

STATUS OF EVIDENCE USE IN HEALTH POLICY FORMULATION IN MALAWI

RESULTS FROM THREE POLICY ANALYSIS CASE STUDIES

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ANALYSIS CASE STUDIES

This research report has been produced by the
African Institute for Development Policy (AFIDEP)



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First published: November 2016

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Abbreviations and Acronyms

ACT	Artemisinin-based Combination Therapy
AFIDEP	African Institute for Development Policy
ART	Antiretroviral therapy
BEmONC	Basic Emergency Obstetric and Neonatal Care
CSO	Civil Society Organisations
DFID	Department for International Development
MICS	Multiple Indicator Cluster Survey
MoH	Ministry of Health
NAC	National AIDS Commission
NACP	National AIDS Control Programme
NMAC	National Malaria Advisory Committee
NMCP	National Malaria Control Programme
ODI	Overseas Development Institute
PMTCT	Prevention of Mother to Child Transmission of HIV
RAPID	Research and Policy in Development
RHU	Reproductive Health Directorate
SECURE	Strengthening Capacity to Use Research Evidence in Health Policy
SRHR	Sexual and Reproductive Health and Rights
KTP	Knowledge Translation Platform
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
USAID	United States Agency for International Development
WHO	World Health Organization

Definition of Concepts and Terms as used in this Report

Policy - A course or principle of action adopted or proposed by a government. This includes written and unwritten policies, guidelines and protocols that have been set by a government.

Policymakers - Includes government officials who were involved in formulation of policies, guidelines and protocols.

Decision-maker - A person who decides things, at their level in an organization.

Evidence - Evidence in this report refers to information arising from routine data collection processes, surveys, and/or research studies.

Evidence-based policy - Any public policy informed by rigorously established objective-evidence.

Evidence-informed policy-making - An approach to policy decisions that aims to ensure that decision-making is well informed by the best available research evidence.

Health system - The sum total of all the organizations, institutions and resources whose primary purpose is to improve health.

Knowledge translation - A dynamic and iterative process that includes synthesis, dissemination, exchanges and ethically sound application of knowledge to improve the health of people.

Acknowledgement

We would like to thank several people and institutions whose support and participation made this study possible, including the staff at the Ministry of Health, led by the Secretary for Health, the Director of Policy, Planning and Development, all Heads of directorates, divisions and units. We would like to extend special thanks to the Research Unit Head, Dr. Damson Kathyola, and the KTP (Malawi Knowledge Translation Platform (KTP) Coordinator, Dr. Collins Mitambo for supporting the SECURE Health Program as well as supporting the Policy Analysis Study. We would also like to thank Dr. Bagrey Ngwira who led the research team for this policy analysis study. Data were collected by a team comprising Nissily Mushani, Misheck Julian Nkhata, Dr. Grace Kumchulesi and Dr. Abiba Longwe-Ngwira.

Our thanks also go to the staff at the National Malaria Control Programme, Department for HIV and AIDS and the Reproductive Health Directorate for providing the policy documents and other associated reference materials. Special thanks also go to Prof. Adamson Muula from the University of Malawi, College of Medicine for the critical review of earlier drafts of this report.

We would also like to appreciate the financial support for this study provided by the United Kingdoms' Department for International Development (DFID) through the Strengthening Capacity to Use Research Evidence in Health Policy (SECURE Health) Programme.

Finally, we thank all SECURE Health Partners (the College of Medicine at the University of Malawi, the East, Central and Southern Africa Health Community, the Consortium for National Health Research in Kenya, and FHI 360), AFIDEP's leadership and staff whose cooperation and technical support was instrumental to the success of the study and finalisation of the report.

Executive Summary

Study Purpose

This report draws from a retrospective policy analysis study of the role of evidence in the formulation of health policies in Malawi. The purpose of the study was to provide an understanding of the status of evidence use in past health policy formulation processes in the country. This study was part of the Strengthening Capacity to Use Research Evidence in Health Policy (SECURE Health) programme and its purpose was to provide baseline information on the status of evidence use that would contribute to the assessment of the impact of the SECURE Health programme. As such, the study results would be compared to the results of a prospective policy analysis study (to understand the role of evidence in on-going policy formulation processes) to be conducted during the implementation of the SECURE Health programme.

Study Methodology

The study was undertaken using a qualitative case study approach. Three past policies were selected in consultation with Ministry of Health actors in Malawi. The three policies were selected from three sub-sectors, namely, Malaria, HIV and AIDS, and Sexual and Reproductive Health and Rights (SRHR). From the three areas, we purposefully selected the following three policies: the Guide for the Management of Malaria (2007), the Malawi Guidelines for Clinical Management of HIV in Children and Adults (2011), and the National Sexual and Reproductive Health and Rights Policy (2009).

The guiding framework for the study was a combination of the Walt and Gilson policy analysis framework that focuses on analysing actors, context, processes and content of policies, and the Overseas Development Institute's Research and Policy in Development (RAPID) framework that emphasizes the importance of analysing the context, evidence used, the links between policymakers and researchers, and the external context within which the policy is formulated.

Data collection involved document review including literature review and the review of the three policy documents and other related documents, and key informant interviews with actors involved in the development of the three policies. Twenty-one (21) key informants were interviewed (6 in Malaria, 6 in HIV and AIDS, and 9 in SRHR). Data were analysed using the framework approach to qualitative data analysis.

Key Findings

Evidence plays an important role in policy formulation within the health sector in Malawi. Indeed, there are deliberate efforts by the Ministry of Health and its development partners to ensure that evidence is used in defining and/or informing the selection of policy options. In the HIV and Malaria management guidelines, evidence played an important role in setting the agenda for the need of policy change as well as in identifying policy options to respond to the policy issue. In the SRHR policy, evidence played a more important role in defining the problem and the need for a new policy, and a considerably less important role in identifying solutions to address the identified problems.

Importantly, evidence had to compete with other factors and considerations within the policy development processes including feasibility of implementing the policy options. For instance, in the HIV and Malaria management guidelines, the options adopted by the guidelines were not necessarily those supported by the evidence as the best options for tackling the problem, rather they were those that were seen to be most feasible to implement within the Malawi context.

Availability of data, generated by the Ministry of Health often with support from partners, was a key facilitator of evidence use. For instance, data from regular reporting by the HIV and Malaria programmes as well as information from Ministry-led surveys such as the regular sentinel surveys by the Malaria programme played an important role in setting the agenda for policy changes as well as in identifying policy solutions. On the other hand, the lack of such data on SRHR issues in the country was noted as a major barrier to use of evidence in the policy development process, with respondents indicating that they often had to rely on pockets of data from partner agencies external to the ministry.

As already alluded to, the ready availability of data in the HIV and Malaria programmes was made possible by the considerable partner support received by these programmes. The relatively low partner support for SRHR programme meant that there was not readily available data to inform policy decisions, indicating that Malawi government's low investments in the health sector greatly reduces the use of evidence in decision-making. Capacity to find, analyse, interpret and use evidence was also an important facilitating factor in enabling evidence use. In the HIV programme, for instance, the presence of Technical Advisors/Assistants funded by partner agencies in the ministry was noted as having been critical in enabling evidence use. The Technical Advisors/Assistants had dedicated time and capacity to find, analyse, interpret and provide evidence needed for decision-making. Without this assistance, it was noted that the use of evidence could have been hampered given the inadequate technical staff in the ministry compounded by their weak capacity to find, analyse, interpret and use evidence in decision-making.

The influence of external actors in the policy development processes was notable, with the processes riding on external support, both technical and financial. External actors, including UN agencies and bilateral and multi-lateral agencies, played an important role in setting the agenda for policy change, funding the generation of evidence needed to inform policy change, and providing funds to support the development of the policies. In this way, these actors played a critical role in enabling policy change and the use of evidence in this change. On the other hand, given the inherently political nature of policy-making, the considerably 'big' role of the external actors in the policy development processes likely shaped the use of certain evidence and not others as informed by the interests of the actors.

The main barriers to evidence use in the policy-making processes as noted by the study included lack of evidence, lack of access to evidence, poor packaging, communication and dissemination of research evidence, non-involvement of policymakers in research processes, generally lacking linkages between policymakers and researchers, and weak capacity among policymakers to analyse data, find, appraise, interpret, synthesize and use evidence in decision-making.

Recommendations

Based on the results of this study, we make the following recommendations, which will contribute to ensuring that evidence plays a more central role in policy-making:

- The Ministry of Health should invest in systems, structures and human resources that enable use of evidence in decision-making. For instance, the ministry should invest in regular data gathering and processing systems for informing its decision-making; where these systems exist as seen in the HIV and Malaria programmes, the ministry should strengthen these systems, and where they do not exist as seen in the SRHR programme, the ministry should invest in the establishment of these systems to enable evidence-informed decision-making. The ministry should also invest in staff whose primary role is to analyse routine data and provide information for decision-making in all its programmes so as to ensure that programmes that do not receive a lot of external support such as the SRHR programme do not suffer from lack of evidence for informing their policy decisions.
- There is need for sustained capacity building programmes for Ministry of Health staff in data analysis and interpretation, as well as in finding, appraising, interpreting and synthesizing evidence for use in decision-making.
- Efforts should be made to improve policymakers' access to evidence including establishing a common repository for all health research in Malawi, this would make evidence search and access easier. Such efforts should also improve research dissemination by researchers through regular forums attended by researchers and policymakers for discussing new research, building capacity of researchers in more effective packaging and dissemination of research.
- Efforts should also be made to improve the linkages between policymakers and researchers. For example, researchers should involve policymakers in their research from the design stage throughout the research process to ensure policymakers' needs are incorporated in the research and to create demand for the research. Similarly, policymakers should involve researchers in the policymaking processes to ensure researchers understand the evidence needs of policymakers as well as the policy process so that they can engage with policymakers more effectively.
- The ministry should invest in the policy formulation process so that this process is not completely driven by development partners who end up providing both technical and financial support to develop policies. While external support is good, over-reliance on external support cedes the policy development process to external actors and this likely affects the use of different types of evidence based on the interests of the external partners facilitating the policy development process.

I. Introduction

Utilization of evidence in decision-making processes in the health sector is limited in many African countries due to bottlenecks that operate at individual, system and institutional levels. Research on how to improve evidence-informed policy-making (EIPM) in developing countries is inadequate. Based on research in developed countries, a number of factors that facilitate use of evidence in policy-making have been documented. These include: good networks with interaction and trust between users and producers; locally generated evidence; and alignment to national research and programme priorities (Innvaer et al 2002; Lavis et al., 2005; Oliver et al., 2014). Broader institutional leadership and organizational support for evidence use in policy-making, including incentives, are documented as strong motivational factors (World Health Organisation, 2014).

Studies on the use of research evidence in policy-making have also noted that the likelihood of research being used decreases when policymakers lack both a good appreciation of the value of research evidence, as well as relevant skills and expertise in accessing, appraising, interpreting, and using available evidence in decision-making processes (Thompson et al., 2001). A common disconnect between the times when research evidence is produced and when it is most needed or most relevant also undermines research uptake in decision-making. Finally, the non-linear and multi-faceted nature of the policy-making process presents an additional barrier, as evidence often competes with many other considerations for influence on key decisions, including ideology, politics, personal experience, intuition or conventional wisdom, and vested interests (Buse et al., 2006; Lin, 2003; Walt, 1994; World Health Organisation, 2007). The shift in language from striving for ‘evidence-based’ to ‘evidence-informed’ policy-making reflects this complex reality.

The Malawi government has put in place some strategies to facilitate the use of research evidence in policy-making. In 2012, the Malawi Government developed the National Health Research Agenda whose aim is to guide researchers, policy makers and other stakeholders on health research priorities in Malawi (Malawi Government, 2012). One of the specific objectives of the Malawi National Research Agenda is to “facilitate translation of research findings into policy and practice” (Ibid: 4). This was followed by the establishment of the Knowledge Translation Platform (KTP) by the Malawi Government and its development partners in 2013 with the aim of promoting evidence-informed policy formulation. KTP Malawi aims to address the lack of engagement between policymakers, clinicians, and researchers in order to improve the uptake of the best available research by policymakers. KTP Malawi provides a way of coordinating and institutionalising such engagements between the different actors. Apart from the Malawi government, the University of Malawi’s College of Medicine established the Evidence Informed Decision-making Centre (EvIDenCe) in 2015 to drive knowledge translation efforts at the college (Mwendera et al., 2016).

1.2. Study Purpose and Objectives

The African Institute for Development Policy (AFIDEP), in collaboration with the College of Medicine at the University of Malawi, the East, Central and Southern Africa Health Community (ECSA-HC), and FHI 360, implemented a programme of work with the Ministry of Health and Parliament on Strengthening Capacity to Use Research Evidence in Health Policy (SECURE Health) programme in Malawi. The programme, funded by the UK Department for International Development (DFID), entailed working collaboratively with the Ministry of Health and Parliament to design, implement and evaluate interventions that optimize access and use of data and research evidence in health-related policy decision-making, planning and programming in Malawi.

As part of efforts to assess the impact of the SECURE Health programme, a retrospective policy analysis study was conducted to understand the status of evidence use in the formulation of past policies in the health sector in Malawi. The purpose was to generate baseline information that would be used to gauge whether the SECURE Health programme made any difference when compared to information gathered from a prospective policy analysis study to understand the role of evidence in on-going policy formulation processes to be conducted during the implementation of the SECURE Health programme.

The retrospective policy analysis study had the following specific objectives, to:

- Examine the process of evidence selection and context within which the evidence was utilised/not utilised to inform policy formulation.
- Provide an understanding of the types of evidence that informed the policy-making process.
- Examine the contributions and influence of different actors and factors in the policy-making process.
- Identify the barriers to research evidence use in policy-making and suggest ways to strengthen the use of evidence.

These objectives were addressed using the following research questions:

- How was the policy development process initiated and developed?
- Who were the main actors in driving the policy-making process?
- What kinds of research evidence were sourced, analysed and utilised in the policy-making process?
- How did research evidence influence the policy-making process?
- What other factors shaped and influenced the policy-making process and the decisions made?
- What were some of the barriers to the use of evidence in the policy-making process?
- In what ways can the use of evidence in the policy-making process be strengthened?

2. Methodology

2.1. Study Design

This study adopted a qualitative case study design in order to draw lessons on the role of evidence in policy-making from different policy development processes. Three policy case studies were selected including: The Revised Guide for the Management of Malaria (2007), Malawi Guidelines for Clinical Management of HIV in Children and Adults (2011), and the National Sexual and Reproductive Health and Rights policy (2009). Below we describe the criteria for policy selection, sampling, data collection and analysis, challenges faced., and study limitations

2.2. Criteria for Selection of Policy Case Studies

Selection of the three policy case studies was purposive guided by various considerations including the following:

1. To enable balanced learning, we selected sub-sectors perceived to be largely evidence-driven and those perceived to be driven by many other factors including culture, religious interests, and politics. Malaria and HIV and AIDS sub-sectors were selected as these were perceived to be largely driven by evidence given the considerable investments in regular surveys and studies. On the other hand, SRHR was selected because often SRHR issues generate a lot of controversy and so evidence has to compete with cultural and religious interests as well as political interests, among others.
2. To enable understanding of use of evidence at different levels of decision-making, we selected both a policy (SRHR) and guidelines (Malaria and HIV). A policy provides overall guidance and framework for tackling an issue, whereas guidelines seek to operationalize a policy. It is possible that evidence plays different roles at these two levels, and so we selected these three documents to enable us understand the different roles of evidence in two different levels.
3. We also considered priority areas for the Malawi government as identified in the Malawi National Health Research Agenda, and these three areas are among the priority areas for the government.

2.3. Conceptual Framework

There are several conceptual frameworks that have been used to understand the use of research evidence in policy-making. One of them is the World Health Organization/Turning Research into Practice (WHO/TRIP) conceptual framework (World Health Organisation, 2006). According to this framework, understanding research utilisation in policy-making involves focusing on three areas: factors that could affect utilization (the research process, stakeholder involvement, communication and dissemination, and macro contextual factors); activities to promote research utilization; and uses of research findings (evidence base, advocacy, policy change and prioritization, programmes and practice). The other framework that is also common in policy analysis is the Walt and Gilson framework (Walt and Gilson, 1994). According to this framework,

health policy analysis ought to proceed by analysing the actors, context, processes and the content of policies. Using this framework, analysing how research was used in policy-making would entail looking at content of policies (whether they were informed by research), the actors involved in policy formulation and the influence of contextual factors (external influences on the research used).

There is also the Overseas Development Institute's Research and Policy in Development (RAPID) framework, which argues that understanding research and policy links entails analysis of four broad areas: context, evidence, links and external influences (Crewe and Young, 2002). By context, Crewe and Young refer to political and other institutions that may have shaped how research influenced the policy. Despite these institutions that may influence direction of policy and the extent to which policy is used or not, Crewe and Young point out that policymakers have some room to manoeuvre by taking "actions and use ideas that attract least criticism or the ones that they are most accustomed to and help to make sense of their reality" (Crewe and Young, 2002: p. 6). In terms of evidence, Crewe and Young (ibid) suggest the importance of looking at the credibility of evidence and how evidence is communicated. This entails focusing on sources, relevance, practical usefulness of evidence and conveyance and packaging of information. The links between policy makers and researchers are important because they entail how they influence one another: how research is informed by needs of policy makers and how policy makers take up research findings. Lastly, the framework looks at the impact of external forces including development partners in influencing policy development. These include impact of international policies and processes, research funding instruments and donor policies.

For this study, we used a combination of the Walt and Gilson and the RAPID frameworks by analysing the policy content, process, context, and the actors involved and their linkages.

2.4. Data Collection

2.4.1. Ethics Approval

Study protocol was reviewed and ethics approval provided by the College of Medicine's Research Ethics Review Committee (COMREC).

2.4.2. Document Review

An analysis template (Annex 1) was used for content analysis of each of the three policy documents identified. Each of the three policies were read by at least two researchers. Upon discussion of the contents, with reference to the content analysis framework, the two researchers then completed the template. The template was used to identify the policy issue, the policy commitments to address the issue (including identification of any missing commitments), the data/research evidence used the selection of policy commitments (as presented in the document), and source of the evidence and how it was used (including synthesis/appraisal). In addition, a literature review was conducted on previous policy documents, local and international literature on policy analysis and the areas whose policies are being studied. The information collected has been integrated in various parts of the report.

2.4.3. Key Informant Interviews

We conducted key informant interviews with actors who had been involved in the formulation of the selected policy and policy guidelines. These included government officials as well as actors from outside government (development partners, academia). Although we intended to interview 30 participants (at least 10 participants for each of the three identified policies), only 21 interviews were conducted due to difficulties tracking some of the actors who had been involved in policy development (see Table 1 below). We interviewed more of the SRHR policy key informants because they were available compared to their counterparts.

Table 1 *Key informant characteristics*

Policy Area	No. of Participants	Gender		Institution		
		Male	Female	MoH	Development Partners	Academia
HIV and AIDS	6	4	2	2	-	4
Malaria	6	6	2	2	1	3
Sexual and Reproductive Health	9	3	6	4	4	1
Total	21	13	8	8	5	8

For each of the policies, we identified a list of participants who were involved in the formulation of the policy and the policy guidelines. In the acknowledgements sections, each of the policies had a list of the participants who were involved in its formulation. Purposive sampling was used to identify the first few to be interviewed based on proximity, availability and willingness to discuss the policy in question. We then used snowball sampling to identify more study participants. At the end of each interview, key informants were asked if they knew someone who was key in the policy formulation and their contact details if they knew them. We then contacted these individuals to request for interviews. This was done to ensure that we do not leave out the most critical players in the formulation of the particular policy document.

For each of the policies identified above, we discussed policy-making processes with emphasis on the role of research evidence/data in the formulation of the policy. Specifically, key informant interviews explored the following themes: who makes and influences policy, influence of research on policy formulation, mechanism for communicating and receiving research/data evidence, barriers to use of evidence and strategies to improve research use.

2.5. Data Management

For respondents who allowed us to record the interviewees, the audio recordings were downloaded from digital recorders and assigned unique names, HIV001, MAL001 and SRH001 for the first interview in HIV and AIDS, Malaria and Sexual and Reproductive Health and Rights, respectively. The audio recordings of the interviews were transcribed verbatim. For interviews that were not recorded, research assistants compiled detailed notes as soon as the interview was completed. The notes from interviews and the verbatim transcripts were then coded in NVivo 10 for analysis.

2.6. Data Analysis

Data from key informant interviews were analysed using NVivo 10. Data analysis used the framework approach to qualitative data analysis (Ritchie & Spencer, 2002). The analysis procedure involved four stages: familiarization, identifying a thematic/coding framework, indexing/coding, charting and interpretation. Familiarization involved reading the transcripts and detailed notes from the interviews by all the team members. This informed development of thematic/coding framework. The coding framework was developed from emerging issues from the transcripts and detailed field notes, policy content analysis and from the key informant interview guide, literature on policy formulation and the RAPID Framework. Thereafter, all the data was indexed/coded in NVivo10. For each policy, a chart was created so as to facilitate reading across the dataset. The charts were organized according to different themes from the data and cases. The process of interpretation involved all the researchers. This involved critically reading the themes organized by cases and analysing emerging patterns and relationships. Findings from the key informant interviews were triangulated with the findings from the document analysis to get a broader picture of the processes of policy-making and how research was used.

2.7. Challenges and Limitations

Two main challenges were experienced during this study including difficulties with tracking actors who participated in the development of the selected policies for interviews, and difficulties with recall by some interview respondents. These challenges were attributed to the fact that the policies had been developed several years before and some respondents had moved on to other jobs/positions, and others could not remember some of the information required by the study.

The study results have two limitations. One limitation is that the results are based on three policies and so these may not be representative of all policy development processes by the ministry. A second limitation is that the results are only limited to the policy formulation stage and do not therefore tell us anything about the use of evidence during policy implementation, which is a critical stage in policy-making as it enables the provision of services to citizens. Despite these limitations, the study results provide important lessons for strengthening the role of evidence in future policy-making processes.

3. Results

3.1. Formulation of the Malawi Guidelines for Clinical Management of HIV in Children and Adults (2011)

From the time the first case of HIV was discovered in Malawi in 1985, the Malawi government has progressively implemented several HIV prevention and control programmes. The national response to HIV and AIDS started in 1986 with the implementation of the Short Term Plan (STP 1986 - 1988) emphasizing blood safety and Information, Education and Communication (Mwale, 2002). In 1988, the Malawi government formulated the National AIDS Control Programme (NACP) to coordinate the country's AIDS education and HIV prevention efforts. The NACP formulated the first Medium Term Plan (MTP 1989-1993) and the second Medium Term Plan (MTP 1994 - 1998). In addition to blood safety and IEC, the first Medium Term Plan included management of Sexually Transmitted Infections (STIs). The second Medium Term Plan included all the issues addressed by the first Medium Term Plan. It was the first plan that included a multi-sectoral response in the fight against HIV and AIDS. In 2000, the NACP formulated the National Strategic Framework. The formulation process was led by the United Nations Development Programme with assistance from the United States Agency for International Development (USAID), Norwegian Agency for Development Cooperation (NORAD), European-Union (EU), Joint United Nations Programme on HIV/AIDS (UNAIDS) and United Nations Children Fund (UNICEF) (National AIDS Control Programme, 2000).

Following an evaluation of the national response in 1996, which showed insufficient coordination of planning and implementation, monitoring and evaluation of activities and overreliance on the health sector for the response, the Malawi government formed the National AIDS Commission (NAC) in 2001. The National AIDS Commission replaced the National AIDS Control Programme, with the aim of improving the multi-sector coordination, planning and implementation. In 2003, Malawi developed its first National HIV Policy with a view to consolidate efforts towards the fight against HIV and AIDS (National AIDS Commission (NAC) [Malawi], 2003). It was also developed out of a growing recognition that despite the various interventions in the country, the prevalence and impact of HIV was still devastating. The formulation of this policy was led by the National AIDS Commission. Other actors who were involved in the formulation were UNDP, USAID and UNAIDS.

In 2001, Malawi started offering triple antiretroviral therapy for patients in designated hospitals (Ministry of Health and Population, 2003). At that time, there was no standardised treatment and standard systems of training, monitoring and evaluation and drug procurement (Ministry of Health, 2006). Following a successful bid to the Global Fund for AIDS, Tuberculosis and Malaria in 2002, the implementation of the national scale-up of antiretroviral therapy started in 2004. To guide the national scale-up, the Ministry of Health and Population developed the first edition of the "Guidelines for Use of Antiretroviral Therapy in Malawi" in 2003. According to the guidelines, the criteria for eligibility among adults is known to be HIV seropositive and understand the implications of ARV therapy and any of the following criteria: assessed as being in WHO Clinical Stage 3 or 4, have a CD4-lymphocyte count of less than 200/mm³ or assessed as being in WHO Clinical stage 2 with TLC less than 1200/mm³. The first line treatment regimen for adults was a combination of Stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP), while the second line regimen was Zidovudine (AZT) + Didanosine (ddI) + Nelfinavir (NFV) (Ministry of Health and Population, 2003). By 2005, the number of people who had ever been started on ART in Malawi was 37,380 (Ministry of Health, 2006).

In 2006, Malawi developed a 5-year ART scale-up plan (2006-2010) to deliver ART to 200,000 HIV infected eligible patients by the end of 2010. The scale-up plan took note of that "the drugs and the field of HIV treatment are changing all the time" (Ministry of Health, 2006, p. iii). To take into account "the experience developed in the country is the last two years as well as the changes that [had] occurred in international recommendations", the Ministry of Health developed the second edition of the "Guidelines for use of Antiretroviral Therapy in Malawi" in 2006 (Ministry of Health, 2006, p. iv). The second edition of the guidelines included the following changes: adult second line treatment regimen changed to Zidovudine (AZT) + Lamivudine (3TC) + Tenofovir (TDF) + Lopinavir/Ritonavir (LPV/r), inclusion of didanosine (ddI) + Abacavir (ABC) + Lopinavir/Ritonavir (LPV/r) as second line treatment regimen for children and a change in the eligibility criterion for CD4-lymphocyte count from 200/mm³ to 250/mm³.

The third edition of the Guidelines for use of Antiretroviral Therapy in Malawi were released in 2008. There were no changes in the eligibility criteria and/or the treatment regimens for children and adults.

In 2010, the WHO released new recommendations for the provision of ART and PMTCT in resource limited settings (World Health Organisation, 2010). Among these recommendations were the following: early initiation of antiretroviral therapy, phasing out of Stavudine based regimens and use of more efficacious PMTCT regimens. Following these WHO recommendations, the Ministry of Health through the Department of HIV and AIDS developed the first edition of the Malawi Guidelines for Clinical Management of HIV in Children and Adults in 2011 to replace all previous editions of the Malawi Antiretroviral Therapy and Prevention of Mother to Child Transmission (PMTCT) guidelines (Malawi Ministry of Health, 2011). In contrast to previous guidelines, these were the first guidelines to fully integrate protocols for PMTCT, Follow-up of HIV exposed infants, Pre-ART follow-up of children and adults and ART (Malawi Ministry of Health, 2011). In 2014, the Malawi Guidelines for Clinical Management of HIV in Children and Adults were revised to incorporate the following changes: all children under 5 years of age with HIV infection to be eligible for ART regardless of CD4 cell count, the ART eligibility based on CD4count for children aged above 5 years and adults changed from 350 to 500cell/mm³ and introduction of new alternative regimens (Malawi Ministry of Health, 2014). It is envisaged that in 2016, the guidelines will be revised to include universal treatment for all patients who test HIV positive.

3.1.1. Policy Agenda Setting

The 2011 Malawi Guidelines for Clinical Management of HIV in Children and Adults were formulated after the WHO released the 2010 recommendations for ART and PMTCT in resource limited settings. According to the revised document, these guidelines were “based on current research evidence and were aimed at increasing access to quality ART and PMTCT services” (Malawi Ministry of Health, 2011, p. 1). According to the Ministry of Health, the guidelines are an adaptation of the WHO recommendations based on experiences from the roll out of PMTCT and ART. These sentiments in the guidelines were supported by key informants as seen in the quote below:

“The guideline revision was done because the guidelines are periodically revised in alignment with WHO recommendations or other emerging evidence.” (HIV006, Female, Funding Agency).

3.1.2. Main Actors in Policy Formulation

The formulation of the 2011 Malawi Guidelines for Clinical Management of HIV in Children and Adults was led by the Department for HIV and AIDS of the Ministry of Health. The guidelines were compiled by the joint technical working groups for PMTCT, ART, HTC and paediatric HIV. Policy actors involved in the formulation of the guidelines included: Ministry of Health (National AIDS Commission and National TB Programme), academic institutions (College of Medicine of the University of Malawi, University of North Carolina, Baylor College of Medicine) and International and local organisations including UNICEF, Centres for Disease Control (CDC), UNAIDS, Management Sciences for Health (MSH), Dignitas International, I-TECH, Medecins Sans Frontieres (Belgium), Clinton Health Access Initiative, CRS Impact, Elizabeth Glaser Paediatric Foundation (EGPAF), MCHIP – JHPIEGO, DREAM Project Malawi and Lighthouse Trust.

3.1.3. Key Policy Changes

Data from content analysis and key informant interviews reveal several changes that were included in the 2011 Malawi Guidelines for Clinical Management of HIV in Children and Adults. One of the significant changes is the integration of PMTCT and HIV services. Previously, there were separate guidelines for ART provision and PMTCT. Other changes were in the eligibility criteria for ART, use of CD4 and the regimens used in the ART programme.

One of the key changes in the guidelines is the eligibility criteria for ART in children aged above 5 years or adults. According to a position paper that was published in July 2011, the main change was a proposal “to offer all HIV-infected pregnant women lifelong ART. This approach is not completely new, but rather is a more feasible alternative to WHO’s proposed option B, which we call option B+” (Schouten et al., 2011, p. 282). One key informant mentioned this as the main change:

“The main policy changes from the previous guidelines was: ... universal eligibility for HIV positive patients who are pregnant (Option B+); children under 5, TB-HIV co-infected patients.” (HIV006, Female, Funding Agency).

According to the guidelines, the eligibility criteria for children and adults aged above 5 years are: confirmed HIV infection using HIV rapid antibody test and any of the following: pregnant or breastfeeding women regardless of CD4 count, WHO stage or the age of the child, or WHO clinical stage 3 or 4 regardless of CD4 count or WHO stage 1 or 2 and a CD4 count of less than 350 cells/mm³. One key informant said:

“The major change that I can remember is that we shifted from CD4 250 to 350 at that time, as the eligibility criteria.” (HIV002, Male, Development Partner).

For children aged between 24 months and 5 years, the criteria is confirmed HIV infection using HIV rapid antibody test and any of the following: WHO stage 1 or 2 and a CD4 count of less than 750 cells/mm³ or WHO clinical stage 3 or 4 regardless of CD4 count. For children under 24 months, there was universal ART. Children aged between 12 months and 24 months were eligible for ART if they had a confirmed HIV infection using HIV rapid antibody test or DNA-PCR regardless of WHO stage or CD4 count. For children aged below 12 months, the eligibility criteria were confirmed HIV infection using DNA-PCR regardless of CD4 count or WHO stage or presumed severe HIV disease (PSHD) - HIV rapid antibody test and PSHD defining conditions for example a combination of severe sepsis and severe pneumonia.

The other change in the guidelines was the use of ART regimens. According to the guidelines, the WHO had recommended the phasing out of Stavudine based regimens to reduce long-term side effects. One key informant mentioned the removal of Stavudine based regimens as one of the main changes in the guidelines.

“Yes, Stavudine was removed in 2011. Because of the pregnant women, we realized that Stavudine, it’s got a lot of side effects and these are women who are not sick, we knew that it was going to add to our problems of early loss to follow up.” (HIV001, Male, MoH).

3.1.4. Policy Gaps

A review of the 2011 Guidelines reveals that it was written for medical doctors, clinical officers, medical assistants, nurses, midwives, health surveillance assistants and medical records clerks in both private and public sector health facilities. It was meant to be a “practical guide for implementation of integrated HIV services” (Malawi Ministry of Health, 2011, p. iii). To guide this implementation, the 2011 Malawi Guidelines for Clinical Management of HIV in Children and Adults has an implementation plan with details about when implementation would start (i.e. July 2011), ART eligibility and the regimens to be used, and use of routine scheduled viral load monitoring. One key informant noted that the implementation plan was not clear on some aspects of implementation. As a result, there were differences in how they were operationalized and implemented in different facilities. One of the key informants said:

“I wouldn’t really call them gaps, but you know it’s something that people thought and you can have something that is plausible enough theoretically, but when you go down on the ground there are more context issues that kind of faked the adoption...so I guess the main issue that I noted was that there wasn’t very clear guidance as to how this was going to be delivered...I think the policy just said that this is the way it should be done and sites were supposed to contextualize the whole process...so decide whether they are going to do it at the ANC for example or if somebody is found to be positive at maternity...so each site had different ways of doing it and I think that to me was a bit of a gap in the sense that there wasn’t a very clear guidance that this should be done like this...” (HIV003, Male, Funding Agency).

Other key informants noted that the communication and messages around the policy were not very clear. As such, some health care workers in facilities continued to implement the previous treatment guidelines.

“And of course we saw that when we are implementing and also the other problem was the messaging. So the message that people were giving, was still that old message about prophylaxis for the child. The message about the mother’s health was not coming out. Therefore, women thought: after I have delivered, there is no need to continue, after all this was for the baby. So we had to actually revise our messages. I think that was about a year into implementation. And say no, no, no, I think we need to change our message and inform the women that this is actually for their own health as well; it is not just to prevent transmission. Because we saw that a lot of women after delivery, they get lost to follow up, they think that’s it...” (HIV001, Male, MoH).

3.1.5. Use of Evidence

Evidence that was used in the policy initiation and formulation stages ranged from programmatic data from the Department for HIV and AIDS in Malawi to research studies (both local and international).

A review of the 2011 Guidelines shows that research evidence was used in the rationale for lifelong ART for pregnant and breastfeeding women. The 2011 Guidelines included three reasons for starting lifelong ART in pregnant and breastfeeding women: it would increase access to ART, reduce post-partum mortality rates in HIV infected women, and reduction in HIV transmission (Malawi Ministry of Health, 2011). In terms of increasing access to ART, the 2011 Guidelines refer to the HIV Programme Quarterly report of Quarter 2 of 2010, which showed high ANC attendance rates of up to 91% and availability of HIV rapid testing at all ANC sites (Ministry of Health, 2010). According to the guidelines, ANC sites provide an ideal entry point for ART for pregnant women and would therefore enable high ART coverage for HIV infected pregnant women. The 2011 Guidelines also refer to Van Lettow et al. (2010) and Hargrove et al. (2010) as part of rationale that lifelong ART for pregnant and breast feeding women reduced post-partum mortality in HIV positive women. These papers show high mortality rates in post-partum women with high CD4 counts (>350 cells/mm³ in pregnancy) who were not on ART.

Key informant interviews revealed that prior to the formulation of the 2011 Guidelines, the WHO asked some low-income countries, including Malawi, to conduct feasibility studies on the implementation of Option A and Option B:

Option A: Twice daily AZT for the mother and infant prophylaxis with either AZT or NVP for six weeks after birth if the infant is not breastfeeding. If the infant is breastfeeding, daily NVP infant prophylaxis should be continued for one week after the end of the breastfeeding period.

Option B: A three-drug prophylactic regimen for the mother taken during pregnancy and throughout the breastfeeding period, as well as infant prophylaxis for six weeks after birth, whether or not the infant is breastfeeding.

Key informants indicated that the results from this feasibility study showed that the implementation of Option B was not feasible because the laboratory test for CD4 count was not readily available across the country.

“Now, what the feasibility study told us was that access to CD4 was very, very limited. And I think we had only less than 30% of our health facilities that had access to CD4 testing. So it became very evident that even option B was not going to be feasible in the Malawian context.” (HIV001, Male, MoH).

“I think we were also fortunate a bit because I think WHO gave us a bit of money to do an analysis on how option B would look like and how the other options would look like which was before the recommendations were announced, yeah so we had I think maybe three or four months before they asked us to use our program data and also to do some investigations trying to cost each of the options and also to estimate the implication on the program, I think they did it in three to four countries, I remember there was Malawi, Nigeria, I don’t know maybe Uganda or Tanzania, something like that. So when the results were out, we had already had a bit of analysis of the respective options.” (HIV002, Male, Development Partner).

According to our key informants, the results from the feasibility study were complemented by programmatic data from quarterly supervision done by the Department for HIV and AIDS.

“So we at the HIV department we have an inventory... thus evidence on the number of CD4 count machines and number of CD4 counts done per year was used.” (HIV003, Male, MoH).

Routine programme data and studies from other countries were also used to inform the decision to change the regimen from Stavudine based regimen (D4T) to Tenofovir based regimen (TDF). Routine programme data had shown the extent of the side effects from Stavudine.

“A lot of studies have shown, even our operational research data, was showing us that d4T had a very high side effect profile. You can count side effects on your two hands for d4T, lipodystrophy, neuropathy...and then there were studies, which were done again comparing TDF and d4T showing the side effect profile and I mean of course every drug has got side effects, but if you look at the difference between the two, it was good decision to drop d4T. And in fact I think in the next guidelines we are going to drop it completely...I mean we collect data every quarter from the sites and we are able to look at side effects profile. We have got a database at the HIV department there where we feed all the information every quarter and it’s able to tell us. So if you look at the side effects data when we were giving d4T.” (HIV001, Male, MoH).

3.1.6. Facilitators of Use of Evidence

One of the main facilitators for the use of evidence in formulation of the ART treatment guidelines was the availability of human resource capacity to use evidence. Apart from the MoH staff, the Department for HIV and AIDS had some Technical Advisors/Assistants who were at the forefront in pushing for the formulation of these guidelines. These are experts sponsored by development partners and placed within MoH departments to assist with a particular task for a specified period of time and are not on government pay roll)

“We were about 4 technical advisors who discussed this in detail and worked out how we should work; what will be the modalities, what were the pros and cons, etc., and we even ended up writing a position paper which was published in the Lancet.” (HIV001, Male, Development Partner).

“I think they [Technical Assistants] played a critical role, they did. The other part is the technical assistants tend to have a clearly defined terms of reference, so they tend to concentrate yeah, it can be a small territory but concentrate on that, so you may find that they tend to achieve more because they are not pulled in all directions like the normal employees would okay, so the normal employees would be pulled left, right and centre.” (HIV002, Male, Development Partner).

The second facilitator for use of evidence was the availability of data in the Department for HIV and AIDS. According to some key informants, the department conducts comprehensive data collection on quarterly basis across the country rather than wait for personnel in various districts to send their data to the department. As a result of this active collection of data, the department has a comprehensive database from which they get evidence to inform decision-making.

“So the goodness with us in our department is that we have the data and we use it to make decisions and we take that data to the management and tell them this is what the data is and this is why we are proposing this change... I think it is the systems that people use. Okay, most departments rely on passive data and it just doesn't work you know. You say ooh Chitipa, send me your data, the deadline is fifth of every month. They will send you, but they will send you crap! Some will not even send. And us as HIV department, our reporting to Global Fund is performance-based; we don't get money if we don't report by a certain time. Okay, so we have to have that data at that particular time to submit it, otherwise we know we are not going to get the next string of money for our next activity. So we have to make sure that we go there and get the data... Every quarter, every site has been visited and data has been verified and collected.” (HIV001, Male, MoH).

The third factor that facilitated the use of evidence was the acknowledgement that this policy was not exactly what the WHO had recommended. It was an adapted version to suit the Malawi context. According to one key informant, the Department for HIV and AIDS recognized that if this were to be accepted, they needed to get and use all the evidence that was necessary. The premise was that the WHO recommendations were based on solid evidence and science and they needed to have as much evidence as possible to push forward the policy.

“From the start in terms of deciding to have the policy changed and also for the...I guess that the awareness that this issue was going to be highly debatable both nationally and internationally led to a thorough preparation by the people who were proposing it...so that awareness helped a lot because you already know that this is not in line with the [WHO] guidelines and therefore it might not easily be supported. That forced preparation, further preparation and the only way to do that was to have very strong backing and that forced a thorough search for evidence that could support the idea.” (HIV003, Male, Funding Agency).

3.1.7. Barriers to Use of Evidence

In formulation of the Option B+ guidelines, one of the main barriers to using evidence was that the evidence was not available. Key informants argued that there were no studies that had been done on starting pregnant and breastfeeding women on ART for life.

“Because Malawi pioneered the policy change therefore there was limited literature available.” (HIV005, Female, MoH).

Other barriers to evidence use included: time constraints within which to come up with a policy and the influence of interest groups that would be negatively affected by policy change.

3.2. Development of the Guide for the Management of Malaria (October 2007)

In Malawi, organised efforts at malaria control started in 1984 with the establishment of the National Malaria Control Programme (NMCP) to spearhead national response and as part of a response to the emergence of chloroquine-resistant *Plasmodium falciparum* (National Malaria Control Programme, 2007). It was formulated in response to escalating morbidity and mortality with the mandate to: to verify the clinical impression of CQ resistance, to study other antimalarial drugs, and to formulate a rational malaria treatment policy for the country. In the same year, NMCP formulated the first five year implementation Plan (1985 - 1989) for Malaria.

Its objective was “to reduce mortality due to malaria among all segments of populations at risk, especially children, pregnant women, the immunosuppressed/debilitated and those with sickle cell disease” and “to reduce duration of morbidity due to malaria by proper treatment of all segments of the population and to thus increase work capacity of adults” (Malawi National Malaria Control Programme, 1985, p. 22). Its targets were reduction in duration of morbidity, reduction in mortality, improved access to chloroquine, improved utilization of health services, training of nurses and supervisory personnel and health education about malaria control. These targets were expected to be met through presumptive treatment of fevers, continuous monitoring of antimalarial efficacy, selective antimalarial chemoprophylaxis, vector control and health education.

Prior to 1984, the treatment of uncomplicated malaria was a single dose of 10mg chloroquine/kg (Brabin et al., 1997). By 1983, clinicians started observing suspected *Plasmodium falciparum* resistance across the country in terms of smear-confirmed chloroquine failures and perceived increase in cerebral malaria among children (Malawi National Malaria Control Programme, 1985). The Ministry of Health established the Malaria Control Committee to study the efficacy of chloroquine and other antimalarial drugs and to develop sound management guidelines (Malaria Control Programme, 1997). This led to the establishment of the national sentinel surveillance system in six sites (three along Lake Malawi and three in higher altitude areas) to investigate chloroquine resistance.

The results of these studies showed that a single dose of chloroquine 10mg/kg failed to clear symptoms and parasitemia. A dose of chloroquine 25mg/kg divided over three days was compared with that of amodiaquine, sulphadoxine-pyrimethamine, quinine, mefloquine and halofantrine (Brabin et al., 1997). The results showed that chloroquine effected a clinical cure in 92% of patients, but resulted in persistence of low grade parasitemia in 57% of patients (ibid). After considering the low cost, high availability and safety of chloroquine, this dosage became the first line treatment for uncomplicated malaria and was included in the first edition of the guidelines for management of malaria.

The second edition of the guidelines were released in 1986 and maintained the recommendation of chloroquine at 25mg/kg given over three days. The second five year malaria control plan (1990 - 1994) was formulated following indications from systematic monitoring that the efficacy of chloroquine was deteriorating. In 1990/91, studies showed that chloroquine had become less efficacious in the management of malaria in children, with 30% and 60% of children treated with high-dose chloroquine becoming symptomatic in 14 days and 28 days post-treatment respectively (Brabin et al., 1997). Following evaluations of other antimalarial drugs which showed that they were highly efficacious in management of uncomplicated malaria, sulphadoxine-pyrimethamine was selected as the first line drug for treatment of uncomplicated malaria in 1993. While the decision to change to sulphadoxine-pyrimethamine had been reached around 1990/91, the extent and complexity of activities within the programme of change resulted in a three year lag (Malenga et al., 2009).

Apart from efficacy, the switch from chloroquine to sulphadoxine-pyrimethamine also considered other factors including: cost, safety and ease of administration (Malaria Control Programme, 1997). Further to this, amodiaquine had been withdrawn from the national drug list, mefloquine had not been registered while halofantrine was considered very expensive for general use. The change resulted in the release of a third edition of the guidelines for the management of malaria in 1994. In 1997, the fourth edition of the guidelines for the management of malaria were released without any new recommendations for management of malaria. It incorporated changes that came up from consultations with a cross section of health care workers from all districts in Malawi (ibid). Malenga and others (2009) noted that by 2004, it had become apparent that Malawi needed to review its first line treatment. This led to the revision of the guidelines for management of Malaria, culminating in the Guide for the Management of Malaria of 2007.

3.2.1. Policy Agenda Setting

A review of the Guide for the Management of Malaria (2007) shows that in 2005, the Ministry of Health, through the NMCP, conducted efficacy studies of various antimalarial drugs in the country. Among other things, these studies showed an increasing failure rate of Sulphadoxine Pyrimethamine (SP). By this time, the WHO had already recommended that countries should switch from SP to Artemisin-based combination therapy. This was based on recommendations that there should be a drug switch when there is a failure rate of up to 10%. Partly, the change in the guidelines was influenced by what was happening in other countries where such changes were already taking place. Key informants highlighted that even though the WHO had made these recommendations, Malawi did not want to change right away before local evidence was established. Especially evidence on what should be the right combinations of the anti-malaria drugs.

“I think the only controversial issue that time was the combination to use and not that there should be a switch. Because WHO was recommending combination you know, combination therapy. Now there were various combinations...so the only discussion there was about which one of these combinations should we adopt as first line in Malawi and which ones as second line? So that was the only controversy. Not, nothing to do with whether there will a change or not.” (MAL005, Male, Research Institution).

3.2.2. Main Actors in Policy Formulation

The 2007 Guide for the Management of Malaria was formulated by the Ministry of Health through the National Malaria Control Programme and members of the Case Management sub-Working Group. The actors involved in the formulation of the guidelines included: academic institutions (Mzuzu University and the Malaria Alert Centre, College of Medicine), international and bilateral organisations (WHO, UNICEF, CDC-USA Malaria/PMI, Baylor Children’s Foundation), Mwaiwathu Private Hospital, Malawi-Liverpool Wellcome Trust, and Pharmacy, Medicines and Poisons Board. In the Ministry of Health, the following contributed to the formulation of the guidelines: Lilongwe District Health Office, Mulanje District Hospital, Kamuzu Central Hospital and Queen Elizabeth Central Hospital.

3.2.3. Key Policy Changes

The main change in the Guide for the Management of Malaria (2007) was the change from Sulphadoxine-Pyrimethamine (SP) to Lumefantrine-Artemether (LA) as the first line drug in the treatment of uncomplicated Malaria (National Malaria Control Programme, 2007). Artesunate Amodiaquine was chosen as the second line drug, Quinine was for treatment of severe malaria cases and for the management of Malaria in pregnancy. The guidelines maintained SP as the recommended drug for preventive treatment of Malaria in pregnancy.

3.2.4. Policy Gaps

One of the gaps in the Guide for the Management of Malaria (2007) was the lack of a clear implementation plan given that SP was a drug that was partly being distributed through local grocery stores while LA could not be distributed through grocery stores.

“I think that there was quite a problem because it was clear that with 14 years of experience of SP, we could realize that you needed that shop to help get SP out to the people and so it was a huge problem too trying to disseminate ACT and say LA instead. And it took years, I don’t think it is completed yet to get it right out of the health centres to the very communities; it has gone a lot further now with the use of village workers and HSAs [Health Surveillance Assistants]. But still I don’t think it’s easy for everybody to access LA as it was to access SP. That was a gap that needed research, probably needs research now; how far is LA getting to the periphery of the population.” (MAL003, Male, Academia).

3.2.5. Use of Evidence

Evidence that informed the decision to change the first line drug from SP to LA came from several sources including data from Ministry of Health sentinel sites and research institutions (Malenga et al., 2009). A review of the Guide for the Management of Malaria (2007) shows several areas where research evidence was used. Except in reference to efficacy studies, reference is made to ‘studies’ without naming them. The foreword and the introduction to the Guide for the Management of Malaria (2007) indicates that in 2005, the Ministry of Health through the NMCP carried out efficacy studies of various antimalarial drugs which showed that SP was showing increasing failure rate. According to one key informant, drug efficacy trials conducted prior to 2007 had necessitated the change.

“That time quinine was second line, actually for severe malaria. So that informed the change of first line and second line treatment to ACTs in 2007, it was based on the findings of the drug efficacy which was done 2 years before 2007.” (MAL004, Male, Government).

Apart from use of research evidence, some participants mentioned that the National Malaria Control Programme also used anecdotal reports of treatment failure of the SP at the time the guidelines were changed in 2007. As a result of these anecdotal reports, the NMCP decided to commission efficacy trials.

“Again [change in guidelines in] 2007 was also based on research conducted after getting anecdotal reports from clinicians, so it’s when we changed from SP to ACTs, so comparing such evidence and routine data, I would say research is more powerful than routine data because routine data has got its own challenges.” (MAL004, Male, MoH).

“I think in 2007 we moved from Fansidar SP to ACTs and this is LA and prior to that I think there was a study which was done and I think the PI was Dr B from the US and CDC. So she headed the study where we were looking at the efficacy of SP compared to the ACTs...in that case I think we were looking at several drugs...one of which was LA. We were also looking at Artesunate Amodiaquine, we also looked at Mahtab.” (MAL001, Male, MoH).

According to one key informant, this study showed that SP was indeed not efficacious and the study recommended the use of Artesunate Amodiaquine rather than LA as its efficacy was not as high. Yet when it was presented to the ministry, through the technical working group, a decision was made to have LA as the first line drug because of the impracticality of using Artesunate Amodiaquine which was then packaged in co-blister packs of Artesunate and Amodiaquine.

“So at that point actually the study had recommended that we use Artesunate Amodiaquine because the efficacy was pretty high and the second option was to look at LA, but LA was equally good, but if you look at the efficacy per se... I think Artesunate Amodiaquine was very good...” (MAL001, Male, Government).

A review of the Guide for the Management of Malaria shows that LA was adopted as the first-line treatment because “[I]t has a high clinical and parasitological cure rate and rapid gametocyte clearance. There are as yet no serious adverse reactions documented, and studies have shown no indications of cardiotoxicity” (National Malaria Control Programme, 2007, p. 9).

On antimalarial prophylaxis in pregnancy, the Guide for the Management of Malaria noted that SP, chloroquine and proguanil are safe in pregnancy and that “there is no evidence that mefloquine is harmful in pregnancy but many still prefer to advise against its use in pregnancy on general grounds” (National Malaria Control Programme, 2007, p. 22). On use of Insecticide Treated Mosquito Nets as part of vector control, the Guide for the Management of Malaria indicates that “[R]ecent studies have demonstrated that mosquito nets impregnated with insecticide are more effective in reducing morbidity and mortality due to malaria than mosquito nets without the insecticide” (National Malaria Control Programme, 2007, p. 25).

3.2.6. Facilitators of Use of Evidence

One of the key facilitators for evidence use in the National Malaria Control Programme is the fact that every two years, the programme conducts drug efficacy trials. As such, evidence is readily available for them to use in formulation of policies.

“Of course looking back let me just confirm one thing on the periodically monitoring of the efficacy of LA. So that I would say is already in place and committed by PMI. So every 2 years, these efficacy evaluations are carried out.” (MAL003, Male, Academia).

Another factor is the availability of human resource capacity to use evidence. These include the experts within the ministry, researchers from University of Malawi and involvement of Technical Advisors.

3.2.7. Barriers to Use of Evidence

While the NMCP has been using evidence in informing formulation of guidelines, there are some barriers that prevent the department from fully utilizing research evidence. The first barrier is lack of human resource capacity to source and utilize research findings. While the government has some staff involved in data collection and management, they do not have the requisite expertise to analyse and use research evidence.

“I think in terms of the programme I think we are having some gaps because though I am saying there are 3 guys one is technical assistant yah...from the USAID yah supported by USAID...so in terms of government the other one just came has a clinical background because he is just supporting that one called... so there is only one person who is government employed full time and with the background of statistics...you see, but the other one is there as a technical assistant. So we can't really bank so much on this guy...suppose anytime this guy says aah we are no longer supporting you it means we will not be able to sustain this person...so it's an important area but then I think we still need to support so much that we are generating that data to help us in the decisions...” (MAL004, Male, MoH).

Key informants noted that another barrier to use of research in policy-making is lack communication between the researchers and policy makers. While this communication has previously been said to be one way, meaning researchers should talk to policy makers, one participant said there is also need for policy makers to inform researchers of the areas that need to be researched. In this regard, a key informant in the NMCP stated that as a programme, it is easier for them to recognize and use research in which they have been involved from the beginning.

“For the studies that have been done outside our knowledge, we just see them as academic studies/research those that do not have influence on the national policy. Studies that have influence on national policy, the program manager and the team have to be aware of the protocol, we have to input in the protocol and sometimes we are requested to supervise the actual fieldwork. We have to know the whole process up to the end.” (MAL004).

Vested interests of those that fund policy-making and implementation were also mentioned as a barrier to use of evidence in policy-making, especially where the funder does not agree with the evidence. This may lead to such groups of people skewing the evidence to suit the directions they want.

“The other factor is that it's about again who calls the shots, it is very critical for a resource poor country. So much as you can have the evidence and you can have that can really inform policy and as well that decisions have to be made. But sometimes those things have dragged because maybe the person who is calling the shots, the persons that are going to resource such a policy implementation, is not the country itself, it could be someone outside. So those two also matter very much, I think they have a final say in the end. It's not only about decisions, but also it's about resources.” (MAL003, Male, Academia).

3.3. Development of the National Sexual and Reproductive Health and Rights Policy of 2009

The process of reviewing the status of SRHR in the country and drafting a new policy was done by a consultant hired by MoH's Reproductive Health Division with funding from UNFPA. The consultant regularly presented progress reports and draft policy documents to stakeholders who provided inputs that informed policy development. The stakeholder groups involved in the process included government departments, development partners, UN agencies, universities, research institutes, NGOs and civil society organisations.

3.3.1. Policy Agenda Setting

Our review of documents shows that in 2009, the Malawi Government, through the Reproductive Health Unit, revised the 2002 Reproductive Health Policy to “incorporate emerging issues in various components of SRHR including Basic Emergency Obstetric and Neonatal Care (BEmONC); Community Based Maternal and Neonatal Care; Cervical Cancer Screening; Youth Friendly Health Services, Anti-Retroviral Therapy, and Prevention of Mother to Child Transmission (PMTCT)” in line with national and international recommendations (Ministry of Health, 2009, p. ii). The revision of the 2002 Reproductive Health Policy in 2009 was necessitated by the fact the policy had outlived its life span of five years. Apart from that, some key informants highlighted that there were some emerging issues that needed to be included in the new policy.

“I know that the revision was done at the expiration of the first version and then we had issues like cervical cancer, fistula and gender based violence that [occasioned] the need to revise the document.... I know that when the first document was being developed some of the areas were not included just because I think by then we did not have data to like provide evidence that it's an issue in Malawi...” (SRH009, Female, Funding Agency).

3.3.2. Main Actors in Policy Formulation

The revision of the SRHR policy was led by the Reproductive Health Unit of the Ministry of Health with technical and financial support from UNFPA (Ministry of Health, 2009). The revision involved consultation with individual health experts, health regulatory bodies, training institutions, programme managers, implementers, and organisations implementing reproductive health services. A team of consultants from the University of Malawi, Kamuzu College of Nursing facilitated the revision process.

3.3.3. Key Policy Changes

One of the major changes that came with the revision of the policy was the explicit inclusion of the human rights and how they relate to Sexual and Reproductive Health. The 2002 policy was called the Reproductive Health Policy while the revised 2009 policy explicitly framed sexual and reproductive health as human rights by taking up the title 'Sexual and Reproductive Health and Rights'. As such CSOs on human rights were very crucial in this process.

"But as well, it was opined that the reproductive health policy of 2002, that's the first policy, didn't really capture the issue to do with rights; as you know SRH is about personal choices, so the revision was taken into account of that so that it should not be a reproductive health policy anymore, but it should be a Sexual Reproductive Health and Rights policy. A policy that respects people's rights." (SRH004, Male, Academia).

A review of the SRHR (2009) policy document shows that it included several new themes which were not in the Reproductive Health Policy of 2002. These include: prevention and management of obstetric fistula, prevention and management of infertility, male involvement in the development, promotion and delivery of SRHR services, and development of human resources for SRHR services. There is also a change in terminology to be more inclusive: from safe motherhood to maternal and neonatal health, adolescent reproductive health to young people in reproductive health and cancer of the cervix, prostate and breast to reproductive cancers. One of the key informants highlighted these changes as follows:

"There were emerging issues around that area that needed to be addressed and also issues to do with sexual violence and the like...those issues were there but not much was included in the policy...so I think that's when we needed to revise and include these issues to make sure the policy is also... addressing issues of violence." (SRH003, Female, Funding Agency).

The revised SRHR policy also includes an implementation plan with clear goals, outcomes, strategies for achieving the goals, responsibility for implementation, and the timeframe for implementation. Among those responsible for implementation are stakeholders from health, education, economic planning and gender.

3.3.4. Policy Gaps

A review of the SRHR (2009) policy document showed several gaps. One of the gaps is that some of the concepts are not clearly defined in the policy. For example, the policy goal in the male involvement theme is to "[t]o promote male involvement in all SRHR issues and services" and the strategy to achieve this is to "[e]mpower men to promote and patronize SRHR services" (Ministry of Health, 2009, p. :16). Yet it does not clearly state what it means by male involvement. Another area that is not clear is on integration of services, what it means in the context of SRHR and its implications. Further to this, while the policy clearly spells out responsibilities for different stakeholders at institutional level, it does not specify clear roles for different cadres that are expected to implement it for example community midwives and HSAs.

Key informants also noted other gaps in the SRHR policy. One of the gaps is in having a clear implementation plan with priorities in terms of the activities. Of course, in some cases this is optional where by, some policies do come together with an implementation strategy that would take care of these issues, while others are accompanied by a strategic plan often prepared later as a separate document.

".... even though the document was developed, there isn't that area that talks about monitoring of how these strategies are being implemented. Isn't any prioritization to say anyway first year will do this and second year will do this and by the time that we reach fifth year we should have done everything? So I think ... even if you ask Ministry of Health of what have you done regarding the strategy since it was commissioned. I don't think they will be able to say we have done this and that according to what has been stipulated in the document." (SRH009, Female, Funding Agency).

3.3.5. Use of Evidence

Content analysis of the SRHR policy shows that the policy used several pieces of evidence to inform it. The evidence sources mentioned in the policy are the 2008 Malawi Population and Housing Census (National Statistical Office (NSO) [Malawi], 2008), the 2004 Malawi Demographic and Health Survey (National Statistical Office (NSO) [Malawi] & ORC Macro, 2005) and the 2006 Malawi Multiple Indicator Cluster Survey (MICS) (National Statistical Office & UNICEF, 2007). In the background to the policy, the SRHR uses evidence from the Malawi Population and Housing Census of 2008 to show that the population of Malawi, which was then estimated at 13 million, was comprised of 45% young people aged below 15 years. The policy also refers to the Malawi Demographic and Health Survey (MDHS) to show differences in life expectancy between males (42.8 years) and females (45.5 years). Evidence from the MDHS also shows that education attainment is higher for men compared to women. Evidence from the MICS is used under the theme of family planning to show that despite efforts of making family planning accessible, fertility rates remain high at 6.3% (6.6 in rural and 4.5 in urban areas). Evidence from the MDHS shows high unmet need for family planning (28%) and a total demand for family planning at 62%.

Key informant interviews revealed that the policy was also informed by other evidence including the Behaviour Surveillance Survey, emergency obstetric care assessment, district routine data and reports.

“Yes, we used evidence because if you see in the SRH policy in the preamble, there is so much data that was quoted and those are the documents that we used...” (SRH008, Female, Government).

“... We didn’t conduct a research as such, but we certainly reviewed the documents that we had, we looked at the reports from the districts that we were getting.” (SRH007, Female, Government).

In the SRHR policy, evidence is mostly used in the rationale and background to various areas, which the policy addresses for example fertility rates and maternal mortality ratio from the Malawi Indicators Cluster Survey and knowledge of family planning services from the Malawi Demographic and Health Survey. Demographic data is also presented in the introduction of the policy. However, in some of the policy areas, the policy does not indicate the source of some of the evidence that is used. For example, under reproductive cancers, the policy states: “[s]tatistics indicate that cervical cancer constitutes 78.6% of all documented female cancers” (Ministry of Health, 2009, p. :12), while admitting that there is paucity of data on the prevalence of cervical cancer in Malawi. Further to this, none of the policy strategies refer to research evidence.

There were several sources of evidence. In some cases, key informants argued that implementing partners put forward evidence based on their interests.

“So most of the times you look at ok this package I think worked in another country then [xxx] would maybe bring that and convince the government that let’s try it in our country...so [xxx] would fund that pilot to see how it works in Malawi...after that then that’s when the government would endorse for national adoption.” (SRH002, Female, Funding Agency).

3.3.6. Facilitators of Use of Evidence

One of facilitators of evidence use was the fact that the evidence was available from different partners involved in sexual and reproductive health. Partners like UNICEF and UNFPA had projects that were being implemented and evidence from these was used to inform the policy.

Some key informants argued that hiring of a consultant to review the 2002 Reproductive Health Policy facilitated the use of evidence in the new policy. They argued that the consultant had access to different research studies and data, which he/she then used in the revision of the policy. They also argued that the consultant had time to devote to do thorough review of literature to incorporate into the SRHR policy. In other words, the consultant had the capacity to review and incorporate evidence in the policy document.

3.3.7. Barriers to Use of Evidence

While some evidence was used in the revision of the SRHR policy, some key informants noted several barriers to using evidence. One of the barriers to use of evidence is the absence of proper communication between policy makers and researchers about their research results. One key informant argued that researchers do not package their information in formats that policymakers can easily use, but also that researchers need to highlight the implications of their results on policies. This is usually not clear in research reports.

“The challenge we have with the researchers it ends on research...if you do a research for the ministry for example you give them the report it ends there... it doesn’t go beyond helping the ministry on how they can utilize the results for policy or programming...it doesn’t go beyond that... helping those people that commission the research on how they can move beyond just knowing the situation...being responsive to policy” (SRH003, Female, Funding Agency).

Lack of research evidence for some indicators was also cited as a barrier to the use of evidence. This was especially evident for new issues that were being incorporated in the policy, for example, cervical cancer.

“...finding the actual evidence, for example, on cervical cancer was a problem... And especially when coming up with standards (targets) that’s when we faced the major challenge.” (SRH008, Female, Government).

“I think we don’t have that information anyway for specific areas that have been included in the strategies... And that’s why even the targets are very problematic to indicate, we just use the information that we have and then put up a target which sometimes is not realistic.” (SRH009, Female, Funding Agency).

The other barrier in using evidence was the lack of standardized data collection tools resulting in different organizations having different sets of data according to their needs. This means that even where two partners are implementing similar projects, the indicators used for data collection may be different and hence the data may not be comparable. Further to this, these data collection methods are not sustainable as they only last as long as the organization is implementing the project. One key informant said:

“The first problem is that we don’t have a standardized way of collecting data. We are still relying on the use of registers, so many registers. When a partner is coming up with some support, we introduce probably a hardcover just to document and the health care providers I think some of them are still weak to gather information. They just have that poor attitude to document and probably collect the information.” (SRH009, Female Funding Agency).

4. Discussion

This study sought to understand the status of evidence use in past policy formulation in the health sector in Malawi. Three policy formulation processes were studied, including two processes that developed treatment or condition management guidelines, namely, the formulation of the Malawi Guidelines for Clinical Management of HIV in Children and Adults (2011), and the formulation of the Guide for the Management of Malaria (2007), and one process that developed a policy, namely the formulation of the National Sexual and Reproductive Health and Rights Policy (2009).

The results reveal that the three policy formulation processes drew on evidence in the agenda setting stage or identification of problem stage as well as in the identification of options for responding to the problem. Specifically, the results show that the two guidelines drew considerably on programmatic data collected and analysed regularly in identifying and defining the problem as well in identifying solutions to the problem. The guidelines also drew on regular surveys conducted by the HIV and AIDS and the Malaria programmes such as the sentinel surveys conducted every two years and the Malaria drug efficacy surveys. On the other hand, the SRHR policy did not draw on similar data mainly because these data were not available. The findings show that the ready availability of context-specific data from programmes is an important enabler of evidence use in decision-making. HIV and Malaria programmes have been prioritised by governments and development actors for several years and as such adequate investments have been invested in these programmes to enable regular data gathering and analysis to inform policy and programmatic decisions. On the other hand, SRHR issues, which have not received such priority and investments, lack regular data from programmes from which to draw lessons for informing policy and programme decisions.

Another type of evidence drawn upon in the formulation of the three policies was research evidence. The HIV guidelines cite research from Malawi and elsewhere that had shown that lifelong ART for pregnant and breast-feeding women reduced post-partum mortality in HIV positive women to make the case for the option proposed by the guidelines. The SRHR policy cites various surveys in defining the SRHR problem in the country. Compared to routine data gathered regularly from programmes, research evidence is not used as much in the three policies. This is especially the case in the guidelines documents and could be because of the different functions of guidelines and policies. Guidelines often seek to provide specific guidance to the treatment or management of certain disease conditions in a particular setting. As such, data from the particular setting on the disease conditions and what works or doesn't work as shown by programmatic data becomes lends itself perfectly to supporting decision-making in guideline documents. Policies, on the other hand, provide broad statements on tackling broadly defined issues in a country and therefore lent themselves to the use of broader information and research evidence from the country and elsewhere.

What emerges from the policies is the fact that the research evidence used to inform these policies is not necessarily the best 'gold-standard' evidence available as depicted in the hierarchy of knowledge in biomedicine. Systematic reviews, meta-analyses and randomised control trials are seen as the best gold-standard knowledge in the health sector (Ackley et al 2008). Review of the three policies as well as the interviews with the actors who developed the policies reveal that neither such 'gold-standard' evidence was used in these policies nor was it even sought to inform any of the policies. Notably, systematic reviews are not available on all health issues and they also do not easily lent themselves to informing policy decisions (Lavis et al 2005). However, the fact that the actors who developed these policies did not search for systematic reviews or the best-available evidence on these issues, indicates that actors in low-income countries may not appreciate the importance of using the best-available evidence in decision-making. This lack of appreciation of the importance of the best-available evidence in decision-making, coupled with the limited availability of the best-available evidence, put to question the focus and championing of systematic reviews and other 'top-quality' evidence in evidence-informed policy-making (EIPM). Is EIPM only about the use of 'top-notch' knowledge? So what happens to EIPM when the 'top-notch' knowledge is not available?

The study confirms existing literature that argues that evidence has to compete with other factors to inform decisions (Buse et al 2012; Lin, 2003; Walt, 1994; World Health Organisation, 2007). In the case studies, evidence mainly competed with feasibility of proposed interventions. For instance, in the Malaria guidelines, although evidence showed that Artesunate Amodiaquine was more efficacious than LA, a decision was made to use LA as the first-line treatment because of the impracticality of using Artesunate Amodiaquine. Similarly in the HIV and AIDS guidelines, the lack of country-wide access to laboratory tests for CD4 count informed the decision to not require CD4 count in

order to put women on life-long ART. In the case studies, we see that while evidence was considered, the practicality of proposed interventions on the ground informed the final decision and often this was against the direction that the evidence pointed to.

Apart from the ready availability of programmatic data as an enabler of evidence use in the policy case studies, the presence of Technical Advisors, sponsored by development agencies, within the Ministry of Health emerged as another important enabler of evidence use. It was argued that not only did the Technical Advisors have the skills to analyse routine data and provide advice for decision-making, they also had dedicated time to do this. This points to two important issues. One is the importance of external actors, mainly development partners, in enabling the use of evidence in decision-making (which we shall return to in the next few paragraphs), and the other is the weak capacity obtaining within the ministry both in terms of inadequate numbers of staffing as well as the lack of requisite skills among existing staff to process, interpret and apply evidence in decision-making. The challenge of weak technical capacity in government agencies has been widely acknowledged as a major barrier to evidence use (World Health Organisation, 2007; Newman et al., 2012). The results of this study vividly illustrate this challenge, with the two policy formulation processes based in programmes with Technical Advisors (i.e. HIV and Malaria programmes) drawing more on evidence, whereas the policy formulation process based within the Reproductive Health Division which did not have Technical Advisors drawing less on evidence. This points out the critical need for governments in low-income settings to address such capacity issues in order to embed a culture of evidence use within decision-making.

Returning to the issue of external actors and their influence in policy formulation in the three case studies, the results of this study underscore the critical importance of development agencies in enabling evidence use in decision-making. Development agencies not only put the policy issues on the agenda and helped make the case for policy change (the WHO in the Malaria and the HIV guidelines), they also contributed to providing the evidence that informed the policy options (the WHO sponsored a feasibility study in Malawi on the options to be considered for the HIV guidelines; and USAID-CDC conducted a study on drug efficacy in Malaria treatment that informed the Malaria guidelines). Development partners also provided technical and financial assistance that facilitated the development of all the three policies. With this reality, it is likely that without the support of development agencies neither the policy formulation nor evidence use in policy formulation would have been possible. It is therefore important for development agencies to continue providing support to low-income countries' development efforts in efforts to enable evidence-informed decision-making.

On the other hand, the fact that policy-making is an inherently political process and the fact that Malawi has ceded the policy development process to external actors, raises the question of whose interests the resultant policies serve. When you narrow down to the use of evidence, then the question that arises is: whose evidence gets used in these policy formulation processes given the dominance of external actors? Even then, the influence of external actors in policymaking is not unique to Malawi. Several studies have noted the role of external influences in the formulation of policies. In Ghana, Burris and others (2011) have noted that issues may gain national importance or may be ignored to accommodate a competing priority depending on the extent to which a donor pays attention to it. This finding, therefore, points to the need for reflection on the side of the Malawi government and the need to recommit to owning and investing in policy development in order to ensure that policies are driven by the country's needs and interests.

A major barrier to the use of evidence reported by the actors involved in the three policy formulation processes was the lack of the evidence they needed to make a decision. Actors involved in the development of the SRHR policy, for instance, argued that the lack of evidence on emerging SRHR issues such as cervical cancer, obstetric fistula, and management of infertility, affected the decisions that the policy made on tackling these issues. This finding points to the fact governments make decisions even when there is no evidence. Therefore, it is important for governments to understand the actions they can take to inform decisions in the absence of evidence. One basic action is to commission the generation of evidence, but often poor governments lack resources to commission such studies, or governments just lack the time to commission studies given that research takes time. However, another important action that government's may not be drawing on regularly is the convening of experts to deliberate the issue and provide some guidance based on their expertise and experience. None of the actors interviewed reported that for the issues where there was no evidence, they called on experts for deliberation and advice. Other barriers to the use of evidence in the formulation of the three policies confirmed documented barriers in existing literature including lacking or weak linkages between policymakers and researchers, poor formatting, communication and dissemination of research to policymakers, irrelevant research, and weak capacity to use research evidence (World Health Organisation, 2007; Oliver et al 2014).

5. Conclusion

Based on the findings of this study, there is commitment and deliberate efforts to use evidence in decision-making in the Ministry of Health in Malawi. External actors, specifically development partners, play an important role in facilitating policy formulation, but also in enabling the use of evidence in policy decisions. UN agencies, specifically WHO and UNFPA, stood out as important actors in setting the agenda for policy change in Malawi as well as investing resources in supporting the policy development process and generating the evidence required to inform policy decisions. Other actors, such as USAID and CDC, were also noted as having contributed to generating the evidence used in the policy decisions made. While notable, the contribution of these actors puts to the fore the fact that the Malawi Ministry of Health may not be investing as much resources in enabling the use of evidence in policy formulation. Barriers that need to be addressed to enable increased evidence use in decision-making included lack of evidence needed for policy decisions, weak capacity to find, analyse or interpret the evidence, weak or lacking linkages between policymakers and researchers, and poor packaging, communication and dissemination of research evidence by researchers. Future efforts towards enabling improved evidence-informed decision-making in Malawi's health sector therefore need to prioritise these barriers.

6. Recommendations

Based on the results of this study, we make the following recommendations, which will contribute to ensuring that evidence plays a more central role in policy-making:

- The Ministry of Health should invest in systems, structures and human resources that enable use of evidence in decision-making. For instance, the ministry should invest in regular data gathering and processing systems for informing its decision-making; where these systems exist as seen in the HIV and Malaria programmes, the ministry should strengthen these systems, and where they do not exist as seen in the SRHR programme, the ministry should invest in the establishment of these systems to enable evidence-informed decision-making. The ministry should also invest in staff whose primary role is to analyse routine data and provide information for decision-making in all its programmes so as to ensure that programmes that do not receive a lot of external support such as the SRHR programme do not suffer from lack of evidence for informing their policy decisions.
- There is need for sustained capacity building programmes for Ministry of Health staff in data analysis and interpretation, as well as in finding, appraising, interpreting and synthesizing research evidence for use in decision-making.
- Efforts should be made to improve policymakers' access to evidence including establishing a common repository for all health research in Malawi, this would make evidence search and access easier. Such efforts should also improve research dissemination by researchers through regular forums attended by researchers and policymakers for discussing new research, building capacity of researchers in more effective packaging and dissemination of research.
- Efforts should also be made to improve the linkages between ministry policymakers and researchers. For example, researchers should involve policymakers in their research from the design stage throughout the research process to ensure policymakers' needs are incorporated in the research and to create demand for the research. Similarly, policymakers should involve researchers in the policymaking processes to ensure researchers understand the evidence needs of policymakers as well as the policy process so that they can engage with policymakers more effectively.
- The ministry should invest in the policy formulation process so that this process is not completely driven by development partners who end up providing both technical and financial support to develop policies. While external support is good, over-reliance on external support cedes the policy development process to external actors and this likely affects the use of different types of evidence based on the interests of the external partners facilitating the policy development process.


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8. Appendices

Appendix 1: Template for content analysis

 African Institute for Development Policy Bridging Development Research, Policy and Practice									
Content Analysis Framework for the Utilization of Research Evidence in Policy-Making									
Name of Policy	Actors	Sectors	Policy Content/ Focus Area	Rationale for choice of focus area (were there other options?)	Was research Evidence used in decision making for the specified focus area	How is evidence used? (As backgroundt background/ rationale, to inform intervention)	What was the source of the research evidence	Any indication of use of locally generated research evidence	Was the research evidence weighted?

Informed Consent

Date of interview:

Start time:

Name of interviewee (optional):

Name of organization:

Name of Division/Unit:

Position of interviewee:

Hello. My name is and I work for the African Institute for Development Policy. The African Institute for Development Policy (AFIDEP), in collaboration with the College of Medicine at the University of Malawi, ECSA-Health Community, and FHI 360, is implementing a programme of work with the Ministry of Health on strengthening capacity for data and research evidence use in health sector decision-making in Malawi – SECURE Health. The project is funded by the UK Department for International Development (DFID).

The programme entails working collaboratively with the Ministry of Health and Parliament to design and implement interventions that optimize access and use of data and research evidence in health-related policy decision-making, planning and programming in Malawi.

The aim of this study is to analyse the development of past policies in the health sector in Malawi in order to provide an understanding of the role of research evidence and data in these processes. In particular, we would like to discuss the use of research in the Policy/guideline. The information will guide the design of appropriate interventions to enhance capacity, in consultation with Ministry of Health/Parliament Officials. The survey usually takes 60 minutes to complete. You will not be identified by name in any reports or analyses of the results of these interviews.

Participation in this survey is voluntary and you can choose not to answer any individual question or all of the questions. You can stop the survey at any time. However, we hope that you will participate in this survey since your views are important.

Will you participate in this survey? Yes/No

RESPONDENT AGREES TO BE INTERVIEWED

0 No 1 Yes

I would also like to ask for your permission to record the interview. The purpose of recording is to enable us produce a detailed transcript of our conversation since it is not possible for me to write everything that you will say during the interview. We will ONLY use the audio-recording to transcribe the interview and we will delete the audio file soon after the transcription.

Is it fine for me to record the interview?

IF YES – Go ahead to record the Interview

IF NO – Try to explain again the purpose, and if the answer is still NO, then continue with the interview, without audio recording but take notes with as much detail as possible and type-up the full transcript of the interview within 24 hours.

RESPONDENT AGREES FOR INTERVIEW TO BE RECORDED

0 No

1 Yes

At this time, do you want to ask me anything about the survey?

Signature of interviewee:

Date:

If you have any questions regarding this study, please contact

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Appendix 3 Key Informant Interview Guide

Background

1. (Interviewer, please note sex of respondent]	1. Male 0. Female
2. How many years have you been working in your current position?	0. < 1 year 1. 1-5 years 2. 6-10 years 3. >10 years
3. How many years have you worked in this organization?	0. <1 year 1. 1-5 years 2. 6-10 years 3. >10 years
4. What are your roles for this position?	

Policy agenda setting

1. Why was the policy needed? What issues was the policy trying to address?
2. What were the main policy changes from the previous policy?
3. How was the policy development process initiated? Who was in charge of the policy development process?
4. What did the government seek to achieve with the policy reform?

Policy commitments / Interventions

1. How does the policy aim to address the issues above?
2. In your view, are there any gaps (commitments, interventions) in the policy? What are those gaps?
3. Why do you think the identified gaps were not covered by the policy?
4. How can the gaps be addressed in future?

Actors in policy formulation

1. Which actors were involved in the policy development process and why?
 - What were the roles and interests of the different actors in the policy-making process?
 - What influence did the different actors have on the policy development process and the decisions made?
 - What strategies did the different actors use in getting their interests addressed in the policy development process?
 - Are there any actors that were left out of the formulation process but ought to have been involved? Why do you think they were not involved?

Role of evidence (Research, routine data, grey literature)

2. What was the role of evidence in whole policy development process?
 - What evidence was needed to inform this policy?
 - How was this evidence sourced, synthesized, appraised, and used and who played these roles in evidence uptake?
 - How did evidence inform or influence the initial agenda setting stage where the decision to develop the policy was made? Which specific research influenced this stage?

- How did evidence inform the selection of the policy or programme options made? Which specific research influenced the selection of policy or programme options?
- Was there evidence to the contrary? Why was this evidence not used?
- How did researchers/scientists influence the policy development process? Which specific researchers were involved and what was their role or influence in the policy development process?
- What facilitated the use of evidence/research in formulating this policy?
- Was the policy-making process adequately informed by evidence? How could evidence uptake have been improved?
- In which ways can the role of evidence in health policy-making be strengthened in future processes?
- Do you think evidence was important in the development of this policy? Why?
- 3. What other factors influenced the decisions made in this policy?
 - Contextual factors – religious and cultural beliefs & interests, interests of the political establishment, existing laws, economic status, etc.?
 - Personal interests, values and/or beliefs, political interests, financial interests?
 - Global and regional health processes or decisions?
 - Who played what roles in tabling such factors and what process was followed in deciding which factor was more important than the other?

Barriers/Constraints/Challenges in research evidence use

4. What were some of the barriers in using evidence to formulate this policy?
5. What strategies can be used to overcome these barriers/challenges/Constraints?

Other data sources

6. Among the actors who were involved in forming this policy, who else can we interview with regard to the use of evidence in formulating this policy?
7. Do you have copies of minutes, reports, drafts and other documents that were used in formulating this policy? If you don't have them, where can we get them?

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