the other hand, experience from many countries has shown how research conducted within the country informs policy [1]. As such, research conducted within a country with valid results is more appropriate to be used to inform policy even though evidence from multi-country studies is more effective for convincing policy makers [1].

However, despite the overwhelming scientific evidence, policy change is not straight forward since it takes into consideration many factors, such as the political environment, costs of alternative choices and stakeholders' views [4, 5]. Choosing the right drug that is efficacious in the treatment of a disease is one step towards policy change, but the change process is often long and tedious, as it involves various stakeholders from both the public and private sectors [5, 6].

The treatment of uncomplicated malaria has, over the years, undergone transitions worldwide, owing to the development of resistance of the *Plasmodium* species to first-line anti-malarial drugs [7]. In a few countries in sub-Saharan Africa (SSA) such as Zambia, Kenya and Tanzania, efficacy data from *in-vivo* studies on chloroquine (CQ) resistance led to policy changes in anti-malarial drug treatment from CQ to SP [1, 8, 9]. However, in most SSA countries, the process for health policy making has proven to be a complex process [6, 10, 11]. For instance, experience from drug policy change in Kenya, from CQ to SP, revealed difficulties in translating data, and the process was complicated with limited options, unknown adverse effects of replacement therapies, cost, including the limited guidance on factors pertinent to changing the drug policy for malaria [9]. In addition, many of the SSA countries are poor and policy change decisions are highly influenced by their economic budget considerations [12]. This was the case in Sudan where the decision to change the policy for anti-malaria drug treatment was delayed despite the evidence of drug resistance to CQ [13].

Malawi, as one of the resource-limited countries in SSA, experienced changes in anti-malarial drug policies amid concerns over *P. falciparum* resistance to the first-line anti-malarial drugs and became the first country to change the treatment policy from CQ to SP in 1993 [14] and later to lumefantrine-artemether (LA), an Artemisin-based Combination Therapy (ACT), in 2007 [15]. However, despite the historical changes in first-line anti-malarial treatment regimens, in particular from CQ to SP, many questions were raised as to whether the change had been done too early and whether the new drugs would develop resistance quickly [16]. These concerns were raised as a result of uncertainty surrounding the usage of clear-cut evidence on drug efficacy from within the country or region.

A systematic review, and documents review were conducted to examine whether evidence from past research on anti-malarial drug efficacy conducted in Malawi influenced anti-malarial drug policy changes from CQ to SP and SP to ACT, amidst economic, political and health systems challenges. In addition, views from key informants were sought on their experience and general perceptions on the policy changes. Results from this case study provide valuable insights into whether the policy changes were justifiable amidst the challenges and the unforeseen uncertainties with the anti-malarial drug policy change in Malawi.

4.1.1 Conceptual framework

A case study approach was adopted in order to understand specific issues that were involved in the anti-malaria drug policy changes. This approach was appropriate as it sought to gain an in-depth understanding of the basis for the policy changes in consideration to the concerns raised. A case study attempts to gain an insight into a single occasion on how it occurred through the experiences of those directly involved in the process. Therefore, getting a few answers from the individuals involved in the case enriches the study itself [17].

This case study forms part of the process in understanding the usage of malaria research with the objective of developing a framework that can be used to facilitate the utilisation of malaria research evidence for policy development in Malawi. The main purpose of developing this framework was to facilitate adoption of malaria research for policy development hence maximising on limited resources available in the country. It was therefore, guided by exploring

the institution set up and the barriers and facilitators on the evidence-to-policy process in Malawi.

One of the most important aspects for policy change is the availability of evidence to justify the change. As aforementioned, the policy changes that occurred in Malawi came with many reservations. Therefore, the basis for the policy decisions required to be justified. One of the justifications is the availability of evidence. This case study explores whether there was sufficient research evidence to justify Malawi's policy changes. This study was conceptualised under the philosophy that sufficient and locally generated evidence is required to justify policy change.

This paper focuses on availability of research evidence; hence it highlights evidence from efficacy studies on levels of first line anti-malarial drug regimens and their alternative drugs, which formed the basis for decision making in the policy changes. In addition, views of key individuals that were directly involved in the policy changes are presented towards the policy changes.

4.2 Methods

The study involved three approaches namely, systematic review of published evidence, review of key documents and key informant in-depth interviews.

4.2.1 Systematic review

A comprehensive literature search was conducted in September 2014. Relevant articles were also searched using the bibliography of all reviewed articles. Combinations of the following specific key words relating to malaria drug efficacy were searched by using the Medical Subject Heading (MESH) strategy: chloroquine (CQ), Fansidar or sulfadoxine-pyrimethamine (SP), Fanasil, pyrimethamine drug combination, lumefantrine-artemether (LA) or artemether-lumefantrine combination, and SSA or Malawi. The search included articles from the periods 1984 to 1993, when CQ was the first-line anti-malarial drug for uncomplicated malaria in Malawi, and from 1994 to 2007, when SP was the first-line drug before being replaced by LA. The following combinations were used during the search: ("key word" [Supplementary Concept]) AND "Malawi"[Mesh] Filters: From 1984/01/01 to 1993/12/31, ("key word" [Supplementary Concept]) AND "sub-Saharan Africa"[Mesh] Filters: From 1984/01/01 to 1993/12/31), "key word"[Mesh] AND "Malawi"[Mesh] AND ("1994/01/01"[PDAT] : "2007/12/31"[PDAT]), "key word"[Mesh] AND

"sub-Saharan Africa"[Mesh] AND ("1994/01/01"[PDAT] : "2007/12/31"[PDAT]). The data bases searched were Ovid, MEDLINE, PubMed, and Google scholar.

4.2.2 Selection criteria

Randomized Control Trials (RCTs) and cohort studies were included on the basis of the following criteria: 1) studies on treatment efficacy for CQ, SP and LA; and 2) studies comparing the efficacies of first-line drugs; i.e. CQ or SP with alternative drugs. Two independent co-authors judged the eligibility of the studies and disagreements were resolved by consensus.

4.2.3 Analysis approach

Quality assessment of the papers was conducted using the Munn *et al.* [18] newly developed and tested tool for the critical appraisal of prevalence studies. The purpose was to check whether the research conducted provided tangible evidence for policy making. This involved examining the methodology used and the findings of the study in comparison to the recommended WHO guidelines to prompt anti-malarial drug policy change.

4.2.4 Document review

Key documents narrating the process of change such as memos, minutes, and reports sought. In addition, anti-malarial drug policy documents [19-21] were reviewed to examine the extent to which they made reference to the published research and, in this way, establish the link of the study findings with policy and guidelines development.

4.2.5 Key Informant Interviews

This involved interviewing individuals, such as policy makers and researchers, who were directly, involved in the policy changes in order to capture their views on how evidence was utilised and their general opinions on the changes. Hence, a purposive sampling technique was employed in identifying the key informants. In total, 12 individuals were identified and interviewed. There were 10 senior malaria researchers who were involved in the production of evidence used during the policy decisions, of which five were part of the national malaria advisory committee, and two policymakers including the director for the National Malaria Control Programme (NMCP). Table 4.1 highlights the experience, current position, and role played by the KIs during the policy changes.

All the interviews were conducted by the Principle Investigator who was able to probe and explore in-depth issues based on the conceptual framework of the study. The interviews were conducted in English using a semi-structured interview tool, whose development was guided by the interview schedule for assessing research utilisation in policy making [11].

Table 4.1: Details of key informants (KIs) including their roles in the policy changes

KI	Sex	Current position	Experience	Role during policy change
1	Male	Child health and development specialist	9 years current position	Researcher
2	Male	Pharmacologist, College of Medicine (COM)	Over 10 years in malaria research	Researcher
3	Male	Medical epidemiologist – Director of Malaria Alert Center (MAC), COM	10 years current position	Researcher and advisor
4	Male	Senior Scientist, Malawi-Liverpool-Wellcome Trust Clinical Research Programme	More than 40 years in paediatric malaria research	Researcher and advisor
5	Female	Retired Paediatrician and Director of MAC, COM	More than 30 years in clinical and malaria research	Researcher and advisor
6	Male	Paediatrician, Ministry of Health	More than 30 years in clinical and malaria research	Researcher and advisor
7	Male	Paediatrician, Ministry of Health	More than 40 years in clinical and malaria research	Researcher and advisor
8	Male	Clinical Trialist	6 years in current position	Researcher
9	Male	Entomologist, MAC, College of Medicine	Over 10 years current position	Researcher
10	Male	Medical epidemiologist, College of Medicine	More than 15 years in maternal and child health	Researcher
11	Male	Chief of Health Services – Ministry of Health	More than 10 years in clinical and malaria research	Researcher and policymaker
12	Female	Director of the National Malaria Control Programme, Ministry of Health	5 years current position	Policymaker

4.2.6 Ethics and consent approval

Ethical approval was sought from the Malawi National Health Sciences Research Committee (NHSRC) and the University of Pretoria, Faculty of Health Sciences Research Ethics Committee during the protocol development. The participants were requested to provide consent approval, to interview and record, before the Interviews.

4.2.7 Themes covered in the in-depth interviews

The interviewees were asked about their perceptions on the policy changes with specific themes covering (1) the availability of evidence for decision making during the policy changes, this verified whether there was enough evidence to form the basis of the decisions that led to the

policy changes, (2) the timing of policy changes, this explored if the policy changes were justifiable and made at the right time, and (3) challenges encountered during the policy changes.

4.2.8 Data management and analysis

The recordings were transcribed and coded based on the themes, the software Nvivo 9 was used to organize the data, while verbatim quotes were used to illustrate concepts, and in order to bring reality to the situations studied. Analysis was based on Giorgi's phenomenological approach, which focuses on the experiences that participants have undergone or through shared life experiences from others that influence their perceptions. This approach documents the findings from the interviewee's point of view in order to collect the descriptions of their lived world in respect to interpretations in meaning of the phenomena being described [22].

4.3 Results

4.3.1 Systematic review

A total of 1285 relevant publications from SSA were identified using the developed systematic review criteria. After applying the inclusion and exclusion criteria, 12 publications from Malawi remained, with four articles identified from 1984 to 1993 and eight articles from 1994 to 2007 (figure 4.1).

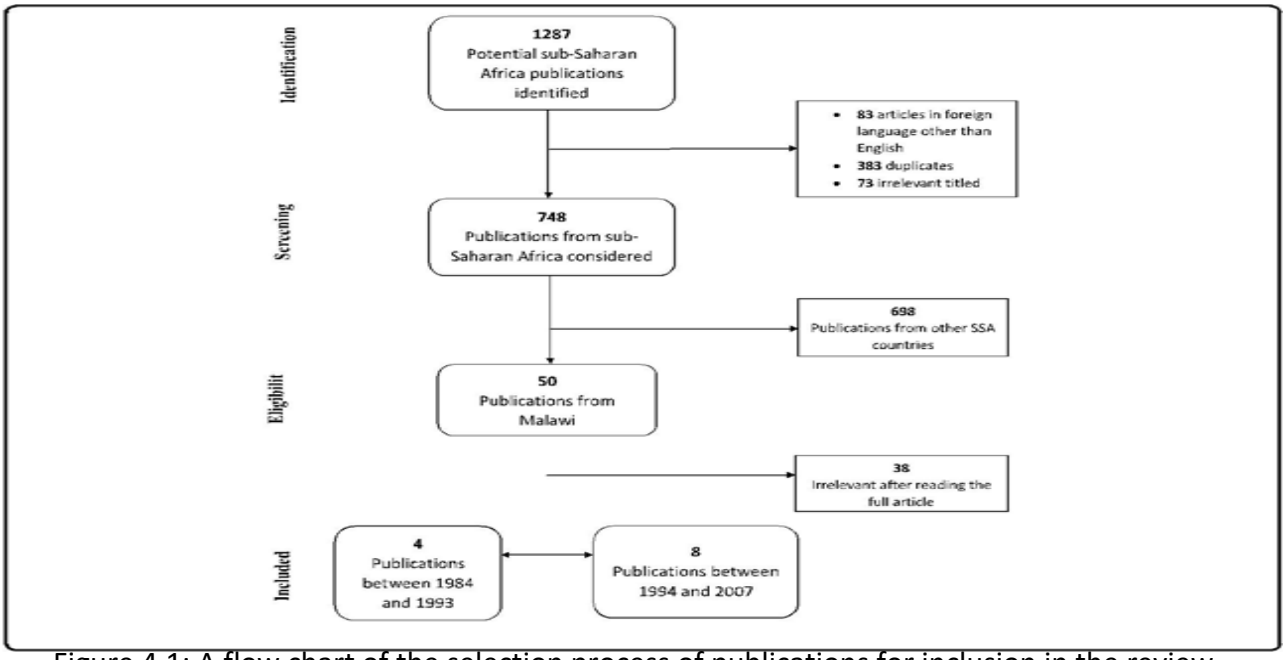

Figure 4.1: A flow chart of the selection process of publications for inclusion in the review

4.3.2 Publications between 1984 and 1993

The review identified four studies that qualified for analysis (Appendix2: Table 4.2). Khoromana *et al.* [23] instituted a study that explored the efficacy of CQ in under-five children at two doses of 10 mg/kg and 25 mg/kg. The study was conducted in six sentinel surveillance sites in Malawi across the three regions where malaria transmission occurs throughout the year. The results from these sites were similar. The overall parasitological failure on day seven of follow up of CQ was 57%, ranging from 41% to 65%. Despite the poor parasite clearance even at a higher dose, CQ was retained as the first-line drug for the treatment of uncomplicated malaria because of its lower cost and availability compared to alternative therapies.

Heymann *et al.* [24] carried out a study that compared the efficacy of CQ to amodiaquine and SP in under-five children. Parasitological failure on day seven of follow up for CQ was at 41% while amodiaquine had a 97% clearance and SP had a 100% clearance. On 21-day follow-up period amodiaquine and SP were further compared in relation to recrudescence and 34% of recrudescence occurred in the amodiaquine group while none occurred in the SP group. Bloland *et al.* [25] compared the efficacy of CQ and SP in Kenya and Malawi and results from Malawi showed that there was 82.3% parasitological failure in the 28-day follow-up period in the CQ group while 70% in the SP group exhibited parasitological response. Bloland *et al.* [25] concluded that CQ was no longer an effective drug for treating malaria and hence recommended SP as its replacement.

Later Heymann *et al.* [26] performed an efficacy study of CQ on parasitaemia during pregnancy. The study found that CQ had a 23% protective efficacy; 37% of the subjects had *P. falciparum* infection despite taking CQ during the study period.

4.3.3 Publications between 1994 and 2007

The era of 1994 to 2007 saw the use of SP as the first-line drug for the treatment of uncomplicated malaria. The review identified eight studies that qualified for analysis (Appendix 3: Table 4.3). Nwanyanwu *et al.* [14] examined the efficacy of SP when it had been just adopted after anecdotal and written reports about *P. falciparum's* resistance to SP. The study found out that SP was still very efficacious as it showed parasite clearance in 98.6% of the subjects by day

seven of follow up. Similarly, Verhoeff *et al.* [27] conducted a study to assess the efficacy of SP just two years after its introduction. SP was found to be efficacious as it had a 90.5% parasitological success clearance rate on day 14 of follow up. These findings built confidence in the efficacy of SP and removed uncertainties about the drug among clinicians. Nwanyanwu *et al*. [28] assessed the efficacy of SP 5 years after its widespread use. The study was conducted in seven sites across the country – three with high transmission and four with low transmission. The study found that parasitological resistance to SP (RII and RIII) ranged between 7% and 19%; with one site reaching up to 36%. The level of treatment failure was at 0.9%. It was, hence, concluded that the efficacy of SP remained at an acceptable level and should therefore be maintained as the first-line drug for treatment of uncomplicated malaria. Takechi *et al.* [29] assessed the status of anti-malarial drugs in Malawi through an *in vivo* study for SP only and *in vitro* study for SP, CQ, mefloquine, quinine, and halofantrine. The *in vivo* results showed that SP was efficacious by clearing the parasites by day 14 of follow up in 83.1% of the patients while 13.8% of the patients failed to clear the infections by day seven (RII/RIII). The *in vitro* study, however, showed dissimilar results, as 62.1% of the isolates showed resistance to SP while resistance was only 3.4% in CQ, 3.2% in mefloquine, 5.7% in quinine and 5.9% in halofantrine. Although the SP showed significant parasite clearance, the rate of failure had increased from less than 3% found by Nwanyanwu *et al.* [14] to 13.8% in the Takechi *et al.* [29] study, indicating a deteriorating efficacy of SP.

MacArthur *et al*. [16] conducted a clinical trial to compare the efficacy of SP and mefloquine as an alternative drug after surveillance data had indicated *P. falciparum's* resistance to SP. The study showed poor efficacy on day 14 of follow up in both SP and mefloquine, as a combined parasite failure of RII and RIII were 20% and 22% respectively. MacArthur *et al.* [16] study was one of the early studies to report on the deteriorating efficacy of SP. Therefore, the authors recommended that other alternative drugs should be considered and tested. Sulo *et al.* [30] conducted a year-long study in Kenya and Malawi to measure the annual incidence of malaria in two groups that were treated with either SP or Chlorproguanal-dapsone (Lapdap) as an alternative therapy. The seven-day follow up period results from Malawi showed that the mean annual malaria incidence was 2.2 compared to 2.8 in the group treated with SP and Lapdap respectively. There was a 5.4% treatment failure in the Lapdap group compared to 20.1% in the

SP group. However, Lapdap was later found to have major negative side effects and was withdrawn [31]. In other related studies, Plowe *et al.* [32] published their findings from an open-label drug-efficacy test for SP that was conducted from 1998 to 2002. The authors established that SP had maintained a good efficacy rate during the 14-day follow up period from the time it had been adopted, with a clinical response rate of 80% or higher. Msyamboza *et al.* [33] conducted their study to assess the efficacy of SP in pregnant women in a rural clinic with high malaria transmission. They found that parasitological failure was at 11%. Msyamboza *et al.* [33] findings showed that resistance patterns in pregnant women followed those observed in under-five children and the level of SP efficacy was still at an acceptable level.

4.3.4 Document review

Availability of records posed a major challenge, in particular minutes and memos were not available for the assessment. Therefore, document review was based on a report outlining the policy change from CQ to SP [34], the 2005 Malawi anti-malarial drug efficacy study [35], and the anti-malaria drug policy guidelines [19-21].

The change from CQ to SP

In 1984, Malawi established its basic structure for the malaria control program whose duty was the development of the national malaria control policy to guide interventions aimed at addressing the malaria burden in the country. The policy outlined a five year plan including the guidelines for malaria treatment. It was recognised that evidence was critical in the development of this policy. Therefore, several studies were conducted between 1984 and 1989 that provided evidence for the malaria treatment policy development.

In this regard, an understanding of the dynamics of malaria as a disease in children was required and hence the National Malaria Research Project (NMRP) instituted operational research with the aim of assessing the impact of malaria in children and to improve treatment strategies. This study found that the overall infant mortality rate in Mangochi district was at 163 per 1000 live births with neonatal mortality rate at 49 per 1000 births and the post-neonatal mortality rate at 111 per 1000 births. However, no specific cause of death was identified in the neonatal period but in the post-natal period malaria related symptoms were identified to be associated with the

deaths. It was also revealed that 70% of the deaths occurred within seven days of the onset of illness. The study further found that almost two thirds of the deaths occurred at home with 53% and 70% of deaths in neonates and post neonates respectively.

This study played a major role in defining the impact of malaria. The findings showed that a high infant mortality rate occurred in rural Malawi and provided an estimate of deaths attributed to malaria with recognition that most deaths occurred in the community than in health facilities. These findings were significant in the formulation of the 1990 National Plan for Malaria Control in which strategies for implementation were improved by emphasizing the prompt identification and treatment of malaria in children at community level. For policy implementation, it ensured the availability of drugs at all levels of health care, training of community volunteers and health workers in effective case management, and the need for rolling out health education in the communities to inform caregivers on recognizing malaria related symptoms and seeking effective malaria treatment.

Concerns were also raised about the emerging of CQ resistance and the need of assessment of the malaria policy, which led to the recognition of a systematic approach in evaluating the malaria control policies. One of the strategies was the identification of six sentinel sites in Malawi for surveillance of malaria focusing on parasitological and clinical response of anti-malarial drugs. This involved the *in vivo* studies testing the efficacy of CQ in single doses of 10mg/kg and 25mg/kg body weight. These studies included in the systematic review above were conducted and published by Khoromana *et al.* [23].

In vivo drug efficacy studies for alternative drugs to replace CQ were also conducted involving two doses of amodiaquine at 10mg/kg and 25mg/kg, and SP at 25mg/kg. These studies were conducted and published by Heymann *et al.* [24].

For purposes of understanding the clinical response, a study was undertaken to compare the clinical response of children to CQ and SP. The study looked at three clinical indicators that included; presence of at least 75% of children with *P. falciparum* infection and correlated with parasite density, history of fever during the preceding 48 hours, and history of altered activity level during the preceding 48 hours, and axillary temperature of greater than 37.2°C. The findings

showed that on the second day CQ had a rapid effect in addressing symptoms consistent with rapid schizonticidal activity and antipyretic effect. However, on the seventh and fourteenth days the clinical failure rates for CQ were not significantly higher than for SP.

The findings from these studies were utilised in developing the malaria therapy policy in 1985, which resulted in discontinuing the routine treatment of under-five children and the country adopted the presumptive treatment of fever with CQ at a dose of 25mg/kg. The studies also influenced the retention of CQ as the first line drug in treating uncomplicated malaria despite parasite resistance, since it demonstrated a positive clinical response by the seventh day of treatment, and its wide availability and general safety in its use. It was recommended from the findings that amodiaquine and SP become therapies of choice after CQ treatment failure in under-five children.

The increased concerns of CQ resistance led to implementation of a re-evaluation of *in vivo* studies to assess the efficacy of CQ, SP, and amodiaquine at the dosages of 25mg/kg. The findings showed the deterioration of CQ efficacy while amodiaquine showed poorer response on day seven compared to SP indicating parasite resistance. These studies were however not considered sufficient to warrant policy change although a routine drug assessment policy was put in place.

The national malaria control committee evaluated its initial five year plan from 1984 to 1989 to feed into its next strategic plan from 1989 to 1993. One of the major findings from this evaluation was the maintained rapid increase of malaria-related morbidity and mortality as the under-five hospitalisations increased by 43% and malaria case fatality rose by 30%. Therefore, the operation research agenda focused on supporting studies that could provide evidence in refining the malaria control policy. The main area of focus was the assessment of alternative drugs that could replace CQ for treatment of uncomplicated malaria. In addition to this the studies assessed the clinical, hematological and parasitological drug response. Based on these studies conducted in Malawi, the WHO adopted the qualification of an anti-malarial drug as efficacious for use in treating uncomplicated malaria in under-five children if it was able to adequately alleviate the symptoms of the disease, clear the parasites, and allows a tolerable parasite free interval for hematological recovery [25].

Bloland *et al.* [25] conducted and published the Karonga and Mangochi follow-up studies that compared the parasitological and clinical responses of CQ and SP. The publication has also been reviewed in the systematic review. As a direct result of these studies the treatment guidelines of the first-line drug for uncomplicated malaria changed from CQ to SP in 1992. The policy change was fully implemented in 1993 when adequate stocks of SP were procured. SP was also advantageous since it was easy to administer as it was tasteless and required a single dose leading to increased compliance.

Sentinel surveillance report for the change of SP to LA

In January 2005, the NMCP convened a meeting with its supporting committees; the Malaria Advisory Committee and the National Malaria Technical Committee. They discussed, among other things, the need to change the country's first line anti-malaria drug policy after considering that efficacy studies had shown SP 14-day clinical treatment failure of above WHO 15% prompting policy change. Although the WHO had recommended ACTs [36] to be the best options for first line anti-malarial drugs, there was need to generate local evidence in order to make an informed choice on the optional ACTs available. Therefore, open label randomized efficacy trials targeting under-five children in three sentinel sites during the malaria season commenced in April 2005. The objective of the study was to assess four drug combinations (amodiaquine plus artesunate (AQ-Art), amodiaquine plus sulfadoxine-pyremethamine (AQ-SP), chlorproguanil-dapsone plus artesunate (CD-Art), and lumefantrine-artemether (LA)). In addition, the efficacy of SP was also conducted for comparison purposes to the new drugs.

The results showed poor efficacy of SP, as it had only 32% of adequate clinical and parasitological response on day 28, while the other drugs showed over 90%, specifically 100% in AQ-Art, 95% in AQ-SP, 94% CD-Art, and 93% in LA. Thus, all the combination drugs were similar in superiority to SP. These findings provided the local evidence for the Malawi government to choose the most appropriate combination drug for treating uncomplicated malaria. Finally, LA was the suitable choice in replacing SP.

Policy and guideline documents

The anti-malarial treatment policies and guidelines were reviewed to assess how they made reference to research evidence that informed their development. A major challenge with these documents is that they did not have a formal reference section that could be assessed as to what specific study was used in their development. However, the documents clearly mention the *in vivo* studies conducted in the sentinel sites as the major sources of local evidence that influenced policy changes. The *in vivo* studies in the sentinel sites that led to the change of CQ to SP were published and included in the systematic review [25], while the unpublished 2005 in vivo efficacy studies provided the evidence for policy change of SP to LA [35].

4.3.5 Findings from the Key Informant Interviews

Key informants provided their experiences and views towards the policy changes and how evidence was critical in driving the changes. As previously indicated, the main concern for the historical change, from CQ to SP, was the uncertainty on the sustainability of SP's high efficacy on *P. falciparum*. Hence, the question was whether the change was justifiable at that time. Therefore, views of Key Informants were sought regarding the change.

Availability of evidence for justification of policy changes

Clinicians and other medical personnel in health facilities observed that CQ was no longer effective in the treatment of malaria. As narrated by one of the researchers, who was also a clinician;

'In the mid-1980s, around 1985, clinicians across the country started observing that people treated with chloroquine were coming back complaining that they do not feel better'.

Timing of policy changes

The several reports from the clinicians raised concerns about using CQ in treating malaria, which prompted the government of Malawi through the Ministry of Health to conduct efficacy studies that would provide empirical evidence to substantiate these reports. The results of these studies revealed that indeed CQ was not working and there was need for change [25]. This was acknowledged by one researcher who is also a pediatrician;

'It was timely, the evidence was clear that chloroquine wasn't working at the time, I'm a child specialist so I actually see the effects or the complications, if the drug is not working, the children do not get well, some even die against severe forms of malaria, so seeing that we decided to make a change, it was quite obvious we needed the change'.

Another researcher also recounted the need for local evidence to base the policy decision on;

"And then of course there a was also need for the research to be done to back up the actual change and again for Malawi that change came about because of drug efficacy studies that were carried out over the years which then meant that it was easy for the policy makers to certainly say hey its indeed high time to change because this drug is obviously not working".

Challenges during policy changes

The main challenge for this change however, was that there were no clear WHO guidelines for policy changes i.e. on what recommended drugs to replace CQ, hence there was limited support from the WHO, as stipulated by one Researcher:

"The first challenge was the fact that there was no buy-in from WHO.... so WHO was saying who is going to pay if we are not supporting it...who is going to pay for this?"

This situation made Malawi to make a strong case of changing the policy since WHO was concerned with early development of parasite resistance to SP. But based on the data generated locally increased morbidity and mortality were a major concern for Malawi. Hence further studies were initiated to gather strong evidence. This was confirmed by one researcher who, on what led to them conducting efficacy studies, said:

"That then prompted government to consult Center for Disease Control to help out with investigations on what was happening, why are several patients treated coming back complaining of the same signs and symptoms?"

Therefore, evidence was generated and presented to the policy decision makers for their next step. It further showed that the policy change from CQ to SP needed to be based on tangible, structured evidence. Hence for this purpose the studies provided the evidence required.

From this case study it can be observed that records were well documented and published regarding the change from CQ to SP and those studies were published during this time including in the early years of change to SP compared to the change of SP to LA. As highlighted from one researcher that:

"Well at this stage from SP to LA they were following the WHO recommendations so I suppose people didn't worry too much about it, you know, getting track with what actually was happening but with the earlier period when we had to change from chloroquine to SP this was new but the advantage we had was that we had locally generated data that could not be refuted".

The WHO plays a vital role in driving policy issues in the world. It will provide guidelines that countries adapt. Recommendations from WHO will easily influence decisions for policymakers as they deem that these recommendations are tangible. The WHO recommended that the first line anti-malarial drugs be replaced by Artemisin-based Combination Therapy (ACT) [36]; therefore, in 2005 Malawi had to carry out efficacy studies that included the assessment of SP in comparison to ACTs for possible replacement. Hence the guidelines were very critical in changing the drug policy from SP to LA as countries including Malawi were following these recommendations but the change from CQ to SP had to rely on strong locally generated evidence to convince policymakers to make the switch since such guidelines did not exist at that time.

4.4 Discussion

Research has been proven to provide vital evidence for decision making and, more critically, for policy development [2]. Research is critical in resource-limited countries such as Malawi in order to maximise the usage of resources. Owing to the constant mutation of the malaria parasite (*Plasmodium sp*.), there has been a major challenge in malaria prevention and control [37], prompting changes in anti-malarial drug regimens across the years in Malawi and other malaria-endemic countries [38]. This case study explored the availability and usage of research evidence that formed the basis for decision making in the policy changes. This was done through the systematic review that examined published research evidence on malaria drug efficacy studies conducted between 1984 and 1993, and 1994 and 2007, examination of documents in the form of reports and policy guidelines to assess their reference to evidence, and In-depth interviews

with Key Informants directly involved in the generation of evidence during the policy changes with the objective of soliciting their general views and perceptions towards the policy changes.

It was found out that there was enough scientific evidence from research conducted from 1984 to 1993 on CQ resistance to support a change in anti-malarial drug policy from CQ to SP in Malawi. Secondly, although the evidence did not come from peer reviewed journals, studies from sentinel sites conducted between 2005 and 2007 showed a reduced efficacy of SP within Malawi, influencing a change in first line anti-malarial treatment from SP to LA. Views of key informants indicate that the policy changes were timely enough although the change from CQ to SP could have occurred earlier. These results, therefore, support the proposition that evidence from drug efficacy studies within Malawi influenced the changes in policy on anti-malarial drug treatment.

Malawi was the first country in SSA to change its first-line anti-malarial drug from CQ to SP [14] and in 2007 it changed its policy again from SP to LA [21]. Amid the economic, political, and other challenges within the country, concerns were raised during the policy change from CQ to SP as to whether the change had occurred too early and the change's implications for the quick development of resistance to SP [16]. Studies conducted between 1984 and 1993 provided ample evidence about the poor efficacy of CQ and the superiority of SP as its replacement. The objectives of some of the reviewed studies strongly indicate that the studies were conducted for purposes of policy formulation [23-25, 39]. The study by Khoromana *et al.* [23] was instituted with the sole purpose of guiding malaria treatment drug policy in Malawi. However, despite its findings of low efficacy of CQ in Malawian children, the dosage of 25 mg/kg was adopted in the treatment of uncomplicated malaria as the first-line drug. Similar studies with such objectives to drive policy have also been conducted and published in other countries [40-42]. A case study on Malawi by the WHO about the development of anti-malarial drug policy in the period of 1984 and 1993 highlighted the findings by Khoromanana *et al.* [23] and Bloland *et al*. [25] as having provided the important information critical for policy- and guideline changes [43] and these findings were also acknowledged by Nwanyanwu *et al.* [14] to have been used for policy development. These studies were conducted in different geographical regions and in areas of high- and low transmission during both rainy and dry seasons when transmission is high and low respectively. The treatment failure observed from these studies exceeded the 25%

recommended by WHO as the cut-off point [43], in this way prompting anti-malarial drug policy change. The studies also presented the findings of alternative drugs studied [24, 25] and have shown evidence that SP was more practical as a replacement for CQ in this period.

Following the change of the anti-malarial first-line drug in 1993 to SP, unconfirmed reports of its poor efficacy subsequently led to five efficacy evaluation studies being undertaken [14, 27-29, 32]. The findings from these studies showed a maintained high acceptable level of efficacy of SP and influenced the policy decision to retain it as the first-line anti-malarial drug for treatment of uncomplicated malaria in Malawi. However, from the publications assessed between 1994 and 2007 the efficacy of SP was still at a level for it not to warrant policy change. Since no publications were found after Plowe *et al.*'s [32] study, conducted between 1998 and 2002, it would be difficult to ascertain when SP started losing its efficacy to levels prompting its removal as a first-line drug for malaria treatment. However, in 2005, the Malawi government through the National Malaria Control Programme carried out unpublished efficacy studies in the sentinel sites in under-five children. The programme tested the efficacies of four combination drug candidates: AQ-SP, AQ-Art, CD-Art, and LA and while SP was also assessed to provide up-to-date data on its efficacy for comparison with the new drug candidates. SP showed deterioration, as it had only 32% of adequate clinical and parasitological response on day 28, while the other drugs showed over 90% of adequate clinical and parasitological response.

Policy development is intricate and not entirely determined by research evidence [44]. In order to establish the impact of research on policy and practice, reports [34] and the Malawi Ministry of Health anti-malarial drug policy documents [19-21] were reviewed to check for any references made to research. These documents did not have a formal reference section. However, the guidelines clearly referred to regular *in vivo* studies, as recommended by WHO [37] and conducted in sentinel sites in varied geographical regions of the country, to have been a major factor influencing policy development, especially the change from SP to LA.

Generally, WHO develops and updates protocols that guide anti-malarial drug efficacy studies [45]. This standardization is necessary in order for those involved in research to produce comparable and viable results to help guide policy making. However, even when not limited to

these protocols, utilisation of RCTs with blinding is essential in order to reduce bias as much as possible [45]. In this study only two studies explicitly indicated to have used randomisation [16, 30] while three studies [16, 23, 30] explained how they arrived at particular sample size using statistical methods. Nevertheless, evidence from the various malaria studies from Malawi showed some agreement in outcome of their findings despite differences in their methodology.

Experiences and views from Key Informants indicate that Malawi required ample evidence to change its policy from CQ to SP when there were no WHO guidelines to recommend the change. The WHO concerns were based on the fact that changing to SP would lead to parasite resistance to SP much earlier, which would also be a concern to neighboring countries due to border crossing that occur and hence lead to a regional problem. However, Malawi demonstrated that the change was eminent and continual monitoring of SP showed that no parasite resistance developed to levels of concern for policy change until in 2007 when eventually SP was replaced by LA based on WHO recommendations.

As for later changes to ACTs, WHO updated its guidelines for countries to follow when switching their first line anti-malarial to ACTs [36]. In this regard, many countries made the changes earlier than Malawi, such as Zambia that became the first African country to change from CQ to LA in 2002 [46], Kenya switched from SP to LA in 2004 [47], and by June 2006 thirty-nine African countries had switched to the WHO recommended ACTs [46]. Malawi only made its switch in 2007 as it required gathering thorough local evidence from the sentinel sites. As already highlighted, the change from SP to LA was smooth since it was done following the recommendations from WHO.

4.5 Conclusion

Substantial malaria drug efficacy studies were conducted in Malawi, which provided tangible evidence for policy decision making. The change from CQ to SP was systematic, at the time when there were no clear WHO guidelines for changing a drug that loses its efficacy, the team from Malawi observed that CQ was no longer efficacious hence they carried out studies that provided strong evidence to justify the change. While unpublished sentinel surveillance studies provided

evidence for policy change from SP to LA [21]. Consequently, there was justifiable evidence from efficacy studies conducted within Malawi that were used for timely policy changes.

Based on the findings, strong locally generated evidence is very crucial for policy decision making. In addition, the study recommends proper record keeping, and that policy documents and guidelines should be formally referenced to allow tracking of evidence used for their development. An example of such referenced malaria guidelines exists in the case of Kenya [48]. In addition, sentinel surveillance findings should be published so that they undergo peer review and become readily available to a wider community. Research and monitoring of drug efficacy should continue to be conducted according to the recommendations of the WHO protocols and methodologies in order to ensure quality of the research results.

List of abbreviations

ACT: Artemisin-based Combination Therapy; AQ-Art: Amodiaquine plus artesunate; AQ-SP: Amodiaquine plus sulfadoxine-pyremethamine; CQ: Chloroquine; CD-Art: Chlorproguanil-dapsone plus artesunate; IPTp: Intermittent Preventive Treatment of malaria in pregnancy; KIIs: Key informant in-depth interviews; LA: Lumefantrine-artemether; Lapdap: Chlorproguanal-dapsone; MESH: Medical Subject Heading; NMCP: National Malaria Control Programme; NMRP: National Malaria Research Project; RCTs: Randomized Control Trials; SP: Sulfadoxine-pyrimethamine; SSA: sub-Saharan Africa; WHO: World Health Organization

Competing interests

The Authors declare that they have no competing interests

Author's contribution

CM (a PhD candidate in Public Health (Health Policy) at the University of Pretoria) conceived the idea, developed the proposal, conducted data collection, analysis and writing of the manuscript. HL improved and shaped the idea, and took part in the analysis and writing of the manuscript. KP provided guidance in the proposal development, identification of key informants and technical expertise in the methodology. TJ provided technical expertise in the proposal development, and writing. CH provided technical advice in issues of evidence to policy and the general approach of

the study. CMM provided supervision and substantial intellectual input during the proposal development and guidance in the manuscript write up. All the Authors read and approved the final version of the manuscript before submission.

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CHAPTER FIVE

Introduction

The findings in chapters three and four revealed that substantial malaria drug efficacy studies were conducted in Malawi, which provided tangible locally generated evidence which was crucial for policy decision making. An understanding of how malaria research actually influenced policy changes and how these changes were made was necessarily. Chapter 5 therefore, explores the role of malaria research from Malawi in influencing policy changes and further explores the process of policy making and the roles various stakeholders played in this process.

5.0 CHANGING THE POLICY FOR INTERMITTENT PREVENTIVE TREATMENT WITH SULFADOXINE-PYRIMETHAMINE DURING PREGNANCY IN MALAWI

Abstract

Background

The growing resistance of *Plasmodium falciparum* to sulfadoxine-pyrimethamine (SP) treatment for uncomplicated malaria led to a recommendation by the World Health Organisation for the use of artemisinin-based combination therapy. Inevitably, concerns were also raised surrounding the use of SP for intermittent prevention treatment of malaria during pregnancy (IPTp) amidst the lack of alternative drugs. Malawi was the first country to adopt intermittent prevention treatment with SP in 1993, and updated in 2013. This case study examines the policy updating process and the contribution of research and key stakeholders to this process. The findings support the development of a malaria research-to-policy framework in Malawi.

Methods

Documents and evidence published from 1993 to 2012 were systematically reviewed in addition to key informant interviews.

Results

The online search identified 170 potential publications, of which eight from Malawi met the inclusion criteria. Two published studies from Malawi were instrumental in the WHO policy recommendation which in turn led to the updating of national policies. The updated policy indicates that more than two SP doses, as informed by research, overcome the challenges of the

first policy of two SP doses only because of ineffectiveness by *P. falciparu*m resistance and the global lack of replacement drugs to SP for IPTp.

Conclusion

International WHO recommendations facilitated a smooth policy change driven by motivated local leadership with technical and financial support from development partners. Policy development and implementation should include key stakeholders and use local malaria research in a research-to-policy framework.

Keywords Malaria, pregnancy, sulfadoxine-pyrimethamine, policy change, Malawi

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5.1 Background

The resistance of the malaria parasite to anti-malarial drugs has led to expensive policy changes in many countries causing strain on available resources [1]. Although the World Health Organization (WHO) is instrumental in guiding health policy development, contextual factors unique to different countries need to be assessed before adopting and implementing these recommendations [2].

Policy development is a tedious process that requires an understanding of the institutional and individual actors and of the context in which the process occurs [3]. Walt and Gilson [4] described this relationship when they developed a health policy framework that explores the context, content, and processes in which actors are engaged. Andersen [5] developed a framework for understanding the policy process incorporating problem identification, agenda setting, policy formulation, policy adoption, policy implementation and policy evaluation.

Malawi established its National Malaria Control Programme (NMCP) in 1984 [6]. The NMCP based their first five-year implementation plan (1985 to 1989) on WHO recommendations for malaria control in areas with proven chloroquine (CQ) resistance in Africa [7]. One of its policies was to provide CQ chemoprophylaxis to special groups of individuals including pregnant women. In response to the growing evidence of CQ resistance, studies assessed alternative drugs to replace CQ. Malawi invested tremendously in research on malaria in pregnancy and became the first country to adopt Intermittent Preventive Treatment in pregnancy with sulfadoxine-pyrimethamine (IPTp-SP) in 1993 [8, 9]. The policy recommended that pregnant women should receive two doses during pregnancy with the first dose being given at the first antenatal visit after the first trimester of pregnancy (typically 16^{th} to 22^{nd} week of gestation) and the second dose at the beginning of the third trimester (between 28 and 34 weeks of gestation) [10]. Over time, growing *P. falciparum* resistance to SP for the treatment of uncomplicated malaria led to the WHO recommendation of switching to artemisinin-based combination therapy (ACT) [11] and related concerns were raised about the efficacy of SP for IPTp. The WHO convened an Evidence Review Group (ERG) on IPTp-SP

in 2012 which reviewed various research evidence relevant to updating the IPTp policy. The ERG acknowledged that more than two doses of IPTp-SP would be more beneficial than the usual two doses that were previously administered [8]. The ERG recommended that IPTp-SP be given at each antenatal visit, with the first dose given early in the second trimester and subsequent doses given at monthly intervals up to the time of delivery. Following these recommendations, in 2013 the NMCP in Malawi adapted its IPTp-SP policy by recommending that women should receive at least three doses of SP during pregnancy [12].

The process of updating the IPTp-SP policy was examined with the aim of understanding policy development. The role of stakeholders and relevant research evidence during the policy development in Malawi was also assessed.

5.1.1 Conceptual framework

This case study forms part of a larger effort to understand policy development and the role of relevant research in this process in order to develop a framework that can facilitate the use of evidence from malaria research for policy formulation in Malawi. One important aspect of policy analysis is to understand the involvement of stakeholders and research in the process while considering the various factors that govern the need for the policy [13]. This study was conceptualised on the premise that different factors besides overwhelming evidence may influence policy development. The Walt and Gilson policy analysis framework [4] stipulates that aside from content analysis, the actors, processes and the context in which policy change occurs are required for policy analysis. The policy analysis was supplemented by the Andersen's model of policy cycle [5].

5.2 Methods

Mixed methods in form of a systematic review of published evidence, a review of key documents and key informant in-depth interviews (KIIs) were utilised in the policy analysis to enable triangulation.

5.2.1 Systematic review

This study aimed to establish the availability of local evidence likely to be used in the policy change process. Relevant articles were sought by searching the references of all reviewed articles. Combinations of the following specific key words relating to IPTp-SP were searched by using the medical subject heading (MESH) strategy: sulfadoxine-pyrimethamine (SP), Fanasil, pyrimethamine drug combination, pregnancy, and Malawi. Articles published between 1993 and 2012 were searched to capture all studies conducted in Malawi related to IPTp-SP from inception to the time of the policy update. These studies were assumed to provide timely evidence and were more likely to be included in the policy development process. The following combinations were used during the search: ("pregnancy"[MeSH Terms] OR "pregnancy"[All Fields]) AND ("fanasil, pyrimethamine drug combination"[Supplementary Concept] OR "fanasil, pyrimethamine drug combination"[All Fields] OR "sulfadoxine-pyrimethamine"[All Fields]) AND ("Malawi"[MeSH Terms] OR "Malawi"[All Fields]) AND ("1993/01/01"[PDAT] : "2012/12/31"[PDAT]). We searched the MEDLINE (Ovid), PubMed, Scopus and Cochrane Library databases.

5.2.2 Selection criteria

From the articles identified by the systematic review above, we selected studies for analysis based on the following criteria: (1) conducted in Malawi between 1993 and 2012; (2) evaluating two doses of IPTp-SP; (3) evaluating three or more IPTp-SP doses; (4) assessing two versus three or more IPTp-SP doses. The selection was limited to studies assessing the optimal response of *P. falciparum* infection to IPTp-SP by excluding studies conducted on HIV-positive women. HIV infection reduces the ability of a pregnant woman to control the malaria infection resulting in a suboptimal response to IPTp-SP [14]. Two independent co-authors, CM and HL, judged the eligibility of the studies and resolved disagreements by consensus.

5.2.3 Document review

Available documents such as reports, circulars, directive letters and minutes from meetings conducted during the policy development process were sought to provide a forum for

triangulation, to verify the stakeholders and to verify important dates and events throughout the process. WHO IPTp policy documents [8, 15] and local IPTp-SP policy documents [12] were reviewed to examine the extent to which they referenced research evidence during policy development.

5.2.4 Key informant interviews

KIIs with key stakeholders involved in policy development comprising malaria researchers/advisors, policy makers, and programme/project coordinators were conducted. Interviewees participated in the policy updating process, and their views were considered to capture what transpired and general experiences on the change. Purposive sampling identified key informants. Fifteen individuals were identified and interviewed. Six interviewees were senior malaria-in-pregnancy researchers and advisors, three interviewees were policy makers and six interviewees were programme/project coordinators. Table 5.1 summarises the experience, current position and role played by each key informant (KI) during the policy changes.

Table 5.1: Details of Key Informants (KIs) involved in the policy update for intermittent preventative treatment during pregnancy with sulfadoxine-pyrimethamine (IPTp-SP) for malaria in Malawi.

KI	Sex	Expertise	Experience	Role
1	Male	Malaria Epidemiologist	Over 15 years in malaria research	Researcher/Advisor
2	Male	Medical epidemiologist	Over 10 years in malaria research	Researcher/Advisor
3	Female	Malaria epidemiologist	Over 30 years in malaria research	Researcher/Advisor
4	Male	Clinician and malaria epidemiologist	Over 40 years in malaria research	Researcher/Advisor
5	Male	Malaria Epidemiologist	Over 10 years malaria research	Researcher/Advisor
6	Male	Senior malaria scientist	Over 40 years in malaria research	Researcher/Advisor
7	Female	Clinical Epidemiologist	Six years	Policymaker
8	Male	Malaria in Pregnancy Coordinator	Over five years in malaria research	Policymaker
9	Male	Chief of Health Services	Five years	Policymaker
10	Female	Malaria in Pregnancy Coordinator	Over five years in malaria research	Programme/Project Coordinator
11	Male	Malaria Advisor	Fifteen years	Programme/Project Coordinator
12	Male	Malaria Advisor	Five years	Programme/Project Coordinator
13	Male	Policy Development and Analysist	Four years	Programme/Project Coordinator
14	Male	Malaria Advisor	Five years	Programme/Project Coordinator
15	Male	Malaria Program Specialist	Twenty years	Programme/Project Coordinator

The principal investigator conducted all the interviews, probing and exploring in-depth issues based on the conceptual framework of the study. The interviews were conducted in English using a semi-structured interview tool.

5.2.5 Themes covered in the in-depth interviews

The participants were asked to narrate their memories of the policy process by contemplating the question: *"Can you please describe the process by which the IPTp-SP policy change occurred in Malawi?"*

Interviews covered specific themes that included: (1) context in which the policy occurred; (2) opportunities during the policy process; (3) challenges encountered during the policy process and (4) lessons learned.

5.2.6 Data management and analysis

The recordings were transcribed and coded based on the themes, and the software Nvivo 11 organised the data, while verbatim quotes illustrated concepts, supported conclusions and brought reality to the situation. The Giorgi's phenomenological approach, which focuses on the experiences of participants with shared life experiences, was used. This approach documents the findings from the interviewee's point of view, collecting their descriptions of their lived world on the interpretation of the meaning of the described phenomena [16].

5.3 Results

5.3.1 Systematic review

One hundred and seventy potential publications were identified using database searches of which eight publications from Malawi were selected using the inclusion criteria and subsequently reviewed (Figure 5.1).

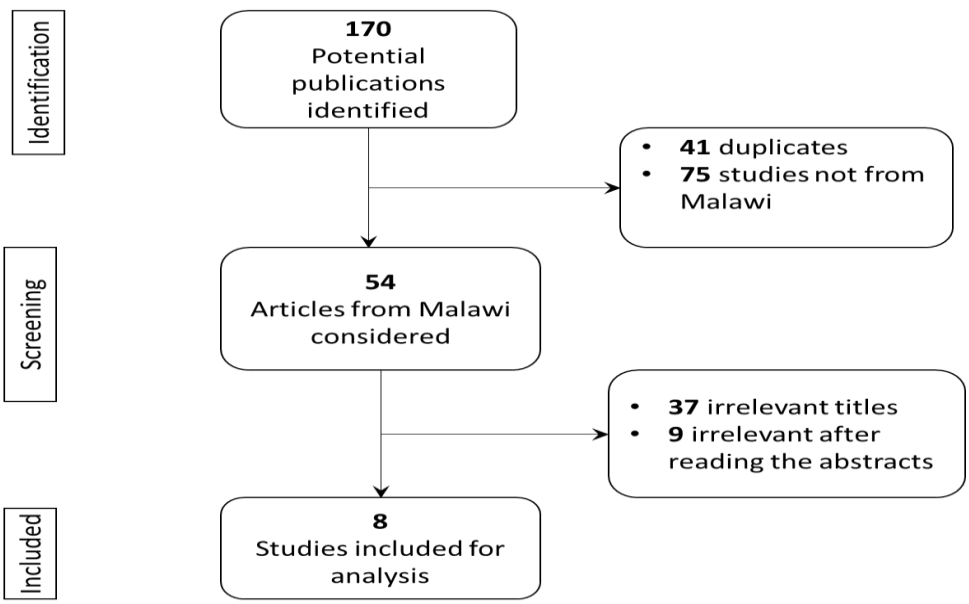

Figure 5.1: A flow chart of the selection process for studies reviewed

5.3.2 Description of the publications

Eight studies that met the inclusion criteria were reviewed (Appendix 4: Table 5.2). Verhoeff *et al.* [17] measured the parasite prevalence in mothers who received one, two, or three SP doses during pregnancy and the associated incidence of Low Birth Weight (LBW) in infants. Although there was no significant difference in peripheral or placental blood parasite prevalence, the mean birthweights of infants were higher, resulting in a decrease of LBW babies born to mothers that received two or more SP doses. Taylor *et al.* [18] Explored the link between IPTp-SP, the presence of resistant parasite at delivery and multiple measures of adverse delivery outcome. Receiving SP as IPTp did not raise pregnancy-associated malaria despite increasing prevalence and fixation of SP-resistant *P. falciparum.* Although LBW prevalence was lower (11.8%) in the full IPTp group than in the suboptimal group (P = 0.48), the difference was not significant. Taylor *et al.* [18] recommended the modified regimen of IPTp-SP for comprehensive antenatal care. Rogerson *et al.* [19] assessed the relationship between the number of IPTp-SP doses and various health indicators. Placental malaria prevalence decreased from 31.9%, in women who did not receive SP, to 22.8% in women with ≥ 2 SP-doses, while LBW prevalence decreased from 23% (no IPT) to 10.3% (IPTp-SP) in the two groups of women. Rogerson *et al*. [19] recommended that IPTp-SP should be continued based on the positive impact, but that researchers continuously evaluate treatment. Filler *et al.* [14] assessed the efficacy of monthly SP compared to the two doses of SP in preventing placental malaria in both HIV positive and negative women. HIV negative women who received a monthly dose of SP had a lower (2.3%) incidence of placental malaria compared to women who received two doses (6.3%). Filler *et al.* [14] recommended areas of intense falciparum transmission adopt a monthly IPTp-SP regimen. This study was included in the meta-analysis that led to the WHO policy recommendation [15, 20].

Several similar studies have assessed the efficacy of the monthly SP dose. Luntamo *et al.* [21] compared the effect of monthly SP, or monthly SP and two doses of azithromycin (AZI-SP) to the standard 2-SP regimen in preventing preterm deliveries and LBW. Preterm incidence was 17.9% in controls (2-SP), 15.4% in the monthly group (P = 0.32) and 11.8% in the AZI-SP group

(P = 0.01). There was a lower risk of LBW in the AZI-SP group (0.61, P = 0.02) and the monthly SP group (0.71, P = 0.71) compared to the control group. Luntamo *et al.* [21] concluded that AZI-SP reduces the incidence of preterm delivery and LBW under certain conditions. Luntamo *et al.* [22] compared the effect of monthly SP, or monthly SP and two doses of azithromycin (AZI-SP) and a standard 2-SP dose (control) on malaria at delivery. HIV-negative women that received a monthly dose of SP (0.26, P<0.0001) and those that received the AZI-SP regimen (0.249, P<0.0001) had a significantly lower risk of malaria compared to the control group. Luntamo *et al.* [22] recommended that frequency of SP doses during pregnancy should be increased; these recommendations were included in the meta-analysis leading to amended WHO policy recommendations [15, 20]. Luntamo *et al.* [23] compared the effect of monthly SP, or AZI-SP and a standard 2-SP dose (control) on foetal and neonatal growth. Pregnant women who received monthly SP had babies with heavier mean birthweights that were taller at four weeks of age, and the addition of azithromycin further increased the benefits in reducing growth faltering. Gutman *et al.*[24] assessed the effectiveness of IPTp-SP on placental infection and composite birth outcomes. Their findings showed that IPTp-SP was associated with a dose-dependent protective effect on composite birth outcomes but did not reduce the frequency of placental infection. They recommended that IPTp-SP be given while exploring alternative strategies and drugs.

5.3.3 Document review

Policy documents were examined to assess how research evidence was used and included in WHO documents [8, 15] and the local treatment policy [12]. The WHO documents used a variety of evidence from across the globe upon which they based their policy formulation. Evidence from Malawi was instrumental in agenda setting [9, 25] and policy development [14, 18, 19, 21-23, 26]. The local document did not have a formal reference section which hampered our assessment of used evidence. The authors of the policy document acknowledged the importance of the WHO recommendations during its development.

5.3.4 Stakeholders and their roles during the IPTp-SP policy change

The Ministry of Health (MOH) (represented by the NMCP and the Reproductive Health Directorate (RHD)), the National Malaria Advisory Committee (NMAC); Malaria Care, Clinton

Health Access Initiative (CHAI), WHO; Support for Service Delivery Integration-Services (SSDI-services) and PMI/USAID were primary stakeholders in the policy change process. Stakeholders gave technical advice, developed guidelines, reviewed and edited guidelines, trained health workers, implemented policies in health facilities, and provided financial support for conferences and other resources (Table 5.3).

Table 5.3: Summary of activities provided by key stakeholders involved in the policy updating process for intermittent preventative treatment during pregnancy with sulfadoxine-pyrimethamine (IPTp-SP) for malaria in Malawi.

Stakeholder	**Main responsibility**	**Role in policy change**
NMCP	Development of malaria policies, and implementation of malaria programs	Drafting of guidelines, leading the process, and finalisation of guidelines
RHD	Implementation of reproductive health services in the MOH	Drafting of the guidelines, and policy implementation
SSDI-Services	Effective integration and delivery of quality services under the Malawi Essential Health Package (EHP), and to strengthen the national health system in line with the National Health Sector Strategic Plan for 2011-2016	Coordination of activities, drafting of guidelines, finalizing, printing, dissemination of guidelines, and training of health workers
WHO	Provision of technical advice and recommendation	Overseeing of the whole process in accordance to WHO recommendations
PMI/USAID	Provision of technical and financial support for the NMCP	Provided financial support for all activities and provided technical advice
NMAC	Provide expert opinion to the NMCP in policy and programme development	Vetting and final approval of the guidelines
Malaria Care	Provision of malaria diagnostic and treatment services	Training of health workers
CHAI	Strengthening of integrated health systems	Revision of case management guidelines, training of health workers
Malaria researchers	Conducting malaria research to provide evidence and guide policy formulation	Provided technical review of evidence and guidelines

NMCP: National Malaria Control Programme; RHD: Reproductive Health Directorate; SSDI: Support for Service Delivery Integration; PMI: President's Malaria Initiative; USAID: United States Agency for International Development; NMAC: National Malaria Advisory Committee; CHAI: Clinton Health Access Initiative; MOH: Ministry of Health; WHO: World Health Organization

5.3.5 The process of change

The policy change began in July 2012 when the WHO ERG made a recommendation to the Malaria Policy Advisory Committee (MPAC) for an interim policy on IPTp-SP [8]. The recommendation was adopted after an assessment of a systematic review and meta-analysis (20). The ERG based their recommendations on findings that associated three or more SP

doses for IPTp with increased mean birth weight and reduced risk of LBW births. Based on the reviewed evidence, the ERG recommended IPTp-SP for all pregnant women with the first dose administered at antenatal visits as early as possible in the second trimester, and the subsequent doses spaced no less than four weeks apart up to the time of delivery [8]. Following this meeting in October 2012, WHO updated its IPTp-SP policy, and in April 2013 a policy brief was issued to support dissemination and urge national health authorities to adopt and implement the new recommendations.

5.3.6 Steps for IPTp-SP policy change in Malawi

Based on emerging literature and WHO recommendations, the NMCP updated malaria treatment guidelines that incorporated rectal and injectable artesunate, malaria Rapid Diagnostic Tests (RDTs) for quick diagnosis of uncomplicated malaria, and the new IPTp-SP policy. Malawian policymakers took the opportunity to adapt the IPTp-SP policy given the challenges experienced during the implementation of the previous policy. The implementation of the previous policy was hampered by health workers' confusion surrounding the delivery of the second dose of SP [27]. The updated WHO recommendations do not specify the number of doses, but highlight that SP should be provided to pregnant women at each scheduled antenatal visit after the first trimester up until the time of delivery. The adapted Malawi IPTp-SP policy indicates that pregnant women should receive at least three doses of SP after the first trimester and with last dose given close to the time of delivery. The new recommendation was strategically planned to coincide with the WHO initiative of integrating IPTp-SP into focused antenatal care (FANC) services that recommend at least four scheduled antenatal care visits [15].

In May 2013, the NMAC convened to vet the treatment guidelines before the Minister of Health and the Secretary for Health approved the new guidelines. Initially, Malaria in Pregnancy (MIP) formed part of the treatment guidelines in Malawi, and it was deemed vital to isolate and develop specific guidelines for MIP. In June 2013, a group comprising of the NMCP, RHD, and PMI/USAID, coordinated by the SSDI-services, convened for one week to develop MIP guidelines and revise the MIP training manual for health workers following the WHO recommendations. The guidelines were approved in July 2013 [12].

From October to November 2013, two Trainer of Trainers (TOTs) workshops were conducted in the northern and central eastern zones of the country to orient TOTs on the updated malaria case management guidelines and new IPTp-SP policy. The TOTs were immediately required to roll out training sessions for other health workers in their work places. Despite this requirement, training sessions for health workers only commenced in August 2014. The delay in transition was due to a change in the per diem policy the government through the Office of President and Cabinet (OPC) on all Developing Partner (DP) programmes in Malawi. The per diem policy changed regarding direct payments to service providers for costs such as accommodation. Participants did not receive sitting allowances and were not paid if they conducted duties for which they received a salary during the training session. These adjustments meant that participants were not able to pay for necessities if they travelled to different training venues. Logistical issues were resolved by conducting training sessions in areas where most of the participants were situated, and the new policy was implemented in August 2014. Evaluation of the new IPTp-SP policy is yet to be conducted. Figure 5.2 illustrates the timeline of policy change process, and the roles played by stakeholders based on Andersen's model of policy change [5].

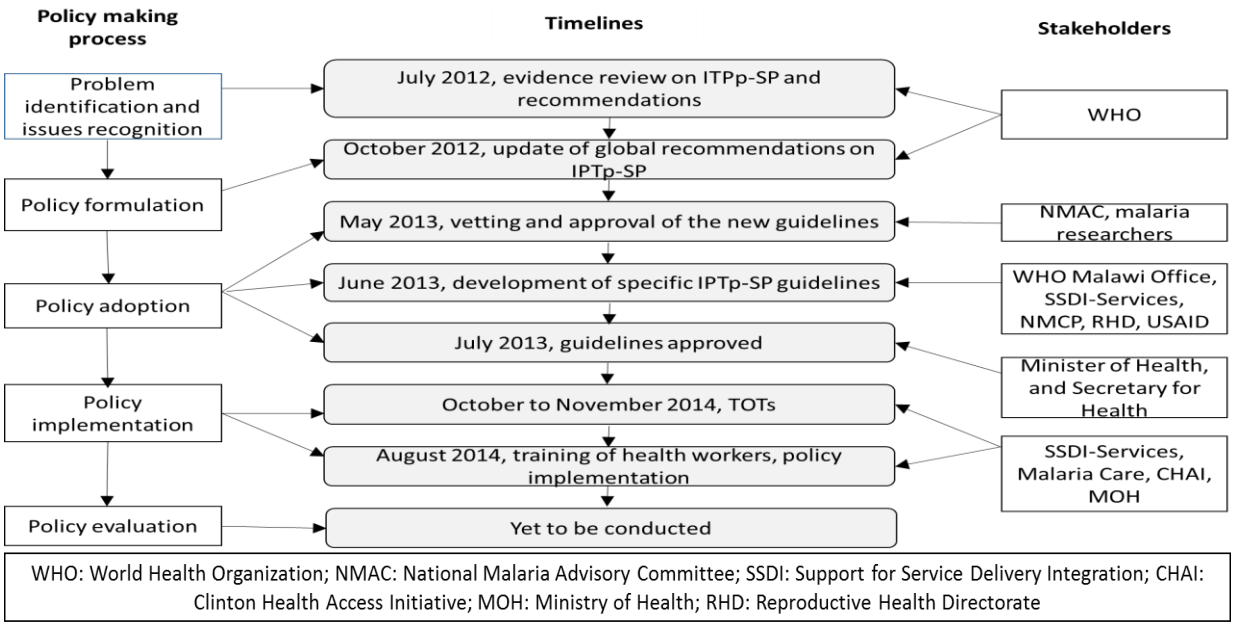

Figure 5.2: The policy making process, timeline of events and stakeholders involved in the policy updating process for intermittent preventative treatment during pregnancy with sulfadoxine-pyrimethamine (IPTp-SP) for malaria in Malawi.

5.3.7 Context of policy change

In 2007, Malawi changed its treatment policy for uncomplicated malaria from SP to artemether-lumefantrine. The change of drug regimen was complicated as it attracted many activities which required approval by the Ministry of Health. The new treatment guidelines for IPTp-SP were introduced in 2013 and was uncomplicated by comparison. Updating the policy did not draw any official launch since it was approved along with the treatment policy. This offered an enabling environment for a smooth transition of the IPTp-SP policy change as narrated below:

"In fact there is no need for launching when it's a revised policy but if it's a new policy that's when the launching comes in" (Programme/Project Coordinator)

The policy update aimed to overcome a flaw of the old 2-IPTp-SP policy. Health workers were confused about the exact time to give the second dose mainly due to late antenatal attendance by women leading to the programme failing to meet the 80% Roll Back Malaria coverage target [27]. The new policy was adapted to address this challenge as highlighted below:

"We noted a big challenge that there was a misunderstanding in terms of application by the service providers because it [the policy] was saying at 13 weeks give the first dose of SP then the second dose at 28 weeks...so people just complied to those dates...so if one comes at 18th week or 20th week then [they] will not be given SP and who comes at 32 weeks would not be given the second dose...so the previous guidelines made some limitation and that was our main challenge for low coverage but this policy change to 3 doses or more means that a pregnant woman can get IPTp even after 36 weeks...there are no restrictions so that's one of the advantages". (Programme/Project Coordinator)

The global lack of an alternative remedy to replace SP for IPTp meant that increasing the doses, as stipulated by evidence, was the only tangible alternative. The challenges of coverage (as highlighted above), lack of an alternative drug and new evidence on dosage increment provided an ideal environment for IPTp-SP policy change.

"We do not have any other alternative that's why they are recommended that we should just use 3 or more doses but studies by College of Medicine are underway to explore other drugs". (Programme/Project Coordinator)

5.3.8 Opportunities for smooth policy transition

Participants revealed that the availability of technical and funding support from partners (USAID/PMI and SSDI-services) supported the completion of policy updating process. This was acknowledged as follows:

"Funding component and technical support was assured by the project…but also PMI who are the funders of the project...a malaria section...I think they have been very supportive....I think they wanted this to succeed as such their pressure made it easier for us to move forward". (Programme/Project Coordinator)

The relatively low cost of SP facilitated smooth policy transition. The low cost of SP meant that increasing doses would not incur a heavy cost, and that partners were willing to fund the policy implementation.

"SP is frankly pretty [an] inexpensive drug...so we can usually cover the entire need for a few hundred thousand dollars a year...compared to ACTs and RDTs and others". (Programme/Project Coordinator)

The WHO policy recommendations, based on a robust evidence review, facilitated smooth policy transition. Such a consensus makes it easier for countries to adopt as stipulated below:

"WHO has also been pushing that we change... and the policy brief was backed by a lot of scientific evidence that was done extensively across the globe… so that push from these global stakeholders also enabled us to work fast". (Programme/Project Coordinator)

"Actually we just adapted the WHO guidelines...revised the malaria treatment guidelines accordingly...that was really straight forward". (Researcher/Advisor)

The NMCP, who are the key stakeholders in implementing malaria control interventions in the country, had a vested interest in updating the policy. The NMCP made all efforts from within the government to adopt and implement the policy change. This was confirmed below: *"Overall the National Malaria Control Programme who are the mandated programme to look at malaria, also had keen interest for this to happen and be implemented". (Programme/Project Coordinator)*

The inclusion of relevant stakeholders at the beginning of the process of change was key in driving the policy update. The inclusion of RHD, who implement IPTp as an integrated reproductive health service, was strategic at policy implementation stage, as described below:

"I need to point out that the reproductive health directorate [as a] key department in malaria in pregnancy issues were also very supportive...you know we cannot talk of malaria in pregnancy without the reproductive health directorate because [it] is a platform that we use to implement IPTp". (Programme/Project Coordinator)

5.3.9 Challenges encountered in the policy process

The NMCP were mandated to develop the new IPTp-SP as a stand-alone malaria control policy. The previous IPTp guidelines were embedded as a component within the malaria treatment guidelines. Developing new stand-alone IPTp-SP guidelines was a cumbersome process that had to incorporate information that was previously part of the Malaria Treatment guidelines, as describe below:

"But now malaria in pregnancy were embedded in malaria case management..... and what was lacking in those documents were the detailed health education that goes with it...financing, partnership...all those things were missing because it was only considered as a treatment component not necessarily as a strategy...so the challenge was that we had to develop [the] guidelines from a scratch". (Programme/Project Coordinator)

Developing separate guidelines meant that health workers needed to be reoriented to consider IPTp-SP as a preventive strategy and an integrated case management tool. As

acknowledged by a stakeholder that it was also difficult to bring together various stakeholders to one gathering and commit their time to developing the guidelines:
"To get different stakeholders come together and agree on something it takes time because people have got a lot of demands on their work...so for them also to dedicate their time to this, it's a little bit of time". (Programme/Project Coordinator)

Orientation of health workers occurred in stages, one district at a time. Thus other districts were still implementing the old policy while training was taking place. This was partly due to funding partners' policies to release funds in stages. Concerns were raised as below:
"This time around we are conducting cascade training not as the way we always do, because things change, partners change the way of doing business, so as we are going down to the districts to do the actual trainings it will be a little bit slow because others are still using the two dose…….because of the way we are implementing due to funders money. But otherwise in a nutshell we just believe that by the end of the year we [will] have finished and the whole country is [will] implement one policy". (Policymaker)

In addition to this challenge was the delay in training health workers due to the change in per diem policy by the government on all Developing Partner (DP) programmes in Malawi.

5.3.10 Lessons learnt during the policy change

Participants highlighted that dedication to the policy process is critical, especially government commitment. Partners can provide resources but if the MOH as owners of health policies are not motivated, the process will face challenges. A stakeholder confirmed this:
"The most important element for a policy to be effectively developed, the relevant government department should have the interest in that policy and they drive the whole process…. the NMCP team were so keen to have this done...that's why we didn't find a lot of problems". (Programme/Project Coordinator)

Another important factor highlighted by participants was the availability of local evidence on which to base changes. An advisor revealed that research evidence forms the foundation for further policy changes:

"Normally when we want to effect a policy change there must have been a study that was conducted or an assessment that was conducted…so that has always been the trend in Malawi that we are guided by studies". (Researcher/Advisor)

Participants stressed that resources should be available at all stages from policy adoption to implementation to achieve smooth policy change, as highlighted below:

"When you are embarking on policy change you should have everything available, you should have the money for the change, for everything that means the drugs themselves, for the guideline change, information to the general public because you can have the money to do the trainings but if you don't inform the public it is very difficult for them to welcome the intervention quickly. So when you have all this together the policy change is very smooth". (Policymaker)

Participants acknowledged the significance of involving relevant stakeholders in the policy process ranging from funding partners, policy makers in the MOH, Policy implementers, and the public.

5.4 Discussion

The reduced efficacy of SP in the treatment of uncomplicated malaria led to its replacement with ACT as recommended by WHO [28]. Inevitably, concerns were raised about the continued use of SP for IPTp. Following these concerns, IPTp-SP was extensively monitored to evaluate its use or explore alternative drugs. Recently a study conducted in Malawi proposing intermittent screening and treatment with dihydroartemisin-piperaquine (ISTp-DP) as an alternative to IPTp-SP did not show superiority in both parasite clearance and birth outcomes. Thus, it recommended continued use of SP for IPTp [29]. Whilst alternative drugs or strategies for IPTp have not yet been found, evaluations of IPTp-SP have revealed that giving SP to all pregnant women at each antenatal care visit from early in the second trimester, with subsequent doses spaced four weeks apart up to the time of delivery, is beneficial for birth

outcomes [8]. Concerns of increased doses of SP for IPTp were raised on the uptake of folic acid and iron during pregnancy because of SP is a folate antagonist. However, evidence has shown that there is no interference with SP when the right doses of 30-60mg of element iron plus 0.4mg/day folic acid supplementation are administered [30, 8].

Comprehensive studies conducted in Malawi have contributed to the body of knowledge on IPTp and have informed local and international IPTp policies. Upon implementation of the first global IPTp-SP policy [6], Malawi immediately started monitoring the policy and [17] confirmed the safety of SP in IPTp and established that multiple doses of SP during pregnancy led to a highly significant reduction in the incidence of LBW. The two SP dose regimen remained unchanged despite these results. Increased *P. falciparum* resistance to SP in the treatment of uncomplicated malaria led to similar concerns regarding the use of SP in IPTp. Several studies monitored the effects of IPTp-SP during pregnancy and birth outcomes. These studies revealed the positive outcomes of IPTp-SP and recommended that more SP doses would have further positive results [14, 18, 19, 21-24]. Despite this evidence originating in Malawi, IPTp-SP policy changes were only made after the amended WHO recommendation was released in 2013. The two studies conducted in Malawi [14] were included in the meta-analysis that led to the change in WHO recommendations [20] which then informed local policy changes. Nevertheless, the WHO does not impose recommendations since countries are at liberty to adopt or adapt them as has been the case for Malawi.

The policy review process in Malawi was largely based on WHO recommendations [8, 15] which incorporated evidence from Malawi for agenda setting [9, 25] and policy development [14, 18, 19, 21-23, 26]. The lack of references in the local policy document [12] hampered the assessment of the degree to which local research was consulted [31]. While the availability of evidence is one content factor that needs to be considered when making a policy [3], the policy process often overlooks actors, processes and contextual factors [4]. In Malawi, the involvement of the right stakeholders during the policy process was strategic. Although the NMCP is the overall coordinating body for malaria intervention, the inclusion of the RHD was

vital since they are responsible for delivery of reproductive health services in the country including IPTp-SP. The importance of this collaboration can never be over-emphasised by the malaria in pregnancy working group meeting in Kenya, which attracted both NMCP and reproductive health MOH country representatives to discuss the Roll Back Malaria guidelines for MIP [32]. Funding partners in the process played a major role through tracking progress and obtaining first-hand reports.

Changing the policy was met with technical and administrative challenges that included the tedious process of developing new IPTp-SP guidelines, bringing together all stakeholders in one place, and the cascade training of health workers which was adversely affected by change of per diem policy by the government. The previous per diem policy left room for public funds abuse when among other things events such as training workshop were conducted away requiring participants to claim for some expenses not incurred and it was widely viewed as method of supplementing one's salary. The change in policy hence led to boycott of such event until resolutions were sought and one of the logistical issues resolved by conducting training workshops in areas where most participants resided.

Nonetheless, many opportunities facilitated a smooth policy process. Most important was leadership by the MOH through the NMCP that showed keen interest in seeing the policy developed and implemented. Similarly the NMCP was identified as critical in driving government efforts in engaging and collaborating with the right stakeholders such as researchers in seeking evidence for policy formulation and its implementation [33]. It is important that the motivation emanates from the government if such a process is to be realised. Policy change in Timor-Leste that contained an escalation of malaria cases during a crisis was similarly supported and driven by government [34]. The use of WHO recommendations as motivation for policy change facilitated support from PMI, who provided technical and funding support to the process.

5.5 Conclusion

Malawi changed its IPTp policy based on the WHO recommendation in 2012. Research conducted in Malawi was instrumental in changing the global IPTp-SP policy due to the inclusion of findings in the systematic review that led to the WHO policy change. Malawi adapted and changed its IPTp-SP policy based on the resulting WHO recommendations. This change did not face many hurdles but was a welcome opportunity to address some of the challenges faced by health workers during implementation of the previous policy. The policy updating process has highlighted the importance of commitment by the concerned government department to be motivated and drive the process. This should be accompanied by a thorough stakeholder analysis to identify and involve relevant key stakeholders from the initial stages of the policy change process. In addition, it is critical to utilise local evidence for this process and address current local health burdens leading to efficient public health care. The local evidence used in the process should be documented in the policy documents and guidelines for purposes of tracking research utilisation and its impact.

Ideally, policymakers should use a framework that facilitates the use of malaria research to champion knowledge translation and work towards addressing the malaria burden in Malawi. Therefore, lessons from this study will inform the development of the malaria research-to-policy framework in Malawi and the process of developing this framework can also advise the development of research-to-policy frameworks in other settings.

Abbreviations

ACT: Artemisin-based Combination Therapy; CHAI: Clinton Health Access Initiative; CQ: Chloroquine; ERG: Evidence Review Group; WHO: World Health Organization; IPTp-SP: Intermittent Preventive Treatment in pregnancy with sulfadoxine-pyrimethamine; KIIs: Key Informant Interviews; LBW: Low Birth Weight; MIP: Malaria in Pregnancy; MOH: Ministry of Health; MPAC: Malaria Policy Advisory Committee; NMCP: National Malaria Control Programme; PMI: Presidential Malaria Initiative; RHD: Reproductive Health Directorate; SSDI-services: Support for Service Delivery Integration-Services; TOTs: Trainer of Trainers; USAID: United States Agency for International Development.

Ethics approval

Ethical clearance was obtained from the National Health Sciences Research Committee (NHSRC) in Malawi and the Faculty of Health Sciences Research Ethics Committee at the University of Pretoria (Ref No. 146/2013). Participants were also requested to provide consent approval to be interviewed and recorded before the interviews.

Consent for publication

Not applicable

Availability of data and material

The datasets generated and/or analysed during the current study are not publicly available due to keeping the identities of respondents confidential as they granted consent for interviews on the basis of remaining anonymous but are available from the corresponding author on reasonable request.

Competing interests

The authors declare to have no competing interests.

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Authors' contributions

CAM conceived, developed the idea, and prepared the manuscript. HL contributed to shaping of the idea. CMM, KP, TdJ, and CH contributed their technical expertise in directing and critiquing of the manuscript. All the authors contributed to the drafting of the manuscript and approved the final manuscript.

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CHAPTER SIX

Introduction

Chapters four and five have revealed how malaria research influence the development of policies in Malawi and globally, while further demonstrating the policy making process. However, chapter five has also exposed some challenges of research utilisation in Malawi. In order to develop a contextual framework it is imperative that a situation analysis is conducted. This step calls for a thorough assessment of barriers and facilitating factors to the process of research utilisation in policy development. Chapter six presents the barriers and facilitators to the malaria research utilisation in policy development in Malawi.

6.0 FACILITATING FACTORS AND BARRIERS TO MALARIA RESEARCH UTILISATION FOR POLICY DEVELOPMENT IN MALAWI

Abstract

Background: Research on various determinants of health is key in providing evidence for policy development, thereby leading to successful interventions. Utilisation of research is an intricate process requiring an understanding of contextual factors. The study was conducted to assess enhancing factors and barriers of research utilisation for malaria policy development in Malawi.

Methods: Qualitative research approach was used through in-depth interviews with 39 key informants that included malaria researchers, policy makers, programme managers, and key stakeholders. Purposive sampling and snowballing techniques were used in identifying key informants. Interview transcripts were entered in QSR Nvivo 11 software for coding and analysis.

Results: Respondents identified global efforts as key in advancing knowledge translation, while local political will has been conducive for research utilisation. Other factors were availability of research, availability of diverse local researchers and stakeholders supporting knowledge translation. While barriers included: lack of platforms for researcher-public engagement, politics, researchers' lack of communication skills, lack of research collaborations, funder driven research, unknown World Health Organization policy position,

and the lack of a malaria research repository.

Conclusion: Overall, the study identified facilitating factors to malaria research utilisation for policy development in Malawi. These factors need to be systematically coordinated to address the identified barriers and improve on malaria research utilisation in policy development. Malaria research can be key in the implementation of evidence-based interventions to reduce the malaria burden and assist in the paradigm shift from malaria control to elimination in Malawi.

Keywords: Facilitating factors, Barriers, Malaria research, Policy development, Research utilization, Malawi

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6.1 Background

Developing countries, in view of their limited resources, need to take advantage of knowledge translation (KT) initiatives to maximize the utilisation of research for health towards implementing interventions with proven track record [1]. It is evident that creative strategies, such as interaction between researchers and policymakers, are needed to promote utilisation of research for policy making since traditional dissemination efforts have not yielded much change [2]. Research-informed policies have led to development of health interventions with improved health outcomes, ultimately saving lives [3]. It has also been recognised that research is critical in strengthening health systems and improving equitable distribution of scarce resources in low and medium income countries (LMICs) [4]. Such recognition should be the basis for supporting and utilising research for the improvement of health systems. However, the effective use of such research remains a challenge in many LMICs where weak health systems exist and poverty-related disease burden remains high [5].

Despite a decrease of malaria prevalence among children age 6–59 months in Malawi from 43 % in 2010 to 33 % in 2014, malaria continues to be a major public health problem [6]. It is estimated that four million cases of the disease occur annually, mostly affecting children under the age of five years and pregnant women [6]. The Ministry of Health (MOH) through the National Malaria Control Programme (NMCP) has strived to implement the National Malaria Strategic Plan for 2011–2016 with the vision to reduce the malaria burden for all people in Malawi and attain a 'Malaria-free Malawi' through the scaling-up of malaria interventions [6]. It is, therefore, through implementation of evidence-based interventions that Malawi can reduce the malaria burden and shift from the paradigm of malaria control to elimination [7]. The adoption of malaria research utilisation in policy development needs a systematic approach. Thus, a framework to facilitate this process needs to be developed. The overall objective of this study is to contribute towards the development of such a framework in Malawi.

6.1.1 Conceptual framework

The majority of research-to-policy frameworks developed for research utilisation are generally in the context of developed countries [8, 9]. Their applicability and relevance pose a challenge in LMICs [10]. It is essential that contextual factors are considered when developing such frameworks [11].

The Ottawa Model of Research Use (OMRU), developed by Logan and Graham [9], guides the development of KT strategies for the improvement of health service in developing countries. Its basic principles require the assessment of enablers and barriers in the utilisation of research for policy development in a particular system in order to develop a contextually relevant framework. This study's conceptual framework (Fig. 6.1) was underpinned by this model. The specific objective of this study was to assess the facilitating factors and barriers to malaria research utilisation for policy development in Malawi.

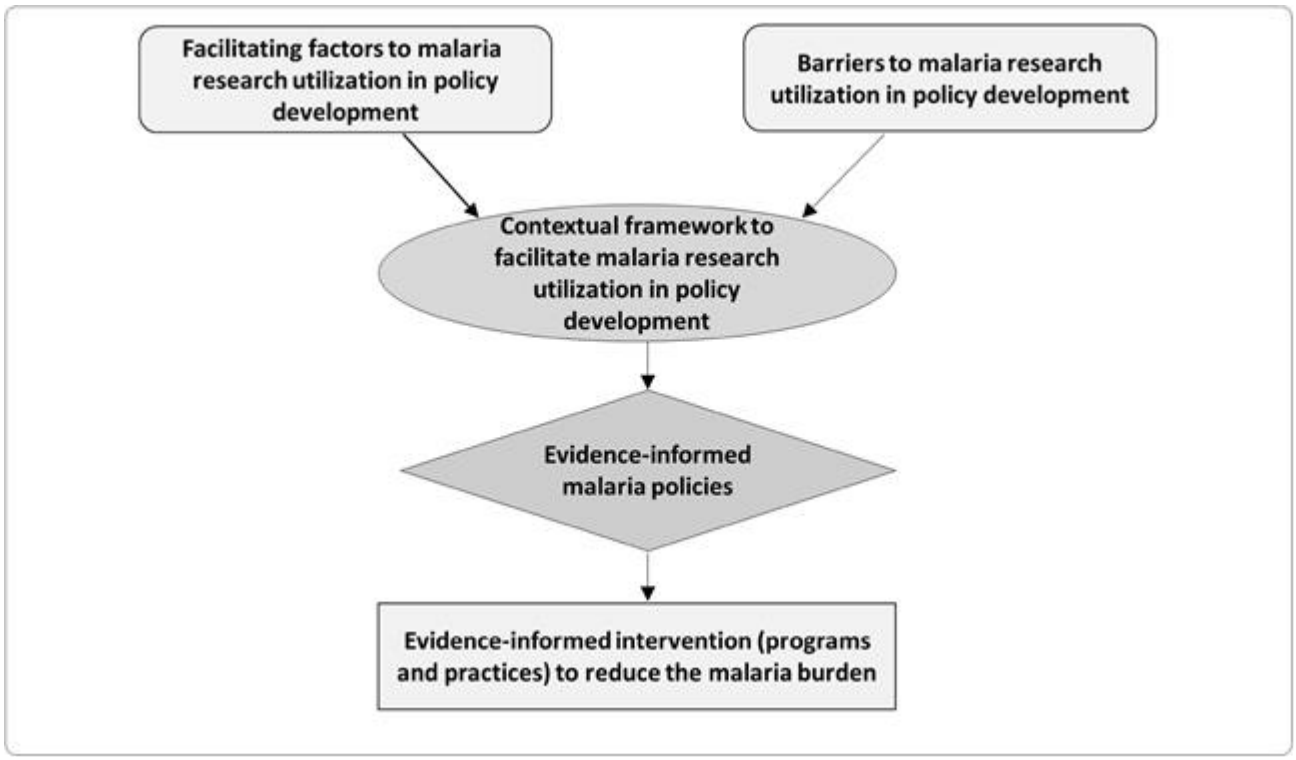

Figure 6.1: Study conceptual framework

6.2 Methods

The study applied qualitative research methods using in-depth interviews with key informants (KIs) conducted between April and July 2015. The sample population comprised individuals from malaria-related professionals, government officials and relevant stakeholders (Table 1). Purposive and the snowballing sampling techniques were used in identifying KIs. The interviews were conducted by the principal investigator. Data were captured using digital audio recorders in English, followed by transcription and importation of transcripts into QSR Nvivo 11, a software package for coding, organizing, management, and analysis. The analysis was based on the Grounded Theory principles in which data are thematically categorised and grouped into common themes and later examined contextually to explain the arising issues [12]. Verbatim quotes were used to illustrate concepts or points of view.

Ethical clearance was obtained from the National Health Sciences Research Committee (NHSRC) in Malawi and the Faculty of Health Sciences Research Ethics Committee at the University of Pretoria (Ref No. 146/2013).

6.3 Results

A total of 39 KIs were interviewed and the categories of participants included: 19 malaria researchers (from College of Medicine, Malaria Alert Centre (MAC), Blantyre Malaria Project (BMP), Malawi-Liverpool Wellcome (MLW) Trust, Centre for Social Research (CSR), University of Northern Carolina (UNC), and other renowned researchers working elsewhere); eight policymakers from the MOH; four programme managers from the NMCP; and eight stakeholders (from the World Health Organization (WHO), African Institute for Development Policy (AFIDEP), Global Fund, United States Aid and Development Fund (USAID), National Commission for Sciences and Technology (NCST), and Abt Associates Inc). Table 6.1 presents the experience and current positions of the KIs.

Table 6.1: Details of key informants (KIs)

KI	Gender	Current position and Institution	Experience	Role
1	Female	Malaria epidemiologist, Malawi—Liverpool Wellcome Trust (MLW)	Over 10 years in malaria research	Researcher
2	Female	Director, Blantyre Malaria Project	Over 20 years in malaria research	Researcher
3	Male	Director, Centre for Social Research	Over 20 years in malaria research	Researcher
4	Male	Medical epidemiologist, Director University of Northern Carolina Project	Over 20 years in malaria research	Researcher
5	Male	Biostatistician, National Malaria Control Programme (NMCP)	Over 5 years in malaria research	Researcher
6	Male	Epidemiologist, MLW	Over 10 years in malaria research	Researcher
7	Female	Public health specialist, MLW	Over 5 years in malaria research	Researcher
8	Male	Public health specialist, Malaria Alert Centre (MAC)	Over 5 years in malaria research	Researcher
9	Female	Senior Nurse, Kamuzu College of Nursing	Over 10 years in malaria research	Researcher
10	Male	Medical biologist, Chancellor College	Over 10 years in malaria research	Researcher
11	Male	Pharmacologist, College of Medicine (COM)	Over 10 years in malaria research	Researcher
12	Male	Malaria epidemiologist, COM	Over 10 years in malaria research	Researcher
13	Male	Medical epidemiologist—Director of Malaria Alert Center (MAC), COM	Over 10 years in malaria research	Researcher
14	Male	Senior scientist, MLW	Over 40 years in malaria research	Researcher
15	Female	Retired pediatrician and director of MAC, COM	Over 30 years in malaria research	Researcher
16	Male	Pediatrician, Ministry of Health	Over 30 years in malaria research	Researcher
17	Male	Pediatrician, Ministry of Health	Over 40 years malaria research	Researcher
18	Male	Clinical trialist	Over 10 years in malaria research	Researcher
19	Male	Entomologist, MAC, College of Medicine	Over 10 years in malaria research	Researcher
20	Female	Clinical epidemiologist, NMCP	6 years	Programme manager
21	Male	Disease control officer, NMCP	5 years	Programme manager
22	Male	Entomologist, NMCP	11 years	Programme manager
23	Male	Environmental health officer, NMCP	6 years	Programme manager
24	Male	Deputy director of planning, Ministry of Health (MOH)	3 years	Policymaker
25	Male	Director of Research, MOH	8 years	Policymaker
26	Male	Health economist, MOH	11 years	Policymaker
27	Female	Health planner, MOH	12 years	Policymaker
28	Male	Research and knowledge translation manager (MOH)	2 years	Policymaker
29	Male	Head of Sector Wide Approach, MOH	6 years	Policymaker
30	Male	Health planner, Director of Planning and Policy Development MOH	2 years	Policymaker
31	Male	Chief of Health Services, MOH	5 years	Policymaker
32	Male	Malaria advisor, World Health Organization	15 years	Stakeholder
33	Male	Health economist, director Abt Associates Inc	4 years	Stakeholder
34	Male	Global fund coordinator, MOH	2 years	Stakeholder
35	Male	Malaria resident advisor, US Centre for Disease Control	3 years	Stakeholder
36	Female	Policy and advocacy coordinator, African Institute for Development Policy	2 years	Stakeholder
37	Male	Policy development and analysis, Abt Associates Inc	4 years	Stakeholder
38	Male	Chief research service officer, National Commission for Science and Technology	16 years	Stakeholder
39	Male	Malaria program specialist	5 years	Stakeholder

The interviews focused on identifying facilitating factors for malaria research utilisation in policy development, and barriers hindering this process. Table 6.2 summarises the identified factors categorised into institutional, personal, and research-based as declared by research participants.

Table 6.2: Facilitating factors and barriers to malaria research utilisation for policy development

	Specific factors
Facilitating research uptake factors	
Institutional factors	Global influence on the emphasis of evidence driven policies
	The establishment of the department of Research in Ministry of Health
	The revival of the Policy Development Unit (PDU) and the development of guidelines for policy development and analysis
	The availability of the National Health Research Agenda (NHRA)
	Availability of funding organization such as NCST, USPMI, and Global Fund
	Establishment of the Knowledge Translation Platform (KTP) and the Knowledge Translation Unit (KTU)
	Establishment of the African Institute for Development Policy (AFIDEP) in Malawi
	Technical Working Groups to discuss research, and annual research dissemination conferences
	Collaboration of the NMCP and research centres such as the Malaria Alert Centre (MAC)
Personal factors	Local Researchers trained in various malaria research disciplines
	Growing number of researchers interested in knowledge translation
Research factors	Availability of malaria research conducted in Malawi
	Availability of the NHRA that includes the malaria research agenda
	A position already established by WHO
Barriers to research uptake	
Institutional factors	Lack of a platform on which researchers can engage with the public
	Lack of research capacity at the NMCP
	Politics
Personal factors–researchers	Lack of research communication skills to policy makers
	Focus on publishing and career advancement
	Lack of collaboration of researchers with policy makers
	Lack of collaboration among researchers of different disciplines
Personal factors–policy makers	Lack of time to find and read research articles
	Inability of research synthesis
	Lack of motivation and rigid to change
	Mistrust of research findings
Research factors	Research not addressing the country's needs
	Funder driven research
	Unknown WHO policy position
	Access to malaria research and lack of a malaria research repository

6.3.1 Facilitating factors to malaria research utilisation for policy development

Institutional factors

Global influence: Respondents acknowledged global efforts in promoting KT and were increasingly aware of the importance of research evidence in policy development. This is supported below:

> *"The current movement worldwide is that research findings must find their way to policy and practice through systematic processes which are now under-going by the title 'knowledge translation platform'". (Policy maker)*

This global effort has compelled developing countries, such as Malawi, to strive towards policies that are research driven.

Government efforts

Ministry of Health: Political will from government through the Ministry of Health was identified to be key in promoting research for policy development in the country. The government established the department of research in Ministry of Health with the aim of driving evidence-driven policies, while in 2012 it revived the Policy Development Unit (PDU) [13]. This was described below:

> *"We had to revitalize from a scratch from 2012 what used to be the policy development unit to make it functional and be able to play a coordinating role to the healthy policies in the healthy sector in Malawi…and am happy to report that now the unit is coordinating various health policies". (Stakeholder)*

To support its function, the PDU developed guidelines that provide a framework for harmonising policy and analysis in the public health sector [13]. Steps two, five and six in the guidelines require research evidence for decision-making. In its support the MOH developed the National Health Research Agenda (NHRA), which identifies priority research areas. As Malawi seeks to implement the NHRA, it is imperative to provide research funding. Government declared commitment through the allocation of at least 2 % of the District Implementation Plan (DIP) budget to research

[14, 15]. However, this directive is not upheld due to constrained funding which results in research not being prioritised. It is against this funding gap that the NCST was established to provide grants to local researchers addressing the NHRA. The task of the NCST was alluded to by a stakeholder:

"The national commission for science and technology is key in terms of contributing towards promoting the undertaking of research to contribute towards development of policy in the identified priority areas of research". (Stakeholder)

While other factors such as international institutions including the Global Fund and the United States' President for Malaria (USPMI) as identified by respondents were committed to assist government in supporting malaria research.

The establishment of the Knowledge Translation Plat-form (KTP) in the MOH with assistance from Dignitas International was also identified by respondents as a government commitment to enhance research utilisation in decision-making. The aim is to communicate research findings to policymakers addressing the challenge of many researchers, as highlighted below:

"How do I make sure I translate my findings in an appropriate way to policy makers…how do we keep on highlighting our individual study findings as something that policy makers can take a decision on…so I think the separate developing groups of people who focus on knowledge translation can really use best practices". (Malaria researcher)

NMCP: Respondents recognised that the NMCP makes specific government efforts to facilitate malaria research utilisation. The setting up of Technical Working Groups (TWGs) enables informal evidence sharing and debate. This was described below:

"I like technical working groups because they are in a way rather informal where you can actually engage with the ministry of health officials and as researchers we can learn the key issues that the ministry is looking for". (Malaria researcher)

In addition to TWGs, the NMCP organizes the annual national malaria research dissemination conferences where malaria research supported by government are disseminated.

Respondents also highlighted as vital the collaborations of the NMCP and research centres. The lack of research capacity at the NMCP has compelled the programme to rely on research institutions to conduct policy -relevant research on its behalf. NMCP will engage a particular research centre based on the type of study required. For example, a strong collaboration exists between NMCP and MAC, which conducts operational research providing evidence that directly feeds into policy. This was described below:

"Malaria Alert Centre is directly involved with the NMCP from the inception of a study, so it's not hard when we are presenting the results for policy changes because they are involved". (Malaria researcher)

Other important research institutions that provide evidence to the NMCP include: MLW trust that builds capacity and conducts high quality clinical research in the country. The efforts of this institution supplement those for the government because it is externally funded by the Wellcome Trust shouldering the challenge of funding faced by the government. Therefore, the research institution is able to conduct research in collaboration with the NMCP for policy development in addition to exploratory or basic research, CSR which conducts social-cultural research, the Blantyre Malaria Project (BMP) focusing on severe malaria research, the UNC conducting clinical research.

University of Malawi, College of Medicine efforts*:* College of Medicine is one of the five constituent colleges in Malawi conducting health research. The establishment of the Evidence Informed Decision-making Centre (EvIDenCe) in 2015 at the institution was identified as key and a reflection on the commitment to enhance translation of research into policy and in conducting policy relevant research. EvIDenCe was established to drive KT efforts at the college including; conducting and teaching systematic reviews, evidence synthesis and writing policy briefs for policy decisions, teaching evidence-based health care, and contributing to the formulation of the NHRA. Similarly, the College of Medicine conducts annual research dissemination conferences where malaria research results are also disseminated. In supporting the NMCP malaria conference, these conferences provide a platform for policymakers to be aware of malaria

research conducted in the country. Challenges emerge when government officials partially attend such conferences and respondents felt that further efforts such as the TWGs by the NMCP should be made to engage with them. Separate interactions with policymakers, which highlight research implications on policy, need to be organized. Research findings should include their policy implications.

AFIDEP efforts

To complement the work by KTP and EvIDenCe, respondents identified the AFIDEP that was established in Malawi in 2013. AFIDEP focuses its work in knowledge utilisation, capacity strengthening, and knowledge synthesis and translation. Through the Strengthening Capacity to Use Research Evidence in Health Policy (SECURE) programme, AFIDEP strengthens the capacity of health policymakers and legislators in research evidence utilization for decision making. Their aim is to consolidate interaction of researchers and policy makers and hence improve on the trust for each other. One of its specific activities of interest is building the capacity of policy makers to access, appraise and apply research evidence in their decision making and policy development. This initiative is vital in instilling a culture of evidence use for decision-making among policymakers and its efforts were recognized by a stakeholder as below:

"The initiative of some programmes like AFIDEP are very good because those can help to mobilize resources for local initiatives". (Stakeholder)

Personal factors

Respondent acknowledged that it was key for knowledge creation since local researchers are being trained in various research disciplines, such as malaria in pregnancy, immunology, parasitology, human immunodeficiency virus (HIV) and malaria, cerebral malaria, and malaria treatment. In addition, some researchers are focusing on knowledge translation and health systems research. The quote below supports this:

"I think there is a real momentum or opportunity now with a building of capacity of people with interest in knowledge translation, in health systems research and in policy process…we have people who know better how to review the current status of research and

internationally link to what is avail-able on the national level and identify the gaps but they also know how to develop policy briefs, which I as a researcher don't have that much experience". (Malaria researcher)

Research factors

The most important element in facilitating research evidence for policy development is availability of local research findings. Respondents acknowledged that ample malaria research is being conducted in Malawi. This is described below:

"I mean too many studies have been done in malaria, sharing of these research results I think sometimes is not there". (Malaria researcher)

Although the amount of available research is critical, the quality of research is equally important for policy development. As indicated above the collaboration between the NMCP and MAC was identified as prominent. MAC is a recognised research program called International Centres of Excellence for Malaria Research (ICEMR) that conducts high quality research with the purpose of addressing the malaria burden locally and internationally. The aim is to develop evidence-based interventions for the Country and hence, research conducted at MAC has direct bearing on policy. Therefore, policymakers have confidence in the evidence they provide. This was highlighted as below:

"Being an ICEMR means that we have what we call a powerful front that when we produce the results they have already been reviewed by all these bodies and when we make recommendation to the ministry it is really powerful because even the ministry knows that it's coming from a very powerful front and it has been reviewed by collaborators internationally". (Malaria researcher)

The research conducted is guided by the NHRA, hence there is availability of research that is specifically responding to needs of the country.

They (respondents) also admitted that the research conducted in most of the time in line with WHO recommendations hence it is often used symbolically in policy development.

6.3.2 Barriers to malaria research utilisation for policy development

Institutional barriers

One of the major barriers to research utilisation identified was the lack of a direct link between researchers and critical societies of policy making other than the MOH. These societies include the Civil Society Organizations (CSOs), influential people such as chiefs, and the public. These sentiments were expressed as below:

> *"If you are going to really influence policy you shouldn't only be influencing people within the Ministry of Health, but the people for whom policy is being made for, without that platform you don't have community based organizations, [Non-Governmental Organizations] NGOs or even traditional chiefs, and influential people in the community actually contributing to the policy makeup". (Malaria researcher)*

Respondents felt that such a platform, as in many developing countries, can have advocacy through news-paper campaigns, television, radio, and other social media channels.

Another identified barrier was the limited research capacity of NMCP, which has often delayed adoption of research findings. The NMCP has on several occasions relied on independent researchers or research institutions. Consequently, the NMCP would rather wait for WHO recommendations, which may come late, while local evidence has shown the need to develop new innovations. This was observed as below:

> *"The NMCP will wait for WHO because they don't have the capacity sometimes to actually evaluate the evidence, now for WHO to have a stamp on it you have to carry out quite extensive studies and there is a lag time and you lose out on possible benefits of a strategy that is more locally effective". (Malaria researcher)*

Participants recognized political impact on policy development. Research can provide good evidence and recommendations but politicians can have preconceived policy positions contrary to the evidence, which leads to researchers' frustration. This was referred by a researcher:

> *"For people to appreciate researchers they have to have an interest in implementing data*

driven policies, so they will always absorb research if they have that kind of interest, sometimes you may get in a situation where you might be discussing certain things but people have preconceived ideas already about what they want the situation to be even if the data may be speaking otherwise". (Malaria researcher)

Personal barriers

Researchers*:* It was revealed that researchers find it challenging to effectively communicate their findings to policymakers. Somehow researchers assume that their work ends once they publish or present their results and it is the responsibility of the policymakers to make use of the findings. A researcher made the narration below to confirm this:

"My role ends when I present the results…if the Ministry wants they can make a decision on how they are going to utilise those results to develop policies. As far as I am concerned as a researcher I will do the research and make a presentation…that's all I know but the question is do I have the skills to translate whatever the results I have into something that the Ministry of Health can easily utilize…I think most of us as researchers don't have that experience of translating the research results into something that the ministry of health can easily use". (Malaria researcher)

Respondents expressed gratitude with the timely establishment of KTP and EvIDenCe which can tackle these challenges by focusing on bridging the gap between researchers and policymakers.

Another barrier highlighted how some researchers are naïve in the policy making process and assume that only their findings can influence policy. In addition, they may not collaborate with the NMCP or policymakers in the research process. The NMCP acknowledged this:

"But one very critical thing is collaboration, because sometimes people do studies, like check for insecticide resistance and tell us that there is resistance in the whole country…we have no idea and [we] don't know the person and the protocol. That will not change the policy even if the results are good, it will not, because that was academic". (Programme man-ager)

In other cases, the NMCP may not be aware of research findings, especially if such research was conducted by foreign researchers. These findings are disseminated externally and published in inaccessible journals, as lamented below:

"Unfortunately some of these studies are not even known to the Ministry…people come to this country from out there to do their research in different parts of this country…it is only when you go to a conference abroad and you find there are a lot of papers on Malawi". (Malaria researcher)

Lack of collaboration among researchers was also mentioned to pose a challenge. In many situations researchers work in isolation by focusing in one area, such as drug or vaccine discovery, without engaging in other research disciplines. The need for collaboration among researchers is important in providing a variety of evidence that policymakers can use. A researcher acknowledged this:

"We are usually working in narrow areas and we don't think about other discipline that would actually strengthen our research work. So in the planning phase of all these research studies we should be looking for collaboration". (Malaria researcher)

Policymakers: Respondents indicated that most policymakers lack time and the ability to find research articles in journals and synthesize the evidence. They lack expertise in research exploration and interpretation of scientific findings. Journals may not be readily accessed and the evidence from different publications might be contradictory, thereby reducing the confidence policymakers have for a given set of research findings. A researcher testified to this:

"Most of the policymakers, do not have time to go through journals and read what research is. They say it but [actually] in actual sense they don't read and even if you read, you will get two [to] three articles [you can get articles] that are saying different things". (Malaria researcher)

Lack of trust in the findings by policymakers may also arise when they do not understand the research process. They may have problems with generalisation of findings. This was supported

by the quote below:

"There are always issues [of] about generalisation… but sir you did this in Chikwawa, how do we know that it applies to the whole country?" (Malaria researcher)

Respondents indicated that collaboration between researchers and policymakers can address such problems as they get oriented to the research process. It was also revealed that in some cases policymakers lack motivation and can be reluctant to change. This is common among personnel who are used to operating on older policies and routine activities. Such personnel are reluctant to adopt current evidence for policy change.

Research barriers

Respondents felt research that does not address the country's needs is difficult to be utilised. Partly this problem comes when research funding is provided by a donor with their own research focus, but respondents felt that it should also be the responsibility of the government, if it intends to utilise such findings, to provide funding that can generate the required evidence. These sentiments are expressed below:

"If Malawi really wants to answer its own questions that are pertinent then Malawians have to come up with resources for research. And most of this research that we are talking about is not expensive research, this is research that can be conducted with very minimal resources". (Malaria researcher)

A further challenge was revealed when the WHO does not have an established policy position on the issue at hand. Policymakers become reluctant to make a move until WHO has a position. This was affirmed as follows:

"Evidence normally translates quite slowly into a policy especially in sub-Saharan Africa. Since we tend to depend a lot on guidance from international agencies. Where we have a feel about a particular thing that does not work really well for us, we still want to wait from some [the] prompting from these international bodies for us to move". (Malaria researcher)

A critical barrier mentioned to malaria utilisation was the lack of a repository for local malaria

research. Usually the research reports are scattered across research institutions or ethical approval bodies, which makes it difficult to access. Such sentiments are shared below:

"The problem is limited access to data, people do research but I don't think you have a platform where you can put your report, like a single repository of malaria research in Malawi where if I want something I'll just click and get a link or get somewhere where I can get malaria specific research. So without that kind of a repository of information for malaria, for us as a country decision makers are often faced with a challenge of knowledge gap when we actually have enough information". (Stakeholder)

6.4 Discussion

The notion of increasing utilisation of research evidence in policy formulation has gained global level focus [16]. However, putting in place structured efforts to support KT is critical for its achievement [1]. One of the initial steps in developing such structures involves the assessment of contextual factors for research utilisation in a system in order to pragmatically address the barriers while maximising on the supportive factors. This study assessed the various factors with the aim of contributing to the utilisation of malaria research in policy formulation for reduction of malaria burden in Malawi.

Global efforts were identified to be key in facilitating research utilisation in policy development. For instance, the Evidence to Policy Network (EVIPNet) [17], an initiative by WHO, has encouraged African countries to establish KTPs [18]. These KTPs aim at bridging the gap between researchers and policymakers by creating an environment for interaction. This initiative compelled Malawi with assistance from Dignitas International to establish its first KTP in 2012 [18], which has advocated and enabled an environment for research utilisation in policy development [19]. Similarly, the College of Medicine, a research and academic institution created EvIDenCe, signifying efforts of translating research evidence into policy.

Political will is important for Malawi if it aims to adopt the malaria elimination paradigm [7]. This can be achieved through implementation of research-informed policies. This commitment has led the government to establish the department of research within the MOH and develop

relevant tools to assist the development of research-informed policies. These tools include guidelines for policy development and analysis, and the NHRA. The guidelines offer fifteen important practical steps in policy development and these include; (1) Assessment of the legal and policy framework in order to prioritize areas in need of new or revised policies, (2) identification or analysis of problems and issues than need to be addressed in or revised policies, (3) organisation of the policy development process, (4) development of policy objectives for the envisioned policy, (5) identification of policy options to achieve the developed goals, (6) Evaluation of the policy options on their feasibility, (7) selection of the appropriate policy option, (8) Drafting the policy, (9) circulation of the draft policy to stakeholders for input and revision, (10) obtaining official policy endorsement from MOH senior management, (11) securing of any needed legal or regulatory changes and explore any lower-level policy documents for support and consistency, (12) launch and implement the policy, (13) monitor and evaluate the policy, (14) learn from the monitoring and evaluation, and (15) revise the policy as needed. Most important are steps two, five, and six, which seek evidence for decision-making [13]. Working closely in support of these guidelines is the NHRA, which identifies the country's health research needs. As researchers respond to the NHRA they provide relevant local evidence that is conveniently available for policy decision-making.

It is thus, imperative for government to support such research. However, amid challenges of government research funding, certain institutions such as the NCST offer research grants supporting studies responding to the NHRA. In addition, organizations such as the USPMI and the Global Fund pledge research support for policy development. These institutions aim to contribute to the shared vision of a malaria-free world by the Roll-Back Malaria partnerships and target for goal number three of the sustainable development goals [20–22].

The importance of interactions between researchers and NMCP or policymakers can never be overemphasized. Through TWGs, researchers have acknowledged that they understand the needs of NMCP and policymakers while they also appreciate the research process. Other interactions occur during the annual research dissemination conferences. Such interactions

enhance the uptake of research findings since policymakers are aware and can contribute to the research process [23, 24].

Another vital interaction occurs during collaboration of the NMCP and research institutions. Similar arrangements between the Ontario Drug Policy Research Network and the Ontario Public Drug Programme have revealed the importance of such a collaboration for research to be timely conducted and used for policy development [25]. Importance should also be placed on multidisciplinary research. With a growing diversity of malaria researchers in Malawi, multidisciplinary research can increase the utilisation of research findings and attract funding since funders are inclined to support such research [24].

The barriers to malaria research utilisation which the study found included the lack of a platform for researchers to engage with the public. Public opinion can be a strong force to influence policy change [1]. If the public grasp policy implications of research, they can be in a position to demand for better policies. It is strategic for researchers to engage with CSOs and the media in order to communicate research findings for purposes of influencing public opinion and advocate policy change [26, 27].

Politics can form a barrier to research utilisation in the system. For instance, many senior positions in the MOH are political appointments which are subject to staff transfers. This can negatively impact policy processes as new personnel bring new ideas or lack the motivation to pursue previous efforts left by others. This is further exacerbated whenever there is a change of government [28]. Efforts should be made to retain personnel who initiate an activity until continuity is established.

Lack of research synthesis skills by policymakers has also been reported in other settings by Santesso *et al.* [1] who identified policymakers' lack of skills and poor education background to apply and use research as common barriers in developed countries. This is amplified by the fact that researchers too lack the skills of communicating their research findings to policymakers. This study has identified the initiative by AFIDEP to strengthen the capacity of health policymakers

and legislators in research evidence utilisation for decision-making. This initiative is vital in instilling a culture of evidence use for decision-making among policymakers, which has been cited as one of the main barriers of knowledge translation [29].

Furthermore, the type of research conducted forms a pivotal role for its adoption into policy. This study revealed how research can be a barrier to its utilisation. This was mainly through research that did not address the country's needs simply because it was funder driven or it was for academic purposes.

Sometimes local evidence can show the need for policy change, but policymakers are reluctant if WHO has not yet made a policy position. This is a barrier as researchers become demotivated to provide evidence. However, if research is strongly siding with a WHO position it is likely to be used symbolically in supporting the policy position [30].

6.5 Limitations of the study

All efforts were made to reach out and include all individuals who were key players in malaria research and malaria policy development. However, some prominent and experienced researchers and policymakers were either out of the country or had retired, rendering them unreachable. Their views could perhaps have provided additional perspectives to the study. However, to strengthen the study prominent individuals were interviewed in their current positions without new themes emerging. This indicated that a point of saturation was attained.

6.6 Conclusion

The study has identified a number of facilitating factors and barriers that can enhance or derail the utilisation of malaria research in Malawi. The identified facilitators and institutions offer hope of overcoming the barriers to malaria research utilisation for policy development. It is important to have a systematic approach in coordinating these factors, and hence the need to develop a framework that can facilitate this process. The development of this framework is built on the identified institutions by creating links of collaborations based on the enhancing factors in order

to tackle the barriers. Therefore, the framework will act as a guide to researchers, stakeholders, and policymakers to engage formally and utilise malaria research in policy development.

Abbreviations

AFIDEP: African Institute for Development Policy; BMP: Blantyre Malaria Project; CSR: Centre for Social Research; CSOs: Civil Society Organizations; DIP: District Implementation Plan; EvIDenCe: Evidence Informed Decision-making Centre; EVIPNet: Evidence to Policy Network; HIV: Human Immunodeficiency Virus; KIs: Key Informants; KT: Knowledge Translation; KTP: Knowledge Translation Platform; LMICs: Low and Medium Income Countries; MAC: Malaria Alert Centre; MLW: Malawi-Liverpool Wellcome Trust; MOH: Ministry of Health; NCST: National Commission for Sciences and Technology; NHRA: National Health Research Agenda; NHSRC: National Health Sciences Research Committee; NGOs: Non-Governmental Organisations; NMCP: National Malaria Control Programme; OMRU: Ottawa Model of Research Use; PDU: Policy Development Unit; TWGs: Technical Working Groups; UNC: University of Northern Carolina; USAID: United States Aid and Development Fund; USPMI: United States President's Malaria Initiative; WHO: World Health Organization.

Authors' contributions

CAM conceived, developed the idea, and prepared the manuscript. HL contributed to shaping of the idea. CMM, KP, TdJ, and CH contributed their technical expertise in directing and critiquing of the manuscript. All the authors contributed to the drafting of the manuscript. All authors read and approved the final manuscript.

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The authors declare that they have no competing interests.

Availability of data and material

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Ethics approval

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CHAPTER SEVEN

Introduction

Further to the notion of promoting the development of evidence-based policies, it is critical that the policies are implemented according to their objectives. Chapters four and five have shown how evidence-based policies were developed in Malawi. However, the burden of malaria has remained high in the country. One of the areas to examine is policy implementation, which needs to be considered if the policy objectives are to be realised. Chapter seven, thus, examines some of the challenges to the implementation of malaria policies in Malawi.

7.0 CHALLENGES TO THE IMPLEMENTATION OF MALARIA POLICIES IN MALAWI

Abstract

Background: An organized approach in tackling the malaria burden in Malawi begun in 1984 when the first National Malaria Control Programme was established and its current malaria policy mission is to reduce the burden of malaria to a level of no public health significance and eventually eliminate malaria. With the implementation of evidence-based policies, malaria prevalence decreased from 43% in 2010 to 33% in 2014, however despite implementation of evidence based policies; malaria remains a major health problem in the country. Therefore, this study was conducted to explore challenges of implementing malaria policies in Malawi and bring awareness to policy makers the importance of considering policy implementation during policy development.

Methods: Qualitative research methods were used through in-depth interviews with 27 key informants in the period of April to July 2015. Purposive and snowballing techniques were utilized to identify key informants including malaria researchers or policy advisors, policymakers, programme managers, and other key stakeholders. Recorded interviews in English were transcribed and imported into QSR Nvivo 11 for coding and analysis. Data was analysed using the grounded theory.

Results: The main challenges to implementation of malaria policies, as explored in this study, include inadequate resources for policy implementation, unavailability of trained staff, poor

supervision and mentorship, and politics, unilateral implementation of policies, lack of a platform for engagement with communities, top-down approach in policy development, lack of understanding of socio-cultural factors affecting policy uptake by communities, and incomplete stakeholder analysis.

Conclusion: Policy makers need to recognize that inadequate support of policy objectives leads to an implementation gap. Therefore, policy development and implementation should not be viewed as distinct, but rather as interactive processes that shape each other. Besides developing evidence-based policies, health policy and systems research should be conducted for health system strengthening and to assess socio-cultural factors that can affect policy implementation. It is also recommended that a detailed assessment of implementation challenges to specific malaria policies be conducted for purposes of addressing them and to support the shift from the paradigm of malaria prevention and control to elimination in Malawi.

Key words: health policy, policy implementation, malaria, Malawi

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7.1 Background

A policy is a statement of intention, which can be declared by governments or private institutions at various levels [1]. The government is responsible for developing public policies, which are aimed to benefit its citizens. These policies are statements of what the government intends to do, ranging from rules, regulations, orders, decisions, to laws or the combination of these. They can also be implicit policy statements if these statements are not highlighted [2]. A health policy is one of the major public policies by the government described by World Health Organization (WHO) as 'decisions, plans, and actions that are undertaken to achieve specific health care goals within a society. An explicit health policy can achieve several things: it defines a vision for the future which in turn helps to establish targets and points of reference for the short and medium term. It outlines priorities and the expected roles of different groups; and it builds consensus and informs people' [3]. As health policies aim at achieving better health for the population, it is important to use tangible evidence in the development of good health policies for this purpose. Thus, health research has a critical role in providing evidence for the development of policies contributing to the current movement of promoting evidence-based policies [4, 5].

However, development of good policies based on evidence is an initial step towards the ultimate goal of improving public health. The critical stage is implementing the policies according to their objectives. Policy implementation is 'what happens between policy expectations and policy results' [6]. As policies stipulate ideal outcomes of their intentions, challenges remain during implementation creating gaps, which are major challenge faced by developing countries [7]. These challenges have mainly been attributed to weaker health systems prompting interventions in health systems strengthening with the aim of improving policy formulation and implementation [8]. Van Horn [9] has proposed a conceptual model for understanding the variables shaping the link between policy and practice. Factors affecting policy and performance, as described in the framework, include policy resources, policy standards, communication, characteristics of implementing agencies, enforcement, disposition of implementers, political environment, and economic and social conditions.

However, the most important mechanism is to understand key actors affecting the policy implementation process and the influence of a country's political context on the process in order to realise that new policies are not the answer but improvement of the processes [10]. In addition, understanding the various approaches adopted in policy implementation will assist in developing better strategies in addressing these challenges. There are mainly three models of policy implementation as described by Birkland [2]. The top-down approach assumes a linear sequence of events in which policies are made at central level and communicated down to implementers on the ground. The reverse of this is the bottom-up approach, which takes into consideration the implementers, who having knowledge on the ground can change and adjust the way the policies are implemented. However, these two approaches have their own challenges, for example the top-down approach is authoritative requiring clear and effective communication and coordination, while in the bottom-up approach the implementers assume power to change implementation of policies that may not reflect the purpose in which they were made. Owing to these challenges Birkland [2] proposed a third model called the 'A Third Generation of Implementation Research', which is a network approach that attempts to merge the concerns of the two approaches. It attempts to create dialogue between policy makers and implementers early in the development of policy goals, outputs, and outcomes.

Malaria has remained a major health problem in Malawi affecting mainly pregnant women and children below the age of five with an estimation of four million cases occurring annually [11]. An organised approach in tackling the malaria burden in Malawi begun in 1984 when the first National Malaria Control Programme (NMCP) was establishment and it was mandated to develop the national malaria policy [12].

The current vision of the malaria policy in Malawi is to eliminate the disease, while its mission is to reduce the burden of malaria to a level where it is of no public health significance [13]. To support this vision and mission, specific policies and guidelines were developed in line with the WHO, Roll Back Malaria Partnership (RBM), and regional policies while taking into consideration the local epidemiological and policy context which includes: the National Malaria Monitoring and Evaluation Plan 2007-2011 (2007); National Malaria Treatment Guidelines (2007); National

Malaria Communication Strategy (2009); Guidelines for Indoor Residual Spray (2008); Trainers Manual on Case Management (2007); Guidelines for the Management of Insecticide Treatment Nets (ITNs) Program (2007); Guidelines for Health Surveillance Assistants for Delivery of Sulfadoxine Pyrimethamine for Intermittent Preventive Treatment (2006); Malawi Health Policy (under review); guidelines on pharmacovigilance (under development); and Guidelines for malaria Rapid Diagnostic Testing (under development) [13].

Through the implementation of these policies and guidelines, the malaria prevalence decreased from 43% in 2010 to 33% in 2014, however malaria remains one of the major health problems in Malawi [11]. Two case studies have established that tangible local evidence has been influential in developing some of the policies in Malawi [14, 15]. Therefore, the challenge in achieving the policy objectives dwells on implementation. It is critical to address policy implementation challenges if Malawi is to shift from the paradigm of malaria prevention and control to malaria elimination as stipulated in its malaria policy [13, 16]. Thus this study aimed at identifying some of the challenges to the implementation of malaria policies in Malawi.

7.2 Methods

Qualitative research methods were used through in-depth interviews with key informants (KIs) during the period of April to July 2015. Purposive and snowballing techniques were utilised to identify KIs, and CAM conducted all the interviews. The malaria-related professionals including researchers or policy advisors, policy makers, programme managers were purposively targeted and these were able to refer others and relevant key stakeholders (Table 8.1). The interviews were focused on providing a general overview of challenges to implementation of malaria policies that are contributing to a maintained malaria burden in the country. However, KIs sometimes provided challenges of specific policies which are also captured in the analysis.

Digital audio recorders were used to capture data in English that were transcribed and imported into QSR Nvivo 11 for organizing, management, coding, and analysis. The Grounded Theory principles were used during analysis in which data were categorized based on the common themes followed by contextual examination to explain the issues arising [17]. In order to illustrate points of view or concepts, verbatim quotes were used.

Ethical clearances from the National Health Sciences Research Committee (NHSRC) in Malawi and the Faculty of Health Sciences Research Ethics Committee at the University of Pretoria (Ref No. 146/2013) were obtained.

7.3 Results

Twenty seven KIs were interviewed including: six malaria researchers who also serve as policy advisors to the NMCP (from College of Medicine (COM), Malaria Alert Centre (MAC), Ministry of Health (MOH), and Malawi-Liverpool Wellcome (MLW) Trust); Eight policymakers from the MOH; Six Programme Managers (from NMCP, Support for Service Delivery Integration (SSDI) project, and Kamuzu College of Nursing); and seven stakeholders (from the World Health Organization (WHO), United States Agency for International Development (USAID), National Commission for Sciences and Technology (NCST), Abt Associates Incorporation, and the African Institute for Development Policy (AFIDEP). The details of these KIs have further been described in Table 7.1.

Table 7.1: Details of Key Informants (KIs) interviewed in this study

KI	Sex	Current position and Institution	Experience	Role
1	Male	Malaria Epidemiologist, COM	Over 15 years in malaria research	Researcher/Policy Advisor
2	Male	Medical epidemiologist – Director of Malaria Alert Center (MAC), COM	Over 10 years in malaria research	Researcher/Policy Advisor
3	Female	Retired clinician and Director of MAC, COM	Over 30 years in malaria research	Researcher/Policy Advisor
4	Male	Clinician, Ministry of Health	Over 40 years in malaria research	Researcher/Policy Advisor
5	Male	Malaria Epidemiologist, COM	Over 10 years malaria research	Researcher/Policy Advisor
6	Male	Senior Scientist, MLW	Over 40 years in malaria research	Researcher/Policy Advisor
7	Male	Deputy Director of Planning, Ministry of Health (MOH)	Three years	Policymaker
8	Male	Director of Research, MOH	Eight years	Policymaker
9	Male	Health Economist, MOH	Eleven years	Policymaker
10	Female	Health Planner, MOH	Twelve years	Policymaker
11	Male	Research and Knowledge Translation Manager, MOH	Two years	Policymaker
12	Male	Head of Sector Wide Approach, MOH	Six years	Policymaker
13	Male	Health Planner, Director of Planning and Policy Development, MOH	Two years	Policymaker
14	Male	Chief of Health Services, MOH	Five years	Policymaker
15	Male	Technical Advisor for Malaria, SSDI project	Five years	Programme manager
16	Female	Senior nurse, Kamuzu College of Nursing	Over 10 years	Programme Manager
17	Female	Clinical Epidemiologist, NMCP	Six years	Programme Manager
18	Male	Disease Control Officer, NMCP	Five years	Programme Manager
19	Male	Entomologist, NMCP	Eleven years	Programme Manager
20	Male	Environmental Health Officer, NMCP	Six years	Programme Manager
21	Male	Malaria Advisor, World Health Organization	Fifteen years	Stakeholder
22	Male	Health Economist, Director Abt Associates Inc	Four years	Stakeholder
23	Male	Global Fund Coordinator, MOH	Two years	Stakeholder
24	Male	Malaria Resident Advisor, US Centre for Disease Control	Three years	Stakeholder
25	Female	Policy and Advocacy Coordinator, African Institute for Development Policy	Two years	Stakeholder
26	Male	Policy Development and Analysis, Abt Associates Inc	Four years	Stakeholder
27	Male	Chief Research Service Officer, National Commission for Science and Technology	16 years	Stakeholder

The challenges, which are presented in table 7.2, have been grouped as follows: 1) Structural challenges emanating from the government through the MOH and these include limited commitment of both human and non-human resources for policy implementation, unavailability of trained staff, poor supervision and mentorship, and politic; 2) Parallel implementation of policies; 3) challenges during policy development including the lack of platforms to engage with communities, top-down approach in policy development, lack of evidence on economic and socio-cultural factors affecting the uptake of policies by the communities, and incomplete stakeholder analysis.

Table 7.2: Challenges to the implementation of malaria policies in Malawi

Challenges to implementation
a. Organizational challenges • Inadequate resources for policy implementation • Unavailability of trained staff • Poor supervision and mentorship • politics
b. Parallel implementation of policies
c. Challenges during policy development • lack of a platform to engage with communities • top-down approach in policy development • lack of understanding of socio-cultural factors affecting policy uptake by communities • incomplete stakeholder analysis

7.3.1 Organisational challenges - Related to the Government - MOH

Commitment of resources for policy implementation

Respondents acknowledged that the government through the MOH is key in driving the implementation of health policies. It should therefore commit all the necessary resources for policy implementation. One of the challenges identified is that some of the effective interventions have not been scaled up due to unavailability of resources. For example, it was noted that for greater impact, interventions need high coverage in the communities, especially the preventive interventions. One such intervention mentioned was the Indoor Residual Spraying (IRS), which has not been scaled up due to shortage of resources despite being an effective and

critical intervention in bringing down the mosquito population that transmits malaria. This was highlighted below:

"IRS is still non-existent here in this country except maybe in one or two districts and even when we do it, we do it so badly"(Researcher/policy advisor)

Sometimes the resources may only be available late, affecting the timing of implementation. Evidence may show explicitly the need to change a policy but its implementation is dependent on availability of resources. In many situations Malawi has relied on donor funding to implement the policies. However, with corruption challenges there are many reservations from the donor community in supporting activities in the country. This has created strains on government priorities which impact on policy implementation. As raised by one respondent below:

"I find the issue of money very challenging, which also borders on the issue of honesty or integrity. This is a problem in Malawi, where policies are driven by funding organizations". (Researcher/policy advisor)

Infrastructure was also identified as critical in supporting the implementation of some policies. For example, in the new treatment policy in which every malaria case identified should be treated within 24 hours has been made possible with the introduction of malaria Rapid Diagnostic Tests (RDTs). However, the challenge comes in when a case of malaria is missed from an individual coming from a distant place to a health facility. If malaria fever develops at home, such cases are unlikely to return to the health facility which may lead to self-treatment or complicated malaria. This concern was raised as follows:

"The challenge is that for most people in our environment [they] live far from health facilities, [and] when you misdiagnose and they go home it is almost impossible for them to come back in the middle of the night when the disease resurfaces again. Because sometimes malaria can't just be diagnosed easily". (*Programme manager)*

This eventually influences health workers to still provide treatment based on the clinical presentation of a patient disregarding the new policy.

Above all resources, unavailability of staff in government institutions was isolated to be a major challenge to implementation of malaria policies in the country. The shortage of health workers in many health facilities has a bearing on the activities such that those required to be carried out by trained health workers are assigned to non-professionals who may not follow what is stipulated in the policy. Another problem with shortage of staff arises when no proper records are filled in the health passport books which are later fed into the Health Management Information System (HMIS). In many circumstances policy decisions will draw evidence from routine monitoring and evaluation data that is fed into this HMIS. The data entry starts at health centre level that feed into the district to regional and finally at the national level. It becomes a challenge with shortage of staff and the responsibility of data entry at lower levels is given to non-professional staff who are not aware of the importance of entering the data correctly. Policy decisions made at central level are therefore, based on inaccurate data:

"The HMIS is the main source of data to inform utilization of health services in Malawi and as much as there is now [an] improvement in reporting but the quality is not that good because the data entry in most facilities is entered by people who are just mere clerks or mere agencies who have never had a good training or understanding and has no clue on why they are doing what they are doing and that data end up at very high levels so when you do validity checks you find that there are so many discrepancies between what is from the source and the reported". (Stakeholder)

"sometimes the issue of short cuts is because that they are understaffed and sometimes when you visit the antenatal clinic what you find is that it is not a midwife who is completing that book it is actually a cleaner who is completing that book and we might look very good at the books that everything is working but when you are on the ground that's when you still see [that] the burden of malaria is still there". (Researcher/policy Advisor)

In other instances, unavailability of trained health workers may be affected by the orientation approach of new policies which may have an effect on the motivation of health workers during implementation. If, for example, the orientation is based on the cascade approach, in which the top management participate in workshops and are required to orient health workers, who form

the critical part of policy implementation. In this regard some health workers are reluctant to follow the new policy if they did not attend the training workshops especially if there were allowances provided. This was supported by the sentiments below:

"If you have a new policy, I mean people [management], will just send for instance a memo during Monday morning meetings, staff meetings, whatever clinical meetings. If you send out a memo to say for instance starting from today, you need to be doing this; people will not adhere to it. They would rather want you to come, organize a work shop, they get an allowance, you disseminate". (Stakeholder)

Respondents further indicated that this challenge is exacerbated by poor supervision and mentorship of health workers once the policies have been introduced. The main assumption is that health workers will adopt the new policy immediately after orientation. However, it is vital that they are supervised and encouraged when the policies are newly introduced. In addition, the shortage of trained staff arises due internal transfers. New staff members may not be oriented but are assigned the responsibilities to implement the new policy.

Similarly, the small team of staff at the NMCP was acknowledged to have an effect on the operation of the organisation. This was described as below:

"The NMCP is doing a great job towards addressing the malaria burden in the country, however, the team at this level is small for the delivery of services. They are hence overloaded with tasks posing a challenge of not doing a thorough job on important activities…..strengthening management and strengthening on how you can deliver on implementing tools will help to improve your progress". (Stakeholder)

The implementation of some policies may be affected politically when there is change of government or job rotations of critical positions within the MOH, as indicated by the respondents. They mentioned that continuity of policies becomes affected when a new government administration or office bearer is reluctant to carry on the activities of the previous administration or change how the policies were implemented. This lack of continuity will always have a bearing on the impact of policies in the communities as alluded to by a policy maker:

"But also sometimes in our case there are certain changes that may happen for instance change of government along the way. So when a government changes while implementing a particular policy, they say all those old policies have gone with that particular administration [and] we are new people [so] we are going in a different direction". (Policy maker)

7.3.2 Unilateral implementation of interventions

Respondents raised concerns on how interventions are sometimes implemented unilaterally by focusing on implementing a policy at a time. Although it requires strong political commitment integrated implementation of policies can have tremendous outcome in reducing the malaria burden in the country. A programme manager attested to this:

"The main prevention strategies adopted in Malawi include Insect Treated Nets, IPTp-SP, and IRS, so all those 3 have been tried separately rather than in combination but of course it's quite costly". (Programme manager)

7.3.3 Challenges during policy development

Respondents agreed on the importance of incorporating views of the public in policy development. However, currently there is lack of a platform on which researchers or policymakers can engage with local communities, community based organisation, and influential people such as chief to solicit their views on policy directions. Therefore, the policies developed are often top-down, as stipulated below:

"If you are going to really influence policy you shouldn't only be influencing people within the ministry of health, but you should be influencing the wider community…..I haven't really seen that kind of a platform here in our setup which is very unfortunate because, without that platform you don't have community based organisations, NGO's or even traditional chiefs, we don't have influential people in the community actually contributing to the policy makeup. So you have a bunch of people in the ministry that will decide, in my opinion that's a lot of top down kind of approach and I don't think that's the way to make policy". (Researcher/Policy advisor)

The top-down approach in policy development affects how the communities respond to the policies during their implementation. Communities are not empowered to own the interventions

when implemented. For example, they may accept the free ITNs but will not use them accordingly. Respondents felt that policies should take into consideration the behaviour patterns of people that will use the intervention. These concerns were raised as below;

"We can have very beautiful policies but we do not know the behaviour patterns of people that are being treated because we do not include them when we start looking at policies and you really do not know if those people can comply with schedules, with feeding, with taking people to the hospital. We will continue developing policies and still not solve the issue of malaria in this country". (Programme manager)

Therefore, respondents recognized that the understanding of socio-cultural factors affecting policy adoption by the communities is very important before policy implementation. These sentiments were expressed below:

"I think there is a huge gap already there because much as the interventions are there I don't think we understand very much on the cultural contexts that influence the use of some of these interventions which is quite unfortunate. Because we don't seem to be driving a lot of that research in that direction maybe a lot of our research is a bit on the higher side where we are looking at other things rather than maybe understanding the cultural, and community issues that would affect the use of these available interventions" (Programme manager)

"Qualitative issues must look at what people do when they have malaria. Focusing more on effectiveness of treatment without looking in the context at which people take medications is a big gap in malaria treatment and eradication of malaria in Malawi".(Researcher/Policy advisor)

Respondents also acknowledged that a thorough stakeholder analysis should be conducted during policy development in order to incorporate views of relevant stakeholders that may be affected or influence policy development and implementation:

"I think even policy construction is a challenge in that you may not have done thoroughly consultations and when you start implementing the policies you find that there is a lot of resistance from the ground. So you need thoroughly consultations so that it's acceptable in the

society…because otherwise if you introduce something which is not acceptable then it is repelled and it doesn't work when you start implementing it on the ground". (Policy maker)

"So you find that if you deliberately miss out some important stakeholders then you end up developing a very beautiful policy...very colourful...but it will just gather dust in the shelf because you have not involved stakeholders". (Stakeholder)

7.4 Discussion

Policies provide guidance for interventions in order to achieve their objectives. However, various challenges are faced during policy implementation despite having them developed from tangible evidence [18]. It is, therefore, important to assess these challenges and devise measures of addressing them so that activities achieve the intentions of policies. Malaria has remained a health burden in Malawi prompting Malawi to review its malaria policy which strives to reduce the burden of malaria to level of no public health significance and eventually eliminate malaria [13]. This policy intent provides guidance to the implementation of activities in Malawi, however, challenges exist during implementation. This study aimed at exploring some of these challenges to bring awareness to policymakers and consider them during policy development and implementation.

Organisational commitment by the government in implementing malaria policies was identified to be paramount. It is, therefore, imperative for the government during planning to commit itself in achieving the policy intents. One of the identified challenges to the implementation of malaria polices in Malawi is the lack of both human and non-human resources. This challenge sometimes arises due to the choices that politicians, who are the policymakers, make by mainly focusing on the objectives of the policy and view its implementation as someone else's problem, and the temptation to achieve the policy objectives with minimum resources in as much as possible [19]. Weaver [19] has argued that availability of these resources is critical in influencing the disposition of policy implementers because inadequate resources will be an obstacle. Therefore, policy makers need to take into consideration that policies require the needed support of resources for their execution and thus a thorough implementation analysis needs to be conducted before embarking on policy implementation.

Human resource is a vital asset for policy implementation which requires to be motivated all the time. In addition to availability of human resource, the relevant trained personnel into a particular policy is key. This can be achieved through clear policy communication to ensure that health workers understand the policy standards. New health workers should be oriented and refresher training sessions should be conducted regularly combined with regular monitoring. This was revealed in a study that assessed the adherence of health workers to treatment guidelines in Malawi [20]. The study showed tremendous progress by health workers in implementing the malaria "test-and-treat" policy but observed the need for further improvement by increasing supervision to enforce and motivate health workers [20].

The availability of health workers has further been affected by job rotations and transfers, which may bring in new personnel of different levels of motivation or those that are not oriented in the policy. In this study, politics has been identified to pose a challenge to policy implementation especially during appointments of senior positions within the MOH which are politically motivated. The problem is further amplified when a new government administration comes into power and changes most of the major technical positions [21]. Ego of politicians plays a major role to continue with the initiatives of the previous government. This was the Nigerian experience when a programme that was initiated by a previous government was changed from its name to objectives despite having similar target [7]. Advancing the needs of the people should always be the focus for leaders, thus, surpassing personal ambitions. It is only through recognition of this that democracy can have a greater impact in developing countries.

Unilateral implementation of malaria interventions has also affected the efforts towards the achievement of the malaria policy in Malawi. This was observed in the implementation of malaria control intervention such the ITNs, IRS, and health education. Although these interventions have shown to reduce the transmission intensity and the malaria burden, it is not clear if implementing them on their own can help reach malaria elimination [22]. Therefore, an integrated approach such as in vector control has shown a remarkable reduction in the malaria burden in Zambia [23]. The Zambian experience provides critical lessons for other malaria endemic countries such as Malawi. It will therefore, take political will to adopt this approach. The IRS programme has shown

major obstacles in its inception in Malawi and will thus require a disciplined focus on its management.

Another overlooked factor by policymakers comes into play when developing policies and that is, the when views of the public, who are the primary beneficiaries of policies, are not taken into consideration. This results in implementation whereby these beneficiaries do not take ownership of the interventions [7]. The lack of public involvement may arise due to lack platforms for engagement, as identified in this study. Being the primary recipients of intended and unintended effects of health policies, public opinion should be highly regarded during policy development, however, their involvement at this stage has been identified to be minimal [24]. Several approaches have been proposed on how the public can be engaged in policy development and these include: public involvement in policy development and implementation; mass media where radios, television, and strategies such as press conferences, or health articles can be used; the civil society groups that would be tasked to involve the relevant groups of society and discuss issues of the policies affecting them [24]. These strategies avoid the top-down approach of policy making by incorporating the views of the public, who will feel a sense of ownership and are compelled to participate in the policy implementation process. In addition to engaging the public on their views, health policy and systems research (HPSR) which includes political, economic and socio-cultural assessments should be conducted to guide both policy development and implementation, and health system strengthening [25-27]. Furthermore, thorough stakeholder analysis during policy development is essential in identifying their interests and incorporating their perspectives, especially the public, in order to enhance their effect on policy implementation [28, 29].

7.5 Limitation of the study

The study only included general policy implementation challenges as viewed by the selected key informants. Views of the public, who are the primary beneficiaries of health policies would have provided interesting and counterbalancing findings. Therefore, exploring challenges to specific malaria policies that would include views of the public are recommended.

7.6 Conclusion

Policymakers need to recognize that there will always be an implementation gap if policies are not fully supported. Various intervening and contextual factors will determine the direction and pace of the policy. Therefore, it is always important for policy makers not to view policy development and implementation as distinct but rather interactive processes that shape each other. Anticipating some potential policy implementation barriers during policy development allows for strategies of overcoming or reducing such barriers. This study explored some of the barriers to the implementation of malaria policies in Malawi which include structural challenges as identified within the government through the MOH, unilateral implementation of policies, and challenges during policy development.

While it is acknowledged that these factors are general challenges to the implementation of malaria policies in Malawi, they offer an opportunity for policymakers to consider issues of bridging the implementation gap during the policy development stage. This can be addressed through the involvement of relevant stakeholders as identified during the stakeholder analysis including views of the communities, commitment of resources and retaining competent health workers within the system, adequate monitoring of interventions, and minimizing political interference in health services.

It is recommended that detailed assessments of implementation challenges to specific malaria policies are conducted for purposes of addressing them and to support the shift from the paradigm of malaria prevention and control to elimination in Malawi. In addition, HPSR needs to be supported for purposes of health systems strengthening in Malawi.

List of abbreviations

AFIDEP: African Institute for Development Policy; COM: College of Medicine; HPSR: Health Policy and Systems Research; IRS: Indoor Residual Spray; ITNs Insecticide Treatment Nets; IPTp-SP: Intermittent Preventive Treatment with Sulfadoxine Pyrimethamine; KIs Key Informants; MAC: Malaria Alert Centre; MOH: Ministry of Health; MLW: Malawi-Liverpool Wellcome; NCST: National Commission for Sciences and Technology; NHSRC: National Health Sciences Research Committee; NMCP: National Malaria Control Programme; RDTs: Rapid Diagnostic Tests; RBM:

Roll Back Malaria Partnership; SSDI: Support for Service Delivery Integration; USAID: United States Agency for International Development; WHO: World Health Organization

Declarations

Ethics approval

Ethical clearance was obtained from the National Health Sciences Research Committee (NHSRC) in Malawi and the Faculty of Health Sciences Research Ethics Committee at the University of Pretoria (Ref No. 146/2013).

Consent for publication

Not applicable

Availability of data and materials

The data that support the findings of this study are available from the corresponding author upon request.

Competing interests

The authors declare to have no competing interests.

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Authors' contributions

CAM conceived, developed the idea, and prepared the manuscript. SK contributed in analysis and manuscript preparation. KP contributed to shaping of the idea. CMM, HL, TdJ, and CH contributed their technical expertise in directing and critiquing of the manuscript. All the authors contributed to the drafting of the manuscript and approved the final manuscript.

Authors' information

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CHAPTER EIGHT

Introduction

This chapter draws from the lessons of the two case studies presented in chapters four and five, and is further guided by the findings presented in chapter six. The chapter presents a proposed framework to promote the utilisation of malaria research in policy development. This framework highlights the arrangement of facilitators to this process in order to address the barriers.

8.0 DEVELOPMENT OF A FRAMEWORK TO IMPROVE THE UTILISATION OF MALARIA RESEARCH FOR POLICY DEVELOPMENT IN MALAWI

Abstract

Background: The existing gap between research evidence and public health practice is viewed as having contributed to the failure to meet certain Millennium Development Goals in Africa. Consequently, this reality has stimulated the development of frameworks to enhance knowledge translation, with the overall aim of maximising health research utilisation in policy and practice to address the world's disease burdens. This study aimed at developing a contextual framework to improve the utilisation of malaria research for policy development in Malawi.

Methods: The study used two approaches including: two case studies of policy analysis exploring the policy making process in Malawi, utilisation of local malaria research, and the role of key stakeholders in policy formulation process; and the assessment of facilitating factors and barriers to malaria research utilisation for policy making in Malawi.

Results: From the case studies' lessons and elements identified and a framework is developed to promote an integrated approach to knowledge translation. In this framework the Ministry of Health is considered as the main user of knowledge from research through the demand created by the research directorate and the National Malaria Control Programme. Key documents identified as being particularly relevant to the MOH for purposes of knowledge translation include the National Health Research Agenda, Guidelines for Policy Development and Analysis, and Guidelines for Evidence Use in Policy making. Institutions conducting academic and policy-relevant malaria research in Malawi are identified and a consolidation of their linkages with the

users of research is established through the Knowledge Translation Unit, the Evidence Informed decision-making Centre, and the African Institute for Development Policy. Equally, key players in this framework are the funding partners for both research and programmes that need to see accountability and impact of their support. Independent advisors, partners, and consultants also have their vital role in the process.

Conclusion: The framework offers a practical basis for the factors identified and their linkages to promote a co-ordinated approach to malaria research utilisation in policy making. Its applicability and success potentially depends on its being widely disseminated and coming under ownership by the government through the National Malaria Control Programme.

Key words: Malaria research, research utilisation, integrated knowledge translation, research-to-policy frameworks, Malawi

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8.1 Introduction

Health research provides evidence that enhances knowledge, addresses health problems [1], and may potentially improve health systems to more effectively tackle the challenges faced by many developing countries such as Malawi [2].

However, the utilisation of research in addressing the health problems has remained a challenge [3] prompting efforts of Evidence Based Practice (EBP), which have mainly been exploited in the clinical set up leading to Evidence Based Medicine (EBM) [4]. The concept of EBM has progressively compelled non-clinical settings, including the health policy itself, to utilise research evidence in policy development [5]. This has led to Evidence-Based Policy Making (EBPM), which urges policymakers to demand and focus on using scientific evidence rather than political ideologies in policy decision making [6, 7]. Despite this global drive, challenges of evidence utilisation in policy making still exist ranging from timely availability of evidence to the type of the evidence itself [8]. This is further exacerbated by how the evidence is produced and the lack of proper channels of communication between researchers and policymakers [9]. The promotion of evidence-based policy making should not only focus on improving communication between policymakers and researchers but rather take into consideration the diverse contextual factors influencing policy making in the complex world [8]. Assessment of these factors assists in developing contextual frameworks attempting to address the barriers while recognising the facilitating factors that need to be embraced in promoting this process. These frameworks also referred to as models of research utilisation [10], are aimed at improving Knowledge Translation (KT). KT is described as "the exchange, synthesis and ethically sound application of knowledge – within a complex system of interactions among researchers and users – to accelerate the capture of the benefits of research through improved health, more effective services and products, and a strengthened health care system" [11-13]. The objective of KT extends beyond the dissemination of scientific information through publications as a primary form of spreading the research results. It involves all the stages of the research process, interaction and engagement between the researcher and research users and other stakeholders for the purposes of addressing the gap between the available large quantities of research evidence and its usage [14], and improving the lives of the general population [11, 15].

Various frameworks exist promoting EBM, but those that informed this study were based on the fact that their focus is in health policy formulation; incorporate the stage of knowledge creation; they promote the integrated model; they consider the contextual factors in their application. These include: the Canadian Institute of Health Research (CIHR) model of knowledge translation [16]; Knowledge-to-Action Process Framework [17]; and Tehran University of Medical Sciences (TUMS) Knowledge Translation Cycle [18]; and the Ontario Drug Policy Research Network (ODPRN) [19]. The CIHR model, Knowledge to Action, and TUMS knowledge translation cycle are conceptual frameworks that provide an overall conceptual picture of how the knowledge translation process should occur. As conceptual frameworks, they do not show specific elements such as individuals, institutions or specific elements highlighting their roles and responsibilities of how to facilitate particular processes in the framework. For an effective KT process it is important to take into consideration the contextual factors and micro-perspective of individuals and institutions to support this process [20]. Therefore, further details showing comprehensive frameworks can augment these models. The ODPRN organizational framework is an example of a detailed framework highlighting specific elements with their roles and responsibilities arranged in a particular setting to boost interaction for purposes of enhancing KT. This framework provides a practical perspective of how a contextual KT framework operates. Despite being a framework for commissioned research, it provides vital lessons on the interaction processes between researchers and policymakers through research question formulation and the involvement of policymakers throughout the research process, which facilitates the acceptability and utilisation of the research findings. These frameworks highlight the importance of KT in policy development, and the constant interaction between researchers and policymakers in influencing this process.

In Malawi, malaria remains a major public health problem as it is estimated that about four million cases occur annually, mainly affecting children below the age of five and pregnant women [21]. Malaria research can play a vital role in addressing this burden by providing evidence for policy development leading to implementation of evidence-based interventions. However, the adoption of malaria research utilization in policy development needs a systematic approach. Currently no such approach exist in Malawi, thus, a framework to facilitate this process is paramount [10, 12]. This study presents the final product of a PhD research that aimed at

developing a contextual framework to improve the utilization of malaria research for policy development in Malawi. The specific objectives that contributed to the development of framework include: to determine the type and amount of malaria research conducted in Malawi and its related source of funding from 1984 to 2016 for purposes of establishing malaria research repository; To explore the influence of malaria research on malaria policy development and review the policy making process in Malawi; To assess the facilitating factors and barriers to malaria research utilisation for policy development in Malawi.

8.2 Methods

The development of the framework was based from lessons drawn from two case studies [22, 23], and the assessment of facilitating factors and barriers to malaria research utilisation in policy development in Malawi [24]. The methodologies for these studies can be accessed from the respective publications. In addition, basic concepts of research-to-policy frameworks were explored during literature review and provided the understanding of how frameworks are developed and operate [16-19]. The framework was finally exposed to a rigorous iterative approach with a sample of stakeholders for their views, validation and applicability.

8.3 Lessons from case studies

Two case studies were conducted to examine the malaria policy development process and the contribution of research in this process.

8.3.1 Case study 1: Malaria research and its influence on antimalarial drug policy in Malawi

This case study, as fully described elsewhere [22], examined the influence of malaria research in changing the antimalarial drug policy in Malawi. Malawi changed its first-line anti-malaria drug treatment for uncomplicated malaria in 1993, from chloroquine (CQ) to sulfadoxine-pyrimethamine (SP) and later in 2007 from SP to lumefantrine-artemether. Since Malawi was the first country to switch from CQ to SP, many concerns were raised on the timing of the change and the early development of resistance of *plasmodium falciparum* to SP. The case study examined whether the policy changes were justifiable by assessing the availability and utilisation of malaria research in this process. The study adopted a systematic literature search of published evidence of primary research from Malawi in the period between 1984 and 1993 when CQ was

the first-line drug, and between 1994 and 2007 when SP was the first-line drug. In addition, relevant documents, such as malaria policy and guideline documents were also reviewed, and interviews were conducted with key informants that were involved in these policy changes.

The online systematic literature analysis included four publications during the period between 1984 and 1993, and four studies during the period between 1994 and 2007. Three studies during the period between 1984 and 1993 reported on CQs poor efficacy that prompted policy change based on World Health Organization (WHO) recommendations. The four studies identified between 1994 and 2007 were conducted in the early years of policy change and were aimed at monitoring the efficacy of SP. They all reported on high efficacy of SP of above 80% and supported the use of SP as the first-line drug. However, towards the policy change in 2007 unpublished sentinel site studies provided evidence that showed a reduction in the SP efficacy prompting a replacement to lumefantrine-artemether. In addition, key informants acknowledged that both policy changes were justified based on local evidence.

This case study revealed how local evidence justified policy change amid the lack of WHO recommendations in 1984 but the change in 2007 was smooth due to availability of WHO recommendations.

This case has provided critical lessons for the framework by informing that it is important to generate local evidence in developing local policies, which may form the basis for decision making despite unavailability of WHO recommendations. This evidence can fully be utilised with the determination by the government as demonstrated in the case study whereby the government through the NMCP commissioned studies to provide the evidence. This has established that research has a high probability of being utilised if the demand is driven by the users (Policymakers). Therefore, the proposed framework emphasises on researchers to engage with policy makers by exploring their research needs for policy development.

8.3.2 Case study 2: Changing the policy for intermittent preventive treatment with SP during pregnancy in Malawi

This case study, also described elsewhere [23], examined the policy change process of intermittent preventive treatment of malaria during pregnancy with SP (IPTp-SP) from the administration of two doses to three or more doses during pregnancy. Malawi was the first country to adopt IPTp-SP in 1993 whereby pregnant women were recommended to receive two SP doses during pregnancy. The growing resistance of *P. falciparum* to SP led to the change in treatment of uncomplicated malaria from SP to lumefantrine-artemether in 2007 and similar concerns were raised in the use of SP for intermittent prevention treatment of malaria during pregnancy (IPTp) amid a global lack of an alternative drug. In 2013 the IPTp policy was changed as it recommended that pregnant women should receive at least three SP doses. The process of changing this IPTp-SP policy was assessed to gain an insight in the policy formulation process and the involvement of stakeholders and local research.

A mixed method approach was adopted by an online systematic literature review, relevant documents assessment, and key informant interviews. The online search reviewed eight studies from Malawi. Two publications were instrumental in changing the WHO IPTp-SP policy that later made a recommendation for national policies to adopt the new policy of administering IPTp-SP at each antenatal visit with the first dose given as early as possible in the second trimester and the following doses given at monthly intervals up to the time of delivery. Malawi utilised this opportunity to adapt its IPTp-SP policy in 2013 to address the operational challenge during the implementation of the first policy of two SP doses. It was recommended that women should receive at least three SP doses during pregnancy with the last dose given close to birth and health workers were no longer confused with the timing of administering the doses.

The policy change revealed that malaria research from Malawi was instrumental in guiding policy change at global level but Malawi only changed its IPTp-SP policy following a WHO recommendation. However, it was highlighted that it is vital for the responsible government department to fully commit to driving the policy change process and involve the relevant key stakeholders. The importance of local evidence was identified to be critical for policy decision making and thus it was recommended that a systematic approach should be adopted to utilise

evidence in developing local policies. Therefore, a malaria research-to-policy framework is ideal in addressing this challenge.

The case study has shown that malaria research conducted in Malawi is capable of influencing global policies and thus development of local policies should fully utilise this evidence in their development. This should also motivate local researchers that they can conduct rigorous research for policy change purposes. In addition, local evidence can assist in adapting WHO recommendations to suit the local context, while the inclusion of relevant stakeholders during policy change is critical. These lessons feed in the framework development as it is emphasised that local evidence is vital and a thorough stakeholder analysis is required before embarking on policy change.

8.4 Assessment of facilitating factors and barriers to malaria research evidence for policy development in Malawi

Utilisation of research evidence in policy formulation has not been straightforward, hence research-to-policy frameworks have been developed for this purpose although most of them have been in developed countries [10]. Consideration of contextual factors is essential in developing these frameworks [25] and Logan & Graham [12], who developed the Ottawa Model of Research Use (OMRU), developed guidelines of developing contextual research-to-use frameworks for the improvement of health services. The basic approach involves the assessment of enablers and barriers in the utilisation of research evidence in policy. Therefore, an assessment of facilitating factors and barriers to malaria research utilisation for policy development in Malawi was conducted whose process is fully described elsewhere [24].

Drawing from the approaches above, we developed a framework appropriate to Malawi as it identifies specific elements or institutions, with their roles and responsibilities and propose how they should interact to be actively involved in malaria research for policy development in the country.

8.5 The Framework

The framework is designed to provide rapid-response research for policy making, which means there is a unique blend between researchers and policymakers reflecting the principles of the integrated model with the aim of providing timely, high-quality, policy-relevant research findings. The elements in the framework were identified in the assessment of facilitating factors and barriers to malaria research utilisation in policy development while lessons from the case studies have provided an insight in how the elements can interact. The assessment revealed the existence of elements promoting the utilisation of health research for policy formulation in Malawi but the main challenge is the lack of a coordinated approach since they are fragmented and work in isolation creating duplication of activities of similar elements. The framework should thus enhance visibility, and strengthen the interactions and coordination among these existing initiatives. A wider dissemination of the framework is paramount to serve this purpose. The interactions of elements are flexible as they can occur in parallel. While the identification of elements is not exhaustive, the framework serves as a guide for new elements to recognise where to fit and who to engage with in order to prevent duplication of activities. Figure 7.1 shows the structural set up of the framework proposing feasible interactions among various elements with the purpose of promoting policy-relevant research in malaria.

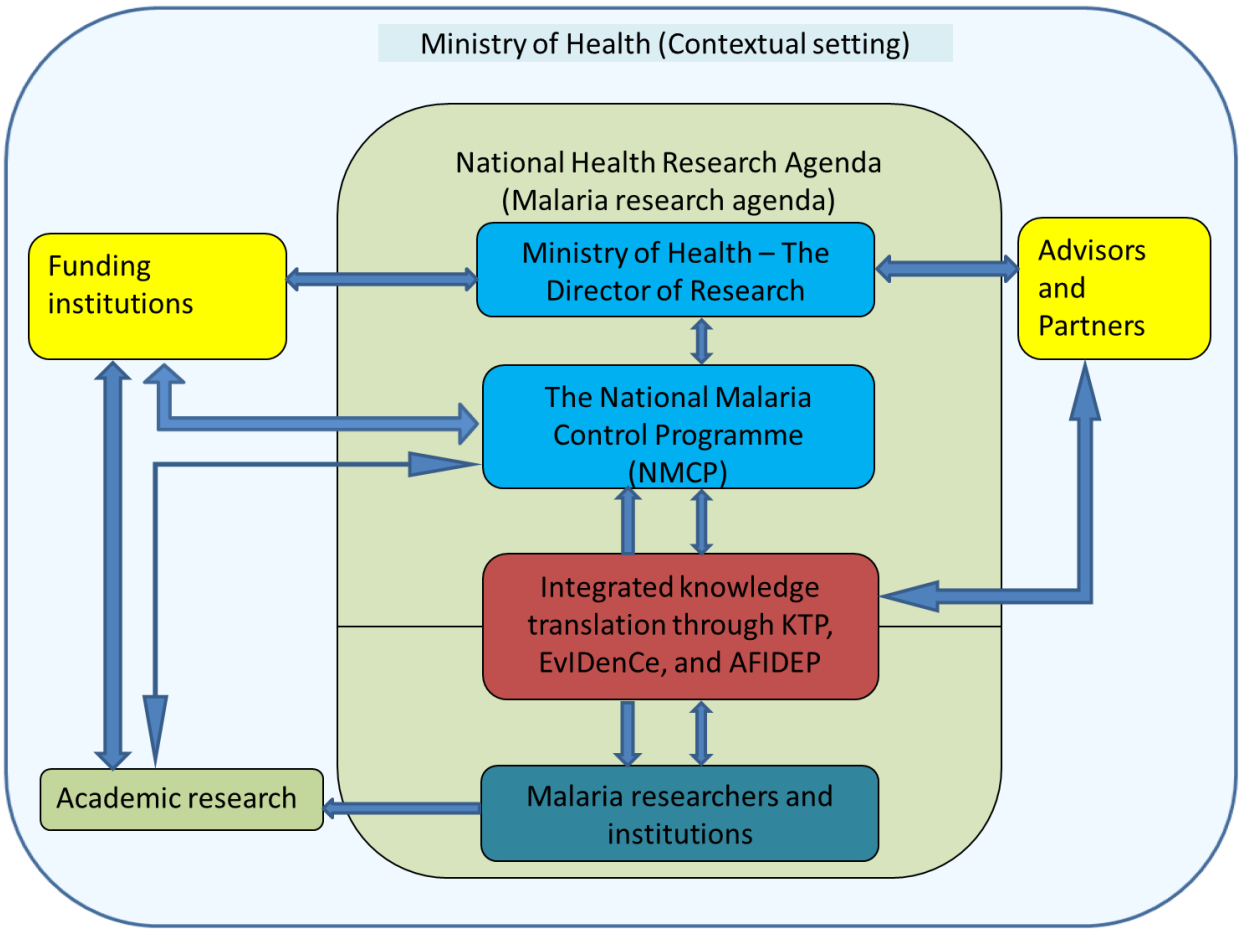

Figure 8.1: The Framework to promote the utilisation of malaria research for policy development in Malawi

Colour code	**Description**
	Institutions representing users of research
	Institutions promoting interaction between users and producers of research
	Institutions and individuals conducting research and producing evidence
	Institutions supporting research and its utilisation in policy development
	Type of research for academic and capacity building purposes

The descriptions, roles, and responsibilities of the elements are described below:

Ministry of Health (MOH) - Contextual setting

The contextual setting is the environment in which the elements exist and whose conduciveness determines the successful interaction of the element in the framework. The contextual setting consists of the political set up, leadership system within the ministry of health, government policies and the cultural set up. Malawi adopted a democratic government system in 1994, which has improved independent decision making within institutions, this is one of the enhancing factors within the ministry. While advocating for research utilisation in the health sector the MOH revived the Policy Development Unit (PDU) and developed the guidelines for policy development and analysis, and for evidence use in policy-making. Another strategic element identified during the study was quality of personnel entrusted in management positions within the MOH. The positions of Chief of Health Services, Principal Secretary, and Director of Research were all managed by enthusiastic individuals with doctorate qualifications of medical or public health background, which makes them value the importance of using research in decision making. Recognising and supporting research emanating from the ministry encourages usage of research for policy development. The main challenge is the politically motivated job rotations/appointments that occur in government institutions, where newly appointed employees may not be as motivated or qualified to pursue the initiatives they inherit.

The National Health Research Agenda (NHRA) – Malaria research agenda

The Malawi government recognises the important role of research in development. The main challenge for the country is that most of this research is funded externally by institutions who may drive their own agenda. It is against this background that Malawi developed its first National Health Research Agenda (NHRA) covering a five year period from 2012 to 2016 and currently under review for a subsequent five year period of 2017 to 2022. The NHRA aims at guiding research conducted to address the country's health needs.

Malaria research agenda, as part of the NHRA, forms the background of the institutional set up in the framework. The main purpose is to guide researchers, policymakers, health development

partners and other stakeholders on malaria research priorities for Malawi. The agenda outlines relevant research areas needing evidence for policy development.

The Director of Research in the MOH

The MOH is responsible for health services delivery in the country and therefore, it needs to promote health interventions with proven track record. Key to this initiative was the establishment of the office of the Director of Research (DOR) with the MOH. This office, which campaigns for policy-relevant research steered by the guidelines for evidence use in policy-making, is also the secretariat for the National Health Sciences Research Committee (NHSRC) a national health research ethical review board. It is thus, tactical for the DOR to enhance the timely ethical review process of protocols addressing the NHRA with the aim of providing rapid-response research for policy development. However, an objective approach should be encouraged to avoid conflict of interest.

The National Malaria Control Programme (NMCP)

It is important that the drive for research emanates from policymakers to create a high probability of research adoption in policy development. The NMCP is the primary coordinator of malaria interventions in the country under the Directorate of Preventive Health Services in the MOH. Its mission is to reduce the malaria burden to a level of no public significance through improved diagnosis and case management, promote prevention, and a robust monitoring and surveillance system. Therefore, the Programme requires tangible evidence for its policy development. One of the critical sections of the NMCP is the monitoring and evaluation department that provides routine evidence by assessing population-level information from the national health databases. It is a key department to timely detect and respond to research requests for policy decision making. It will identify areas in malaria that require further understanding through research. However, the quality of population-level information depends on the quality of the national datasets, which have challenges originating from the sources at district levels. If poor data capturing is made at the district level, it becomes a challenge to rectify at central level leading to decision or policy development based on inadequate or poor quality evidence. Another important initiative at NMCP is the setting up of Technical Working Groups

(TWGs), which enable informal sharing of evidence and dialogue between researchers and NMCP. In this regard, there is a continuous interaction between the two parties.

The Knowledge Translation Platform (KTP), Evidence Informed Decision-making Centre (EvIDenCe), and African Institute for Development Policy (AFIDEP)

The role of these three KT institutions are vital in promoting the integrated knowledge translation that emphasizes the involvement, at an equal level, between researchers and knowledge users such as policy makers to develop and conduct relevant research that is likely to be used [26]. They are tasked to make all efforts and strengthen communication, which has been identified as one of the challenges in evidence-based policy development [9]. Their interaction is vital to prevent duplication of roles. It is, indeed, encouraging to note that their establishment signifies the importance Malawi has placed on maximising the utilisation of research evidence for decision making and policy development.

The KTP: housed under the DOR, its key mission is to provide an environment through which researchers, policy makers, and stakeholders can discuss essential local or international research findings to increase the relevance and contribution of research to high-priority issues in Malawi. In promoting usage of research evidence for policy making, the KTP specifically aims at identifying high-impact policy issues in relation to established national priorities for which primary research and other evidence-based inputs are required, coordinating efforts to use timely local and international evidence in policy making through policy dialogues and inputs such as policy briefs, reviews, publications and report, and initiating and facilitating opportunities for researchers, policy makers, and stakeholders to build their capacity to use evidence in policy making.

The KTP serves the entire MOH, it is thus tactical for NMCP to engage with the KTP in addressing issues specific to malaria. Housing the KTP under the MOH is advantageous when accessing information since the ministry commands some greater authority than if it were independent. In addition, securing of external funding is easier if the request is channelled through the government for national interests.

The EvIDenCe: The Evidence Informed Decision-making Centre (EvlDenCe) is the first, recently established, academic unit in the country to promote evidence-based health practice and economic evaluation. Based at the College of Medicine, a constituent college of the University of Malawi, this provides an opportunity to fill a key gap in research capacity, health economics and evidence synthesis that could inform policy formulation as well as practice. Its main purpose is to strengthen translation of research into policy through conducting and teaching systematic reviews, evidence-based health care, evidence synthesis, development of health research databases that update the health research activity in Malawi. It also undertakes other tasks such as the renewal of the NHRA and carrying out such research in collaboration with capable institutions or individuals. Since academic institutions are recognized to passively disseminate their research mainly through publications, which are insufficient to guarantee adoption by policy makers [27], the EvIDenCe is responsible for synthesising the research findings and disseminating to the relevant stakeholders through various dissemination tools such as policy briefs.

The EvIDenCe has the advantage of easily accessing research output within the institution and assembling and collaborating with the right expertise to conduct quality research. It is also important for the EvIDenCe to access various academic research that can later be used in policy development.

AFIDEP: As an independent organisation, AFIDEP complements the work by KTP and EvIDenCe as it focuses on capacity strengthening, and knowledge synthesis, translation and utilisation. Through the Strengthening Capacity to Use Research Evidence in Health Policy (SECURE) programme, AFIDEP strengthens the capacity of health policymakers and legislators in research evidence utilisation for decision making. Their aim is to consolidate interaction of researchers and policymakers and hence improve on the trust for each other. One of its specific activities of interest is building the capacity of policymakers to access, appraise and apply research evidence in their decision making and policy development. This initiative is vital in instilling a culture of evidence use for decision making among policymakers.

Malaria researchers and institutions

This block constitutes various institutions and individuals that conduct malaria research in Malawi. International institutions and individuals should access the NHRA to familiarise themselves with the country's priority areas of health research. Notably, among others, the major malaria research institutions in Malawi are the University of North Carolina (UNC) project, MOH, and COM whose affiliates are the Malaria Alert Centre (MAC), Malawi-Liverpool-Wellcome (MLW) Trust, and Blantyre Malaria Project (BMP). MAC conducts both basic medical and operational research, in partnership with the NMCP responds to research needs relevant for national health policy development. While the UNC, MLW and BMP, mainly conduct clinical malaria research with the aim of contributing to evidence-based malaria policies and capacity building in the country.

The advantage that these institutions have in conducting malaria research is their financial support, research capacity, and infrastructure to support quality research. Another vital feature is the existence of the College of Medicine Research and Ethics Committee (COMREC) under the COM, which conducts ethical reviews for these research institutions reducing the burden on the NHSRC, making it convenient for academic research to be timely conducted.

Academic research

The NHRA highlights priority policy-relevant research needs in Malawi. However, researchers can also conduct other types of research for academic purposes, which can play a vital role in providing evidence that can be used at a later stage while strengthening the capacity of researchers to eventually conduct quality policy-relevant research. In this respect researchers are engaged in impactful academic research independent of the malaria research agenda needs, which can also be shared with the NMCP for their reference.

Advisors and partners

These institutions provide advice, consultation, and work in partnership with the MOH in either supporting the ministry in policy and guideline development or training of policy makers in the ministry to view research evidence as vital for policy decision making. These institutions can

collaborate with the KTU, EvIDenCe, and AFIDEP in refining messages to be communicated to policymakers and the general community in understanding research findings. The WHO plays the advisory role of making sure that the health policies implemented in the countries are in accordance to WHO guidelines. However, the WHO will not impose but provide current health policies based on global research for countries to adopt or adapt based on their context. It is therefore, the responsibility of the KTU, EvIDenCe, and AFIDEP to assess the evidence on which the WHO policies are based in comparison to local evidence if available and advise the NMCP on the way forward.

Another prominent partner working with the MOH identified during the time of the study was the Support for Service Delivery Integration (SSDI), a consortium of three project; services, systems, and communications. Through SSDI the systems project led by Abt Associates is aimed at improving the health system in Malawi by building capacity for policy development, strengthen capacity and leadership, assisting MOH in the development of evidence-based policies, and improving the usage of routine health information.

Funding institutions

Funding institutions comprise research and programme funders. Challenges of research funding have always existed in Malawi, hence its commitment to establish the National Commission for Science and Technology (NCST) to play an advisory role to government and stakeholders on matters of science and technology in development. One of NCST's schemes is the provision of small research grants supporting studies addressing the NHRA. However, these grants are not adequate for larger studies prompting the government to liaise with other independent research funding institutions, hence the need for a wider dissemination of the NHRA. Some of the main funding institutions supporting malaria research and programmes are the United States President's Malaria Initiative (PMI), the Global fund, WHO, United Nations Children's Fund (UNICEF) and the United States Agency for International Development (USAID), which may have a greater bearing on how their funds are used. They can play a critical role in advocating for their funded research to impact on policy and practice [28].

8.5.1 Application of the framework

The research-to-policy process is complex with no particular blueprints fitting the process [10]. Various frameworks exist in a particular context, however most of the frameworks are conceptual that explain the process of knowledge translation and assume that the context in which they are applied are uniform ignoring the intricacy of specific environmental factors [10]. It is for this reason that this framework dwells on the identification of specific contextual elements to augment the process of KT while utilising the concept of dynamic multi-directional process, which recognises that KT is a function of multiple stakeholders' collaboration and that interaction can occur simultaneously.

As described above, the framework has highlighted the existing elements promoting utilisation of research for policy development in Malawi. These elements have thus been organized to promote this process. The guiding principle in the structural set up of the framework is promotion of the integrated knowledge translation model.

The integrated approach to knowledge translation seeks to bring together knowledge users and researchers to commonly pursue health challenges and find solutions together. Knowledge users are described as "individuals who are likely to be able to use research results to make informed decisions about health policies, programs and/or practices" [26]. Understanding the various knowledge users is critical in adopting strategies to engage them in the research process. Depending on the research focus users can include among others policymakers, programme managers, clinicians, health-related training lecturers, and patients or the public itself [29]. In consideration to contextual factors including the research focus, knowledge users can be engaged at various stages in the research process which can include research question identification, definition and development, conducting research, and interpretation and application of research findings [30]. The targeted knowledge users in this framework are policymakers who are the MOH and NMCP. The malaria research agenda is the guiding principle, and its development provides the initial stage of interaction between researchers and policymakers. It is through a thorough involvement of the two parties that a viable relationship can emerge promoting participatory research. Since the agenda provides broad areas of research

needs, researchers need to formulate their research questions based on these areas and engage the NMCP for a common understanding. This engagement is aimed at refining the objectives of the research and confirming its feasibility while developing timelines, in order to confirm that the research focusses on the needs of the NMCP. It is important to seek the approval of the NMCP if the intention of the findings from the research is to have a bearing on policy. Therefore, despite the researcher's effort in securing funding, the research requires to be representative and conducted in a manner in which the NMCP can utilise the findings.

In addition, the TWGs at the NMCP are opportunities in which a continued relationship is established where the NMCP can express further research needs while researchers can update the NMCP on various stages of the research process. In this way both policymakers and researchers are aware of the available research evidence and research needs respectively, increasing the relevance and utilisation of research findings.

Once the research has been conducted, researchers and policymakers can further be engaged through the KTP, EvIDenCe and AFIDEP to package and communicate the research findings in an appropriate format.

However, researchers are also encouraged to publish the research findings for the wider scientific audience, which will also serve well for their academic advancement.

From the researchers' recommendations, a policy position requires to be established while highlighting alternative options. It is at this level that researchers are required to understand that their research can be used for different purposes during policy development. The findings can be instrumental if they directly lead to policy change, conceptual if they are used gradually as theories, concepts and perceptions, and as symbolic if they support an already known policy stand [10]. In addition the findings can be used either during policy agenda setting, policy formulation, or policy implementation stages as identified by Lavis *et.al* [31]. This requires documentation to track how the research evidence was utilized in this process. However, the evidence-to-policy development process can be enhanced through the researcher-policy-maker model [32]. Therefore, collaboration and understanding between researchers and policymakers

is vital in facilitating usage of evidence in policy making and address the knowledge to action (KTA) gap affecting health systems globally with knowledge transfer labelled as the dominant problem [29]. The knowledge transfer paradigm assumes a unilateral approach in which either researchers conduct research, mostly in isolation, and seek the best approach to disseminate the findings to passive research users such as policymakers (the push model); or research users seek for evidence or commission for research to be conducted (the pull model) [29]. This has emphasized the need for knowledge brokers to focus on finding the best approaches, requiring skills and resources, in knowledge transfer [33]. But dissemination of research findings alone has limited impact despite using creative approaches [34]. Therefore, a participatory approach engaging users of research in the research process has predicted a high use of research findings [35].

The NMCP's role is pivotal in this framework because it is responsible for developing malaria programmes implemented in the country. It is accountable in the development and implementation of intervention that work, which can only be identified through research. The NMCP will strive to access research evidence for its planning and hence develop research questions and work with researchers. Therefore, the NMCP should be custodian of this framework, which should be included in the malaria research agenda, the guidelines for policy development and analysis, and those for evidence use in policy-making for purpose of its formal institutionalisation and wider dissemination.

Being a results oriented institution, the NMCP should make all efforts to facilitate the conduct of policy relevant research and its uptake for policy development. The NMCP has already shown that engaging researchers at various stages of the research process is important. For example its unique partnership that exists between the NMCP and the Malaria Alert Centre in facilitating research that provides evidence for the programme to utilize is important because research commissioned by the users has greater chance of being used for policy development [36]. Similar arrangements exist between the mental health research unit and the mental health reform branch of the Ontario government, which make it strategic to commission research specific for policy and programme development [37].

Understanding each institution's role and collaboration during the research process between researchers and policymakers (NMCP) can lead into an equally positive partnership. This collaboration should start at the stage of the malaria research agenda development in which researchers and policy makers realise common areas of research required for policy development in Malawi, while further interactions are needed during the research process up to utilisation. If these collaborations are maintained, a rapid-research process should be established and enhanced leading to timely availability of research findings for policy development. This incorporation of research into the policy making process should result in informed decisions that positively impact on the health of the communities.

8.6 Conclusion

The framework identifies specific elements or institutions that should be actively involved in malaria research for policy development and their linkages to promote a co-ordinated and integrated approach to knowledge translations. Its applicability and success hinges on its wider dissemination and ownership by the government through the National Malaria Control Programme.

This framework will be useful to researchers conducting non-commissioned research as it provides direction if they intend to influence malaria policy in Malawi. In addition, it will guide policymakers on the procedures to be followed when seeking evidence for policy development. The framework further offers a visual presentation of elements involved in the research-to-policy process hence bringing visibility and coordination in their roles and responsibilities.

Abbreviations

AFIDEP: African Institute for Development Policy; BMP: Blantyre Malaria Project; CIHR: Canadian Institute of Health Research; CQ: Chloroquine; COMREC: College of Medicine Research and Ethics Committee; DOR: Director of Research; EBM: Evidence Based Medicine; EBP: Evidence Based Practice; EvIDenCe: Evidence Informed Decision-making Centre; IPTp-SP: Intermittent Preventive Treatment of malaria during Pregnancy with SP; KTA: knowledge to action; KT: Knowledge Translation; KTP: Knowledge Translation Platform: MAC: Malaria Alert Centre; MLW: Malawi-Liverpool-Wellcome; MOH: Ministry of Health; NHRA: National Health Research Agenda; NHSRC:

National Health Sciences Research Committee; NCST: National Commission for Science and Technology; NMCP: National Malaria Control Programme; ODPRN: Ontario Drug Policy Research Network; OMRU: Ottawa Model of Research Use; PMI: President's Malaria Initiative; PDU: Policy Development Unit: SP: Sulfadoxine-pyrimethamine; SECURE: Strengthening Capacity to Use Research Evidence in Health Policy; SSDI: Support for Service Delivery Integration; TUMS: Tehran University of Medical Sciences; TWGs: Technical Working Groups; UNC: University of North Carolina; UNICEF: United Nations Children's Fund; USAID: United States Agency for International Development; WHO: World Health Organization.

Ethics approval

Ethical clearance was obtained from the National Health Sciences Research Committee (NHSRC) in Malawi and the Faculty of Health Sciences Research Ethics Committee at the University of Pretoria (Ref No. 146/2013).

Consent for publication

Not applicable

Availability of data and material

The datasets generated and/or analysed during the case studies and the assessment of facilitating factors and barriers to malaria research utilisation in policy development are not publicly available due to keeping the identities of respondents confidential as they granted consent for interviews on the basis of remaining anonymous but are available from the corresponding author on reasonable request.

Competing interests

The authors declare to have no competing interests.

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Authors' contributions

CAM conceived, developed the idea, and prepared the manuscript. HL contributed to shaping of the idea. CMM, KP, TdJ, and CH contributed their technical expertise in directing and critiquing of the manuscript. All the authors contributed to the drafting of the manuscript and approved the final manuscript.

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CHAPTER NINE

9.0 GENERAL DISCUSSION AND CONCLUSION

It is well known that there is an existing gap between the amount of available research and how much of that research is being utilised for policy and practice.[1] One of the leading factors contributing to this gap has been the poor interaction between knowledge users such as policymakers and the knowledge creators (researchers).[2] The two parties have most of the time worked in isolation as researchers believe that once they have conducted research, it will automatically be adopted by the users, while the users do not appreciate the contribution of research to the policy making process as they may not be aware of or trust the findings.[3] This challenge is mostly brought about by the lack of collaboration between the two parties to reach a common ground. This collaboration needs to start at the stage of question development, and throughout the research process to the stage of translation of the findings.[1] The process becomes easier if the research is commissioned by the users because they have vested interests. However, it is a challenge for non-commissioned research as researchers do not know the proper channels of communicating their research findings to influence policy.[4] This study aimed at developing a contextual framework to guide researchers conducting malaria research in Malawi to be aware of steps to take, and who to engage with, if they need to contribute to policy development. In addition, it brings awareness to knowledge users (policymakers) of the procedure to take when seeking evidence for policy decision-making. This final chapter therefore, presents the overall discussion from the findings of each objective presented in chapter three to eight. In addition, it draws out recommendations and discusses proposed areas that need further exploration in future studies.

Consistent and structured engagement of researchers and policymakers in promoting the utilisation of research for policy development is vital. However, this type of framework does not exist in Malawi and more specifically there is no such framework that promotes malaria research for policy development. The development of this framework has been guided by the review of literature on research-to-policy frameworks, lessons from malaria policy development and the role of research in this process, and the assessment of facilitating factors and barriers to the process of utilising malaria research in policy development. In addition to promoting the

development of evidence-based policies, it is important to understand the challenges of policy implementation so that policy makers are aware that the processes of policy development and implementation are interactive.

The first step in the development of this framework was to understand how the existing research-to-policy frameworks operate and how they are developed. This review has been thoroughly discussed in chapter two. There were three conceptual frameworks[5-7] and a contextual model.[8] These frameworks are based on the interactive model of knowledge translation, which emphasizes the collaboration of knowledge creators (researchers) and knowledge users (policy makers). This collaboration begins at the stage of knowledge creation when a mutual understanding is reached during question development. Researchers interact with the users at various stages of the research process so that the users are aware of the rigorous processes of research. During the translation of research findings, researchers become aware of the policy making process and the various factors that influence the process besides availability of research evidence. In this way the two parties understand what is involved in each party's work and a mutual respect is developed. The conceptual frameworks provide the process of what should be done if research evidence needs to be utilised in policy. However, they do acknowledge that a specific contextual model can be developed to augment this process.[9] The contextual model offers an example of a detailed framework which highlights specific elements with their roles and responsibilities arranged in a particular setting to boost interaction for purposes of enhancing KT. Despite being a framework for commissioned research, the contextual model provides vital lessons on the interaction processes between researchers and policy makers through research question formulation and the involvement of policy makers throughout the research process, which facilitates the acceptability and utilisation of the research findings. It also provides room for capacity building for researchers to conduct academic research when there are no specific policy research needs.

Developing contextual frameworks requires the assessment of facilitating factors and barriers to promoting research utilisation in policy making. The facilitating factors, depending on their roles and responsibilities, can be arranged in a manner that enhances interaction, communication, partnership, and address the existing barriers to promote knowledge translation.

The development of the framework in this study began with the assessment of available primary malaria research from Malawi since 1984 when the first NMCP was established[10] to the time when this assessment was conducted in 2016. This review is presented in chapter three and its purpose was to confirm the availability of evidence in addition to understanding the type of malaria research. The evaluation showed that clinical and basic research in the fields of malaria in pregnancy, severe malaria, and vector and/or agent dynamics was highly published while in ethical approved studies, morbidity studies, severe malaria, and health policy and systems research dominated. It was also established that the contextual-specific Health Policy and Systems Research (HPSR) was the least supported as most research funding is towards the creation of new knowledge in basic and clinical research. This bears testimony to similar findings during research gap analysis in Malawi where HPSR was the least conducted.[11] This is reflected in the most type of funded research, as global institutions are inclined to support basic research, knowing 'what works', and development of new technologies, while the implementation of 'what works' is contextual and is the responsibility of national institutions.[12] In addition research on implementation of 'what works', which is a form of HPSR, finds itself challenges of being published in international journals since it mainly appeals to the local setting.[13] HPSR is vital in understanding challenges or bottlenecks of health systems in the delivery of health services, therefore, each country should be responsible for mobilising resources towards this type of research whose findings can be published in local or regional peer-reviewed journals that are indexed in recognised databases such as the Medline.

Chapters four and five present case studies aimed at assessing the contribution of malaria research in policy development in Malawi in addition to the understanding of the policy making process. The first case study in chapter four assessed how malaria research influenced the anti-malarial drug policy changes in Malawi. Malawi was the first country to change the treatment policy for uncomplicated malaria from CQ to SP in 1993[10] and later to LA, an ACT, in 2007.[14] The first change brought regional concerns as to whether it had happened too quickly and the uncertainty surrounding the usage of clear-cut evidence from within the country.[15] The case study revealed that there was substantial local evidence from which the policy changes were based on. Local evidence formed a strong case for changing the policy when there were no WHO

guidelines during the change from CQ to SP. This case study showed how evidence from commissioned studies can be instrumental in changing policy within the country.

Chapter five presents the second case study that examined the policy change process and provides lessons on how it was conducted and the role of evidence. The case study is based on changing the Intermittent Preventive Treatment in pregnancy with Sulfadoxine-pyremethamine (IPTp-SP) policy in Malawi. Malawi was the first country to adopt IPTp-SP in 1993, which stipulated that women should receive two doses of SP during pregnancy.[16] But with growing resistance of *P. falciparum* to SP, the WHO revised the IPTp-SP policy and recommended that more than two doses are more beneficial and that SP should be given at a monthly interval on every antenatal visit starting early in the second trimester up to the time of delivery.[17] In 2013, based on these recommendations, Malawi adapted its IPTp-SP policy by specifically recommending that pregnant women should receive at least three doses of SP.[18]

The case study revealed that research conducted in Malawi was instrumental at changing the IPTp-SP policy at global level but Malawi only changed the policy after WHO recommendations. The process of changing the policy was smooth and effective because it was driven by the ministry of health through the NMCP, who had high interests in seeing the policy take off. However, the involvement of relevant stakeholders from the beginning of the process was tactical with the support from the donor community. Despite the change only coming after WHO recommendation, the case study reveals hope and motivation to Malawian researchers that they can conduct rigorous research to influence global policies. Therefore, they can also influence local policies if there are proper channels of communication, where the framework developed in this study fits.

Development of a contextual framework requires the assessment of environmental factors in which the framework will operate.[5-7] Chapter six presents the findings from the assessment of facilitating factors and barriers to the promotion of malaria research in policy development in Malawi. The study identified facilitating factors supporting the promotion of research utilisation in policy making emanating from global level through the movement of supporting evidence-based decision-making such as the WHO Evidence to Policy Network (EVIPNet).[19] The local

political will was shown to offer a conducive environment for the promotion of research in policy development. The specific elements identified include tools such as the National Health Research Agenda, guidelines for policy development and analysis, guidelines for evidence use in policy making, revival of the Policy Development Unit, and establishment of the Department of Research and the Knowledge Translation Platform. In additional, important elements identified at the NMCP were the technical working groups (TWGs). Other facilitating factors included research institutions and trained researchers conducting malaria research, the establishment of the Evidence Informed Decision-making Centre and the African Institute for Development Policy including donor support in research funding. On the other hand, the barriers to malaria research utilisation in policy development, included the lack of platforms for policymakers to engage with the public and drive policy agendas, poor communication and collaboration of researchers and policymakers, and funder driven research among others. The facilitators have formed an integral part of the framework and are arranged in a specific format to address the barriers.

Development of evidence-based policies should be an initial step towards attaining the ultimate goal of health research, which is public health improvement,[20] and achieving policy objectives is the primary purpose of policy implementation. Policy implementation should be taken into consideration during the stages of policy development. This should include a thorough assessment of envisioned challenges to the implementation of a particular policy in order to strategise and address them. Challenges of policy implementation have always existed in both developed and developing countries but developing countries should always take into consideration these challenges when planning since they cannot afford to waste limited resources.[21] This study further examined the overview challenges of implementing malaria policies in Malawi that are presented in chapter seven. The identified challenges include inadequate resources for policy implementation, unavailability of trained staff, poor supervision and mentorship, politics, parallel implementation of policies, lack of a platform for engagement with communities, top-down approach in policy development, lack of understanding of socio-cultural factors affecting policy uptake by communities, and incomplete stakeholder analysis during policy development. These challenges are commonly faced in weaker health systems.[22]

Therefore, the emphasis in addressing these challenges should be on the support of HPSR which will assess and provide solutions to a country's health systems bottlenecks.

Chapter seven presents the framework for promoting malaria research utilisation in policy development in Malawi. From the case studies' lessons and elements identified, a structural framework is proposed to promote an integrated approach to knowledge translation of malaria research. In this framework the government through the Ministry of Health is key in setting a conducive environment since it is the main user of research through the demand created by the research directorate and the National Malaria Control Programme (NMCP). Key documents identified as being particularly relevant to the MOH for purposes of KT include the National Health Research Agenda, Guidelines for Policy Development and Analysis, and Guidelines for Evidence Use in Policy-making. The linkage between individuals or institutions conducting academic, and policy-relevant malaria research in Malawi and the users of research (policymakers) is enhanced by the Knowledge Translation Unit, the Evidence Informed decision-making Centre, and the African Institute for Development Policy. Equally, key players in this framework are the funding partners for both research and programmes, who need to see accountability and impact of their support. Independent advisors, partners, and consultants also have their vital role in the process.

This study contributes towards maximum utilisation of malaria research for policy decision making in Malawi. It is therefore, important that every malaria research conducted in the country should strive towards contributing to policy. Through wide dissemination of the framework, researchers and policy makers will be compelled to work together and achieve a common goal towards reducing the malaria burden in Malawi.

Recommendations

The success of implementing this framework hinges upon a number of factors and places the responsibility of promoting the framework on the NMCP, as the ultimate beneficiaries of the conducted research. Several recommendations have therefore been drawn and are detailed below:

- There is need for a wider dissemination of the framework so that researchers planning to conduct malaria research are aware of the institutions to engage with, for their findings to be useful in effecting policy change. This should come along with the dissemination of the National Health Research Agenda that highlights health research needs in Malawi. The NMCP should be the lead institution to advocate for this framework so that the research findings are relevant to its needs.

- Individual researchers conducting non-commissioned research should be encouraged to collaborate with the NMCP for shared research interests. This should also be the trend for foreign researchers. While capacity building should be the emphasis for students conducting academic research.

- Health policy and systems research should be supported by the government or researchers should be encouraged to be aggressive in sourcing research grants. Government should emphasize on getting the benefits from research they support. Therefore, a requirement should be made for researchers seeking ethical clearance to indicate the policy implications of their research.

- There is need to have an established track record of malaria research being conducted in Malawi. This can be tracked from the ethical approving bodies where a requirement should be placed for Researchers to submit a copy of their findings to the NMCP leading to a malaria research repository.

Limitations

I acknowledge that more case studies should have been conducted in the development of this framework. The major limitation for this was funding and hence further research could not be conducted as research bursaries were only secured through the University of Pretoria postgraduate office. Nonetheless, two case studies were conducted in addition to conducting an overview of challenges to the implementation of malaria policies in Malawi which provided adequate data to develop the framework. However, we suggest that further detailed

assessments of specific malaria policies should be conducted in order to examine their implementation challenges and devise targeted strategies.

Areas for further research

The framework developed from this study constitutes a consented attempt to promote the utilisation of malaria research in policy development. However, the major challenge will be tracking its usage. Thus, further research needs to be conducted in coming up with an established approach of monitoring the usage of this framework. Possibly, researchers could be encouraged to document how they use the framework and through its citation to give an indication of how often the framework is used.

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APPENDICES

Appendix 1: Table 3.1: Description of research types covered in the review

Type of research	Description of research type	Example
Secondary research	This type of research involves analysis of already conducted studies (primary research) that have been published. It involves analyzing, summarize and interpreting relevant primary research based on the writing topic [25].	Kabaghe AN, Visser BJ, Spijker R, Phiri KS, Grobusch MP, Vugt M. Health workers' compliance to rapid diagnostic tests (RDTs) to guide malaria treatment: a systematic review and meta-analysis. Malaria journal. 2016; 15(1):1.
Primary research	**This is a type of research where the collection of primary data from subjects or experiments is involved. It is sometimes referred to as original research [26].**	**Includes basic, clinical, epidemiological, and Health Policy and Systems research**
• Basic research	This is also referred to as fundamental or experimental research, which involves studying life processes to generate new knowledge or theories that can be applied universally. It includes among others cell studies, animal experiments, and genetic and physiological investigations [26].	Barnes KG, Irving H, Chiumia M, Mzilahowa T, Coleman M, Hemingway J, Wondji CS. Restriction to gene flow is associated with changes in the molecular basis of pyrethroid resistance in the malaria vector Anopheles funestus. Proceedings of the National Academy of Sciences. 2016: 201615458.
• Clinical research	This can be experimental or observational with the purpose of answering specific questions on diseases and normal functioning by using human subjects. It intends to assess the safety and effectiveness of drugs, or diagnostic products for human use [26].	Dambe R, Sande J, Ali D, Chilima B, Dodoli W, Michelo C, Malenga G, Phiri KS. Monitoring the efficacy of artemether-lumefantrine for the treatment of uncomplicated malaria in Malawian children. Malaria journal. 2015: 14(1):1.
• Epidemiological research	This can be descriptive, analytical or interventional with the purpose of investigating the distribution of determinants and patterns of disease frequencies in a given population. Understanding of the factors lead to strategic disease control and prevention [26].	Jonker FA, Calis JC, van Hensbroek MB, Phiri K, Geskus RB, Brabin BJ, Leenstra T. Iron status predicts malaria risk in Malawian preschool children. PLoS One. 2012; 7(8):e42670.
• **Health Policy and System Research**	**Its aim is to improve a health system and involves the generation of new knowledge on how societies can organize themselves for the achievements of health goals. This type of research is mainly used by policy makers and health service manager for decision making [27].**	**Includes Operational, implementation, health systems, and health policy research**
➢ Health systems research	This is a multidisciplinary field of scientific investigation on any or several WHO six building blocks of a health system that include service delivery, information and evidence, medical products and technology, health workforce, health financing, and leadership and governance [22].	Yoder PS, Nsabagasani X, Eckert E, Moran A, Yé Y. Perspectives of health care providers on the provision of intermittent preventive treatment in pregnancy in health facilities in Malawi. BMC health services research. 2015; 15(1):354.
➢ Health policy research	This type of research seeks to understand the nature of health policies and the interaction of various factors in the policy development process and implementation [27].	Mwendera C, de Jager C, Longwe H, Phiri K, Hongoro C, Mutero CM. Malaria research and its influence on anti-malarial drug policy in Malawi: a case study. Health Research Policy and Systems. 2016; 14(1):1.
➢ Implementation research	The purpose of this research is to find tangible strategies of scaling up or implementation of an existing or new intervention proven efficacious in order to improve its accessibility to the wider population [22].	Almond D, Madanitsa M, Mwapasa V, Kalilani-Phiri L, Webster J, Kuile F, Paintain L. Provider and user acceptability of intermittent screening and treatment for the control of malaria in pregnancy in Malawi. Malaria Journal. 2016; 15(1):574.
➢ Operational research	This seeks to find solutions to address operational challenges to a specific health programme in a given area. The challenges are usually identified through the routine monitoring and evaluation activities [22].	Ewing VL, Tolhurst R, Kapinda A, Richards E, Terlouw DJ, Lalloo DG. Increasing understanding of the relationship between geographic access and gendered decision-making power for treatment-seeking for febrile children in the Chikwawa district of Malawi. Malaria Journal. 2016: 15(1):521.

Appendix 2: Table 4.2: Characteristics of malaria publications from Malawi between 1984 and 1993

No.	Publication	Drug (s) under study	Study objective and type	Study population	Protocol used for assessment	Approach	Outcome measured	Results found	Conclusion
1	Khoromana et al.[23] •1984 year of study	CQ	To assess the appropriate CQ dosage to be used in the Combating Childhood Communicable Diseases (CCCD) program in Malawi	224 under five children presenting at the 6 outpatient facilities	Modified WHO 7-day *in vivo* test (1984)	Two CQ dosages of 10mg/kg and 25mg/kg were administered	Parasite reduction and clinical response	84% of children given the 10mg/kg dosage had detectable parasites on D7, while 57% of 25mg/kg dosage had a detectable parasite density	Considering the study results and the higher cost and limited availability of alternative therapies, CQ 25 mg/kg therapy was adopted as the primary therapy for malaria.
2	Heymann et al.[24] • 1985 year of study	• CQ • AQ • SP or Fansidar	To test alternative drugs in under-five children	Under five children (39 receiving CQ, 39 at 10mg/kg AQ, 36 at 25mg/kg AQ, and 34 at 25mg/kg SP)	WHO (1984) modified 7-day *in vivo* test and 21-day follow up for recrudescence	A comparative trial of AQ in doses of 10 and 25 mg/kg, SP at 25mg/kg, and CQ at 25mg/kg	• Parasite clearance by day 7 • Recrudescence at day 21 for AQ 25mg/kg and SP 25mg/kg	Parasite clearance of 59% in 25mg/kg CQ dose, 90% in 10mg/kg AQ dosage, 97% in 25mg/kg AQ dosage, and 100% clearance in 25mg/kg dosage 34% of recrudescence in the 25mg/kg AQ group and no recrudescence in the SP group (the results were significant (P=0.01))	The results suggested that, in Malawi, AQ and SP are superior to CQ in producing prompt parasite clearance among young children, and that SP alone is superior to the 4-aminoquinolines in sustaining P. falciparum clearance
3	Heymann et al. [26] • 1988 year of study	CQ	Experimental study to evaluate the protective efficacy of CQ on P. falciparum	334 pregnant women in 4 antenatal clinics		P. falciparum infection rates were measured before and after a 4-week period of CQ prophylaxis	P. falciparum parasites in thick smear	48% had P. falciparum infection before prophylaxis and 37% had the infection after prophylaxis, making the protective efficacy of CQ at 23%	Research needs to further conducted to define more cost-effective interventions, including more effective drugs, and health education programmes to improve compliance among pregnant women.
4	Bloland et al.[25] •1990 year of study	CQ and SP	Evaluation of drug efficacy for both short-term parasitological and clinical response to therapy and the long term implications of the persistent parasitemia	153 Under five children attending the outpatient department	Modified WHO *in vivo* test (1973)	28-days follow up period on two groups. 124 given CQ and 37 SP	Parasitological resistance	82.3% on parasitological resistance occurred in the CQ group, while 70% in SP group exhibited a parasitological response	Children treated with SP maintained clinical improvement and improved hemoglobin concentration during follow-up period that those treated with CQ. Therefore, CQ was longer considered as an adequately effective therapy of clinical treatment of malaria in very young children.

AQ, Amodiaquine; CQ, Chloroquine; SP, Sulfadoxine-pyrimethamine

Appendix 3: Table 4.3: Characteristics of malaria publications from Malawi between 1994 and 2007

No.	Publication	Drug (s) under study	Study objective and type	Study population	Protocol used for assessment	Approach/methods	Outcome measured	Results found	Conclusion
1	Nwanyanwu et al. [14] • 1994 year of study	SP	To determine the level of SP efficacy amid numerous anecdotal reports of widespread parasite resistance to SP	145 under five children attending the outpatient clinics	28-day follow up Modified WHO *in vivo* test (1973)	Half a tablet of SP and half tablet of paracetamol for 3 days	Parasite density	97.9% exhibited RI/sensitive pattern, 98.6% had parasite clearance by day 7	These data showed that after one year of widespread use of SP in Malawi, *P. falciparum* parasite resistance remained very low contradicting reports of widespread parasite resistance to SP.
2	Verhoeff et al. [27] •1995 year of study	SP	To determine the parasitological and haematological response to SP after being adopted as the first line drug for treating uncomplicated malaria	84 under five children attending the outpatient clinic with uncomplicated malaria infection	28-day follow up Modified WHO *in vivo* test (1994)	SP was given according to guidelines of halt a tablet to children under four years and one tablet to those over four years	Parasitological success rate clearance rate and the haematological recovery	90.5% parasitological success rate, while the haematological recovery was not significantly different for parasitological successes or failures.	These results showed that, 2 years after the introduction of SP in Malawi for the treatment of uncomplicated, P. falciparum malaria, the drug combination remained effective in 90.5% of cases.
3	Nwanyanwu et al.[28] • 1997 and 1998 study period	SP	To assess the efficacy of SP 5 years after its widespread use as the first-line drug for uncomplicated malaria	641 Under five children attending outpatient clinics in selected hospitals were studied	WHO (1996) 28-day modified *in vivo* test	Children were treated with the standard malaria treatment guidelines and follow up examination on days 3,7 and 14	Parasitological and clinical response	Parasitological resistance (RII and RIII) ranged from 7% to 19% with one clinic reaching 36%); 0.9% of the patients met the WHO clinical failure by day 7	It was found that after more than 5 years of widespread use of SP in Malawi, its efficacy remained acceptable for treatment of uncomplicated malaria, and it was therefore, recommended to be retained as first-line treatment.
4	Takechi et al. [29] •1998 year of study	SP, CQ, MF, QN, and HF	To assess the status of antimalarial drug resistance in Malawi	60 under five children attending the outpatient clinic, while in vitro study, 29 isolates of P. falciparum were tested for SP, 29 for CQ, 31	For in vivo study, WHO (1973) protocol for parasitological follow up was done at days 3, 7, and 14 after treatment,	*In vivo* efficacy study for SP and *in vitro* sensitivity study for SP, CQ, MF, QN, and HF	Parasite clearance for the *in vivo* study, Inhibition of schizont maturation for *in vitro* study	*In vivo* test showed 83.1% RI/S resistance, while *in vitro*, 62.1% isolates showed resistance to SP, 3.4% in CQ, 3.2% in MF, 5.7% in QN, and 5.9% in HF	The results suggested possible recovery of CQ sensitivity after long-term absence of drug pressure, although resistance remained a major problem in malaria control, while in vitro monitoring provides early warning signs of drug efficacy loss, and may detect changing

				for QN, 29 for HF, and 26 for MF.	while an *in vitro* micro test kit was used to assess susceptibility of P. falciparum to the drugs				patterns in alternative drug resistance.
5	MacArthur et al.[16] • 1998 year of study	SP and MF	A randomised trial to compare the efficacy of SP and MF, a potential successor amid reports of P. falciparum resistance to SP	102 under five children attending the outpatient clinic qualified for the study	A modified 14-day WHO (1996) *in vivo* protocol	40 children were randomized to receive SP 25mg/kg, and 54 received MF 15mg/kg	Parasitological response, clinical failure, and haematological response	20% combined RII & RIII parasitological failure in SP and 22% in MF; 81.4% had Adequate Clinical Response in SP group and 89.8% in MF group; haemoglobin increase of (1.82 ± 2.29g/dL) in SP, and (1.64± 1.67 g/dL) in MF (P= 0.70)	With the decreasing efficacy of SP as the first-line antimalarial drug and the high failure rates of MQ at the tested lower dosage, Malawi should consider assessing the efficacy and feasibility of alternative drugs for treatment of uncomplicated malaria
6	Sulo et al.[30] • 1997 and 1999 study period	Lapdap, and SP	A randomized clinical trial to assess whether Lapdap results in higher retreatment rate for malaria than SP	500 under five children with uncomplicated malaria at the outpatient clinic	WHO (1996) protocol follow up on days 7 and 28 and thereafter, active follow-up was every 28 days with the aim to complete 12 months of follow-up	A group of 222 given Lapdap another group of 224 given SP	Annual malaria incidence and treatment failure	Mean annual malaria incidence was 2.2 in the Lapdap group and 2.8 in the SP group; 5.4% treatment failure in Lapdap group and 20.5% in the SP group	Despite the rapid elimination of Lapdap, children treated with Lapdap did not have a higher incidence of malaria episodes than those treated with SP. Treatment failure was more common with SP.
7	Plowe et al.[32]	SP	A prospective open label drug-efficacy study to measure the efficacy of SP in treating falciparum	1377 Patients aged 3 months or over presenting at a health centre with	The standard 14 days and 28 days of follow up	Standard treatment SP doses	Therapeutic efficacy, and parasitological resistance	80% of adequate clinical response rate throughout the five years; and significant decrease	Contrary to expectations, SP retained good efficacy after 10 years of use in Malawi and other countries can benefit from interim use of SP while

	• 1998 to 2002 period of efficacy monitoring		malaria from 1998 to 2002	uncomplicated malaria				in RI parasitological response	awaiting implementation of combination antimalarial treatments
8	Msyamboza et al.[33] • 2004 to 2005 study period	SP	To determine the rate of parasitological failure after SP treatment in pregnant women	74 pregnant women presenting with uncomplicated malaria at the clinic	WHO (2002) *in vivo* protocol	The standard treatment dose was used and a follow-up at days 3,7, an d 14	Parasitological failure	11% parasitological failure	The prevalence of anemia was high at first antenatal visit and the rate of parasitological failure had increased from 5% in 1996 to 11% in 2004. But the low prevalence of malaria in the population could indirectly indicate acceptable SP drug sensitivity.

CQ, chloroquine; HF, halofantrine; QN, quinine; Lapdap, chlorproguanil-dapson; MF, mefloquine; SP, sulfadoxine-pyrimethamine

Appendix 4: Table 5.2: Characteristics of intermittent preventative treatment during pregnancy with sulfadoxine-pyrimethamine (IPTp-SP) related studies conducted in Malawi

No.	Publication	Study objective and type	Study population	Study type	Approach	Results found	Conclusion
1	Verhoeff *et al.* [17] • March 1993 to June 1994 study period	Compared and evaluated parasite prevalence, anaemia and LBW in mothers who received one, two or three doses of SP during pregnancy, and the incidences of LBW in the infants	575 pregnant women attending antenatal facility at Chikwawa district hospital in Malawi	Interventional, longitudinal study	Assessment was in women who received one, two or three doses of SP during pregnant	No significant difference in parasite prevalence in peripheral or placental blood between women who received one or two SP doses although multigravidea with two dose SP had higher haemoglobin concentrations than those who received one dose (P = 0.009). The mean birthweights were higher, and incidence of LBW lower in babies born to primi- and multi-gravidea who had received two or three doses of SP than those from women who received just one dose (P < 0.03 for each)	SP use was not associated with maternal side-effects or perinatal complications and that multiple doses of SP during pregnancy will lead to a highly significant reduction in the incidence of LBW.
2	Taylor *et al.* [18] • July 1997 to August 2006 study period	Explored relationships between IPTp-SP, the presence of resistant parasite at delivery, and multiple measures of adverse delivery outcome, including parasite densities, placental histology, maternal haemoglobin concentration and birth weight.	177 genotyping and antenatal data of pregnant women delivering at Queens Elizabeth Central Hospital in Blantyre, Malawi	A serial cross section analysis	SP receipt records were obtained from antenatal clinical cards, peripheral and placental blood obtained, and a subset of 25% of available sample from women with positive peripheral blood thick smear were tested for genotyping	Women who received full IPTp with SP (≥2 doses) had lower peripheral (P = 0.018) and placental (P < .0001) parasite densities than women who received suboptimal IPTp (<2 doses), mean birthweight in the full IPTp group of 2892g compared to 2776g in the suboptimal group (P = .086), or LBW prevalence of 11.8% in the full IPTp group compared to 15.8% in the suboptimal group (P = .481)	The receipt of SP as IPTp did not raise PAM morbidity despite the increasing prevalence and fixation of SP-resistant *P. falciparum* haplotypes and therefore SP may be used in modified IPTp regimens as a component of comprehensive antenatal care.
3	Rogerson *et al.* [19] • July 1997 to April 1999 study period	Assessed operational effectiveness of SP by examining the relationship between number of doses of	1044 women attending the maternity unit at Queen Elizabeth	Clinical study	Samples from peripheral and placental blood were collected and tested. With 251	SP was associated with a decrease in placental malaria prevalence from 31.9% with no SP to 22.8% with ≥ 2 SP-doses. Decreased prevalence	IPTp-SP had a positive impact on some indicators while improved implementation and surveillance are critical.

		SP prescribed in antenatal clinic and health indicators	Central Hospital in Blantyre, Malawi		women having received no SP, 555 received 2SP-dose, and 238 received ≥ 2 SP-doses.	of LBW from 23% in women not receiving SP to 10.3% in the group receiving ≥ 2 SP-doses, while maternal and cord blood malaria prevalence and mean cord blood haemoglobin concentrations did not differ with SP usage.	
4	Filler *et al.* [14] • October 2002 to March 2005 study period	Determined the efficacy of monthly SP compared to the 2-dose regimen in preventing placental malaria in both HIV positive and negative women. (Results of HIV negative women only are considered in this review)	432 HIV negative women were randomized (216 received 2-dose SP while 216 received monthly SP)	Randomized, non-blinded study	Participants were randomized into either receiving 2-dose SP or monthly SP.	In the HIV negative group 2.3% who received monthly SP compared to 6.3% who received 2-dose SP had placental malaria (RR, 0.37)	Monthly IPTp-SP is more efficacious than a 2-dose regimen in preventing placental malaria and that monthly IPTp-SP should be adopted in areas of intense transmission of falciparum malaria.
5	Luntamo *et al.* [21] • December 2003 to October 2006 study period	Examined the potential to prevent preterm deliveries and LBW through intensified gestational intermittent preventive treatment containing antibiotics against malaria and reproductive tract infections	1320 women with uncomplicated second trimester pregnancies at Lungwena Health center, Mangochi, Malawi	A single-center, randomized, partially placebo controlled, outcome assessor-blinded clinical trial	The compared interventions included a standard 2-dose SP as a control group (436), monthly SP (441), and monthly SP combined with two doses of azithromycin (AZI-SP) (443)	Preterm incidence was 17.9% in the controls, 15.4% in the monthly SP group ($P = 0.32$), and 11.8% in the AZI-SP group ($P = 0.01$). While comparing with the controls the AZI-SP group had a risk ratio of 0.61 ($P = 0.02$) and the monthly SP group had a risk ratio of 0.71 ($P = 0.09$) for LBW	The incidence of preterm delivery and LBW can in some conditions be reduced by treating pregnant women with monthly SP and two dose azithromycin
6	Luntamo *et al.* [22] •December 2003 to October 2007 study period	Assessed the effect of monthly SP and AZI-SP treatments on peripheral malaria parasitemia at delivery in a population of both HIV-positive and – negative women of all gravidities using the PCR-methodology	484 samples from women with uncomplicated second trimester pregnancies at Lungwena Health center, Mangochi, Malawi	A single-center, randomized, partially placebo controlled, outcome assessor-blinded clinical trial	The compared interventions included a standard 2-dose SP as a control group (162), monthly SP (151), and monthly SP combined with two doses of azithromycin (AZI-SP) (171)	Comparing with controls, the monthly group had a risk ratio of 0.33 ($P < 0.001$) and in the AZI-SP group 0.23 ($P < 0.001$) for malaria at delivery. While in only HIV-negative women the corresponding figures were 0.26 ($P < 0.001$) in the monthly SP group ad 0.24 9 ($P < 0.001$) in the AZI-	Increasing the frequency of SP doses during pregnancy improves efficacy against malaria at delivery among HIV-negative women, including a population of both HIV-negative and – positive women of all gravidities.

						SP group for malaria at delivery.	
7	Luntamo *et al*. [23] •December 2003 to October 2006 period of study	Assessed the ability to reduce foetal and neonatal growth faltering through IPTp of malaria and reproductive tract infections with monthly SP, alone or with two doses of azithromycin	1320 women with uncomplicated second trimester pregnancies at Lungwena Health center, Mangochi, Malawi	A randomized, partially placebo controlled, outcome assessor-blinded clinical trial	Participants received either two doses of SP (control) (436), SP monthly (441), or SP monthly and azithromycin (1g) twice (AZI-SP) (443)	• Babies in the AZI-SP group were on average 140g heavier at birth and 0.6cm longer at four weeks of age than in the control group • Babies in the monthly SP group were on average 80g heavier and 0.3cm longer than in the control group • Compared to controls, the AZI-SP group had a relative risk of 0.61 LBW, 0.60 stunting, and 0.48 underweight at four weeks of age • Compared to controls, the monthly SP group had a relative risk of 0.71 LBW, 1.02 stunting, and 0.87 underweight	Monthly IPTp-SP regimen provided to all pregnant women is likely to increase mean birthweight and length at four weeks of age in malaria holoendemic areas and adding azithromycin to the regimen seems to increase the benefit in reduction of fetal and neonatal growth faltering
8	Gutman *et al.* [24] • March and August 2010 study period	Assessed the effectiveness of IPTp-SP	703 HIV-negative women were enrolled at Machinga district hospital in Malawi	Cross-sectional delivery survey	Assessment was made in 22% (154) of women who received < 2 SP-doses and those that received ≥ 2 SP-doses	IPTp-SP was associated with a dose-dependent protective effect on composite birth outcomes in primigravidae of an adjusted prevalence ratio of 0.50, 0.30, and 0.18 for 1, 2, and ≥ 3 doses respectively when compared to 0 doses.	IPTp-SP did not reduce the frequency of placental infection but was associated with improved birth outcomes and that IPTp-SP should still continue to be administered although alternative strategies and drugs should be explored.

Appendix 5: Participant's informed consent for interview and interview guide
Student Number: u13422228

Introduction

I am Chikondi Mwendera, a PhD student in Public Health in the Department of **School of Health Systems and Public Health** University of Pretoria. You are invited to volunteer to participate in my research project on **Development of a framework to facilitate malaria research utilization for policy development in Malawi.** The final product of this research is a framework that will facilitate the utilization of research evidence in malaria for policy making and eventually inform interventions that can address the malaria burden in Malawi. As someone who has the experience in malaria research and/or health policy development in Malawi, you know a lot about the processes that occur in either the research process and/or the policy development. The major issues to be explored are the barriers that may exist in this process and developing strategies that can address them. There are no direct benefits to you in the participation of this research but what we will learn from you will help in this research and eventually contribute in addressing the malaria burden in Malawi.

The purpose of this interview is to draw on your expertise and experiences which will eventually guide in the development the framework to link malaria research and practice through development of research informed policies**.** This may take about 60 minutes.

This introduction gives information to help you to decide if you want to take part in this study. Before you agree you should fully understand what is involved. If you do not understand the information or have any other questions, do not hesitate to ask me. You should not agree to take part unless you are completely happy about what we expect of you. Your participation in this study is voluntary. You can refuse to participate or stop at any time without giving any reason.

For purposes of capturing all the interview details, I will use a voice recorder. In this way we can capture all the important information. At that point only the research team will have access to the audio tape. The recorded interview will be transcribed and only the research team will be able to read the transcription and your name and other identifying information will not appear anywhere in the text. The data will be kept in a safe place to ensure confidentiality.

The Malawi National Health Science Research Committee (NHSRC) and Research Ethics Committee of the University of Pretoria, Faculty of Health Sciences have granted written approval for this study.

Declaration

I have read the above information and have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research. I have also been given a copy of this form.

Name: **Signature:** **Date:**

In-depth interview tool

Age:…… sex: □ Male □ Female

Profession:……..

Qualification:……..

Position in organization:……

Period of work in the current position:……

Category of the organization: □ Policy maker □ Researcher □ Research funder

Others (specify):.....

Name of Organization:……

Guide questions for malaria researchers

Subject area	Key Questions
Research utilization and impact	• As a researcher what is your motivation for conducting malaria research in Malawi? What is your ultimate goal in conducting malaria research? • What do you think is the impact of malaria research? • In your opinion, do you think malaria research conducted in Malawi is having any impact? Explain. • How do you think malaria research is utilised in Malawi? • Are you satisfied with the way malaria research is utilised in Malawi? • What do you think are the challenges in the utilization of research in Malawi? • What would you think should be put in place in order to maximise the utilisation of research in Malawi? • Which areas of malaria research have been extensively explored? • Do you think enough malaria research is being conducted in Malawi that can address the malaria burden in the country? • Which institutions in Malawi are responsible for conducting malaria research and translating them for policy and practice? • Who do you collaborate with when conducting research to maximize its adoption for policy and practice? • What kind of research is likely to be utilized for policy development and why?
Policy development	• As a researcher, what process should be followed in order for malaria research to be utilized for policy development and practice? • What are the barriers, in the process mentioned above, for policy development in Malawi? • How do you think the barriers can be addressed and by whom? • What facilitators or enhancing factors are there in Malawi for malaria research to policy development?

	• What kind of research is likely to influence policy development? • Do you think Malawian research influences policy development? • Can you give any examples of such policies? • How do they influence the policy development?
Translating research results into practice	• The other crucial thing is that we may develop evidence based policies and assume that research is being transformed into policy, but the situation is not improving on the ground. What do you think are barriers of implementation to sound policies and what could be the strategies to address these barriers and the responsible offices for this? • In your view, who do you think should initiate and facilitate or demand for knowledge use (to explore if it is going to be a "pull side" or "push side"? or should we focus on the researchers or the policy makers? • Have you had any personal involvement in projects where research results were taken up and developed further with a view to improving the treatment or control of malaria? If so, please give examples • Are you aware of research findings that might have influenced the treatment or control of malaria but have not been developed further? If so, please give examples and reasons

Guide questions for Policy makers

Subject area	Key Questions
Research utilization and impact	• How do you seek information about malaria research for policy development? • In your opinion, do you think malaria research conducted in Malawi is having any impact in policy development? Explain. • Do you think enough malaria research is being conducted in Malawi that can address the malaria burden in the country? • Do you think Malawian research influences policy development? In what ways does it do that? • What do you think are the challenges in the utilization of malaria research in Malawi? • What would you think should be put in place in order to maximise the utilisation of malaria research for policy development in Malawi? • What kind of research is likely to be utilized for policy development and why?
Policy development	• What is your responsibility in the research to policy cycle? • What process do you think should be followed in order for malaria research to be utilized for policy and practice? • What are the barriers, in the process mentioned above, for policy development in Malawi? • How do you think the barriers can be addressed and by whom? • Currently what do you think are the enhancing factors for malaria policy development in Malawi?

Translating research results into practice	• The other crucial thing is that we may develop evidence based policies and really upload ourselves that research is being transformed into policy, but the situation is not improving on the ground. What do you think are barriers of implementation to sound policies and what could be the strategies to address these barriers and the responsible offices for this? • In your view, who do you think should initiate and facilitate or demand for knowledge use (to explore if it is going to be a "pull side" or "push side"? or should we focus on the researchers or the policy makers? • Are you aware of research findings that might have influenced the treatment or control of malaria but have not been developed further? If so, please give examples and reasons

Guide questions for malaria research funders in Malawi

Subject area	Key Questions
Research funding	• Do you think funding for Malaria research in Malawi enough? • What type of malaria research do you fund and why? • What process do you think should be followed in order for malaria research to be utilized for policy and practice? • What are the barriers, in the process mentioned above, for policy development in Malawi? • How do you think the barriers can be addressed and by whom? • What determines the availability of funding for malaria research? • How do you benefit from funding malaria research? • How do you assess the impact of the funded malaria research? • Do you think the funded research is giving returns as they intended to? • How do you collaborate with other stakeholders (i.e. Government) in harmonising areas of malaria research to be funded? • What is your ultimate goal for funding malaria research? • Dou you think this goal is being realized? Explain • Has any of your funded research been utilized for policy development in Malawi? • What do you think are the barriers to malaria research utilization for policy development in Malawi? • As a funding organisation, do you have any role in influencing policy development in Malawi? If yes, how do you influence it?

Appendix 6: University of Pretoria, Faculty of Health Sciences Research Ethics Committee approval

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 22 May 2002 and Expires 20 Oct 2016.
- IRB 0000 2235 IORG0001762 Approved dd 13/04/2011 and Expires 13/04/2014.

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

30/10/2017

Approval Notice
New Application

Ethics Reference No.: 146/2013
Title: Development of a framework to facilitate malaria research utilisation for policy development in Malawi
Dept: School of Health Systems and Public Health;University of Pretoria.

Dear Chikondi Mwendera / Prof Kuku Voyi

The **New Application** for your research received on the 25/04/2013, was approved by the Faculty of Health Sciences Research Ethics Committee on the **29/05/2013**

Please note the following about your ethics approval:
- Ethics Approval is valid for 4 years till the end of May 2017 .
- Please remember to use your protocol number (**146/2013**) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

Ethics approval is subject to the following:
Standard Conditions:
- The ethics approval is conditional on the receipt of 6 monthly written Progress Reports, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

We wish you the best with your research.

Yours sincerely

Dr R Sommers; MBChB; MMed (Int); MPharMed.
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

♦ Tel:012-3541330 ♦ Fax:012-3541367 Fax2Email: 0866515924 ♦ E-Mail: manda@med.up.ac.za
♦ Web: //www.healthethics-up.co.za ♦ H W Snyman Bld (South) Level 2-34 ♦ Private Bag x 323, Arcadia, Pta, S.A., 0007

Appendix 7: Malawi Health Sciences Research Committee ethical approval

Telephone: + 265 789 400
Facsimile: + 265 789 431
e-mail doccentre@malawi.net
All Communications should be addressed to:
The Secretary for Health

In reply please quote No. MED/4/36c

MINISTRY OF HEALTH
P.O. BOX 30377
LILONGWE 3
MALAWI

17th July 2013

Chikondi Andrew Mwendera
University of Pretoria

Dear Sir/Madam,

Re: Protocol # 1203: Development of a framework to assess the impact of research on policy and practice: The case of malaria control in Malawi

Thank you for the above titled proposal that you submitted to the National Health Sciences Research Committee (NHSRC) for review. Please be advised that the NHSRC has **reviewed** and **approved** your application to conduct the above titled study.

- **APPROVAL NUMBER** : **NHSRC # 1203**
  The above details should be used on all correspondence, consent forms and documents as appropriate.
- **APPROVAL DATE** : **17/07/2013**
- **EXPIRATION DATE** :This approval **expires 16/07/14**
  After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the NHSRC secretariat should be submitted one month before the expiration date for continuing review.
- **SERIOUS ADVERSE EVENT REPORTING** :All serious problems having to do with subject safety must be reported to the National Health Sciences Research Committee within 10 working days using standard forms obtainable from the NHSRC Secretariat.
- **MODIFICATIONS**: Prior NHSRC approval using standard forms obtainable from the NHSRC Secretariat is required before implementing any changes in the Protocol (including changes in the consent documents). You may not use any other consent documents besides those approved by the NHSRC.
- **TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the NHSRC using standard forms obtainable from the NHSRC Secretariat.
- **QUESTIONS**: Please contact the NHSRC on Telephone No. (01) 724418, 0888344443 or by e-mail on moh@gmail.com
- **Other:**
  Please be reminded to send in copies of your final research results for our records as well as for the Health Research Database.

Kind regards from the NHSRC Secretariat.

.....
FOR CHAIRMAN, NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE

Appendix 8: Malawi Health Sciences Research Committee ethical renewal approval

Telephone: + 265 789 400
Facsimile: + 265 789 431
e-mail doccentre@malawi.net
All Communications should be addressed to:
The Secretary for Health

In reply please quote No. MED/4/36c

MINISTRY OF HEALTH
P.O. BOX 30377
LILONGWE 3
MALAWI

11 April 2016

Chikondi Mwendera
University of Pretoria

Dear Sir/Madam,

RE: Protocol # 1203: Development of a framework to assess the impact of research on policy and practice: The case of malaria control in Malawi

Thank you for the above titled proposal that you submitted to the National Health Sciences Research Committee (NHSRC) for review. Please be advised that the NHSRC has **reviewed** and **approved** your application for **continuation** to conduct the above titled study.

- **APPROVAL NUMBER** : **NHSRC # 1203**
  The above details should be used on all correspondence, consent forms and documents as appropriate.
- **APPROVAL DATE** : **11/04/2016**
- **EXPIRATION DATE** :This approval expires on **11/04/2017**
  After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the NHSRC secretariat should be submitted one month before the expiration date for continuing review.
- **SERIOUS ADVERSE EVENT REPORTING** :All serious problems having to do with subject safety must be reported to the National Health Sciences Research Committee within 10 working days using standard forms obtainable from the NHSRC Secretariat.
- **MODIFICATIONS**: Prior NHSRC approval using standard forms obtainable from the NHSRC Secretariat is required before implementing any changes in the Protocol (including changes in the consent documents). You may not use any other consent documents besides those approved by the NHSRC.
- **TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the NHSRC using standard forms obtainable from the NHSRC Secretariat.
- **QUESTIONS**: Please contact the NHSRC on Telephone No. 0888344443, 0999218630 or by e-mail on doccentre@gmail.com
- **Other:**
  Please be reminded to send ing copies of your final research results for our records as well as for the Health Research Database.

Kind regards from the NHSRC Secretariat.

.....

FOR CHAIRMAN, NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE

SECRETARY FOR HEALTH
2016 -04- 11
P.O. BOX 30377, CAPITAL CITY
LILONGWE 3

Appendix 9: Approval for PhD research title change

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
Denkleiers • Leading Minds • Dikgopolo tša Dihlalefi

Faculty of Health Sciences
School of Health Systems and Public Health

20 September 2016

CA Mwendera
13422228
PhD (Public Health)

Dear Mr Mwendera

Approval Academic Advisory Committee

This is a confirmation that your request for the amended title was served via e-mail and approved by the Academic Advisory Committee on 13 September 2016.

Your title: *Development of a framework to facilitate malaria research utilisation for policy development in Malawi* should be reflected on your dissertation.

Sincerely

Prof S Feresu
Chairperson
SHSPH Academic Advisory Committee

cc *Prof CM Mutero*

School of Health Systems and Public Health
University of Pretoria
Private Bag x323
Pretoria South Africa 0001

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Fax Number +27 12 354 2071

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