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Accelerating Access to New Malaria Vector Control Tools: A National and Global Health Policy Analysis

Thesis submitted in accordance with the requirement of the University of Liverpool for
the degree of Doctor of Philosophy

By

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Statement of own work

I, Oluwakemi Tesfazghi, confirm that the work presented in the thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis. I acknowledge the work of Mr Adama Traore the fieldwork for the key informant interviews, the findings of which are presented in Chapter five and the contribution of my supervisors (Dr Eve Worrall, Professor Hillary Ranson and Dr Jenny Hill) to the development of manuscripts for publication.

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ABSTRACT

Background

New malaria vector control tools hold the promise of sustaining gains in malaria control achieved to date and achieving the goal of elimination set for 2030. However, insecticide resistance has the potential to derail these malaria control achievements. Access to innovative vector control tools is key to surmounting the threat of insecticide resistance and will play a major role if malaria elimination is to be achieved. The aim of this thesis is to gather new evidence and provide insight into strategies for accelerating access to new malaria vector control tools. This is done by examining access to new malaria vector control tools in two national settings (Nigeria and Burkina Faso) as well as at the global level.

Methods

Three retrospective policy analyses were carried out using an analytical framework to guide the selection of key informants (KI), data collection and analysis. Semi-structured interviews were carried out with KIs in Nigeria (2013), Burkina Faso (2014) and at the global level (2014). Interviews were conducted in English (French in Burkina Faso) audio recorded, transcribed and entered into NVivo10 for data management and analysis. Data were coded according to the framework themes and then analysed to provide a description of the key points and explain patterns in the data.

Results

A total of 40 interviews were conducted with policymakers, researchers, donors, multilaterals, Non-governmental organizations and private sector. The synthesized findings of the three case studies show that, in the context of insecticide resistance, the evidence required to facilitate policy change is nuanced and context specific; national policymaking may be well defined and appear to be evidence based, but can be open to being circumvented and hindered by inefficiencies in global policymaking and lack of donor funding; price rather than cost-effectiveness is the key financial variable at the

national level; and no readily identifiable policy champions exist to facilitate global and national adoption of new vector control tools.

Conclusions

This thesis has identified five areas that need to be strengthened in order to facilitate access to new malaria vector control tools by fostering their global and national adoption. The thesis demonstrates that, without a well-coordinated architecture to: facilitate the development of robust and appropriate evidence; support a transparent and timely global policymaking process; diversify the available funding base, and facilitate price reductions without stifling innovation, accelerating access to new vector control tools and achieving malaria elimination goals is unlikely.

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Abbreviations

ACT	Artemisinin Combination Therapy
ALMA	African Leaders Malaria Alliance
DfID	Department for International Development
ECOWAS	Economic Union of West African States
ERG	Evidence Review Groups
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	Global Malaria Programme
IRM	Insecticide Resistance Management
ITN	Insecticide-Treated Net
IVCC	Innovative Vector Control Consortium
IVM-SC	Integrated Vector Management Sub-Committee
LLIN	Long-Lasting Insecticidal Nets
LSM	Larval Source Management
MoH	Ministry of Health
MPAC	Malaria Policy Advisory Committee
NGO	Non-Governmental Organization
NMCP	National Malaria Control Programme
PBO	Piperonyl Butoxide
RBM	Roll Back Malaria
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VCAG	Vector Control Advisory Group
VCTEG	Vector Control Technical Expert Group
WHO	World Health Organization
WHOPES	WHO Pesticide Evaluation Scheme

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1 Introduction, Context and Background

1.1 Introduction

This thesis aims to gather evidence and provide new insights into the available strategies to accelerate access to new malaria vector control tools. This introductory chapter sets out the global malaria context including the contribution of malaria vector control to malaria control achievements to date. The threat, scale, impact and options for addressing insecticide resistance are introduced. The chapter concludes by setting the context for the research, which conducts three retrospective health policy analysis case studies 2 at the national level (Nigeria and Burkina Faso) and 1 at the global level.

1.2 Global Malaria Context

Malaria control has been recognized as crucial to achieving key international health-related targets. Indeed, its control forms part of Sustainable Development Goal (SDG) 3 – Ensuring healthy lives and promoting well-being for all, at all ages (1). Significant progress in malaria control is also central to achieving SDG1 – Ending poverty; SDG2 – Ending hunger; SDG5 – Achieving gender equality; SDG8 – Promoting sustained

economic growth and decent work for all; and SDG10 – Reducing inequality within and among countries (1). Achieving effective malaria control is dependent on attaining and sustaining universal access to effective preventive measures and to appropriate case management (2). Indeed, the availability of vector control tools remains an important factor to achieving malaria elimination as well as the SDGs (3). Vector control is a core preventive measure considered *“an essential component to malaria control and elimination”* (4) and *“remains the most generally effective measure to prevent malaria transmission”* (5). The two core methods of vector control, as recommended by the World Health Organization (WHO), are indoor residual spraying (IRS) and the provision of LLINs to all people at risk of malaria (6).

Progress in malaria control has been recorded over the past two decades. Between 2000 and 2015, malaria mortality rates declined by 60% globally – resulting in an estimated 6.2 million malaria deaths being averted, particularly in children under the age of 5 (3). WHO’s Action and Investment to Defeat Malaria report on malaria showed that 55 countries were set to achieve a 75% reduction in malaria burden by the end of 2015 (2). As of 2013, an estimated 198 million malaria cases occurred worldwide, resulting in over 500,000 deaths, mostly in children under the age of 5 (4). Indeed, malaria remains one of the most significant public health challenges of our day, and is a barrier to economic development. Sub-Saharan Africa carries most of the malaria burden, with two countries, the Democratic Republic of Congo and Nigeria, accounting for almost half of all malaria-related mortality (4).

The global community has pledged to reduce malaria mortality and morbidity by 90% by 2030 (4) and progress in achieving malaria elimination goals has been made, with eight countries recording malaria elimination since 2000 (4). The rapid scale-up of vector control tools, such as IRS and LLINs, is recognised to have led to significant reductions in malaria transmission in a number of countries (4) and will be directly linked to the possibility of achieving malaria elimination (figure 1) (2).

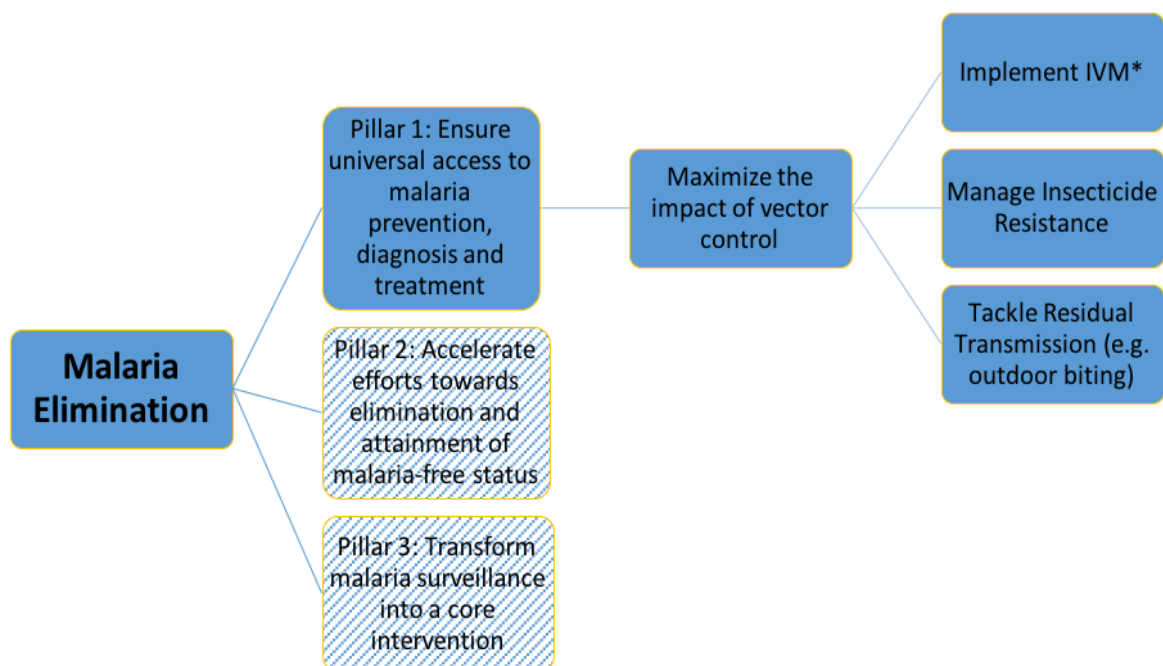


Figure 1. Link between malaria elimination and vector control

*IVM, Integrated Vector Management, adapted from AIM 2016-2030(2)

The ability to sustain malaria control achievements and attain elimination is threatened by a number of challenges, including the availability of sustained funding and political commitment for malaria control, parasite resistance to antimalarial medicines, and vector resistance to insecticides (4). The Global Plan for Insecticide Resistance Management recognises that a collective strategy is required to tackle the issue of insecticide resistance, with the strategy being predicated on five pillars: i) implementing insecticide resistance management (IRM) strategies in malaria-endemic countries; ii) ensuring proper and timely entomological and resistance monitoring as well as effective data management; iii) developing and deploying new, innovative vector control tools; iv) filling gaps in knowledge on the mechanisms of insecticide resistance and the impact of current IRM strategies; and v) ensuring that enabling mechanisms (e.g., human and financial resources) are in place (5).

1.3 Malaria Vector Control Context

Current malaria vector control efforts are based on two main interventions, namely Indoor residual spraying (IRS) and LLINs, with larval source management (LSM) as a supplemental intervention (7). IRS is the application of insecticides on the internal walls of houses in order to kill vectors that come into contact with the insecticide by resting on the wall surface following a blood meal. IRS reduces malaria transmission by killing mosquitoes, thereby reducing the density of adult vectors (8). Bednets act as a vector control tool by forming a physical barrier between humans and malaria-transmitting mosquito vectors. The addition of an insecticide to bednets kills mosquitoes that come into contact with the insecticide. Insecticide-treated nets (ITNs) provide personal protection for those that use them (9). LLINs are ITNs incorporated with long-lasting insecticides that last up to 4 years or 20 washes. LSM involves the management of water bodies that are potential breeding sites for malaria vectors (10) and includes temporary or permanent habitat modification (e.g., clearing drains or filling land) or the addition of chemicals to water bodies to prevent the development of adult vectors (larviciding).

1.4 A Brief History of the Contribution of Vector Control to Malaria Control and Elimination

Vector control has been the linchpin of malaria prevention since the late 19th century (11, 12). Vector control efforts have been recorded as far back as 1899, implemented by Ronald Ross in Sierra Leone; this early effort was documented to be relatively successful but not sustained due to a lack of funds (12). Several noteworthy vector control intervention programmes were also implemented in a few countries in the early 20th century (11).

LSM is one of the earliest forms of vector control and is considered to have contributed to most successful malaria eradication efforts (13-15) before being largely abandoned for a single blanket approach to malaria eradication using IRS (16). By the mid-20th century, the discovery of the insecticidal properties of dichlorodiphenyltrichloroethane (DDT) as well as the establishment of the first expert committee, convened to deal with

the social and economic burden of malaria, revolutionised malaria control efforts (17). This led to the first malaria eradication objective articulated by WHO in 1956 (17) based on IRS using DDT and the mass administration of antimalarial drugs. The reliance on IRS using DDT for the eradication of malaria, while cited as a contributory factor for the failure of malaria eradication (due to insecticide resistance and the lack of funding and political will to sustain efforts), attests to the fundamentality of vector control in any malaria eradication effort. Vector control, notably IRS, was central to the success of malaria eradication efforts in Asia and America during the 1950s and 1960s (18). With the use of DDT, eradication was documented in most of Europe, the West Indies, the Middle East, North America, Australia, Japan, Singapore, Korea, Taiwan, and Sardinia (12, 19). Furthermore, vector control is recognised as the only approach that has led to lasting malaria eradication (20). However, by 1969, it was recognised that, in some areas and particularly sub-Saharan Africa, malaria control was a more feasible goal than malaria eradication. An important lesson learnt from the eradication era was the recognition that every available effective vector control method is required to tackle malaria, taking into account each context's epidemiological and entomological diversity (21).

In the 1980s, studies of ITNs showed that pyrethroids were safe and highly efficacious in reducing all cause childhood morbidity, and that ITNs had an impact on various measures of mosquito biting by both repelling and killing mosquitoes (22). In addition, researchers demonstrated the highly the cost-effective nature of ITNs (23, 24) and the optimal doses of various insecticides with different materials (25, 26).

ITN use can reduce the incidence of uncomplicated malaria by 39% compared to untreated bednets and up to 50% compared to no nets (27, 28). The early forms of ITNs proved successful (29); however, the insecticides used had short lived residual effects and programmes promoting the retreatment of bednets resulted in relatively low uptake rates (29). Thus, over the in the late 1990s efforts focused on the development of bednets treated with long-lasting pyrethroid-based insecticides – LLINs. In some contexts, retreatment programmes are still important for untreated bednets, particularly in regions like South East Asia, where they represent a significant

proportion of bednets sold in the private sector. This thesis recognises the importance of retreatment of bednets in these contexts, but further discussion of this issue is beyond its scope.

It took 20 years from the initial evaluation of insecticide treated bednets (30) to the landmark Cochrane review confirming that they led to a 20% and 50% reduction in child deaths and malaria episodes, respectively (28), and an additional 3 years for a WHO recommendation for universal coverage of LLINs for all populations at risk (31). In sub-Saharan Africa, the percentage of people sleeping under an ITN increased from 2% to 55% between 2000 and 2015 (32).

In 2010, a systematic review reaffirmed the benefit of IRS for malaria vector control, particularly in areas of unstable malaria transmission (33). The efficacy of IRS for malaria control is dependent on the susceptibility of malaria vectors to the insecticide being used, the residual efficacy of the insecticide (i.e., the time-frame during which the insecticide continues to kill vectors following spraying), and the quality and sustainability of the IRS spraying programme (33). As of 2014, 3.4% of the global population at risk for malaria was covered with IRS – a decline of 5% from peak levels in 2010 (32).

Over the past decade, there have been significant advancements made towards achieving malaria control-related goals and the scale-up of interventions has resulted in declines in malaria mortality and morbidity (4). The scale-up of vector control, and in particular the increased coverage and use of LLINs, is considered a major contributor to these achievements. Bhatt et al. (34) estimated that 68% of the deaths averted between 2000 and 2015 were due to bednet use and 10% due to IRS.

1.5 Insecticide Resistance

There is global consensus that insecticide resistance has the potential to derail the malaria control achievements to date (35-40). Insecticide resistance in malaria vectors is defined, in simple terms, as a situation where *“vectors are no longer killed by the*

standard dose of insecticide [they are no longer susceptible to the insecticide] *or manage to avoid coming into contact with the insecticide*" (5). Insecticide resistance has been reported in 53 countries globally (5).

An in-depth analysis of insecticide resistance is beyond the scope of this thesis, however, the main forms of insecticide resistance are described briefly below. For the purposes of this thesis, it is sufficient to consider that insecticide resistance is complex and can occur through various mechanisms and at low levels for many years.

Target site resistance: This occurs due to changes in the site targeted by the insecticide as a result of mutations. For example it can, result in vectors being able to tolerate up to 1000 times the insecticide concentration that would kill susceptible mosquitoes, without being knocked down (5, 37, 40).

Metabolic resistance: Occurs when changes in the vector result in it being able to more rapidly metabolise the insecticide, resulting in a lower dose of the insecticide reaching the targeted site (5). Metabolic and target site resistance are considered the main forms of resistance. However, as mentioned above, it is currently difficult to ascertain the impact this form of resistance has on malaria control failure (37).

Cuticular resistance: This occurs when the tarsal cuticle (the most likely route of entry for the insecticide into the vector's system) thickens, resulting in a reduction in the insecticide's ability to penetrate it and, therefore, in less insecticide being taken up by the malaria vector (5).

Behavioural resistance: This refers to changes in vector behaviour aimed at reducing contact or avoiding exposure to insecticides (5). To date, there is insufficient evidence to assess the extent of this form of resistance. However, it is recognised that genetic changes that lead to vectors shifting from indoor to outdoor feeding could have major implications for malaria control, particularly since the core vector control tools currently only tackle indoor biting mosquitoes (37).

Operational resistance: This refers to changes in vector sensitivity to insecticides as reflected by reduced effectiveness or complete failure of the vector control tool (37). Operational resistance can be conceptualised simply as the manifestation of the various forms of resistance described above on the effectiveness of vector control tools.

1.5.1 The Scale and Impact of Insecticide Resistance

There are major gaps in knowledge of the impact of resistance on vector control. For example, there is insufficient proof to show whether knock down resistance alone leads to operational failure of malaria vector control tools. Further, the extent to which behavioural resistance occurs remains unclear and there is limited evidence of the epidemiological impact of any of these forms of resistance, i.e., whether they lead to a loss of effectiveness of malaria control tools in field settings or to an increase in malaria cases and deaths (5, 41). However, when a tipping point is reached, resistance rises rapidly to a level that can lead to the failure of vector control tools (42). Ultimately, there is consensus that additional research is required to improve our understanding on how this growing trend affects the efficacy/effectiveness of malaria control interventions (37, 41).

Currently, there are only four classes of insecticides approved by WHO for use in IRS (organochlorines, carbamates, organophosphates, and pyrethroids), with pyrethroids being the only insecticides recommended for use on LLINs and the cheapest and longest lasting for IRS (5). However, of the countries reporting insecticide resistance, 75% reported resistance to two or more classes, with the most common form of documented resistance being to pyrethroids, the most frequently used insecticide in malaria vector control (43). For example, Benin, Burkina Faso, Cameroon, Côte d'Ivoire, and Ghana reported widespread resistance to at least two classes of insecticide, whereas Ethiopia reported resistance to all four (5). Furthermore, resistance to one or more insecticide classes has been observed in all other regions of the world (5). Worryingly, these observations are likely an underestimation of the true incidence of resistance given that several countries and programmes do not perform sufficiently robust insecticide resistance monitoring (5).

More often, the mortality and feeding success of resistant vectors (entomological impact) is used as a proxy in defining the impact of insecticide resistance (5). In Benin, trials showed that IRS and LLIN efficacy was reduced when testing in resistant compared to susceptible areas (44). A recent study in Burkina Faso also demonstrated that insecticide resistance is compromising LLIN activity in the southwestern region of the country (45). The most compelling evidence to date of the epidemiological impact of insecticide resistance is the 90% decrease in malaria cases observed in Mozambique and South Africa following a change of insecticides (46-50). More recently, Senegal experienced a rise in malaria cases associated with a significant increase in resistance in the malaria vector population (51).

It is argued that, without concerted effort to halt and reverse the growing trend of insecticide resistance, an increase in malaria cases and deaths will be observed (4). However, as mentioned above, establishing the link between insecticide resistance and epidemiological impact has not been easy to achieve (5).

1.5.2 Insecticide Resistance Management

The potential for insecticide resistance to reverse malaria control achievements and compromise the attainment of malaria elimination goals necessitates urgent action. Lessons of successful IRM strategies can be gleaned from past malaria eradication efforts, agriculture, and other disease vector control activities such as the onchocerciasis control programme in West Africa (5, 52-54). These IRM strategies include i) the annual rotation of two or more insecticides with different modes of action; ii) combining two or more insecticide-based vector control interventions in households; iii) spraying with a given insecticide class in a geographic area and a different one in neighbouring areas; and iv) mixing two or more insecticides from different classes to make a single product (the latter is not currently available for malaria vector control) (5).

1.5.2.1 Insecticide Resistance Management Options for Indoor Residual Spraying

While all four classes of insecticide approved for public health use are appropriate for IRS, there is widespread resistance to pyrethroids, the cheapest and longest lasting (5). This widespread resistance limits the available options for IRM strategies such as rotation. While resistance to other classes of insecticide for IRS is relatively lower, their higher cost and shorter residual effect make them a less attractive option for national malaria control programmes (21, 55). With this in mind, a non-pyrethroid, long-lasting insecticide for use in IRS (Actellic 300CS[®]) has recently been developed.

Actellic 300CS[®] provides an alternative to pyrethroid-based insecticides and extends the residual effect of IRS from 3 to 9 months compared to other non-pyrethroid-based formulations. While more expensive the longer residual effect of Actellic 300CS[®] which surpasses the average peak transmission season in most endemic countries potentially provides a balance against the relative high cost of the product (56, 57). The availability of this new formulation provides a viable option for national malaria control programmes seeking to rotate insecticides used for IRS as an IRM strategy aimed at delaying the emergence/spread of insecticide resistance (56). However, like other non-pyrethroid-based IRS insecticides, Actellic 300CS[®] has a high cost. UNITAID has launched a US\$ 65.1 million initiative to support countries in the implementation of next generation IRS insecticides such as Actellic 300CS[®] at lower prices (58).

WHO Pesticide Evaluation Scheme (WHOPES) was set up in 1960 and its key mandate is to *'collect, consolidate, evaluate and disseminate information on the use of pesticides for public health'* (59). WHOPES establishes the relevant testing guidelines for safety and efficacy, makes recommendations on use after their safety and efficacy assessment, and develops specifications for their quality control and international trade. [Annex 1](#) provides a list of WHOPES approved insecticides for IRS.

1.5.2.2 Insecticide Resistance Management Options for Long Lasting Insecticidal Nets

The increasingly widespread resistance to malaria vector insecticides, particularly to pyrethroids, is especially dangerous for LLINs, considering that, to date, only pyrethroids have been approved by WHOPES for use on LLINs. [Annex 2](#) provides a list of the 16 LLINs approved by WHOPES as of April 2016. Combination LLINs that incorporate the use of non-pyrethroid-based insecticides need to be developed and approved, with WHOPES providing recommendation for their use in areas of insecticide resistance.

Two next generation LLINs, PermaNet[®] 3.0 and Olyset[®] plus, are currently available on the market. Both of these products are treated with a pyrethroid and a synergist – piperonyl butoxide (PBO). PBO does not have insecticidal properties but inhibits the major enzyme families that detoxify insecticides in the vector, and thus can increase the potency of conventional LLINs. PermaNet[®] 3.0 and Olyset[®] plus received WHOPES interim approval as standard LLINs in 2008 and 2012, respectively (60, 61). In 2014, the Vector Control Advisory Group (VCAG) recognised that PermaNet[®] 3.0 has *“increased bio-efficacy compared with pyrethroid-only LLINs in areas where malaria vectors have P450-based metabolic resistance mechanisms that reduce the efficacy of pyrethroid-only LLINs”* (62). In December 2015, the WHO Global Malaria Programme released recommendations on the conditions for use of LLINs treated with PBO (63). The recommendation is for pilot exploratory implementation with robust monitoring and evaluation and deployment where universal coverage of LLIN and/or IRS is not compromised (63).

Two additional next generation LLINs treated with a combination of two insecticides are currently being tested in Phase III trials or are being considered by WHOPES. One of these, Interceptor 2.0, was submitted to WHOPES for approval in 2014, with potential first use anticipated between 2016 and 2018. The second, Olyset[®] Duo, contains an insect-sterilizing agent and thus has a different mode of action than conventional LLINs

(64). AvecNet is currently conducting a randomised control trial of Olyset[®] Duo in Burkina Faso¹ (65).

1.5.2.3 Insecticide Resistance Management and Larval Source Management

The use of LSM to control malaria is significant, particularly in light of behavioural resistance and the over-reliance on pyrethroid-based insecticides. Unlike IRS and LLINs, LSM addresses the issue of outdoor biting vectors at the larval stage and is not dependent on pyrethroids, but rather a wider range and different set of insecticides than those used in IRS and LLINs (16). [Annex 3](#) provides a list of WHOPEs-recommended larvicides for vector control.

In the context of growing insecticide resistance, the reliance of LSM on a different set of insecticides and its ability to tackle both indoor and outdoor biting are important considerations for its modern-day role in malaria elimination. Furthermore, non-chemical biocontrol/bacterial pesticides, such as *Bacillus thuringiensis israelensis* and *Bacillus sphaericus*, which have been shown to be safe and effective at low cost and dosage, can effectively be used for LSM (66). A significant drawback for LSM use is that, in order to achieve significant impact, the implementation (logistics) of an LSM programme can be challenging in settings where there are widespread vector breeding areas, to the point of rendering LSM virtually ineffective (16). Thus, WHO recommends that, in sub-Saharan Africa, LSM should only be implemented as a supplement to LLINs and IRS in clearly defined habitats, particularly in urban areas where malaria vector breeding sites are few, fixed and findable (7, 67). The rise of insecticide resistance necessitates the development of new vector control tools.

1.6 New Paradigms in Vector Control

The Innovative Vector Control Consortium define a vector control paradigm as a mode of delivering an active ingredient to a vector by targeting vector behaviour or its

¹ TRIAL REGISTRATION: ISRCTN21853394 - AvecNet, registered on 3 April 2013.

environment (e.g., ITNs) (68). Vontas et al. (64) note that paradigms are composed of a group of products categorised by the way in which they work. Product categories, in turn, possess a common target product profile.

WHO states that a product or group of products is considered a new paradigm if they satisfy at least one of the following criteria:

- i) tackles a new kind of vector or works in a new setting, covers a new and different human population group, or works on a different mechanism;
- ii) is an existing intervention sufficiently changed to the point where entomological effect is not sufficient to imply an epidemiological effect based on current knowledge;
- iii) when a product is not adequately described by an existing target, product profile validation results in the development of a new target product profile (69).

There are currently seven new malaria vector control paradigms with tools and prototypes at various stages of development – ITNs against resistant vector populations e.g next generation LLINs; insecticide-treated walls against resistant vector populations; attract and kill baits; spatial repellents interrupting human–vector contact; insecticide-treated materials for specific risk groups; vector traps for disease management; and lethal house lures. [Annex 4](#) provides a summary of the new paradigms and examples of product categories and prototypes, as well as the operational settings within which these tools operate as articulated by the VCAG (70).

While the array of potential new vector control tools is cause for enthusiasm, the majority of new paradigms have products currently undergoing small-scale trials and which will need to be tested in large-scale trials expected to last 3 years prior to policy adoption and wide scale use (64), a process that for ITNs took two decades.

1.7 Research Context

This PhD has been conducted as part of the African Vector Control: New Tools (AvecNet) consortium research project. AvecNet is a multi-partner, interdisciplinary consortium funded by the European Commission with the overarching objective of developing and assessing new tools for malaria vector control in Africa. AvecNet specifically aims to ensure the *'sustainability of current intervention strategies by investing in the development and evaluation of new insecticides and approaches to overcome insecticide resistance, designing new tools and interventions that target mosquitoes that evade these current practices and increasing the knowledge base on the biology and behavior of mosquitoes and planning for vector control in a changing environment'*(71) Specifically activities include optimizing existing insecticide based vector control tools; developing new tools to detect insecticide; the testing of new insecticides and formulations; optimizing the delivery of insecticides, by observing the mosquito's response to insecticide treated surfaces and the field evaluation of new tools, or improved methods of targeting existing vector control interventions.

AvecNet emphasises the importance of ensuring a clear pathway for the transfer of a tool from basic science to epidemiological effectiveness and, ultimately, to its implementation (71). As part of this approach, AvecNet has assessed potential new vector control tools from the perspective of community and end-user acceptability via social research activities conducted alongside intervention trials (65, 72, 73). AvecNet also recognises that successful policy adoption is critical to accelerating access to new malaria vector control tools (64, 74). This in turn depends on perceptions and actions of policymakers and actors at the national and global levels, which are addressed in this thesis through the application of policy analysis. Policy analysis is a multidisciplinary endeavour that underpins this research. Policy analysis can be performed either prospectively or retrospectively, and is used to aid the understanding of interactions that bring about the success or failure of a given policy process(75).

1.8 Policy Analysis

Walt et al define health policy analysis as a multi-disciplinary approach to public policy that seeks to explain the interaction between institutions, interests and ideas in the policy process (75). Parsons further states that policy analysis is the processes through which ideas, knowledge, interests, power and institutions influence decision-making. Gilson argues that a key attribute of policy analysis is the understanding that it is a process of continuing interactions between these three elements (76). Policy analysis is used to understand past policy outcomes (retrospective policy analysis) and plan for future policy implementation (prospective policy analysis)(75). Walt et al also recognize that health policies outcomes are influenced by both political and social factors, as well as state and non-state actors including the private sector and international organisations (75). Walt et al argue that policy analysis is central to a comprehensive approach in determining how low and middle income countries can achieve health reforms (77). Health policy analysis has been used in low and middle income countries to examine agenda setting (78), policy adoption and policy implementation (79). Within the context of this research policy analysis forms the lens through which access to new vector control tools are analysed in two national contexts and at the global level.

1.9 Thesis Structure

In Chapter 2, the thesis firstly examines the concept of health policy: its definitions, the main theoretical underpinnings and the frameworks used to understand how policies are made, including the role of evidence in the policy process. The concept of access as it pertains to the introduction of new health interventions is also presented, followed by outlining the foundation for the modified framework used to carry out the three case studies. The current literature regarding the adoption of new health interventions, particularly in relation to malaria and vector control tools is reviewed, highlighting the gaps in knowledge that this thesis aims to address. The chapter concludes by outlining the study's research questions, aims and objectives.

Chapter 3 provides a comparative overview of the methods used to answer the posed research questions, presenting the modified analytical framework, an overview of data

collection and analysis. The chapter concludes by setting out ethical considerations and the steps taken to ensure rigor in the research process.

The first of the two national level case studies, in Nigeria, is presented in Chapter 4. The case study provides an analysis of a contentious decision of nationwide scale-up of larviciding in Nigeria using a product not universally accepted as appropriate for the Nigerian context. The analysis of the decision examines the actors, policy process, context, and evidence used to support the decision. This national level analysis provides valuable insight into the factors that influence vector control policymaking at the national level.

The second national level policy analysis case study and the global policy analysis case study are presented in Chapters 5 and 6, respectively. The two case studies analyse the context, content, processes, actors, power, and evidence involved in malaria vector control policymaking in Burkina Faso and at the global level. The challenges and opportunities associated with the adoption of a next generation long-lasting insecticidal nets (LLINs) are analyzed as a means of identifying the potential challenges and opportunities for accelerating access to new vector control tools in Burkina Faso and at the global level.

A synthesis of the results of three case studies (Chapters 4 to 6) is presented in Chapter 7 along with a discussion on five areas that need strengthened in order to accelerate sustained access to new vector control tools.

The concluding chapter (Chapter 8) reflects on the contribution this research has made to the knowledge gaps identified in Chapter 2, the implications of the research findings for theory and practice, and concludes by identifying areas for future research.

1.10 Conclusions

This introductory chapter has set out the general backdrop against which this thesis is set. The chapter outlined the thesis structure, the global malaria context including the

contribution of malaria vector control to malaria control achievements to date. The threat, scale, impact and options for addressing of insecticide resistance have been introduced. The chapter concluded by setting the context for the research, which conducts three retrospective health policy analysis.

2 Literature Review

2.1 Introduction

This chapter presents a critical summary of the existing literature on the concept of health policy – its definitions and main theoretical underpinnings – as well as the frameworks used to understand how policies are made, including the role of evidence in the policy process. The definition of policy as employed in this thesis is outlined, as well as the concept of access as it pertains to the introduction of new health interventions and the foundations on which the modified framework used to perform the three case studies is based. The current literature regarding the adoption of new health interventions, particularly in relation to malaria and vector control tools is reviewed, highlighting the gaps in knowledge that this thesis aims to address. The chapter concludes by setting out the research questions, aims and objectives.

2.2 Defining Health Policy

WHO defines health policy as *“decisions, plans, and actions that are undertaken to achieve specific health care goals within a society. An explicit health policy can achieve several things: it defines a vision for the future which in turn helps to establish targets and points of reference for the short and medium term. It outlines priorities and the expected roles of different groups; and it builds consensus and informs people”* (80).

Policies can be defined in a number of ways, broadly as a written or unwritten position that directs an organisation’s courses of action (and inaction) over time (81). Policies can clarify official positions, express an organisation’s intent, determine the allocation of resources and set standards (81). Baggott (82) specifically includes statements, documents or programmes of action in his definition of policy. A policy can also be narrowly defined as an individual item in a multi-component policy, a strategy or even a tool, in so far as these relate to the achievement of the organization’s goals (83). Some argue that policy should be evidenced by the organization’s actions (77). However, this definition fails to recognise that failure to adopt a policy (such as a tool) is in itself a

policy, and may result in the failure to analyse the impact of unwritten decisions or inactions.

This mix of tangible (actions, documents and tools) and intangible (inaction and unwritten decisions) concepts makes policies difficult to analyse, but underscores Exworthy's (84) argument on the importance of "*policy being conceptualised as a process, as well as a product*". Therefore, policy analysts need to clearly define the object and scope of their analyses as well as consider the intangible factors. Over the course of this thesis, policy is conceptualised in two ways: as a decision to scale-up larviciding in the Nigerian case study, and as a tool (PBO LLIN) in the Burkina Faso and global studies.

2.3 Theories and Frameworks on Policymaking

Understanding the policy process is an important step in understanding the factors that influence policy adoption. Exworthy maintains that understanding and describing the processes by which policies are made is tricky, as often decisions emerge rather than take place at a point in time (84). A number of models exist that identify elements of the policy making process and their interrelation (85). One of the best known public policy models is the *stages heuristic*, which divides the policy process into four stages: agenda setting, formulation, implementation and evaluation (86, 87). The stages model is underpinned by the theory of rationalism in decision-making, which postulates that decisions are (should be) made through a rational process. Alternatives should be weighed and the most optimal selected (88). March and Simon refine this argument by recognizing that policymakers seek to be rational but are bounded by their individual and collective capacity for logical economic or maximizing behaviors (89).

Variants of the stages model have been developed by policy analysts and define the policymaking process as comprising of broadly similar stages that range in number from four stages (86, 87, 90) to nine stages (91). Policy analysts including Sabatier have criticized these demarcation of policymaking into discrete stages as being flawed because they assume that policy making is a rational and well defined linear process

(92). They argue that it is naïve to assume that issues come to the attention of policymakers and rationality is employed to make the best policy response, resulting in that option being implemented and evaluated. Instead Sabatier asserts that the reality of policymaking is more muddled than the *stages* model represents (92). Furthermore, it has been cited that the *stages* frameworks fail to postulate a causal driver within and across identified stages thus they provide little insight for studies seeking to influence how policies are made (91). In other words, the stages model would fail to explain how new vector control tools reach the attention of the policymakers and what convinces them to adopt implement the vector control tools.

John argues that the policy making process often has no start or end point. He argues that new policies are made within the context of existing constraints and opportunities (93). This is known as the incremental model of policy making which argues that policymaking focuses on small changes to existing policies (95). Greener defines a path dependency as the pre-existing context that creates parameters from which policymakers may find it difficult to diverge (94). It embraces the notion that few, if any, problems are solved once and for all (77). Lindblom describes the reality of the policy making process as muddled in contrast to rational models which he argues are concerned with what ought to happen (96). The incremental model of policy is useful because it is recognized that there are several new paradigms of vector control tools in the pipeline and decisions around the adoption of new one will have to be made in the context of already existing tools. However, many analysts, most notably Dror, criticize the incremental model as being conservative. He argues that there are at least three instances where incrementalism would be inadequate: i) where present policies are wholly inadequate and warrant fundamental change; ii) where problems change so fast or so fundamentally that policies based on past experience would not suffice and iii) where the means for problem solving is expanding to new dimensions (97). In relation to new vector control tools the incremental model does not help prepare or explain how to gain policy adoption of a radically different or a truly novel vector control tool not based on an existing paradigm.

Baumgartner and Jones, in challenging the incremental model, argue that the policy is marked by long periods of little change, which is punctuated by fundamental policy change. They argue that policy monopolies maintain policies in a stable equilibrium over a long period of time until exogenous shocks bring about far reaching change (98). At least two examples of these exogenous shocks exist in the malaria vector control context: the demonstration of the effectiveness of ITNs/LLINs which shifted the policy focus from IRS and the discovery of DDT which shifted the policy focus to IRS in the early 20th century.

Walt argues that the dichotomy of rational versus incremental models is artificial as both models serve to explain different things. The rational model describes the way things *ought* to be and the incremental model the way things *are* (77).

The mixed scanning model of policymaking proposes a middle ground between the idealism of the rational approach and the realism of the incremental approach (81). Amitai Etzioni (99) describes the mixed scanning approach as one that involves a broad sweep of the problem with detailed analysis of components of it. He distinguishes between major and minor decisions that need to be made. He states that policymakers carry out broad analysis of a problem area, with detailed analysis being carried out on important steps which may flow from or lead to a fundamental (major) decision (99). Critics of the mixed scanning maintain that the approach fails to distinguish between major and minor decisions (81).

A useful way to carry out analysis of the policymaking process is to examine theories that explain specific stages of the process. The literature on the agenda setting stage of the policy process provides critical insight into the policymaking process, as they seek to explain why some issues receive attention (77). Kingdon argues that policy windows open (and close) as a result of interactions from three streams: problem, policies and politics. His theory asserts that these three relatively independent streams combine to make the potential for policy highly likely (90). The problem stream refers to issues that are recognised as significant problems. Major events, publication of evidence or feedback from existing policies can work to make an issue be recognised as a problem

(81). The emergency and spread of insecticide resistance threatening the utility of the best available malaria vector control tools arguably, constitutes a problem stream.

The policy (solution) stream refers to the range of competing options available to address the identified problem. These options are proposed and considered by technical specialists for feasibility and acceptability (81). The emergence of new vector control tool options such as the longer lasting insecticide solutions for IRS, next generation LLINs as well as the ongoing research and development across the new paradigms provides a modest range of options for consideration. However, the range of options are limited given that majority of the tools within the new paradigms still need to be proven to be safe and effective for public health use.

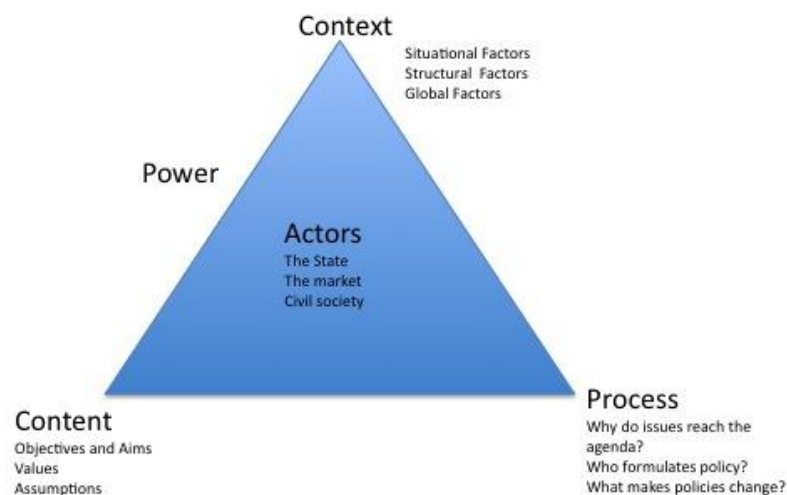
The political (political will) stream refers to the political environment including the prevalent public opinion and the actions of stakeholders such as advocacy groups (81). Kingdon incorporates the role of policy entrepreneurs who attempt to orchestrate the coupling of the streams to bring about their preferred policy solution. Kingdon points out that solutions may need to be advocated for over a long period of time before the appropriate policy window opens (90). Critics of the Kingdon model argue that it fails to explain why some issues do not make it to the agenda. Bachrach and Baratz argue that the ability to keep things off the agenda is as important as the power to get things on to the policy agenda (100). Considering that policy is defined by both the actions and the inactions of decision makers, explaining why and how issues do not get on to the agenda is critical, albeit difficult task.

Kingdon's multiple streams model concentrates on the timing and flow of policymaking, taking a bigger-picture perspective (77). The network model comprises of a set of theories that take into account the wide range of networks and relationships that shape the policy agenda. (101). Network theories are based on the premise that decisions makers, though autonomous, depend on each other within a given policy (93). Furthermore, Kickert et al state that policymaking takes place in '*networks consisting of various actors (individuals, coalitions, bureaux, organizations)*' (102). These positions support the premise that the policy process operates through networks of stakeholders,

each with their own interests and motivations. Networks lobbying to raise the profile of a problem and promoting their preferred solution have become fairly common (84).

A number of types of networks have been identified including policy communities (103), issue networks, advocacy coalition (104) and epistemic communities (101). Bowen and Zwi argue that policy networks like epistemic communities can shape the way policies are formulated, by influencing the way is evidence gathered, synthesized, and disseminated during the policy process. (101).

These theories and frameworks are useful for conceptualising, stages in the policy process as well as examining how actors engage and organise to influence policy outcomes. However, other frameworks, such as the Walt and Gilson policy triangle (105) (Figure 2), provide a more comprehensive analytical lens. Walt and Gilson (105) developed a seminal policy framework which incorporates the policy content, context, actors and process into policy analysis (81).



Adapted from Walt and Gilson, 1994

Figure 2. Policy analysis triangle

Walt and Gilson (105) define context as the environment within which policies are mediated. The context is comprised of systemic factors (political, economic, cultural and social, local, regional, national, and international) that may affect policy (81, 106). International factors play an increasingly important role in national policies, particularly in an area like malaria where the health issue at hand necessitates regional and international cooperation (81). The relationship between the context and the policy is interactive in that the policy is shaped by the context and vice versa (84). Thus, in order to understand how health policies (in this case malaria vector control policies) may or may not change, the extent to which the national and global contexts will impact the policy outcomes needs to be understood (81). The content aspect of the policy triangle examines the details of the policy being analysed, which may be technical or institutional and explores the aims, objectives, intrinsic values, and impact of the policy in question (77).

Actors within the Walt and Gilson framework are at the centre of the triangle and may denote individuals and/or institutions, including organizations such as WHO, private sector companies, the state/government, civil society organizations and interest/pressure groups who seek to influence, direct or change policy (77). A crucial element of the policy triangle is the way in which power is mediated (77). Actors may be facilitated or hindered by their power, which is characterised by *“wealth, personality, access to knowledge or authority”* as well as an individual’s organizational affiliations and status. In essence, who you are, what you know and who you can influence impacts how malaria vector control policies are made. Exworthy (84) states that *“power draws attention to the interplay of interests in negotiation and compromise”*.

Walt and Gilson (105) integrate the process of policymaking into their framework, categorised in line with the prevailing theories on the stages within the policy of process. They further identify pertinent questions with regards to the policy process, such as ‘Why do issues reach the agenda? Who formulates policy? How is policy implemented? What makes policies change?’ For the purposes of this study, the

relevant questions are: Who formulates policy at the national and global levels in relation to vector control and what factors facilitate policy change.

The strength of the policy triangle lies in its approach to policy analysis, recognizing that it is both a product and a process in an arena within which actors with varying degrees of power and influence interact to bring about a policy change. Thus, the framework accommodates the iterative nature of the process while using a systematic approach to its examination. This makes it an incredibly powerful framework for analysing malaria vector control policymaking, which is often comprised of both a tool and a process to adopt it. The '3-i' framework approaches the understanding of the policy process in a similar fashion by incorporating i) interests, i.e., the policy actors' desire to achieve a policy outcome; ii) ideas, encompassing knowledge, values and research; and iii) institutions, which are the formal and informal structures, networks and organizations involved in policymaking (107). Nevertheless, the 3-i framework does not offer significant advantages over the policy triangle with regards to addressing the research questions posed herein. However, various other frameworks do exclusively and more robustly address the issue of evidence and the policy process compared to the Walt and Gilson policy triangle, as discussed below.

2.4 Evidence and the Policy Process

The proponents of evidence-based policies echo theories that conceptualise policymaking as a rational process and argue that the relationship between evidence and policy should be "*direct, sequential and relatively rapid*" (81). However, Young (108) highlights the increasingly prevailing view that the link between research and policy is a complex two-way process shaped by "*multiple relations and reservoirs of knowledge*". Despite the opinions held by scholars criticizing the naivety of rational theories on policymaking, the Mexico Statement on Health Research prescribes that "*health policy, public health, and service delivery should be based on reliable evidence derived from high quality research*" (109).

Key to understanding the use of evidence in policymaking is Weiss’s (110) classification of research utilization into seven models, which range from the ‘problem solving’ model of the use of research in policymaking (which is rational and sequential) to the ‘political’ model, where research is ammunition to support predefined positions. In malaria control, the rational model of policymaking is persuasive because, arguably, more lives will be saved if interventions are adopted and implemented based on the best available evidence.

The Overseas Development Institute Bridging Research and Policy project collected and analysed 50 case studies on the links between research and policy (111). The aim of the analysis was to understand why some research ideas were seen to have an impact on policy while others were ignored. This resulted in the Research and Policy in Development (RAPID) framework (108), which looks at three interlinked areas within which the links between research and policy are facilitated or hindered. The RAPID framework demonstrates that evidence-based policies are a product of the interaction of a myriad of factors, including conducive political contexts, the availability of sufficient and credible evidence, and strong links between researchers and policymakers.

The strength of the RAPID framework within the context of this thesis is that it overtly examines the use of research in policymaking, an area which is implied but not exhaustively explored in the Walt and Gilson policy framework. Furthermore, the RAPID framework summarises key barriers to the use of evidence in policymaking and, along with other studies, identifies the strategies for improvement (Table 1).

Table 1. Barriers and facilitators to the use of research in policymaking

	Barriers to the use of evidence in policymaking	Strategies to overcoming barriers to linking research to policy
1	Absence of personal contact between researchers and policymakers	Embedding research institutions in policymaking bodies (112) Providing policymakers with access to ongoing research, site visits, etc. (112) Involvement of policymakers in research planning and

		design
2	Lack of timeliness or relevance of research Limited time to implement policy change	Inclusion of short-term objectives to satisfy policymakers (113) Collaboration in identifying research questions, aims and objectives (114)
3	Poorly communicated research findings, including lack of definitive message	Clear summaries with policy recommendations (114) Audience-specific communication (115) Use of knowledge brokers (114) Use of credible sources and experts to communicate research (113)
4	Mutual distrust, including perceived political naivety of scientists and scientific naivety of policymakers	Building of trust through sustained personal contact and relationships (113)
5	Poor quality research	Good quality research – applying The Grading of Recommendations Assessment, Development and Evaluation (GRADE) assessments to the research process and results (116)
6	Policy-making staff lack of capacity to access research	Capacity building for policymakers in accessing and utilizing research findings (114)

2.5 Access to New Health Interventions

Given that access to new vector control tools is the policy being examined in this thesis, it is necessary to understand the concept of access and to incorporate issues specific to promoting access within the policy analysis framework used.

Health interventions are useful to the extent that they are available to appropriate population groups (117). Nevertheless, widespread failures to implement cost-effective health interventions persist in both developed and developing countries (118). Haines et al. (118) propose the improvement of uptake of high quality research in the policy process to address this. This thesis will explore the use of evidence in policy with the aim of understanding the complexities surrounding this process and identify possible solutions.

2.5.1 Defining Access

The United Nations Development Group (UNDG) defines access to medicines as having them “*continuously available and affordable at public or private health facilities or medicine outlets that are within one hour’s walk of the population*” (119). Frost and Reich (120) consider the concept of access in relation to medical interventions by looking at vaccines, medicines and diagnostics across a number of diseases, and define access as “*people’s ability to obtain and use good-quality health technologies when they are needed*”. Thus, both UNDG and Frost and Reich conceptualise access as a series of iterative processes, from product development to appropriate use by the end-user.

The concept of wide scale access to new tools is different from the translation of a new/novel tool, wherein translation is said to be achieved once a product demonstrates efficacy in the research environment as well as effectiveness in implementation settings (121). Components of the translation pathway include producing basic science, developing a target product profile, and product development and implementation (121). For example, Vontas et al. (64) developed a framework for validation of new vector control tools, which outlines the pathway of a new product from a basic idea to its approval and uptake. The framework includes the policy adoption of new tools but does not comprehensively assess and provide recommendations for achieving policy adoption. While the concept of translation is clearly embedded in the concept of access, the focus of translation is on the viability of the product/tools and their performance in research and implementation settings. Unlike access, translation does not sufficiently consider wider factors such as the architecture and affordability of a product, components that Frost and Reich (120) demonstrate are key determinants of achieving wide-scale access. This thesis goes beyond the AvecNet project and Vontas et al. [63] conceptualisation of translation and examines the more encompassing concept of access.

Frost and Reich (120) applied their framework to analysing access to a number of health interventions, ranging from female condoms to malaria rapid diagnostic tests, and

demonstrated that ensuring wide-scale access to a new intervention requires detailed analysis of the facilitating and limiting factors, which are organised into four streams: architecture, availability, affordability and adoption (Figure 3). They further argue that this analysis should result in the implementation of strategies around the four streams that promote access to a new tool.

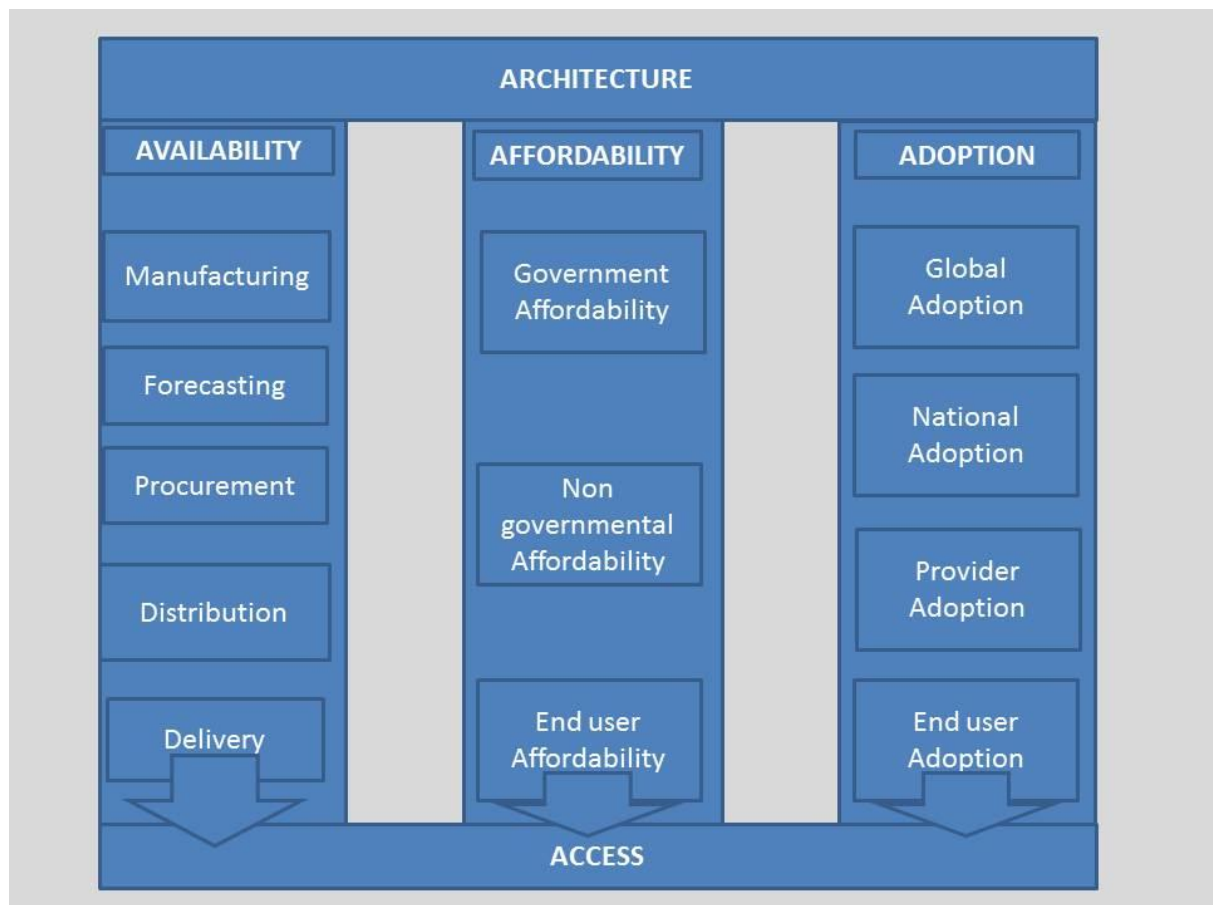


Figure 3. Frost and Reich access framework [70]

2.5.2 Components of the Access Framework

Within the access framework, architecture refers to the network of organisations and the coordinating structure for the introduction of a new health intervention. Availability is comprised of five processes that contribute to the reliable and regular supply of the new health intervention. Affordability refers to government, non-governmental organisation (NGO) and end-user willingness to purchase the health intervention. Adoption at the global, national, provider and end-user levels constitute the final element of the framework. Embedded in adoption is the issue of demand for the

intervention by four main groups of stakeholders: global policymakers, national policymakers, health providers and end-users (120).

At least two other frameworks examining access incorporate similar concepts of availability, accessibility, affordability, adequacy and acceptability in considering access to healthcare and health interventions (122, 123). However, their utility for analysis in the context of the aims of this thesis are limited, since the Obrist et al. (122, 123) framework focuses on consumer level considerations in relation to the health intervention, while Mahoney et al. (122, 123) address adoption issues solely at the global level. In contrast, Frost and Reich (120) provide a more comprehensive framework by incorporating global, national and consumer level considerations into the concept of access from product development to the consumer adoption stage.

The three access frameworks are consistent in the view that access is dependent on national and global policy adoption of new health interventions. As stated, the focus of this thesis is on global and national level drivers of policy adoption. Sub-national issues, while important, are not considered herein.

The following section reviews the current evidence on the adoption of new health interventions, particularly in the area of malaria and vector control.

2.6 Evidence from the Literature: Policy Adoption Process for Malaria Control Tools and Other Health Interventions

In 2008, the first systematic review on the health policy processes of low- and middle-income countries was published (124); only six of the 391 studies reviewed were on malaria and all six focused on treatment policies. Since 2008, a number of studies have been published on malaria policymaking, including vector control policymaking (125-135). These studies show that financial considerations (including the cost of the new intervention) are the most important factors for determining national malaria control policies. They also highlight the importance of scientific evidence, donor preferences, the ability to reduce malaria prevalence, opinions of current leaders, and popular

pressure in influencing the decision to adopt a malaria control policy. At least two of these studies highlight that donor influence is disproportionately dominant in the policy process (30, 127). Another study highlights the added importance of local conditions, logistic feasibility of implementing the policy option, past experience in relation to the current or proposed policy, and community acceptability (125). In a more recent review of barriers to malaria control policymaking in East Africa (136), the authors cite implementability, the lack of capacity, resources and sustained political will power, as well as flaws in the policy process, e.g., the determination and adoption of the appropriate policy option compounded by institutional fragmentation, as some of the most significant barriers to malaria control policy adoption.

In relation to methods utilised in developing this body of literature, all but one (125) fail to explicitly describe the framework with that is used to organise its inquiry and none talk about theoretical underpinning. A number of these studies investigate the policy process, actors and the timelines within which the policy change occur (129-131, 133, 137, 138). However, these studies fail to systematically organise their enquiries into a multi-dimensional framework such as the Walt and Gilson. This limits the scope of the studies analysis and results in only a few of the key concepts (policy content, context, actors, power and process) being analysed with none explicitly considering power. All of the studies utilise the case study methodology which helps provide strong insight and clear descriptions of the process of policy change (130, 139) however, without the multi-dimensional perspective that a policy analysis framework like Walt and Gilson offers, they provide little insight into casual relationships between factors e.g actors and the process or context and the policy process. Three studies (128, 129, 136) use quantitative methods to elicit stakeholder views on the factors or barriers that influence the policy change. While this is a useful way to gather a wide range of perspectives on general factors that influence policy change, they fail to elicit information on the specific factors in relation to a specific policy change. This leaves the malaria policy analysis arena with a paucity of studies that use robust policy analysis methodologies. This is in line Walt et al's (75) findings in 2008 that highlighted the fact that few policy analysis in low and middle income countries explicitly discuss methodology. The paucity of malaria control policy analysis underscores Walt et al's

(75) call for studies that explicitly outline research methods including a robust justification for choice of frameworks, critically apply existing policy analysis frameworks and sound theoretical knowledge, including theories from political and social science.

In contrast to the malaria policymaking arena, significantly more attention has been paid to the adoption of vaccines into health policy. The adoption of vaccines provides the richest available source of insight into the factors that influence policy adoption. A recent systematic review of vaccine adoption identified 26 vaccine decision-making frameworks and 39 examples of vaccine adoption (140).

The combination of the literature on vaccine adoption and what is available on malaria control have been used to draw inferences on the factors that facilitate the adoption of new malaria control interventions. These include:

- i. Finance and economic issues, including the price of the intervention, its cost-effectiveness, and the availability of financing (128, 141-143)
- ii. The influence of national and global actors such as donors and technical agencies (126, 140)
- iii. Global consensus on the appropriateness of the intervention (142)
- iv. The appropriateness for use and technical feasibility of the intervention in the intended context (141, 143-146)
- v. Scientific evidence to support the intervention (through a demonstration of efficacy and effectiveness in various geographic/epidemiological settings) (64)
- vi. Clearly defined evidence requirements for international/national policy recommendations (147-149)
- vii. Research communicated in way that supports policy decisions (150, 151)
- viii. Product championing/coordination amongst stakeholders for policy adoption (128, 151, 152)
- ix. Innovative procurement mechanisms, including robust forecasting plans (142, 149)
- x. The existence of a clearly defined policymaking process (66)

The ten factors outlined above demonstrate that policy adoption of new health interventions can be influenced by factors associated with finance, politics and scientific evidence. While the studies above present evidence of the barriers and facilitators of policy adoption, very few address malaria vector control policy and none address the interrelation of global and national policy adoption of new tools as done in this thesis. Furthermore, as Burchett et al. (140) indicate, within the existing reviews the policy adoption, process itself is poorly examined, resulting in a paucity of robust policy analysis on the adoption of new malaria vector control tools.

2.7 Research Aims and Objectives

This thesis aims to gather evidence and provide new insights into the available strategies to accelerate access to new malaria vector control tools.

This thesis is based on the following premises:

- i. Accelerated access to new vector control tools is required to achieve the ambitious global malaria control and elimination targets that have been set;
- ii. Increasing insecticide resistance requires rapid, clear and evidence-based global and national adoption of new and innovative malaria vector control tools;
- iii. The development of a safe and effective tools is necessary but not sufficient for its wide-scale access (120);
- iv. A better understanding of the vector control policymaking process can provide insights that could accelerate access and
- v. Some of the delays in accessing new vector control tools can be avoided by optimizing their adoption into policy at the national and global level.

The objectives of this study are:

1. To carry out two national policy analyses to identify what factors influence the adoption of new malaria vector control tools at the national levels.

2. To carry out one global policy analysis to identify what factors influence the adoption of new malaria vector control tools at the global level.
3. To identify what opportunities, exist at the national and global levels to accelerate the adoption of new malaria vector control tools.

The underlying assumptions inherent in these lines of enquiry are that:

- Policy processes at the national and global levels are discernible, rational and influenced by factors, such as evidence and finances, that can be optimised to accelerate access to new vector control tools;
- Developing evidence of the effectiveness and cost-effectiveness of the new tool is central to accelerating access to new vector control tools; and
- Unlocking international donor funding is at the core of facilitating access to new vector control tools.

2.8 Conclusions

This chapter has presented a brief introduction to health policy, including the definition of policy which for the purposes of this research encompasses the adoption of new vector control tools. An overview of the Walt and Gilson policy analysis triangle, the RAPID framework and the Frost and Reich access framework was presented herein. These form the basis for the thesis analytical framework to be presented in Chapter 3. A review of the evidence as it pertains to the adoption of new health interventions, particularly in relation to malaria and vector control tools, highlighting the gaps in knowledge that this thesis aims to address. The Chapter concluded by setting out this research's aims and objectives.

3 Methods

3.1 Introduction

This chapter provides an overview of the methods used to address the overall research questions outlined in Chapter 2. It describes the modified analytical framework through which the case studies were designed and the data collected and analysed, based on the Walt and Gilson policy analysis triangle (77) and Frost and Reich Access Framework (120) introduced in Chapter 2. The final sections of the chapter outline the case study selection, study participant recruitment, and data collection and analysis, concluding by outlining the steps taken to ensure methodological rigour and ethical considerations. Throughout the chapter, the rationale and comparative analyses performed are described to justify the methodological choices made in each case study.

3.2 Methodology

As previously described, access to new health interventions is dependent on an understanding of the factors that influence policy adoption at both the global and national levels. Therefore, the research in this thesis is presented as case studies addressing access considerations at both levels.

Case studies are a method of carrying out in-depth investigations of events their real-life context (153) using a range of data collection methods such as interviews, observation and document reviews. Case studies are particularly useful in investigating phenomena that are heavily influenced by their context (153). Yin argues that case studies are useful for understanding complex real life events (153). This makes them ideal for carrying out policy analysis given that context is an important component of policy adoption. Walt et al state that a well-chosen case can provide a valuable basis for comparison, while an unusual case can provide unique insight into factors that facilitate policy change (75). However, a potential shortcoming of the case study methodology are instances where the results are so specific to the event being investigated that there is little room for the findings to be applied or offer broader insight to other events, i.e. the findings from the case study are not generalizable. A strategy to increase

the generalizability of the case study finding is to conduct multiple comparative case studies (75). This is a factor that informed the decision to conduct multiple case studies using a common framework. The case study methodology has been used to explore policy change in malaria control (80, 126, 129, 131, 154) primarily in East and Southern African contexts.

The three case studies presented here were carried out in the West African context and the Global level. The case studies were carried out sequentially with the Nigeria case study being carried first, the Burkina Faso second and the Global last. Conducting the studies in this manner allowed for instruments, frameworks and approaches to be modified and refined as lessons were learnt and incorporated into the research process. However, the dichotomy into national and global levels is somewhat artificial as the access issues discussed traverse these levels, with an inherent inter-relationship between them. The organisation of research into case studies discussing national and global level issues provides a useful structure to the study; however, overall analyses and findings (Chapter 7) will consider the general issues and draw collective conclusions.

A number of underlining views can influence the choice of methods used to answer the research questions. These paradigms are characterized by their position on what is reality? (*ontology*); *How can we know reality?* (*epistemology*) and *What techniques should you use to uncover/discover reality* (*methodology*). An interpretive view to what knowledge is and how it is developed underscored the development of the research question and the methods used to collect data. The ontology of an interpretive paradigm states that reality is socially constructed i.e. there is no single reality or truth rather there are peoples' subjective perspectives of reality (155, 156). The epistemology of an interpretive paradigm seeks to discover and interpret the underlining meaning of events using a variety of methods, which are primarily qualitative and can include case studies (155, 156). In this research effort was made to elicit, documents and understand the key stakeholders' perspectives on policy processes in the three study settings. This is in contrast to a positivist paradigm which states that there is only one reality, and discovers this single reality through measurements made by an objective observer (156,

157). On the other hand, the Subjective paradigm asserts that reality is based purely on perspectives of individuals and all knowledge is what we perceive to be real.

The interpretive stance utilised in this research also differs from the Pragmatic paradigm, which views reality as being constantly negotiated, debated and renegotiated (155). The Pragmatic paradigm seeks to discover knowledge primarily with a view to solving problems/ effect change. While the interpretive paradigm was the primary influence in this research the influence of the Pragmatic paradigm are evident in its results (particularly the synthesis section in chapter 7) given that the aim is to develop strategies to accelerate access to new vector control tools. Finally, the Critical paradigm states that realities are socially constructed and both reality and knowledge are influenced by power relations within the society (156, 158). Elements of the Critical paradigm can be gleaned from the research methods given the deliberate effort to gain insight into power and sources of influence in the policy process.

3.3 Analytical Framework

An adapted version of the Walt and Gilson framework (159) was used to inform the analysis of the contentious decision to scale-up larviciding in Nigeria (Chapter 4) and the role that evidence played in the process using the lens of the RAPID framework (111). The policy triangle is limited when addressing availability and affordability of a new vector control tool as a precursor to its access. Therefore, a modified analytical framework combining the Walt and Gilson policy analysis framework (159) with the Frost and Reich access framework (120) was developed for the Burkina Faso and global level case studies. Two of the four elements (availability and affordability) of the Frost and Reich access framework are synonymous with the four elements of the Walt and Gilson policy triangle. Table 2 shows the modified (Thesis) analytical framework indicating where overlap exists between the two frameworks.

Table 2. Analytical framework of the Thesis

Walt and Gilson concept	Walt and Gilson definition (77) (Policy Framework)	Corresponding Frost and Reich streams	Frost and Reich (120) definition (Access Framework)	Modified (Thesis) Framework
Actors	Individuals, institutions and movements that seek to influence policy	Architecture	The organisational structure and relationships that interact and coordinate availability, affordability and adoption activities, i.e., the network of stakeholders involved in ensuring access to new vector control tools Note although power is implicit in the relationships and interactions of organisations, it is not explicitly considered in this framework	Actors
Power	Power is defined as the ability to influence, and in particular to control, resources		Note Not explicitly considered in the Frost and Reich Framework	Power
Context	Context refers to systemic factors such as political system, type of economy, employment base, national and international actions/cooperation that may affect health policy		Incorporated in architecture	Context
Process	Process refers to the way in which policies are initiated, developed and/or formulated, negotiated, communicated, implemented and evaluated. It incorporates the use of evidence in the policy process using the lens of the RAPID framework (111)	Adoption	Involves gaining acceptance and creating demand for new vector control tools at all levels, i.e., global national and community level Note In this study, the scope of adoption is restricted to policy endorsement and demand for tools by actors at the national and global level	Policy adoption process
Content	The content of the policy, which reflects the interplay between actors, processes and context		Note Not explicitly considered in the Frost and Reich Framework	
		Availability	Involves the logistics of making, ordering, shipping, storing, distributing and delivering new/novel vector control tools Note In this study, national level availability is restricted to ordering (i.e., choosing and procuring a new vector control tool) while, at the global level, it is focused on the development of the tool	Availability
		Affordability	Involves the willingness to invest in a new vector control tool by global organisations and national governments	Affordability

3.4 Case Study Selection

Three policy analyses case studies were performed to answer two overall research questions:

i) What factors, at both the national and global levels, influence access to new malaria vector control tools? ii) What are the existing opportunities, at both the national and global levels, to accelerate access to new malaria vector control tools?

A combination of factors influenced the selection of the three policy analyses to be performed.

The criteria for case study selection were:

- Recent vector control policy adoption/recent decision to scale-up a vector control intervention;
- The relevance of the recent decision to the scale-up new vector control tools aimed at tackling insecticide resistance;
- Feasibility of the study, i.e., relevance to the AvecNet project, country knowledge and local partners for collaboration;
- The need to understand policy drivers in the relevant influential policy context, i.e., both at the global and national levels.

One global level and two national case studies were performed; on the basis that two case studies were sufficient to provide comparisons and reduce the likelihood of eliciting findings that were unique to only one national setting while being a feasible number to conduct in the study timeframe.

The first case study was done in Nigeria. Nigeria was chosen due to its recent decision to scale-up larviciding², which provided an opportunity for a recent national decision around vector control to be analysed and to assess the extent to which policy decisions conformed to the rational theory of policymaking. Further, Nigeria fulfilled the feasibility criterion. The student is

² Professor Ranson personal communication

a Nigerian and who spent a number of years working with the National Malaria Control Programme, thereby providing insider knowledge of and access to stakeholders involved in national malaria policymaking.

The second case study was performed in Burkina Faso since it fulfilled all four criteria for case study selection. In 2010, a decision was made to distribute a next generation LLIN treated with an insecticide and a synergist (PBO LLIN) PermaNet[®] 3.0 in Burkina Faso as part of the national distribution of LLINs in the country³ (satisfying criteria i and ii). The feasibility criterion was also satisfied as the AvecNet project (under which this PhD thesis resides) was running a randomised controlled trial in partnership with the Ministry of Health in Burkina Faso and the Centre National de Recherche et de Formation sur le Paludisme, Burkina Faso (CNRFP), to evaluate the effectiveness of Olyset[®] Duo (65). The combination of the distribution of a PBO LLIN and the network of partners through AvecNet made Burkina Faso an ideal context to explore the challenges and opportunities for the national adoption of PBO LLINs.

The final case study was a policy analysis at the global level. The WHO mandate for health policymaking at the global level is well established (80). As in Burkina Faso, PBO LLINs were used as the object of study to understand the policy drivers for access to PBO LLINs at the global level. Carrying out concurrent national and global malaria vector control policy analysis was an opportunity to provide novel analysis, which as highlighted literature review is currently limited.

3.5 Data Collection Methods

The data collection for all three case studies involved a combination of document review and semi-structured interviews. The fact that this research seeks to understand and explain the factors that influence access to new malaria vector control tools from multiple perspectives within the policymaking context made the qualitative method for data collection and analysis ideal (160, 161). This is in contrast to quantitative methods, which assume that a singular truth

³ Dr N'Fale Personal Communication

may be deduced through the research process (162), making it unsuitable for this study. However, quantitative data such as numbers of LLINs distributed and their cost was extracted to provide additional insight where relevant.

3.5.1 Document Review

An initial document review was performed at the beginning of the research period to gain an understanding of policy analysis, malaria and vector control, and access to new health interventions. These results were used to refine the research question and develop data collection tools. The document review was repeated in order to refine information to specific case studies and gain an understanding of the relevant policy context. The results were also used to identify key informants (KIs) and to refine data collection tools. For example, framework themes were defined and institutions relevant to the framework themes were identified through the document review. Finally, during analysis of the research results, another document review was performed to identify updates to the policy context and triangulate data collected from KIs. [Annex 5](#) provides a summary of the search strategy used to source published papers, including dates, databases and search terms used across the case studies and in general.

Grey literature was reviewed, including national and global malaria policies, strategies and guidelines; national and global malaria vector control policies, strategies and guidelines; organograms and structures of national ministries of health; terms of reference and minutes of meetings of national and global policymaking bodies; policies, strategies and action plans of research, implementing and financing organisations involved in malaria vector control in Nigeria, Burkina Faso and globally. These documents were retrieved during the literature review and through requests to relevant organisations and individuals. Review of published and grey literature provided insight into the policy actors, content, context and processes of global and national vector control as discussed in each of the relevant chapters. Specifically, reviews

provided an outline of the global and national vector control architecture and context, and of the process for global national adoption of new tools.

Document review was also used to identify the key actors (KIs) involved in ensuring new tool availability, affordability and adoption, and to develop the semi-structured interview guide.

3.5.2 Key informant (KI) Interviews

Sample selection: KI sample selection was a two-step process involving the identification of relevant institutions followed by the identification of KIs from each selected institution for participation in the study. [Annex 6](#) provides a sample of the framework used to identify institutions and KIs. The selection of institutions and KIs throughout the study was purposeful, i.e., guided by the institutions and individuals that would provide information and insight to the themes in the research framework while representing a range of perspectives (163). KI lists were also verified during the interview process.

Selection of institutions: Initial document reviews generated data on the national and global architecture, identifying all institutions involved in ensuring the availability, affordability and adoption of new vector control tools at each level. Institutions were categorised as follows: i) Policymaking organisations. At the global level, this refers to the WHO Global Malaria Programme and members of the committees, structures and regulatory mechanisms established to support and provide advice to WHO policymaking functions such as Malaria Policy Advisory Committee (MPAC) and, for the purposes of the study, WHOPES. At the national level, policymaking institutions were considered to be the national ministries of health, including the national malaria control programmes. ii) Research organisations, including academic or research institutions engaged in vector control and/or insecticide resistance research expertise. iii) Private sector, including those institutions in the commercial for-profit sector as well as public-private partnership organisations involved in the development, manufacture and/or sale of vector control tools; iv) NGOs include KIs from national NGOs

implementing malaria control projects. v) Donor organisations, referring to international donor organisations that fund vector control activities such as the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM) and United Kingdom Department of International Development (DfID) and vi) Multilaterals, including United Nations technical agencies as well as multilateral funding institutions supporting malaria control.

Selection of individuals: KIs within each institution were considered the most senior person and/or the individual within the organisation tasked with the overall responsibility for vector control. All KIs were contacted either by telephone or by email to request participation in the study. They were sent an information sheet on the purpose of the research, key research background documents, including the glossary of research terms [Annex 7](#), and the interview guides Annexes 8-10. It was not feasible to interview KIs from every organisation identified, as more than one institution was identified in each category. A number of principles guided the selection of KIs. Firstly, the KIs were selected to ensure that the sample captured all of the perspectives (principle of maximum variation) and efforts were made to include KIs who could speak with expertise (critical cases) on each of the analytical framework themes. Where a KI declined to participate, they were asked to recommend an alternative individual within or outside their organisation that could offer a similar perspective, who was then approached to take part in the study. While the sampling method as described above was purposeful incorporating principles of maximum variation and critical cases, validity was ensured through triangulation of information across all interviewee perspectives, and by the end of the interviews no new information was being elicited from KIs.

3.5.2.1 Interview Guide

Semi-structured interviews with KIs were conducted using an interview guide. The choice of semi-structured interviews allowed KIs to discuss their opinions, views and experiences in detail without the inhibition that closed-ended questions entail (164). In total, 40 interviews were

conducted across all the three case studies (Table 3), representing 88.8% of the number of interviewees targeted to answer the research questions.

Table 3 A breakdown of key informant profiles

	Policy maker	Researcher	Private sector for profit/Product manufacturers	NGOs	Donor	Multilateral	Identified but unable to participate	Total targeted	Total interviewed
Nigeria	3	1	1	5	1	3	1 private sector (Refusal) 1 multilateral (Unavailable)	16	14 (87.5%)
Burkina Faso	4	2	0	3	2	2	1 donor (Refusal) 1 policymaker (Unavailable)	15	13 (86.6%)
Global	4	3	2	0	4	*	1 policymaker (Refusal)	14	13 (92.8%)
Total	11	6	3	8	7	5		45	40 (88.8%)

*Key informants played multiple roles, i.e., an organisation may fit into more than one category, e.g., researcher as well as a policymaker

The guide was developed prior to the interviews based on 5 of the 7 (Content and Context were gleaned from desk reviews) *a priori* themes from the study's analytical framework. The initial semi-structured interview guides (Annexes 8–10) consisted of approximately 15 open-ended questions. However, during fieldwork, the guides were further developed allowing for the incorporation of emerging themes and exploration of developing lines of investigation (164). There was some variation in the guides and data collection methods used between case studies. Across all three studies, all but one interview was audio recorded. Details of steps taken in these instances are given in the relevant chapters (5 and 6).

3.5.2.1.1 Interview Guide Nigeria

The semi-structured interviews (March 2013) for Nigeria aligned more to the Walt and Gilson policy framework (77) and explored the national policymaking process (including use of evidence in the process), context, actors, power and the content of the national policy. The guide was administered in English and face-to-face, allowing observations to be made regarding any non-verbal communication and to seek any clarification if necessary.

3.5.2.1.2 Interview Guide Burkina Faso

The guide for Burkina Faso focused on five of the seven areas of the analytical framework as the policy context and content were gleaned from document reviews. A Burkinabe research colleague from the CNRFP (Mr Traore) conducted 12 of the 13 interviews in French (April 2014). To ensure quality, the researcher provided Mr Traore with an orientation on the research topic and interview guide prior to the commencement of the study, providing knowledge and insight into the aims and objectives of the research. Mr Traore and the researcher conducted four out of the 13 interviews together. After each interview, the audio recording was reviewed, translated and discussed for quality assurance, after which Mr Traore conducted the remaining nine interviews.

3.5.2.1.3 Interview Guide Global

The global study interviews, covering five of the seven areas of the analytical framework, were all conducted by the researcher, in English in June-July 2014. However, since the KIs were located in more than one country, about 50% of the interviews were conducted by telephone. All but one of the United Kingdom-based interviews were performed in person.

3.6 Qualitative Data Analysis

3.6.1 Framework Approach

All three studies followed the framework approach (160) to data analysis; the details of steps in individual studies are outlined in the relevant chapters. The coding framework for the three studies was based on the modified analytical framework. A portion of the chart used for analysis is provided in [Annex 11](#).

The framework approach to data analysis is described by Richie et al. (160) as a *“matrix based analytic method which facilitates rigorous and transparent data management such that all stages involved can be systematically conducted”*. This method of analysis was deemed the most appropriate for this study in order to provide explanations within the policy process as it allows for the utilisation of deductive as well as inductive qualitative analysis, i.e., the use of pre-established as well as emerging themes (165). Thus, given that data collection was performed across three contexts, the framework approach to data analysis provided structure whilst allowing for the exploration of any emerging context-specific issues. This permitted a comparable set of data to be collected whilst considering context-specific issues arising during the course of data collection, which is in contrast to other qualitative methods such as ethnography, which simply describe or narrate events (160).

The framework approach consists of five main steps:

Familiarisation: Immersion in the data through transcribing, reading and rereading the data (160).

Identifying a thematic framework: An iterative process that continues throughout the study using *a priori* and emerging themes in the indexing stage (160).

Indexing: NVivo10 was used to carry out indexing and support the next process – charting.

Charting: This involved the development of matrices where each respondent is allocated a row and the themes are presented across columns, allowing for all KI responses in relation to a given theme to be analysed (i.e., responses across rows) as well as for each theme to be summarised and analysed across all KIs' answers (i.e., responses across columns) (160).

Mapping and interpretation: The development of a matrix allowed for the data to be explored and for areas of congruence and divergence to be identified, as well as for summary positions according to themes and respondent type to be developed and initial conclusions (subsequently interpreted in light of the wider literature) to be drawn (160).

3.6.2 Document Analysis

Key national and global policy documents collected for the preliminary fact-finding review were also analysed for content and context (166). Handwritten notes were used to support the review of each document and capture pertinent points. For content, the documents were reviewed by capturing key messages of the document, gaps in the evidence outlined, and the type of evidence used to support positions/assertions made in the document. For context, documents were reviewed in relation to the wider literature noting authors and affiliation, target audience, timeframe of the document and relevant political/socioeconomic factors that may have influenced its production or content. The analysis of organisational documents in this manner supported their use in triangulating KI

interviews and interpreting findings in case studies in light of the current literature, i.e., whether the findings of this research contradicted or confirmed the literature reviewed.

3.6.3 Synthesis of Findings from the Three Case Studies

The synthesis of the findings from the three case studies was carried out in four overlapping stages. The aim of the synthesis was to systematically compare the three case studies and using the framework approach to produce further insight into the findings from the individual case studies. The first step in the synthesis of the results was the in-depth review of the results of each case study. Secondly, the coding of the findings of the three case studies according to the thesis framework; thirdly the development analytical themes and finally the use of the analytical themes as the basis for developing strategies to accelerate access to new vector control tools.

The first step was a process of re-familiarisation with the data through an in-depth review of the findings. This involved rereading the findings of the three case studies all of which had been conducted at least year before the synthesis was carried out.

The second stage of the synthesis involved the coding of the key findings from each case study according to the thesis framework (the adapted Walt and Gilson and Frost and Reich). This involved collating the findings from each case study in relation to the relevant framework theme. For example, the findings in Nigeria, Burkina Faso and at the Global level in relation to the framework theme – adoption were collated and summarized into a matrix.

The third stage of the synthesis involved the generation of analytical themes. Up to this stage the synthesis exercise had involved collating the findings from the three case studies according to the thesis frameworks. However, this third stage sought to go beyond the findings of the individual case studies by generating higher level analytical themes (167). Therefore, factors that influence policy were elicited from matrix developed in step two.

This involved seeking common factors that either positively or negatively influenced policy adoption in the three case studies. This resulted in eight factors that were found to influence policy (policy influencers in Table 10).

In the final stage, the aim of the synthesis was to use the findings of the three case studies to develop strategies to accelerate access to new vector control tools. Therefore, the implications of each policy influencer were considered with a view to leveraging positive influencers and mitigating negative ones. This resulted in the identification of five areas that required intervention in order to accelerate access to new vector control tools. For example, four of eight the policy influencers are evidence related. Thus, the first of the five areas identified for intervention addresses the evidence related findings from the three case studies.

In order to ensure rigour, the synthesis methods, policy influencers and five areas for intervention were presented to and interrogated by the thesis supervisors. The coding of findings, the development of analytical themes and associated strategies for accelerating access to new vector control tools was an iterative process informed by the results of the three case studies and documents reviewed.

3.7 Ensuring Rigour

In order to ensure the validity of the research and the robustness of its findings, the steps described below were taken to ensure rigour.

3.7.1 Triangulation

The data collected was triangulated, i.e., considered from at least two different points (157). As described above, two data collection techniques were used to ensure the validity of the data and to provide a comprehensive picture of the study (163). Responses from the KIs, where possible, were triangulated using the documents reviewed by looking into the

wider literature on policymaking in order establish similar or contrary explanations for the research findings.

3.7.2 Transparency of Methods and Analysis

Transparency of the research and analyses conducted was achieved by providing a full description of the research process. In addition, KI interview results and interpretation of the data quotes are provided to demonstrate findings.

3.8 Ethical Considerations

This thesis was carried out with a view to ensuring no harm was done to the participants of the research, that their privacy and anonymity was ensured, that their confidentiality was respected, that informed consent was obtained, and that the data collected was not misrepresented when interpreted or disseminated (157, 160). This was achieved by obtaining the following:

3.8.1 Ethical Approval

Prior to commencement of data collection, ethical approval was obtained from the Liverpool School of Tropical Medicine Ethics Committee in relation the studies in Nigeria, Burkina Faso and at the global level. In addition, in Nigeria, ethical approval was obtained from the Nigerian National Research Ethics Committee ([Annex 12](#)); in Burkina Faso, approval was obtained from the National Research Ethics Committee - 'Comite D'ethidue pour La Recherche En Sante' ([Annex 13](#)) as well as the CNRFP Research Ethics Committee ([Annex 14](#)). Approval from the CNRFP ethics committee was required in order for their member of staff to take part in data collection (i.e., KI interviews) in Burkina Faso. The ethics approval from Liverpool School of Tropical Medicine ([Annex 15](#)) covered the global study and no additional ethics approval was deemed necessary.

3.8.2 Informed Consent

Prior to interviews, each KI was provided with a copy of the research information sheet ([Annex 16](#)), a copy of the consent form ([Annex 17](#)) and, where requested, a copy of the interview guide. At the start of each interview, the interviewer went through a printed copy of the consent form with the KI and reiterated what their involvement in the research would be, what would be done with the information provided and that they could withdraw from participating at any time. The consent form asked for preferences to be indicated in terms of use of quotes and permission to be audio recorded. All KIs were asked to sign the consent form before participating in the study. Across the three studies, only one KI agreed to take part in the study but not be audio recorded; in that instance, detailed notes were taken and typed up within 24 hours of the interview. In three instances, once in the Nigerian study and twice in the global study, the KI asked for the recorder to be stopped at certain points during the interviews and then restarted when the sensitive information had been shared. Such information was not quoted or used as part of the formal analysis but added to the context and lens through which the data was analysed.

3.8.3 Confidentiality and Anonymity

Procedures were taken from the research design stage through to the data collection, analysis and dissemination stages to ensure that confidentiality and the anonymity of the KIs was maintained, particularly given that the KIs in this research are relatively high profile individuals, as follows:

- i. Interview data was separated from any means of identifying the KIs (codes linking interview data to individuals were stored separately and securely);
- ii. All data collected was stored securely in a password-protected computer. Only those directly involved in the research (researchers and supervisors) have had access to the primary data files;
- iii. Data from individual interviews has not been discussed or disseminated in ways that might make an individual identifiable;

- iv. In order to avoid the possibility of individual identification quotes have been made anonymous. Furthermore, where requested, each KI was given the opportunity to read their section/quotations of the analysis before it being included in the report and were given the option of not being quoted at all, anonymously or otherwise;
- v. Where direct quotations are used to illustrate a point, they have been made non-attributable to the individual and only the perspective of the individual providing the quote has been indicated, e.g., researcher; vii) Given the relatively small and connected pool of actors in this field, there is a risk that KIs can be identified by their perspective and responses. KIs were fully informed of how the study would utilise their data and opinions so they could moderate their responses accordingly;
- vi. In instances where data has been collected from one individual within a given category – anonymity has still been maintained as interviewees have been sampled from a wider pool of possible respondents (e.g researchers in Nigeria) or the classification of respondent has been broadened. For example in the global study where the policymaker category was broaden to policy advisors in order to include WHO (technically the only policymaker at the global level) as well as its policy advisors structures.
- vii. When writing up the study results, care has been taken to present the arguments in a constructive action-oriented way.

3.8.4 Protection from Harm for Key Informants and the Researcher

The research, and consequently the interviews, focused on decision-making procedures within the malaria vector control field, and did not cause undue physical distress. A potential source of sensitivity was in discussing the intimate decision-making processes within national and global organisations, resource allocation decisions and/or power play with/between institutions. In order to minimise this risk, KIs were reassured of their ability to withdraw from the study at any point; secondly, KIs were encouraged to only share what they felt comfortable sharing and could choose not to respond to some questions if they so

wished. As stated above, on three occasions, KIs opted to go off record and, on a number of occasions, KIs opted not to respond to a question.

Care was taken to choose an appropriate interview time and venue and to keep the duration of the interview to a maximum of 90 minutes so as to avoid any problems with using up valuable working time of KIs.

A potential source of discomfort to the researcher was in the review and dissemination of information provided by influential actors within national and global vector control policymaking processes. Where the findings of the research were deemed to be sensitive, the researcher was guided by her thesis supervisors in the presentation of the results in a manner that maintained the integrity of the research while ensuring diplomacy on sensitive issues.

3.8.5 Reciprocity and Dissemination

KIs will also be provided with an opportunity to access the full study report upon request. Results of Chapter 4 have been published in a peer-reviewed journal ([Annex 20](#)). Results of Chapter 5 have been accepted for publication in a peer-reviewed journal, whereas the results of Chapters 6 and 7 will be submitted for publication in due course.

4 Results: National Malaria Vector Control Policy: An Analysis of the Decision to Scale-up Larviciding in Nigeria

ABSTRACT

Background: New vector control tools are needed to combat insecticide resistance and reduce malaria transmission. WHO endorses larviciding as a supplementary vector control intervention using larvicides recommended by WHOPES. The decision to scale-up larviciding in Nigeria provided an opportunity to investigate the factors influencing policy adoption and assess the role that actors and evidence play in the policymaking process, in order to draw lessons that help accelerate the uptake of new methods for vector control.

Methods: A retrospective policy analysis was carried out using in-depth interviews with national level policy stakeholders to establish normative national vector control policy or strategy decision-making processes and compare these with the process that led to the decision to scale-up larviciding. The interviews were transcribed, then coded and analyzed using NVivo10. Data were coded according to pre-defined themes from an analytical policy framework developed a priori.

Results: Stakeholders reported that the larviciding decision-making process deviated from the normative vector control decision-making process. National malaria policy is normally strongly influenced by WHO recommendations, but the potential of larviciding to contribute to national economic development objectives through larvicide production in Nigeria was cited as a key factor shaping the decision. The larviciding decision involved a restricted range of policy actors, and notably excluded actors that usually play advisory, consultative and evidence generation roles. Powerful actors limited the access of some actors to the policy processes and content. This may have limited the influence of scientific evidence in this policy decision.

Conclusions: This study demonstrates that national vector control policy change can be facilitated by linking malaria control objectives to wider socioeconomic considerations and through engaging powerful policy champions to drive policy change and thereby accelerate access to new vector control tools.

4.1 Introduction

The scale-up of vector control has been critical to the reduction in malaria transmission seen over the past decade (5). Key tools for vector control include LLINs and IRS (168). In sub-Saharan Africa, the percentage of households owning at least one insecticide-treated net increased from 3% to 54% between 2000 and 2013 (168), with the number of nets delivered to malaria endemic countries by manufacturers increasing from 6 to 136 million between 2004 and 2013 (168). However, new vector control tools are urgently needed to combat the increasing resistance that is threatening the effectiveness of existing insecticide-based interventions (5, 37) and to control malaria vectors not targeted by current interventions (e.g., those that bite outdoors).

LSM is the management of water bodies that are potential breeding sites for malaria vectors. It includes habitat modification or the addition of chemicals to water bodies to prevent the development of adult mosquitoes (larviciding). Larviciding has been recognised as a valuable addition to malaria vector control in specific settings. WHO recommends that, in sub-Saharan Africa, LSM should only be implemented as a supplement to LLINs and IRS in clearly defined habitats, particularly in urban areas where malaria vector breeding sites are few, fixed and findable (7, 67). In 2012, national malaria control programmes in six African countries reported using larviciding (67).

In recent years, Economic Union of West African States (ECOWAS) has generated a renewed interest in scaling-up larviciding in West Africa. A tripartite agreement between ECOWAS, Venezuela and Cuba was signed in 2009 to provide financial and technical support to scale-up larviciding in the region with a view to eliminating malaria. Technology transfer for the establishment of microbial larvicide factories in Ghana, Nigeria and Cote d'Ivoire forms part of the agreement, in a bid to create jobs and make larvicides readily available in the region (169). Microbial larvicides have been shown to be protective against malaria, but only one strain (*Bacillus thuringiensis* subsp. *israelensis*, strain AM65-52, WG) has been approved for larviciding by WHOPES (170). The ECOWAS larviciding plans involve the use of two larvicides produced by the Cuban

company, Labiofam. These larvicides, Bactivec® (*Bacillus thuringiensis* SH-14) and Griselesf® (*Bacillus sphaericus* stump 2362), do not currently have WHOPES approval.

Malaria is endemic in Nigeria and remains a serious public health problem with 97% of the total population at risk of infection (171). LLINs are the main prevention strategy in the country, with the current National Malaria Strategic Plan (NMSP) aiming for 80% LLIN ownership and use by 2013 (172). However, only 41% of households have at least one LLIN (171). IRS is considered a complementary strategy to LLINs in Nigeria and has been piloted in some states (coverage 1% within the targeted states), with the objective of being scaled-up to cover 20% of the targeted states' population, primarily in urban areas, by 2013 (171). LSM (including larviciding) is included in the current NMSP (172, 173), but its use to date has been extremely limited. Thus, plans to scale-up larviciding nationwide, using non-WHOPES-approved products, represents a deviation from the current malaria control strategy in Nigeria.

Given the alarming rise in insecticide resistance in Africa, it is likely that many countries are going to have to consider changing their vector control policy and deploying additional vector control interventions. The decision to scale-up larviciding in Nigeria provided an opportunity to investigate the factors influencing policy adoption and assess the role that actors and evidence play in the policymaking process in order to draw lessons that help accelerate the uptake of new methods for vector control.

4.2 Methods

4.2.1 Analytical Framework

A review of the literature on policy analysis was carried out to identify suitable analytical frameworks for policy analysis. An analytical framework which combines the policymaking context, actors, process, content, power (77), and the role of evidence in policymaking (151) was developed (Figure 4 and

Table 4).

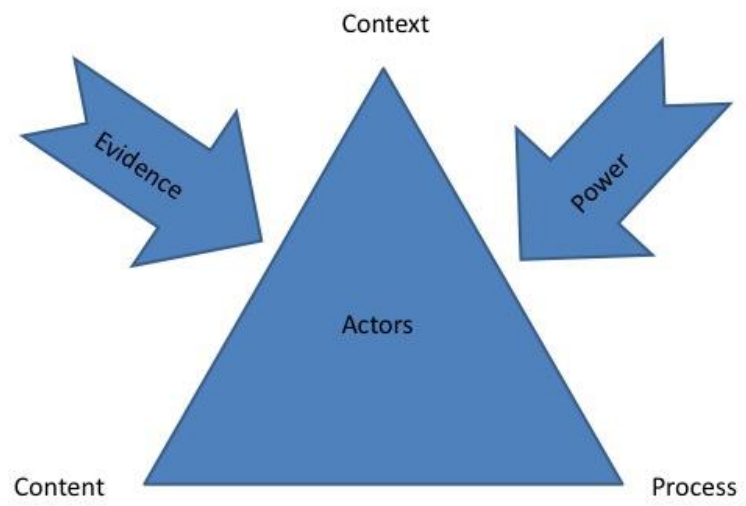


Figure 4. Analytical framework

Table 4. Definitions of terms used in the Analytical Framework (Adapted from Walt and Gilson [103])

Framework Category	Definition
Context	Systemic factors, including political, economic and social, at national and international levels, that influence vector control policy
Actors	Stakeholders (individuals or organisations) that make/influence vector control policy
Process	The way policies are developed
Content	The technical content of the specific policy under analysis
Evidence in policymaking	“Any form of knowledge, including, but not confined to research, of sufficient quality to be used to inform decisions” (81)
Power	The ability to influence, and in particular, the ability to control resources; power is characterized by authority, finances, and access to knowledge

The framework was used to guide all aspects of the study from the identification of documents for the desk review, identification of KIs, development of study instruments, and data analysis. The concept of power, which can be expressed in various ways, is a crucial element of the Walt and Gilson framework (77). In this article, we investigate a number of dimensions of power expressed in the policy process including ‘decision-making’ (174), ‘agenda setting’, (175), ‘thought control’ (176), and the ability to undermine influence (177). Recognising that power is methodologically difficult and sensitive to investigate (79, 178), we sought to gather information by asking questions on which actors carried the most influence in the policy process and why.

4.2.2 Document Review

A review of published and unpublished national documents was undertaken to understand the national vector control policy context, identify the content of the

national vector control policies, identify the key actors involved in national vector control, and inform the development of the semi-structured interview guide. Documents reviewed included national malaria policies, strategies and guidelines; national malaria vector control policies, strategies and guidelines; organograms and structures of the Federal Ministry of Health (FMOH); and terms of reference and minutes of meetings of national policymaking bodies; policies, strategies, action plans, press releases and web pages of policymaking bodies as well as research, implementing and financing institutions involved in malaria vector control in Nigeria.

Documents were sourced through online searches (Google Scholar and PubMed) and requests to relevant individuals and organisations. The review was supplemented with documents identified by stakeholders during interviews. To guide the document review, different categories of policy (health, meso and macro) and strategy, as used by Mays (179) and Buse (81), were defined (

Table 5).

Table 5. Definitions of levels of policies

Term	Definition
Health Policy	Decisions, plans, and actions that are undertaken to achieve specific healthcare goals within a society; it defines a vision for the future which in turn helps to establish targets and points of reference for the short and medium term; courses of action (and inaction) that affect the set of institutions, organisations, services and funding of the health system
Macro-level policies	National high level policies that are generally broad in nature and require several inputs to achieve their aspiration, e.g., reduce child mortality
Meso-level policies	National programme level translation of a macro policy into a working structure for an implementable programme, e.g., universal coverage of LLINs, targeted use of IRS
Strategy	Strategy is the direction in which the human and physical resources will be deployed and applied to achieve the objectives of the policies, e.g., universal coverage of LLIN (the policy) through the free mass distribution to households (the strategy)

4.2.3 Identification of Key Informants (KIs)

The document review identified a broad range of stakeholders involved in the vector control policymaking process in Nigeria. These were categorised as policymakers, researchers, private sector representatives, multilateral agency representatives, and NGO representatives. For the purposes of this study, policymakers include staff of the FMOH working in the National Malaria Control Programme (NMCP); NGOs include respondents from national NGOs implementing malaria control projects; multilaterals include United Nations technical agencies as well as multilateral funding institutions supporting malaria control; researchers include those working in academia as well as those in national institutes of research; and private sector refers to those in the commercial for-profit sector involved in the sale of vector control tools and insecticides. KIs were purposefully sampled to cover a comprehensive subset of the national stakeholders and represent each stakeholder category.

A list of KIs was drawn up and contacted to request interviews. A greater number of participants were interviewed from the NGO category as they made up the largest number and diversity of organisations and individuals contributing to the policymaking process. The initial list of KIs was expanded to include additional KIs identified during interviews.

All KIs were anonymised by assigning interviewee numbers so that their names and affiliations/institutions were not identifiable. However, quotes are assigned to their stakeholder category, e.g., policymaker or NGO, in order to highlight their perspective.

4.2.4 Data Collection

The interviews followed a semi-structured, open-ended format and were structured to explore the context, actors, process, content, power, and the use of evidence in both i) national vector control policy decisions and ii) in the planned scale-up of larviciding. See [Annex 9](#) the interview guide. In March 2013, the researcher conducted the interviews in English in Abuja, Nigeria. The interviews were transcribed by a transcription service and the researcher checked all for accuracy.

4.2.5 Data Analysis

The researcher entered interviews into NVivo10 for data management and analysis, and coded data according to the pre-defined themes in the policy framework using content analysis. Key themes were then summarised into areas of consensus and divergent views across stakeholder perspectives, and quotes used to illustrate key themes. All authors were involved in the analysis and interpretation of data.

4.3 Results

A total of 14 national level stakeholders were interviewed: three policymakers, one researcher, one private sector representative, four multilateral agencies, and five NGOs. The interviewees were a comprehensive subset of the potential respondents. All key in-country Roll Back Malaria (RBM) and 14 of the 20 members of the Integrated Vector Management Subcommittee (IVM-SC) (the main technical body coordinating government and stakeholder input into vector control policy) were interviewed, encompassing all identified stakeholder categories. Table 6 presents the matrix of all *a priori* themes and sub-themes that emerged from analysis.

Table 6. *A priori* themes and emergent sub-themes Nigeria Policy Analysis

	A Priori Themes from thesis analytical framework	Emergent Sub-themes
1	Context	-
		Larviciding Context
2	Actors	Policy/strategy decision making actors
		Advisory/technical Actors
		Consultative Actors
		Evidence generation Actors
		Larviciding Actors
3	Process	Larviciding policy process
4	Content	Larviciding Policy content
5	Evidence in policymaking	Larviciding Evidence in policymaking
6	Power	

The narrative for the results is based on the document review and KI perceptions. The normative process is as described by the Framework for the coordination of malaria control programme in Nigeria (180) and the WHO Malaria Programme Review 2013 (181) supplemented by the respondents' perceptions of the 'normal' policy process. The larviciding decision-making process is then compared and contrasted with this 'norm'.

4.3.1 Normative Vector Control Policy Analysis

4.3.1.1 Context

Nigeria is a Federation of 36 states, with three tiers of government (federal, state and local), each of which has a constitutional mandate to formulate and implement health policies and programmes (181). The primary effect of the federal nature on the vector control policymaking context was the recognition by all respondents that, while the federal government has oversight of health policy, states can choose which vector control strategies to resource and implement based on their local context.

“You see the nature of Nigeria is such that even when policies are made in the national level it is now left to the State to adopt it” (Researcher)

Vector control policymaking is heavily influenced by WHO policies and recommendations of universal coverage of LLINs and the scale-up of IRS.

“... We align A LOT with the Global Malaria Programme, WHO” (Policymaker)

The health policy context is also influenced by the NMCP’s role in contributing to the wider national health, social and economic development objectives as articulated in the 2010 Nigerian National Strategic Health Development Plan (182) and the Nigerian Vision 2020 strategy (183). National policy documents revealed that national malaria vector control policymaking largely involves meso-level policies and decisions around appropriate vector control strategies, i.e., the working structure of implementation. Thus, when KIs were asked about policymaking, they invariably spoke about strategy decision-making.

4.3.1.2 Actors

Actors involved in vector control strategy decision-making generally participated in one or more of four main capacities: i) policy/strategy decision-making; ii) advisory/technical; iii) consultative; and iv) evidence generation. Figure 5 presents a synthesis of respondents’ views on the actors and their roles in the strategy decision-making process.

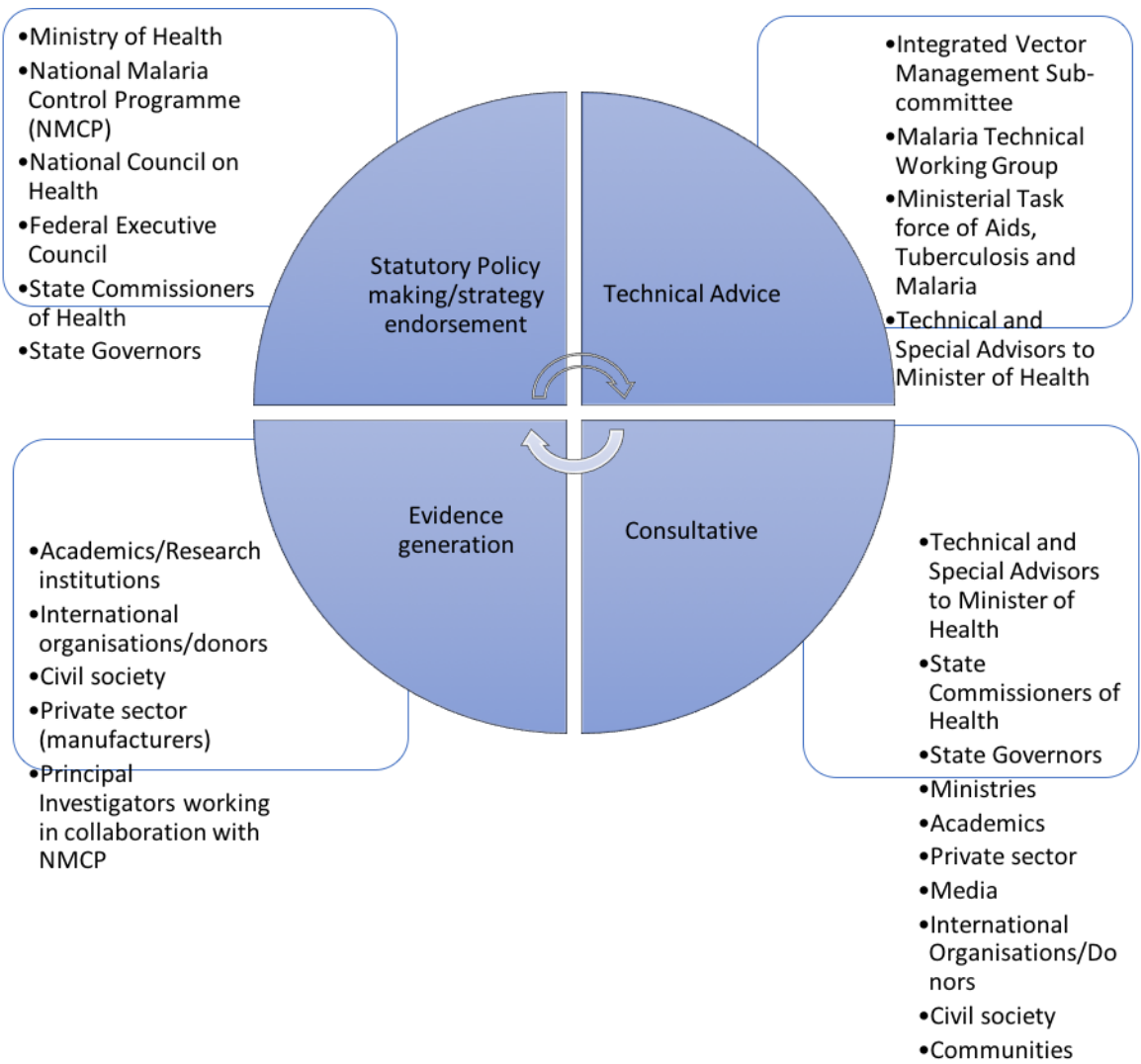


Figure 5. Functions of actors in vector control policymaking

All KI's recognised that the FMOH has ultimate responsibility for health policymaking in Nigeria. The NMCP, as a department of the FMOH, executes policy and fulfils a coordination role. States have concurrent jurisdiction to make policy and strategy decisions.

“National malaria control program is statutorily responsible for policymaking, as a division in the federal ministry of health because, you know, in Nigeria health is decentralised, national, state and then the local government levels” (Policymaker)

Respondents cited the ministries of education, information, women's affairs, environment, agriculture and finance as stakeholders in the vector control strategy decision-making process. Regulatory bodies such as the National Agency for Food and Drug Administration and Control, who oversee the use of products such as insecticides, were also cited as being critical to vector control strategy decision-making and implementation.

Advisory/technical: All partners involved in malaria control in Nigeria are members of the RBM, led by the FMOH (181). They provide advice to the NMCP, helping steer the overall direction of malaria control activities. As a group, they engage with the strategy decision-making process through the Ministerial Coordination Committee on AIDS, TB and Malaria (181), which is composed of three technical working groups (one for each disease). The Malaria technical working group has six sub-committees (mirroring the six NMCP departments) including the IVM-SC. The main technical input into vector control strategy decisions by stakeholders is through the Integrated Vector Management Sub-Committee (IVM-SC) (180).

Consultative: KIs recognised that stakeholder consultation and consensus building is an integral part of the vector control strategy decision-making process. While there were no clearly defined junctions where consultations take place, it was recognised, across all respondent categories, that consensus should be built across a wide range of actors to facilitate strategy adoption and successful implementation.

“It is recognised that malaria control is a collective responsibility and that in coming up with a strategy the platform for debate needs to be expanded to segments of the public, private, civil society” (NGO)

Evidence generation: All KIs recognised that WHO recommendations provide the first line of evidence used to support or oppose a vector control strategy. However, it was also recognised that WHO recommendations are broad, leaving room for tailored interpretations at country level depending on local context.

“... but we cannot just grab it [evidence] and change our policy ... everything that comes into the country must be piloted, so the evidence we generate from that pilot will inform our decision as to whether we can include it in our policy” (Policymaker)

The NMCP coordinates with researchers from academic and research institutions to test new products in local trials for vector susceptibility and community acceptability. KIs from the public and private sector reported that the norm is for manufacturers to finance these trials with the NMCP and researchers overseeing the testing. This locally generated evidence is a prerequisite for the adoption of a vector control strategy, particularly in determining which insecticides to use.

“Everything that comes into the country that has a potential of adding value into vector control must be piloted, so the evidence we generate from that pilot will inform our decision as to whether we can include it in our policy” (Policymaker)

Research institutions, such as the National Institute of Medical Research and individuals from a number of universities at national and, in some cases, state level, also participate in the IVM-SC. However, without a clearly formalised link or tradition of commissioning research by the NMCP this interaction is more opportunistic and based on personal relationships.

“... The country as a whole does not have a health research plan and so when people do research they do research to publish, to get promotion ... there is no formal channel, if

I find something that is interesting the only thing I can do is talk to my director who can then call a press briefing” (Researcher)

4.3.1.3 Policymaking Process

Interviewees from all categories reported that the normal policy process is initiated by a recognised failure in this strategy, the potential for new funding or the availability of new evidence. The IVM-SC is the forum for debating the need for, and evidence in relation to, a strategy adoption or change (180). Interviewees all agreed that strategy is normally developed primarily by the NMCP in collaboration with the members of the IVM-SC, and channelled to the national coordinator and then the Minister of Health for endorsement with consultation of wider stakeholders at key points in the process.

“These sub-committees are made up of partners who are experts ... so when a policy is about to be made, these partners come together and brainstorm and take a decision on if that policy will benefit the country and if they think it would, then they work on it and then send it to the Honourable Minister of Health for him to ratify” (NGO)

In some instances, the decision is referred to the National Council on Health (NCH) and the Federal Executive Council (FEC). While there was uncertainty around what factors trigger the involvement of NCH and FEC, the use of government funding was cited as one potential factor.

“A lot of time if that policy involves Nigeria’s money it will have to go to the FEC” (NGO)

4.3.1.4 Content

The policy targets and progress against them for malaria vector control in Nigeria are summarised in Table 7.

Table 7. Targets and progress: malaria vector control in Nigeria

Intervention	Progress to 2010 (184)	2013 Target (172)
Indoor Residual Spraying (IRS)	1% of target population received IRS	At least 80% of targeted population protected
Distribution of Long Lasting Insecticide-treated Nets (LLINs)	42% ITN household ownership and 29% use achieved	At least 80% of households with two or more LLINs/ITNs and 80% use by 2013
Larviciding	Piloted in four states	As appropriate in some selected areas

4.3.1.5 Evidence

When asked about evidence, KIs cited a wide range of sources as trusted forms of evidence. These included WHO recommendations, results from household surveys, systematic reviews, meta-analyses, published literature, implementation research, feedback, and results of locally generated evidence.

“First and most important will be WHO recommendations, second will be published literature and documents from RBM working group, and then the last will be lessons learnt documentation and reports” (NGO)

KIs viewed scientific evidence as being useful for lobbying, creating awareness, documenting objective positions, defending decisions, and catalysing change. However, it was recognised that the necessary evidence was not always available. Furthermore, different stakeholders value and prioritise evidence differently. For example, respondents involved in funding malaria, typically external donors, appeared to place more value on the use of cost-effectiveness in decision-making.

“...most of it is donor money, so donors are more aware of trying to get the best bang for their buck” (NGO)

“Cost-effectiveness has been a concept of donors, UN agencies, partners and not government, sensu stricto” (Multilateral)

Whereas policymakers prioritise locally generated evidence.

“What I am trying to say is that, local evidence is very critical, but you must compare it with the standard” (Policymaker)

Finally, it is recognised that, in the process of decision-making, evidence can be ignored. As the debate proceeds from the technical to the political levels, wider political and socioeconomic factors can come more strongly into play.

“But the disconnect is when it gets to minister of health a lot of political influence comes into play” (NGO)

4.3.1.5.1 Power

Interviewees identified two main groups of actors as having the most influence in the policy process. First, all stakeholder categories recognised the national and state government’s mandate to endorse policy decisions, thus conferring significant influence over the process.

“For national policymaking, policy change decision-making, definitely as I told you before is the government” (Multilateral)

Second, donor influence was viewed as a key driver in the policy process. Respondents generally viewed the biggest catalyst for policy change as donor funding with one respondent citing the Global Fund to Fight AIDS, Tuberculosis and Malaria as an actor that has been able to utilise its financial power to drive through a number of policy changes.

“The potential for new funding could drive a policy process, for instance if a donor has an interest in helping in the country changes its policy ... And this is very common with

Global Fund, for instance it has been able to drive a number of policy changes that go faster than ordinarily because the motivation to change the policy is there” (NGO)

4.3.2 Larviciding Policy Analysis

4.3.2.1.1 Context

One of the key factors that facilitated the decision to scale-up larviciding was its potential to contribute to national economic development objectives through the technology transfer and the establishment of a microbial larvicide factory in Nigeria.

“In a country like Nigeria definitely there is interest to see more job creation, more wealth creation” (NGO)

“At the point at which an intervention is targeted at economic development but is said to have benefits for malaria control be it remotely or otherwise, and the audience for that has a bigger agenda and malaria control is just the smallest part of it, the tendency is that the malaria message gets drowned out” (NGO)

These views recognise that contributions to the wider socioeconomic context can be highly influential in malaria vector control strategy decisions.

4.3.2.1.2 Actors

When asked about the actors involved in the decision to scale-up larviciding in Nigeria, interviewees cited ECOWAS, the office of the Presidency of Nigeria, and the Minister of Health. None of the interviewees mentioned that the decision had been technically debated at the IVM-SC level. A number of actors who normally participate in vector control policy decisions felt excluded from the larviciding decision, particularly those that play advisory, consultative and evidence generation roles.

“It’s a closed [discussion] ... in fact it’s not something we should talk about. That’s why the donor agencies or development partners in Nigeria are against that project, because it is shielded from them” (Private sector)

“The discussion on larviciding did not include donors” (NGO)

4.3.2.1.3 Process

Interviewees reported that the decision-making process for larviciding deviated from the normal vector control decision-making process. The process flowed from the top (ECOWAS and presidential levels) to the bottom (NMCP level). The prevailing perception by all interviewees was that decisions were taken at high levels.

“There is nothing people like us can do where the minister meets and ECOWAS takes a decision that this is what we want to do” (Researcher)

The normal vector control policy process is contrasted with the larviciding process in Figure 6. The larviciding decision process, as described by the respondents, was shorter, appears to have been started by a decision at the highest levels of government, and circumvented a number of policy processes and actors that are reflected in the normal processes of vector control policymaking.

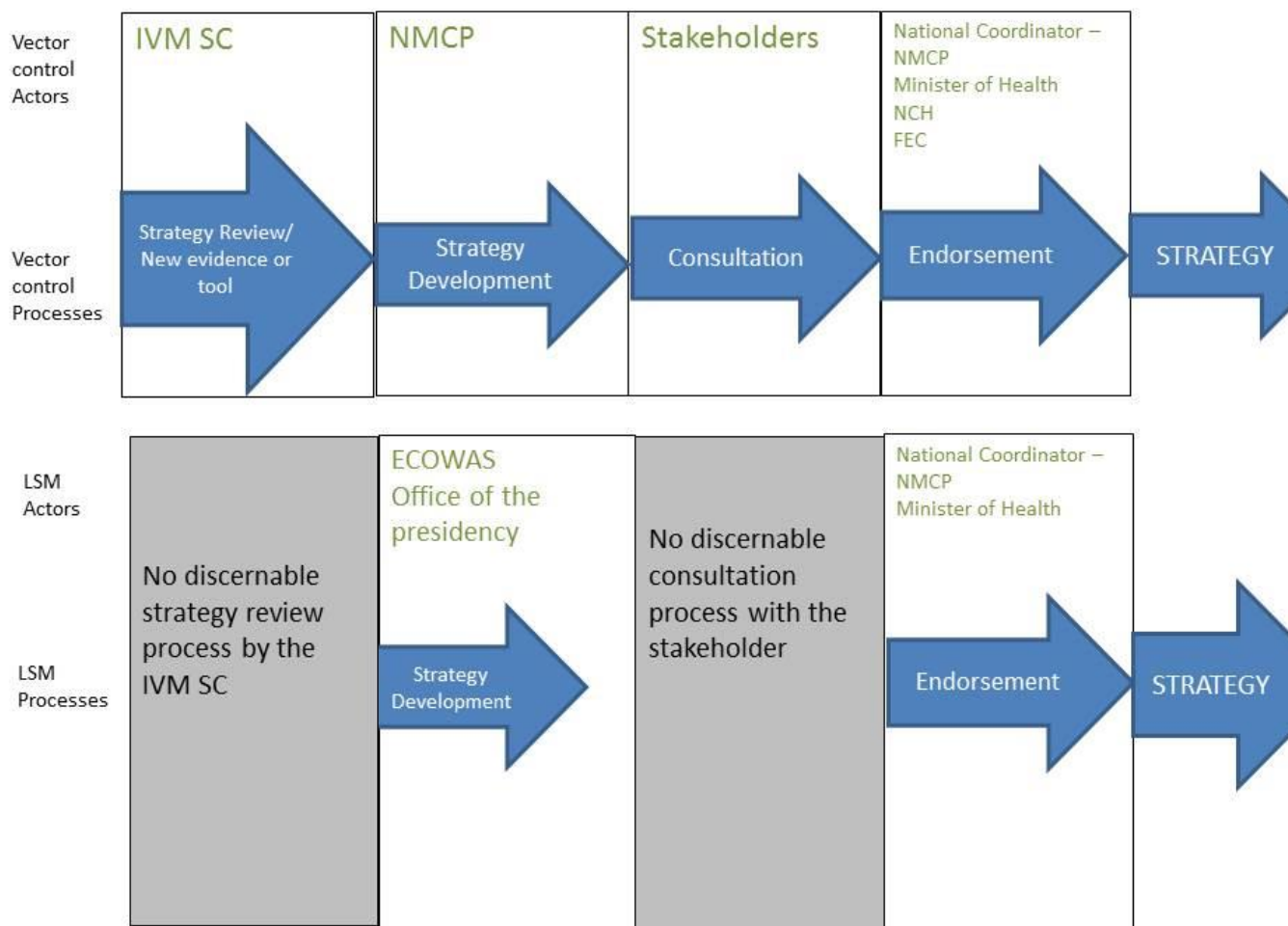


Figure 6. Vector control actors and processes: normative versus larviciding example

4.3.2.1.4 Content

The Nigerian NMSP 2009–2013 currently recognises the “*limited application of larviciding and environmental management*” for vector control (172). A new NMSP for 2014 and beyond is being developed and it is expected that it will feature larviciding more prominently to reflect the country’s commitment to nationwide scale-up. Beyond that, KIs were unable to give details of what the larviciding strategy would entail.

4.3.2.1.5 Evidence

Most respondents cited the use of some evidence to support the larviciding decision. KIs reported that ‘small’ evidence, i.e., evidence from the local pilot projects supported by the larvicide manufacturer, was used as the basis for the decision to implement larviciding at scale. This is in line with the reported norm for evidence in policymaking, with locally produced evidence being used to validate international evidence in the local context. However, in this instance, results from local trials were used to support the use of the Bactivec[®] strain, which is not recommended by WHOPES, and some actors, primarily those outside of government, perceived that the evidence produced was not open to scrutiny and debate.

“It may not be big evidence, because I know people are looking for the big evidence, ... we don’t have that type of evidence we are still generating” (Policymaker)

“These studies were just to find out the efficacy of some of the larvicides, it is not an extensive one but just to determine the efficacy and once that has been determined, we said ok if we deploy this thing, following the appropriate standard and the best practices that will be able to achieve much hence we decided to do that” (Policymaker)

Members of the broader stakeholder group were either unaware of the role of evidence or questioned the quality of the evidence used in the decision-making process.

“I’m sure it [evidence] would have played some role, but then like I said, the decisions were taken at a higher level ...” (NGO)

“I don’t want to use the word ‘questionable’. But also there are doubts, there are concerns as to the concrete, you know like the strength of their evidence” (NGO)

“There is no evidence there. In fact, from what I know the matter has gone up high before the evidence were being gathered” (Private sector)

“There was this larviciding project that was embarked upon by Rivers State government by Labiofam where they used some insecticide and the report indicated that malaria prevalence in Rivers State actually had come down” (Policymaker)

The prevailing view amongst the wider stakeholders is that there exists little evidence and no policy framework to support nationwide larviciding in Nigeria with Bactivec®. All stakeholders, except for the policymakers, held this view.

“No scientific evidence to support the decision to carry out nationwide larviciding” (NGO)

“In Nigeria they got it wrong; the larviciding they want to do is not based on any policy” (Private sector)

The stakeholders’ objection to the larviciding strategy in Nigeria is summed up by three arguments. First, that Nigeria does not represent an appropriate context for the larviciding:

“I think we do not represent the kind of place that larviciding would be effective on a large scale” (NGO)

However, the policymakers assert that the implementation of larviciding will be aligned to the WHO position on larviciding.

“It is going to be in the context of that “few, fixed and findable,” unfortunately many people who are inside the box think that we are taking larviciding everywhere in Nigeria is not like that ... no reasonable technical person will, it doesn’t make sense”
(Policymaker)

Second, there were concerns that the selection of larvicide strain used was not WHOPEP recommended, which contradicts the usual reliance on WHO recommendations and that the local evidence generated and used to support this decision was not sufficiently robust or independent.

Finally, and perhaps where the strength of the wider stakeholder’s argument lies, is in the fact that larviciding represents a distraction from the primary malaria control interventions.

“When you look at malaria control, spending all this money on larviciding when you don’t have sufficient funding to fill all your gaps for other commodities, you know, from a cost effective perspective, it would be more cost effective to take that money and put it into nets, if you’re doing vector control or RDTs [Rapid Diagnostics Test] or ACTs [Artemisinin-Combination Therapy] right, from a whole perspective of Malaria control”
(NGO)

4.3.2.1.6 Power

The tripartite agreement between ECOWAS, Venezuela and Cuba features financial and technical support to scale-up larviciding and technology transfer. Hence, financial power played a major role in the larviciding decision, but those exercising power were different to those perceived to wield this power in the normative situation.

Rivers State, the site of some of the pilot studies used as evidence for scaling-up larviciding, is the proposed site of the bio-larvicide factory (169). The Rivers State governor is a highly influential politician, hence the technological and direct

socioeconomic benefits of larviciding to Rivers State potentially created a formidable champion for scaling-up larviciding.

The commitment to scaling-up larviciding at the highest levels of government in Nigeria made the decision virtually unstoppable, with the hierarchical structure of the FMOH making the decision difficult to challenge.

“At the point at which decisions are taken at the highest level of government the natural tendency from the government standpoint is you support the decisions that are made by our superiors” (NGO)

In addition, there was an apparent restriction of information flow whereby all respondents, including those in NMCP, could not outline the details of the strategy for implementing larviciding beyond the fact that it will be scaled-up nationwide. This control of information limits the policy actor’s ability to debate and build consensus around the intervention in the usual way.

4.4 Discussion

This study is the first time that the decision to scale-up larviciding has been compared with normal policymaking processes in Nigeria. A review of the health policy analysis literature up to 2007 (124) included only six articles on malaria, all of which focused on treatment policies in Africa. Since then, there have been a number of policy analyses in sub-Saharan Africa looking at malaria treatment policy (128, 129, 185, 186), malaria in pregnancy interventions (187), and diagnosis (132).

Changing malaria policy is generally seen to be a complex process (138, 188). For example, the adoption of LLINs as global and subsequently national policy across sub-Saharan Africa was a lengthy process involving multiple studies to demonstrate efficacy, effectiveness, cost-effectiveness, and acceptability to end-users (22). In the southern and east African contexts, policy analyses have been carried on integrated vector management (127, 189), malaria control including vector control (126, 133), malaria

vector control (125) and IRS (190). These studies have highlighted the value of local champions, international networks and the involvement of researchers in policy development in translating research into policy (133). They also identified the critical importance of empirical data in informing decision-making and a need for a coordinated multipronged approach to vector control (189). These studies demonstrate how factors, such as outside influence and past experience of an intervention, can slow the process of policy change (125).

Policy analysis literature from South East Asia identifies similar critical factors in shaping policy despite being primarily focused on HIV/AIDS and universal health coverage (75, 191-193). Only one study in this context addresses malaria policy change, but focuses on the region's unique epidemiological challenges. The focus on regional cooperation to deal with cross border malaria transmission and elimination is not currently directly comparable to the sub-Saharan African context (194).

The larviciding decision in Nigeria demonstrates a number of examples of power in policymaking. The decision was characterised by a top-down policy process with the FMOH overtly exercising its power to involve new actors and restrict the involvement of some traditional actors. All participants recognised that the Nigerian government had the ultimate decision-making power in policymaking. However, a tradition of involving the RBM partners, private sector, NGOs and the research community has created the expectation of wider participation and power sharing. This consultative process usually creates opportunities for debates to occur and promotes the production and exchange of evidence (108). Hence, the decision to restrict the actors involved and knowledge shared in the policy process allowed for selective use of evidence, akin to what Weiss describes as the political use of research (110), causing concern over the quality of research evidence used in policymaking as observed in other contexts (127). The actions of the FMOH undermined the norm of closely adhering to WHO policies, which traditionally set the context (agenda) for policymaking in malaria control.

Studies have cited a belief that donor preferences and agendas were exerting too much influence on malaria policies in the countries and that national level government actors

are not adequately engaged in malaria control policymaking (126). In this instance, national leadership/ownership of a policy decision and engagement of different actors was highly controversial and heavily criticised. In 2012, WHO published an interim position statement on the role of larviciding in malaria control (7) in a bid to provide clear recommendations as a number of countries explored the use of larviciding. Alongside WHO's technical mandate, it is arguable that this statement had the power to influence global opinion, i.e., an exercise of power as thought control. It is difficult to ascertain if the reaction of traditional actors was based only on the cited technical reasons, or if it was also due in part to displeasure at their power to influence being undermined. Either way, this analysis highlights a potential conflict between greater national ownership of malaria policy decisions and adherence to internationally recognised standards and policy guidance which some view as an externally imposed donor construct.

This study demonstrates the persuasive power, especially to national policymakers, of considering the wider socioeconomic context of vector control. The proposed local manufacture of the product, and the labour intensive nature of the intervention delivery, has potential to create large numbers of jobs and benefit the local and national economy. National level political actors may have selected the intervention based *inter alia* on the potential domestic economic benefits. The societal and economic benefits of controlling malaria are commonly used to justify intervention in malaria control. However, when it comes to selecting between alternative interventions to control malaria, the process and actors tend to focus on evidence of health benefits (effectiveness) and cost-effectiveness. Cost-effectiveness analysis ignores the wider economic benefits of malaria control to domestic economies. Economic evaluations of alternative vector control interventions at country level would do well to consider the domestic economic impact of each approach and, where these differ between interventions, it should form the basis of discussion/debate with stakeholders beyond the malaria/health sector. If interventions are effective and can be shown to have a positive economic benefit (either directly or indirectly through their impact on malaria) this could help generate additional domestic financing for malaria control. This would

help achieve the Abuja declaration target of 15% government contribution to health expenditure (195).

Political analysts recognise that the policymaking process is highly variable, ranging from a set of clearly defined stages followed by the rational weighing of competing options with the selection of the most optimal choice (91), to a process of muddling through a complex and messy reality (92). In this study, interviewees reported a clearly defined decision-making process where evidence is weighed and the most appropriate option implemented. The decision to switch from targeted to universal distribution of LLINs was cited as a particularly successful example. The larviciding decision is a deviation from the reported norm, arguably falling on the messy end of the policymaking spectrum. Stakeholders seeking to engage in the process need to be aware of the risk that, even in countries with rational policymaking systems, deviations from the established norm may occur and each decision can be different.

4.5 Conclusions

This Chapter reaffirms that engaging powerful policy champions at the global and national levels can drive policy processes forward and thereby accelerate access to new vector control tools. It also suggests that a greater focus on the domestic economic benefits of malaria control could help generate greater domestic policy support and potentially finance for its control. However, care needs to be taken to ensure that inclusion of economic or other national goals does not result in health policies that are not based on evidence of intervention effectiveness and internationally recognised standards of best practice.

5 Results: Challenges and Opportunities Associated with the Introduction of Next Generation Long Lasting Insecticidal Nets for Malaria Control: A Case Study from Burkina Faso

ABSTRACT

Background: Reductions in malaria incidence in Africa can largely be attributed to increases in malaria vector control activities; predominately the use of LLINs. With insecticide resistance affecting an increasing number of malaria endemic countries and threatening the effectiveness of conventional LLINs, there is an increasing urgency to implement alternative insecticides. The aim of this study was to identify potential challenges and opportunities for accelerating access to next generation LLINs in Burkina Faso, a country with areas of high levels of insecticide resistance.

Methods: An analytical framework was used to guide the selection of key informants, data collection and analysis. Semi structured interviews were carried out with key informants in April 2014 in Burkina Faso. Interviews were conducted in French and English, audio recorded, transcribed and entered into NVivo10 for data management and analysis. Data were coded according to the framework themes and then analysed to provide a description of the key points and explain patterns in the data.

Results: Interviewees reported that the policy architecture in Burkina Faso is characterised by a strong framework of actors that contribute to policymaking and strong national research capacity which indirectly contributes to national policy change via collaboration with internationally led research. Financing significantly impacts the potential adoption, availability and affordability of next generation LLINs. This confers significant power on international donors that fund vector control. National decisions around which LLINs to procure were restricted to quantity and delivery dates; the potential to tackle insecticide resistance was not part of the decision-making process. Furthermore, at the time of the study there was no WHO guidance on where and when

next generation LLINs might have a more positive impact on malaria transmission, severely limiting their adoption, availability and affordability.

Conclusions: This study shows that access to next generation LLINs was severely compromised by the lack of global guidance. In a country like Burkina Faso where WHO recommendations are relatively quickly adopted, a clear WHO recommendation and adequate financing will be key to accelerating access to next generation LLINs.

5.1 Introduction

Reductions in malaria incidence in Africa are largely attributable to improved vector control, predominately the use of LLINs, IRS and, to a lesser extent, LSM (5, 34). LLINs are one of the most cost-effective measures against malaria (24, 196), with WHO recommending universal coverage with LLINs (defined as universal access and use) for all people at risk of malaria (197). Currently, pyrethroids are the only class of insecticide approved for use on LLINs, and therefore the rapid increase in mosquito resistance to pyrethroids represents a serious concern (5, 37). The loss of LLIN effectiveness would be catastrophic, jeopardising the ability to achieve malaria control and elimination goals (198).

Insecticide resistance management strategies and alternatives to conventional LLINs need to be implemented. One option is to provide access to 'next generation LLINs' treated with two or more insecticides (combination LLINs), or with an insecticide and the synergist PBO (PBO LLINs), designed to be more effective against pyrethroid-resistant vectors. Access to new LLINs requires the ability to acquire and use them. In this study we adopt the Frost and Reich view that access is a series of logistical, economic and political processes that affect acquisition and use (120).

Two PBO LLINs (PermaNet[®] 3.0 and Olyset[®] Plus) are currently available on the market after receiving WHOPES interim approval as standard LLINs in 2008 and 2012, respectively (60, 61). In 2014, the WHO VCAG, whose remit is to advise WHO on new forms of vector control, recognised PermaNet[®] 3.0 as having "*increased bio-efficacy*" compared to pyrethroid-only LLINs in areas of insecticide resistance (62). Recommendations for evaluating next generation nets have recently been published (62), but at the time the study was conducted, there were no normative guidelines on when and where these should be deployed. Burkina Faso is one the few countries where a PBO LLIN was deployed as part of a national campaign in 2010 and 2013 (199).

Chapter 5 presents an analysis of the context, content, processes, actors, power, and role of evidence in malaria vector control policymaking in Burkina Faso and of the

decision to deploy PBO LLINs in a national campaign in Burkina Faso. The study aims to identify potential challenges and opportunities for accelerating access to new vector control tools in Burkina Faso.

5.2 Methods

5.2.1 Study Site

Insecticide resistance is widespread in Burkina Faso (200) and, in the southwestern region of the country, the high level of resistance is reducing the susceptibility of insects to insecticides on conventional LLINs (45). Furthermore, despite two LLIN distribution rounds in 2010 and 2013, and over 70% of children under the age of 5 years reportedly sleeping under LLINs (201, 202), the national prevalence of *P. falciparum* was 61% in children aged 6 months to 5 years in 2014 (202). Detailed follow-up studies in different regions of the country have found no reduction in malaria rates following the 2010 distribution programme (203, 204). It has recently been confirmed that a third of the nets procured by Le Programme d'Appui au Développement Sanitaire (PADS, the procurement department of the Ministry of Health) for the 2010 distribution were counterfeit, non-WHOPEs-approved LLINs, packaged as genuine WHOPEs-approved LLINs (205). The GFATM Office of the Inspector General has highlighted significant weaknesses in the procurement process for the 2010 campaign. These weaknesses were exploited by two suppliers who provided almost 2.7 million nets that were not properly treated with insecticide and reportedly caused side effects to recipients (205). At the time the interviews for this study were conducted, knowledge of this fraud was not in the public domain and the study team were not aware of it. Approximately 1.6 million (20%) of the LLINs distributed in 2010 were a PBO LLIN, PermaNet® 3.0 (H Pates Jamet, Vestergaard Frandsen, personal communication), but there was no accompanying monitoring and evaluation plan to compare the efficacy of the PBO LLINs with conventional LLINs.

5.2.2 Analytical Framework

The modified analytical framework comprised of seven themes derived from all five concepts (actors, power, context, content, and process) in the Walt and Gilson policy analysis framework (77), with two additional themes, availability and affordability, from the four themes in the Frost and Reich framework (120) (Table 8) Given that the policy under review relates to the introduction of a malaria vector control tool, the themes of availability and affordability (not contained in the Walt and Gilson framework) are important. The themes of architecture and adoption from the Frost and Reich framework are the equivalent of the actors and process themes in the Walt and Gilson framework.

Table 8. Framework used for sampling, interview guide and data analysis

		Definition (Adapted from Walt and Gilson unless otherwise indicated)
1	Context	The systemic factors, such as political system, type of economy, employment base, national and international actions/cooperation, which may have an effect on health policy
2	Content	The content of the policy, which reflects the output of the interplay between actors, processes and context
3	Actors	The network of institutions and individuals that influence the adoption of a new policy
4	Power	The ability to influence, and in particular to control, resources; it can be seen in a number of dimensions including decision-making (174), agenda setting (100), thought control (176), control of financial resources and access to/level of knowledge (81)
5	Policy Adoption Process	The way in which policies are made, i.e., initiated, developed/negotiated/formulated/endorsed; in this study, this includes the use of evidence in the policymaking process
6	Availability	In this study we restrict consideration of availability to ordering (i.e., choosing and procuring a next generation LLIN (Frost and Reich)
7	Affordability	Involves the willingness to pay for (finance) a next generation LLIN by global organizations as they are the primary donors of vector control (Frost and Reich)

The modified framework was used to guide the selection of relevant policy stakeholder groups for interview, develop themes for the semi-structured interview guide, and for data analysis. For the purposes of this study, the definition of policy extends beyond a broad statement of goals (81) to include individual aspects of a policy such as the use of a specific tool (83).

5.2.3 Desk Review

In March 2014 and March 2015, PubMed-Medline, Web of Science, Global Health, Jstor, and Taylor & Francis were searched for peer reviewed literature using the following search terms: “Burkina Faso”, “malaria”, “malaria control”, “malaria prevention”, “vector control”, “policymaking”, “policy analysis”, “decision-making” and “evidence-based policy”.

In addition, using the same terms, Google, Google Scholar, the Programme National de Lutte Contre le Paludisme (PNLP) website, as well as partners’ websites, were searched for relevant reports, strategies, policies and meeting minutes. The purpose of the desk review was to identify the key actors (institutions and individuals) involved in national vector control for interview, to refine the research question and semi-structured interview guide, and to supplement findings from these.

5.2.4 Study Participants

The identification of the study participants was a two-step process. Using the literature and the local knowledge of two Burkinabe collaborators (Mr Traore and Dr N’Fale), institutions that participated in national malaria vector control policymaking were identified. An initial list of 15 institutions was drawn up and one KI from each was contacted to request participation. KIs were considered to be the most senior person tasked with LLIN policy, implementation, procurement, and research or funding. One additional KI was identified during the interviewing process

KIs were categorised into six groups: policymakers – staff of the Ministry of Health (MoH) working as part of the PNL; implementers – working for NGOs to implement malaria control projects; multilaterals – employees of United Nations technical agencies supporting malaria control; donors – including employees of organisations that finance and procure malaria control tools; researchers – those working in academia/national institutes of research; and private sector – those in the commercial for-profit sector involved in the sale of vector control tools and insecticide products. While the sample

size was guided by feasibility, KIs were selected to encompass viewpoints from all six categories.

5.2.5 Key Informant (KI) Interviews

Interviews were carried out in April 2014 in Ouagadougou, Burkina Faso. All interviews were conducted by the lead researcher and Mr Traore; 12 of the 13 interviews were conducted in French by Mr Traore and one in English by the lead researcher. The interviewers jointly reviewed the first four interviews conducted to establish consistency in data collection. The interviews followed a semi-structured, open-ended format, which was developed in English and subsequently translated into French ([Annex 8](#)).

The semi-structured interview guide included questions on who was involved in the policymaking process; who carried the most influence and why; how vector control policies were made (including the role of evidence); and factors that influenced the availability and affordability of PBO LLINs.

All KIs gave signed consent for participating in the audio-recorded interviews and for the use of anonymous quotes. In reporting quotes KIs roles (e.g., policymaker) are disclosed to highlight their perspective. Ethical clearance was obtained from ethics committees at Liverpool School of Tropical Medicine and Burkina Faso ([Annex 13-15](#))

5.2.6 Data Analysis

Translated and accuracy-checked transcripts were entered into NVivo10 for data management and analysis through the following four steps: i) familiarisation (reading of transcripts); ii) coding data according to themes in analytical framework; iii) summarising data by KI and themes; and iv) synthesis of the key points in each theme and exploration of patterns in the data.

5.3 Results

A total of 13 KIs were interviewed: two researchers, four policymakers, three implementers, two donors, and two multilateral agencies. Three KIs (one donor and

two policymakers) did not participate; one declined and two were not available. The KIs represented five categories as no national private sector actor was identified or interviewed. However, this perspective was later captured informally through discussions with a representative of Vestergaard Frandsen. We present findings according to the analytical framework themes, including one sub-theme that emerged during interviewing, i.e., the classification of forms of power. Table 9 presents the matrix of all *a priori* themes and sub-themes that emerged from analysis.

Table 9. A Priori Themes and Emergent Sub themes Burkina Faso Policy Analysis

	A Priori Themes from thesis analytical framework	Emergent Sub-themes
1	Context	-
2	Content	-
3	Actors	Policymakers (Decision makers)
		Policymakers (Technicians)
		Researchers
		Technical and Financial Partners
4	Power	Power as decision making
		Power to influence opinion
		Financial Power
5	Adoption	-
6	Availability	-
7	Affordability	-

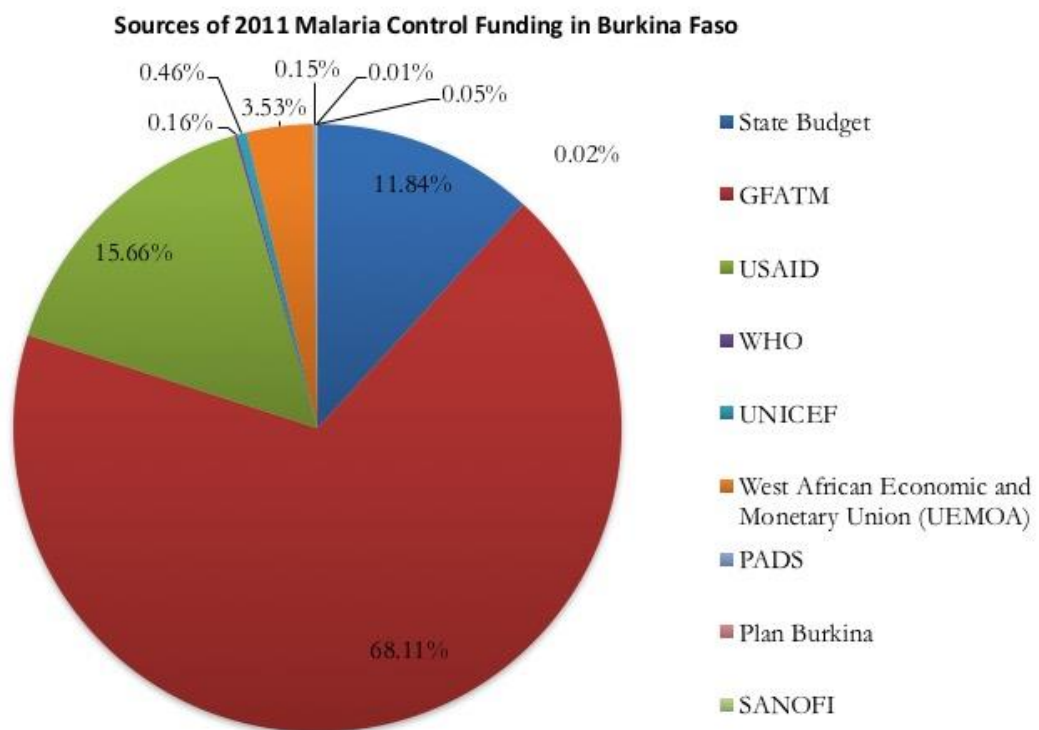
Within each theme, we highlight barriers and opportunities for accelerated access to next generation LLINs in Burkina Faso. Additional quotes to support the themes are presented in [Annex 19](#).

5.3.1 Policymaking Context

In Burkina Faso, the entire population is at risk of malaria. In 2013, there were approximately 3.7 million reported confirmed malaria cases and over 6,000 deaths (43). Malaria accounts for 50% of all outpatient consultations, 57% of hospitalisations, and 46% of deaths (206).

At the national level, the MoH (Ministère de la Santé), through the PNLP, is responsible for all health policy and strategy development, partner coordination and resource mobilisation (207, 208). The regional and peripheral levels focus primarily on implementation activities.

As one of the world’s poorest countries (209), Burkina Faso is reliant on external organisations to finance most aspects of its malaria control interventions. In 2011, over US\$ 70.6 million was spent controlling malaria (210), 68% of which was provided by GFATM, 15% by the United States Agency for International Development (USAID), and about 12% by the government (210). Figure 7 shows the breakdown of 2011 expenditure on malaria control by funding source.

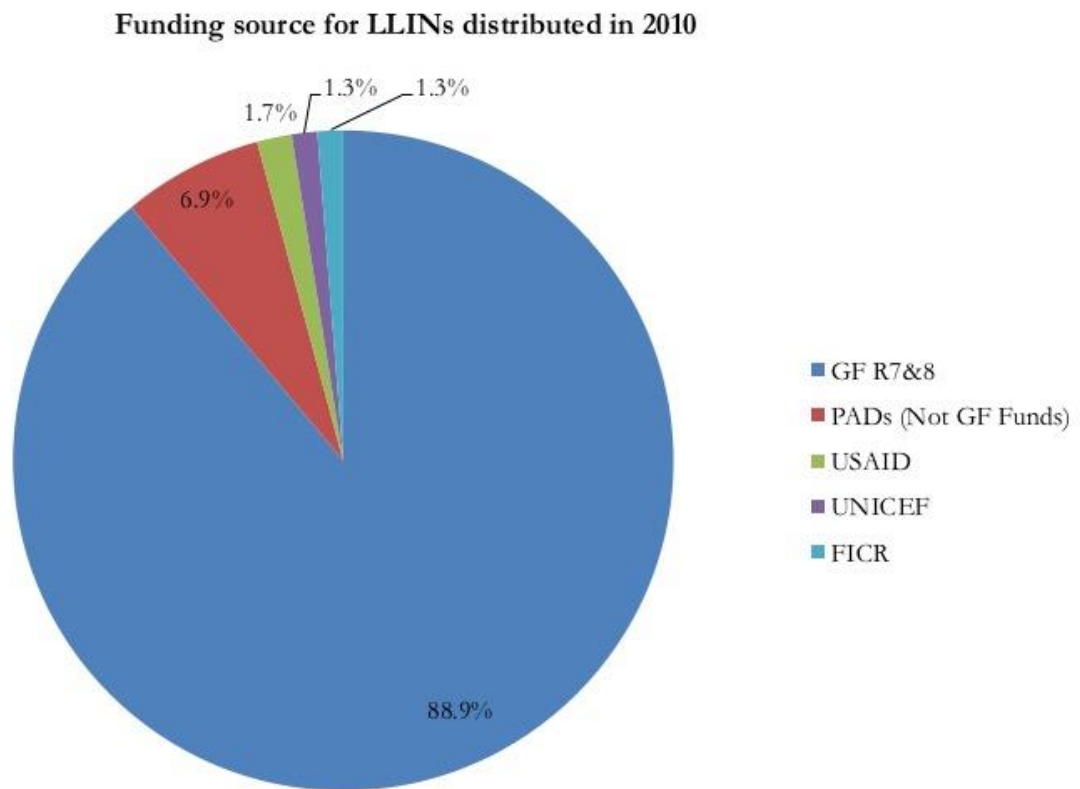


Source: Ministère de la santé (2014) Rapport de la revue A mi-parcours du plan stratégique de lutte contre le paludisme 2011-2015

Figure 7. Sources of malaria control funding in Burkina Faso, 2011

In 2010, almost 8 million LLINs were distributed nationwide, 88.9% were financed by GFATM through two funding rounds 7 and 8. Other sources of LLINs include those

procured using donor basket funds by PADS (6.9%) and by USAID (1.7%), International Federation of Red Cross and Red Crescent societies (1.7%), and United Nations Children’s Fund (UNICEF) (1.3%)⁴. Figure 8 shows the sources of support for LLINs in the 2010 LLIN nationwide distribution campaigns. In 2013, GFATM financed over 90% of the LLINs distributed.



Source: Unpublished data - Programme National de Lutte Contre le Paludisme (PNLP)

Figure 8. Funding source for LLINs distributed in 2010

5.3.2 National Vector Control Policy Content

The overall goal of the Burkina Faso National Malaria Strategic Plan 2011–2015 is to reduce malaria morbidity by 75%, compared to 2010 levels, and malaria mortality to a level close to zero by the end of 2015 (210). Table 10 summarises the vector control objectives in the Strategic Plan (210), the coverage of interventions of populations at risk as at 2012 (211), and the revised national objectives as of March 2014. In line with

⁴ Unpublished data Programme National de Lutte Contre le Paludisme (PNLP)

WHO recommendations, one objective is to achieve and maintain 100% of the population sleeping under a LLIN by the end of 2015.

Table 10. Original and revised vector control policy objectives in Burkina Faso's National Malaria Control Strategic Plan

	Vector control objectives in the 2011-2015 strategic plan (210)	Progress towards target in Burkina Faso as of 2012 (211)	Revised vector control objectives 2014 (210)	2014 Malaria Indicator Survey Results (202)
1	100% of the population sleeping under long-lasting insecticidal-treated nets (LLINs)	Approximately 50% of total population at risk	Achieve and Maintain 100% coverage	71% of the households have access to at least one LLIN In households with at least one LLIN, 74 % of the population of these households slept under mosquito nets at night
2	100% of the populations of the four health regions targeted (South-West, Cascades, Hauts-basins and Mouhoun) benefit from indoor residual spraying (IRS)	Approximately 1% of population covered	Suspension of IRS	
3	100% of the targeted breeding sites in the Central and Hauts-Bassins regions are covered by larviciding.	No data	Extension of larviciding to Bobo-Dioulasso region	

5.3.3 Policymaking Actors

The KIs identified actors involved in policymaking as the MoH and its technical departments such as PNL; other ministries such as those for finance, communications and environment; research centres, including the CNRFP and Centre Muraz; technical and financial partners, including WHO, GFATM, UNICEF, USAID, International Federation of Red Cross and Red Crescent societies, and PLAN Burkina.

All KIs recognised the central role of the Comité National de Pilotage de la Lutte Contre le Paludisme (Comité de Pilotage), the national steering committee for malaria, in

supporting PNLP in delivering its mandate. The Comité de Pilotage is composed of five commissions, including one focused on vector control. The main responsibilities of the vector control commission are to make recommendations to PNLP in defining vector control strategies, support the development and revision of guidance documents, monitor the implementation of vector control activities, and monitor insecticide resistance (212).

The KIs and the terms of reference of the Comité de Pilotage (212) outlined four main groups of actors and the roles that they played in the policymaking process (Figure 9).

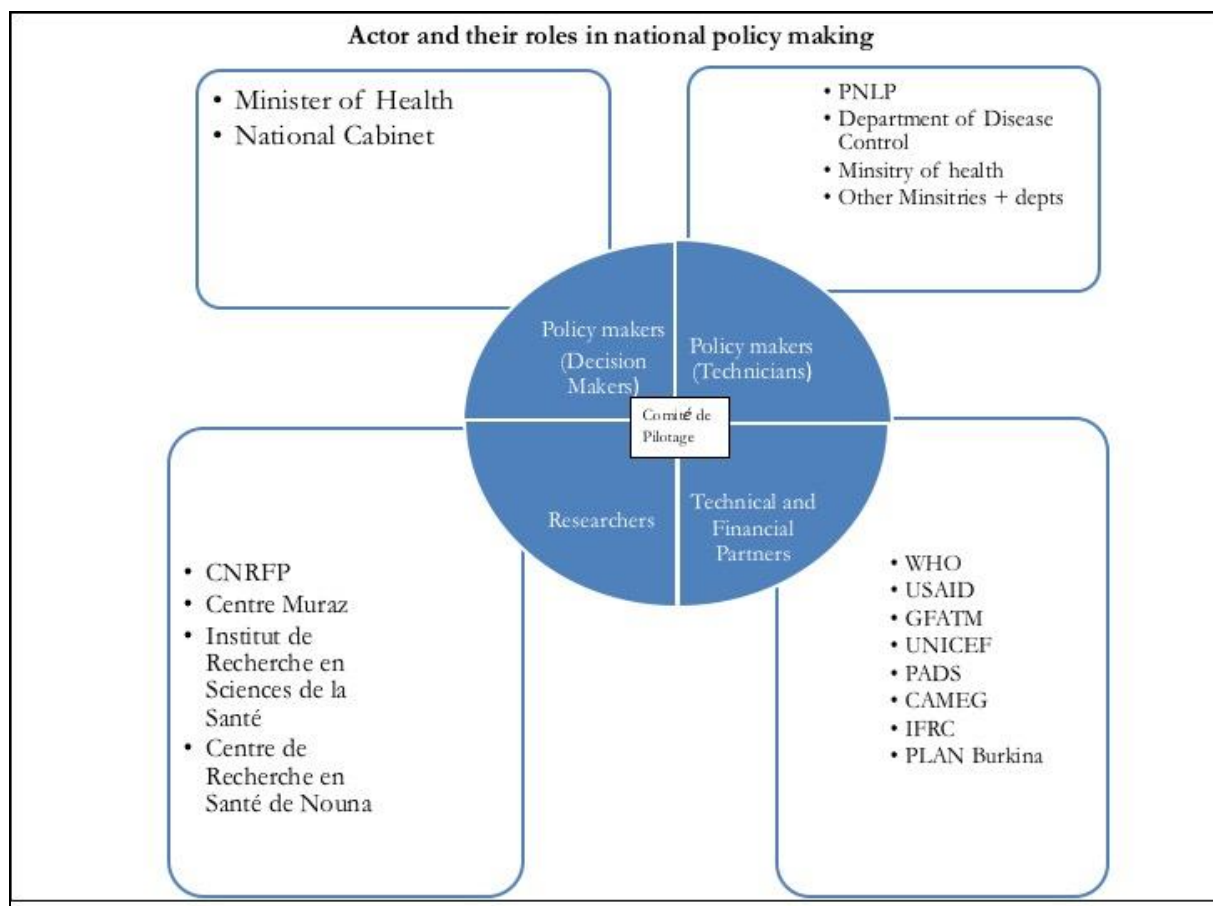


Figure 9. Actors and their roles in national policymaking

Researchers: Four national research centres conduct malaria research across the country. Data generated feeds in to the national policymaking process through the MoH and Comité de Pilotage (207, 213). However, KIs, particularly researchers, multilaterals

and donors, outlined that, while local research/researchers are valuable, there is a need to collaborate with international research institutions to strengthen the credibility of research outputs.

“Even if a research is made in Burkina Faso, if the signature is international it means that you have done it in collaboration with an international institute, this is very important. That is because in the eyes of donors, the international character is of great value” (Policymaker)

Technical and financial partners: Multilaterals, donor and NGOs are collectively known as technical and financial partners. They provide technical advice and financial input to the policy development and implementation.

“The TFP [Technical and Financial Partners] ..., they have money and they have the ideas, knowledge. Ok? Money and knowledge” (Researcher)

Policymakers: KIs considered policymakers to be the technicians that drafted the policies and the decision-makers who ratified these.

Technicians: All KIs recognised PNLP as the technician who drafts the policy document coordinating inputs from researchers, the technical advisers and other stakeholders.

“Technical departments are really conducting daily follow-up-evaluation of the Programmes, which lead to new information which requires that a policy be changed. They also give a technical draft to the Office of the Ministry of Health where they decide on what needs to be done” (Researcher)

Decision-makers: All KIs recognised the role of the national government through the MoH and the cabinet to make final decisions on ratifying policies that had been drafted by the technicians.

“...but now when the policy goes for decision making, the decision is taken at another level that I called politicians; when I say politicians. I mean the ministries, the Parliament who approve policies” (NGO)

5.3.4 Perceptions of Power

Power was observed when KIs identified the actors they thought carried the most influence and when KIs described the roles various actors played in the policymaking process.

KIs identified different forms of power:

- i. Power as decision-making: This dimension of power was expressed as the national government’s ability to endorse or reject a policy.

“As a technician you can write policies, write strategies that are relevant enough according to you; and they will go to the highest level for decision making, that’s something else. Those at the highest level will decide on whether they are going for this policy or not” (NGO)

- ii. Power to influence opinion: WHO was viewed as an important actor as its recommendations influenced national policy content and directed what donors support, thereby mediating actor’s (e.g., PNLP’s) options when drafting policy documents. National researchers also saw themselves as having a role (and to some extent influence) in contributing to the global evidence base, which in turn influences WHO recommendations.

“If the WHO recommends something, tomorrow you will see that people put it in application very quickly” (Policymaker)

- iii. Financial power: All KIs cited financial resources as being the most powerful reason for policy adoption. Consequently, GFATM who funds most of malaria control in Burkina Faso was perceived as the most influential actor (210).

“The Global Fund plays the most important role because the Global Fund is financing the malaria control programme by 80%. So for many policies concerning malaria control, the Global Fund influences much even if it is not making [the] decision all alone” (Donor)

Although donors were viewed to possess a great degree of power, their power was not absolute. All KIs recognised WHO recommendations’ influence over policy content and donor funding and two KIs viewed decision-makers to be the most powerful actors.

5.3.5 Policy Adoption Process

KIs recognised that the first step in the policy adoption of a new vector control tool would be international endorsement/recommendation of the tool.

“First step in [the] adoption process is the international adoption of the product. If Burkina Faso wants to adopt a new policy, first of all that policy must be proved internationally” (NGO)

The PNLP draft the policy document with input from the partners in the Comité de Pilotage, acting in an advisory capacity. The policy is then submitted to the MoH and the national assembly for endorsement.

“The country adopts; when I say the country adopts I mean the coordinator of the national programme of malaria control must prepare the case file and submit to the hierarchy. That is to say, the directorate of disease control, the General Directorate of Health, the General Secretariat, and the Ministry. Now, if it is accepted, it becomes part of the policy” (Policymaker)

A donor’s willingness to finance was perceived to be one of the most powerful incentives for policy adoption.

“Locally here what I’m saying is just come with your resources saying that you have money to support such strategy, it will be accepted” (Researcher)

All KIs expressed a certain level of pointlessness in going through the adoption process without global adoption and funding already being in place.

“The Government has very few resources to put in, so resources are coming usually from the donors. They [donors] want to have it approved by the WHO first before putting their money. So meaning that you can have a very nice and promising result, but you need to put in place a lobby group just to push it and get it approved internationally before coming back” (Researcher)

Figure 10 outlines the policy adoption process as described by KIs showing that the genesis of the national policy process is at the global level.

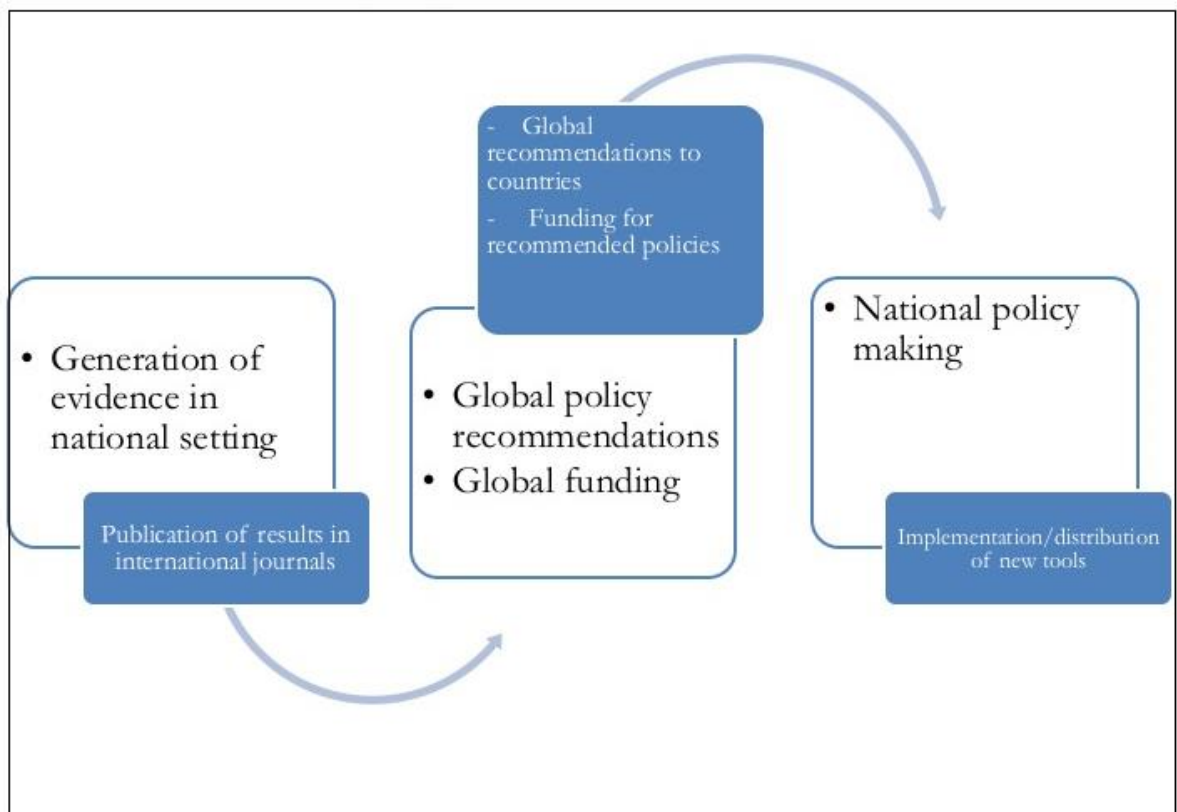


Figure 10. National policy adoption process for a new vector control tool

5.3.6 The Role of Evidence in Vector Control Policymaking

There are strong formalised relationships between research centres, the MoH and Comité de Pilotage, with clear channels for communicating research results to key policymakers within the MoH and the wider stakeholders (213).

“At national level, you have the research institutions who will, based on the new findings, just report by [MoH] hierarchy which also transfer these findings to the Comité de Pilotage” (Researcher)

While this should foster increased use of research in policymaking, as described above, nationally generated research was perceived to have limited impact on policy.

“Nationally here you have a very nice result, but after you finish, you close your reports, you publish, you go and report, nobody is talking about it. You have to wait to get it approved internationally and now it comes back” (Researcher)

In this context, it is worth noting that PermaNet[®] 3.0 was evaluated in Burkina Faso using WHOPES protocols and included in a publication describing the results of a similar trial from multiple settings (214).

5.3.7 Availability

Five brands of LLINs were distributed in 2010: Interceptor[®], Dawa plus[®], PermaNet[®] (including PermaNet[®] 2.0 and 3.0), Netprotect[®] and Olyset[®] net (45). When KIs were asked about factors influencing availability (choosing and procuring LLINs), a number of issues came to light.

Firstly, the primary factor determining LLIN availability is WHOPES recommendation.

“A decision maker before accepting a brand of nets must make sure that it is a net that is recognised by the WHO; and accepted in line with WHOPES standards” (NGO)

Secondly, in line with the perceptions on the importance of financial power, all KIs noted that, for current and future vector control tools, such as next generation LLINs, price would be a key factor in determining availability.

“Alright, money is the issue because even the Global Fund is considering the price. When you want to buy mosquito nets through the Global Fund you cannot budget for any

mosquito net which costs 5 or 6 dollars each because the Global Fund could buy at 2 or 3 dollars each if they need a huge quantity of it. So the Global Fund will not accept those prices” (Multilateral)

The factors influencing the decision to distribute a PBO LLIN (PermaNet® 3.0) were explored. A few KIs were aware that PermaNet® 3.0 had been distributed but none were aware of what influenced the decision to purchase and distribute them.

“They provided us with that product [PermaNet® 3.0], there’s no criteria on which we can ourselves choose PermaNet 3.0 just because we think resistance is lower with it than other products” (Policymaker)

The decision to distribute PermaNet® 3.0 appeared to be based on price and actions of international/external actors, i.e., net manufacturers.

“[I was] not aware of the decision, [it] looks like it was taken outside. The materials [PermaNet® 3.0] were ordered by an external body and sent to the country” (Researcher)

Currently, once approved by WHOPEs, all brands and types of LLINs (including PBO LLINs) are considered the same. Therefore, country decisions focus on articulating specifications (physical characteristics, insecticide, binding process, dimensions, etc.) to the relevant procurement department. This choice can be influenced by a desire to stick to tried and tested products or a protection of individual interests. Taken in the context of the counterfeit nets distributed in 2010, comments made by some KIs have added significance. They seem to confirm that some actors were aware of the fraud and of the potential for high value contracts to be mismanaged for personal financial gain.

“So people are afraid of the unknown, they fear anything which is new, they think the other tools are already effective, and then they limit themselves to the old tools, but most often it is because some people have their own interests [claps] because if they import nets, they know what it's worth. People have their own deal in the contract. It is

the same people who awarded the mosquito net contracts in 2010 to their friends that we all we know.” (NGO)

It is worth noting that nets distributed in 2013 were procured through the GFATM voluntary pooled procurement system. Recognising weaknesses in their own practices, GFATM have also initiated a number of improvements including pre-shipment testing of nets, greater oversight of bidders’ relevant experience and the appropriateness of tender specifications, and are seeking to recover funds from those implicated in the counterfeiting (205).

5.3.8 Affordability

In Burkina Faso, the affordability of LLINs effectively means the willingness of international donors to finance it, which in turn is influenced by global recommendations.

“If the WHO approves the new tool, I believe that international initiatives will agree to finance the tool and I’m sure it will become more accessible” (Policymaker)

Cost was viewed as a major influence on donors’ willingness to finance, with one KI citing the case of IRS being halted due to its relatively high cost.

“There is not only the issue of effectiveness but also the problem of cost. Why is it that the indoor spraying which is very effective is unfortunately stopped? Because it is very expensive! It is so expensive that we cannot afford it” (Multilateral)

A barrier to affordability, raised by all KIs, is the need to meet set targets, which is jeopardised if the new tool is more expensive and the funding envelope remains fixed.

“You have set amount of money but still need to achieve universal coverage. While your target remains universal coverage because you have signed up the Abuja declaration if

you want to buy more expensive nets you will have to find additional funds.”
(Multilateral)

Just one KI raised the issue of differences in performance between net types.

“Now they need to show us the methods that allow us to have more impact, The Global Fund is naturally interested in the impact, the efficiency and the effectiveness, and we will not get away too much from the prescribed actions at the international level in relation to a resistance that occurred, this for sure.” (Donor)

KI's highlighted that an opportunity for improving availability and affordability would be more independence from international funding in the form of allocation of national funds to malaria control.

“So the first issue would be just trying to work with the policymakers to allocate resources for their own policy instead of just waiting for resources coming somewhere”
(Researcher)

5.4 Discussion

Case studies have proven to be an effective method in exploring real life policy events (75, 153), including examining gaps in access to drugs (215), the development of family planning programmes (216) and the coordination of donor aid policies in developing countries (217). In Burkina Faso, much of the national policy analysis in the malaria field has focused on the adoption of artemisinin-based combination therapy and home-based management of malaria (213, 218-220). However, Burkina Faso appears amenable to the timely translation of global guidance on malaria control into national policy; being one of the first countries to adopt intermittent preventive treatment for infants and seasonal malaria chemoprevention (211).

This is the first time the Frost and Reich framework has been used to analyse national malaria vector control policymaking in Burkina Faso. The framework and its elements, when combined with those of the Walt and Gilson framework (77), are suitable for

national level policymaking analysis (recognising that sub-national factors, while important, were beyond the scope of the present study) and all responses fitted into the themes contained within the framework. However, the different dimensions of power and the different categories of policy actors are nuances within existing themes that emerged during the interviews.

A strong framework of actors linked to research centres has been identified as one of the key strengths of malaria control in Burkina Faso (210). Burkina Faso has a strong track record of malaria vector control research with two internationally recognised research groups; they are at the forefront of insecticide resistance research with in excess of 14 publications with Burkinabe first authors on this topic in the past 10 years. More recently, a Burkina-based study was one of the first to demonstrate that standard LLIN effectiveness is compromised by insecticide resistance (45). Despite this, the researchers interviewed felt that the ability for their outputs to influence national policy was dependent on collaboration with international researchers.

While not mentioned by any KIs, the desk review showed that WHO's Evidence Informed Policy Network (EVIPNet) in Burkina Faso (consisting of Burkinabe policymakers and researchers) has successfully supported evidence-based policymaking on wide-scale access to artemisinin-based combination therapies and has been pivotal in getting this funded by the GFATM (219, 221).

This study identified three dimensions of power. While only the government had power over which policies were endorsed, this was limited by its relatively low financial power. Conversely, those with financial power, such as the GFATM, are limited by the commitment to only support tools endorsed by WHO. While no actors were seen to have absolute power, financial resources conferred significant power on those that fund vector control. This is captured by the KIs' perception that it is futile to adopt a policy without financial backing. This finding is consistent with studies that have observed the potential for new funding to change the policymaking landscape (220) and push through policy adoption (222). In a country like Burkina Faso, where financial power is concentrated in the hands of one institution (GFATM), the potential for

scaling-up access to a new tool is tied to their willingness to finance it. This is in contrast to studies that show instances of policies being driven by actors involved in its implementation (bottom up approach) (178, 223). This contrast is not surprising given that the LLINs are predominately delivered and financed from the top down (197).

This study highlights the need for increased domestic funding for malaria control commodities (208) to reduce donor dependence (126) and increase the power of policymakers in Burkina Faso to choose appropriate interventions for their setting. Other studies have demonstrated the potential for high-level global subsidies to improve the availability of affordable high quality malaria control interventions (224). This may be something that needs to be considered if the new vector control tools replacing those whose efficacy is being eroded by resistance have a higher unit cost.

The GFATM new funding model is a potential opportunity to improve access to new malaria control tools like next generation LLINs. The new funding model directs up-front allocations, aligned to national strategic priorities (225). Thus, a country like Burkina Faso would be able to make a case for the purchase of next generation LLINs using GFATM resources, even where these are more expensive, if it were able to document reductions in the effectiveness of standard LLINs and greater effectiveness of new tools.

Vector control policymaking in Burkina Faso is largely based on policy transfer, i.e., policy ideas from one space and time influencing another (83). The national policy process is well defined, but is dependent on global malaria policymaking and available resources. Despite the recognition by VCAG of potential additional benefit of PBO LLINs against insecticide resistant mosquitoes (62), at the time the study was conducted there was no WHO guidance on where and when next generation LLINs might positively impact on malaria transmission, severely limiting their ability to be adopted at the national level and financed by the main donors. In December 2015, the WHO Global Malaria Programme (GMP) released recommendations on conditions for use of LLINs treated with PBO (63). It recognised that PBO LLINs have increased bio efficacy in certain settings, but argued that the evidence was too limited to justify a complete switch to PBO nets in all settings. It is evident that a switch from conventional LLINs to

PBO LLINs would not be appropriate in all settings as, in areas where mosquito populations remain susceptible to pyrethroids, there is no rationale to implement a product that is likely to have a higher unit cost. However, rather than provide guidelines on when and where a switch to PBO LLINs may be justified, WHO recommends pilot exploratory implementation with robust monitoring and evaluation (63). Nevertheless, it also states that PBO LLINs should “*only be used where universal coverage [...] will not be reduced*”, which means that pilot studies are only likely to be possible where PBO nets are provided free of charge or at the same price as standard LLINs.

Donor policies only permit WHOPES-recommended LLINs (226, 227) with countries having little control over the net selection. As WHOPES do not currently distinguish between PBO and conventional LLINs, the potential to tackle resistance is not part of the decision-making process in LLIN procurement in Burkina Faso. In Burkina Faso, KIs confirmed that the donor’s procurement department or agent oversaw the competitive bidding process where the cheapest LLIN was bought. Vestergaard Frandsen, the manufacturers of PermaNet® 3.0, have since confirmed that it was offered at a competitive price in Burkina Faso to ensure they were used in the right context (H Pates Jamet, Vestergaard Frandsen, personal communication).

The price of a next generation LLIN was viewed by KIs as the single most important factor in determining its affordability (i.e., willingness to purchase). This was linked to donors desire to get the highest LLIN coverage for a given level of expenditure which, in turn, stems from global and national targets for universal coverage with LLINs. While not suggesting that these targets should be abandoned, it is important to review them in light of the potential for insecticide resistance to reduce LLIN performance. In the absence of a clear recommendation of when and where to target next generation LLINs, countries may be left deploying LLINs that are less effective in areas with insecticide resistance to meet coverage targets at the expense of potentially more effective solutions.

The benefits of PBO LLINs, which can be up to US\$ 2.30 more expensive than standard LLINs (199), might be clearer if donors and national programmes incorporated impact

measures (overall reduction in transmission) into procurement decisions and focused on the cost-effectiveness of alternative tools (as opposed to unit cost). In order for this to make a difference, evidence-based global recommendations on when and where next generation LLINs are likely to provide the greatest protection, and the likely magnitude of this effect, are urgently required. The current absence of global guidance on the role and cost-effectiveness of next generation LLINs in vector control in countries with insecticide resistance is a critical barrier to donor funding and national adoption of next generation LLINs.

5.5 Conclusions

This study shows that access to next generation LLINs was severely compromised by the lack of global guidance on where and when they should be deployed. In a country like Burkina Faso, where WHO recommendations are relatively quickly adopted, a clear WHO recommendation is the key to unlocking financial resources for and accelerating access to next generation LLINs. It remains to be seen whether the December 2015 WHO recommendation will impact on access to these products.

Furthermore, evidence collected by national research institutions on insecticide resistance should be extended to monitor (changes in) effectiveness of standard LLINs. As well as supporting evidence-based national policymaking, these data should be given greater credence in funding applications to key donors and in global policymaking.

6 Results: Global Adoption of Next Generation Long-Lasting Insecticide-Treated Nets: Challenges and Opportunities for Accelerated Access

ABSTRACT

Introduction: Vector control has been attributed to averting 3.3 million deaths from malaria between 2001 and 2012, however insecticide resistance has the potential to derail these achievements. Access to innovative vector control tools is required to sustain achievements and attain malaria elimination goals. This study aimed to identify the opportunities and barriers at the global level to accelerating access to the next generation of LLINs, using synergist nets treated with both pyrethroids and piperonyl butoxide (PBO LLINs) as an example.

Methods: Semi structured interviews were carried out with key informants between June and July 2014. Interviews were conducted in English, audio recorded, transcribed and entered into NVivo10 for data management and analysis. Data were coded according to themes in a modified analytical framework and emergent themes using content analysis.

Results: Key informants (KIs) were interviewed including policymakers (4), researchers (3), donors (4) and representatives of the private sector (2). KIs reported that the adoption of PBO LLINs can be facilitated by independent and clearly communicated evidence which demonstrates the failure of current tools and the effectiveness of PBO LLINs as well as secondly a policy process that is clear and timely policy adoption process. The KIs reported that the availability PBO LLINs is predicated on factors including: the ability to forecast the PBO LLIN market size; willingness of donors to pay for PBO LLINs (affordability); fostering of innovation and clarity on the process and evidence required to convince policymakers. Affordability of PBO LLINs is influenced by WHO recommendation and the price of PBO LLINs being comparable to conventional LLINs.

Conclusions: Four fundamental factors that need to be addressed in order to facilitate increased access to PBO LLINs were: i) robust quality evidence on the effectiveness (including cost effectiveness) of PBO LLINs compared to conventional LLINs; ii) clear recommendations on where and when PBO LLINs should be used; iii) innovative procurement mechanisms that support forecasting of demand and facilitate price reductions; and iv) more effective coordination amongst the vector control stakeholders to increase awareness and concerted action around tackling the threat of insecticide resistance with short and long-term solutions.

6.1 Introduction

Vector control is recognised as the only approach that has led to malaria elimination in parts of Europe, Middle East, South Asia, North and South America, and North Africa (20, 228). Significant progress in malaria control has been recorded in the last decade, with 3.3 million deaths being averted between 2001 and 2012, and a decrease in the incidence of confirmed malaria, contributing to the progress towards achieving Millennium Development Goals 4 (a two-thirds reduction in the mortality rate from all causes among children aged under 5 years), 5 (improving maternal health) and 6 (combat HIV/AIDS, malaria and other diseases) (211, 229). The scale-up of access to (coverage and use) LLINs is recognised as a major contributor to these successes (34, 211). However, there is global consensus that insecticide resistance has the potential to derail the malaria control achievements to date (230). Concerted action is required to ensure the continued success of malaria control efforts with current strategies and the development and timely introduction of innovative vector control tools (5) such as next generation LLINs.

Two next generation LLINs (PermaNet[®] 3.0 and Olyset[®] Plus) treated with pyrethroid and piperonyl butoxide (PBO LLINs) are currently available on the market. Two additional next generation LLINs treated with a combination of two insecticides (combination LLINs) are currently being tested in Phase III trials or being considered by WHOPES, with potential first use anticipated between 2016 and 2018. In addition, various other new vector control tools are currently being evaluated by WHOPES, including insecticide treatment kits for bednets and insecticide formulations for IRS and larviciding, some of which are being repurposed from agricultural insecticides in order to address insecticide resistance (231).

Potential obstacles to access of a health intervention include its cost, weak health systems, low political commitment, and barriers to its manufacture and delivery (120). This study aimed to identify the opportunities and barriers at the global level to accelerate access to next generation LLINs using PBO LLINs as an example.

6.2 Methods

The study involved an initial desk review followed by a series of semi-structured in-depth interviews with identified key stakeholders involved in vector control tool development, research, policymaking and funding at the global level.

6.2.1 Analytical Framework

A modified analytical framework comprising all five themes (actors, power, context, content and process) in the Walt and Gilson policy analysis framework (77) and two themes (availability and affordability) from the Frost and Reich framework (120) was used in this study (see Chapter 3). The framework was used to guide the development of search terms for the desk review, the selection of relevant policy stakeholder groups for interview, the development of themes for the semi-structured interview guide, and for data analysis. Given it has been demonstrated that policy can be defined as a tool (83), for the purposes of this global level analysis, policy adoption refers to WHO policy recommendation of a PBO LLIN.

6.2.2 Desk Review

In March 2014, an initial search was conducted in PubMed-Medline, Global Health and Google Scholar using the following search terms: “malaria vector control”, “malaria health policy”, “malaria vector control policymaking”, “health policy analysis”, “evidence-based health policy”, “evidence-based policy-making”, “access to: health interventions, medicines, vaccines”. Data on the global policymaking context and global policymaking actors (used to inform KI identification) was extracted and was used to refine the research question and develop semi structure interview guides for data collection.

In May 2015, after key informant interviews and during the data analysis and write up stage, a further search was conducted in the same databases using the same terms to update the information retrieved in the initial document search. Articles were restricted to those published in English between 1990 and 2015. See [Annex 5](#) for the full search strategy.

Additional documents were identified through recommendations from colleagues, reference lists of included articles and the websites of identified institutions, and included book chapters; presentations from conferences and unpublished consultancy reports; old and current global malaria policies, strategies and guidelines on vector control and insecticide resistance; terms of reference and minutes of meetings of bodies such as RBM, MPAC, VCAG, Vector Control Technical Expert Group (VCTEG), and WHOPES; and policies, strategies and action plans of global research, implementing and financing organisations involved in malaria vector control including USAID, DfID, GFATM, and the Innovative Vector Control Consortium (IVCC).

Data on the global policymaking context and global policymaking actors (used to inform key informant (KI) identification). The document review was supplemented by reviewing further studies and reports provided by KIs during interviews.

6.2.3 KIs

KI sample selection was a two-step process, i.e., the identification of relevant institutions and then the identification of KIs from within each institution for participation in the study.

The initial document review identified relevant institutions by examining the institutions/committees that contributed to the development/manufacture, testing/evaluation, and assessment of PBO LLINs for policy adoption and those that would potentially be involved in the funding of PBO LLINs by using institutions who have funded LLINs in the past as a proxy. Institutions identified were categorised as follows: i) private sector representatives, referring to those in the commercial for-profit sector and public-private partnership organisations involved in the development, manufacture and/or sale of PBO LLINs; ii) researchers, including those working in academia or research institutions with vector control and insecticide resistance research expertise; iii) donors, referring to international donor organisations that fund vector control; and iv) WHO and members of its technical advisory committees,

structures and regulatory mechanisms established to support WHO policymaking functions such as MPAC, VCAG, VCTEG and WHOPES, henceforth referred to as 'policy advisors'.

KIs were considered the most senior person and/or the individual within the identified institution tasked with the largest responsibility concerning the relevant framework theme and/or LLIN intervention. Through this process, 14 stakeholders were identified and contacted for participation in the semi-structured interviews.

6.2.4 KI Interviews

In June and July 2014, Ms Tesfazghi conducted all interviews in English. As the location of KIs included the United Kingdom, United States of America, and Switzerland, half of the interviews were conducted by telephone or Skype and the other half face-to-face. The interviews followed a semi-structured, open-ended format using a guide ([Annex 10](#)) that was pretested by Ms Tesfazghi on a colleague. The semi-structured interviews focused on the 5 of the 7 themes in the modified analytical framework; data on policy context and content were gleaned from document reviews.

6.2.5 Data Analysis

Ms Tesfazghi transcribed recorded interviews. Transcripts were entered into NVivo10 for data management and analysis and were re-read to gain familiarity. Data were coded according to the themes in the analytical framework. An analysis matrix was developed summarizing coded data by KI and themes ([Annex 11](#) shows an excerpt of the matrix). Summaries of the themes were further analysed and refined to provide a description of the key points in each theme and explain patterns in the data. Two KIs were contacted for follow-up information in light of recommendations made by WHO in December 2015 on the conditions for use of PBO LLINs, after initial interviews had been conducted. Additional documents sourced after the recommendation was also used to provide insight into the initial document reviews and KI responses. These have been reflected in the results and discussion sections.

6.2.6 Ethics

Ethical approval for the study was obtained from the ethical committee of the Liverpool School of Tropical Medicine. All KIs gave informed signed consent for participating in the interviews. All but one KI gave consent for their interviews to be audio-recorded. Anonymity was maintained by assigning all KIs with numbers so that their names and affiliations/institutions were not identifiable to anyone other than the primary researcher during data collection, analysis and write up. However, their roles (e.g., researcher), are disclosed alongside quotes to highlight differences and similarities in perspectives.

6.3 Results

A total of 13 interviews were performed (four policy advisors, four donors, two private sector representatives, and three researchers). One identified policy advisor was not available for participation. These categorisations do not reflect the fact that half of the KIs played multiple roles and therefore carried multiple perspectives, e.g., one individual was primarily a researcher but also served on policymaking advisory committees. The illustrative quotes shown represent the KIs identified based on the study categorisation in Section 2.3. Additional quotes to support the themes are presented in [Annex 18](#).

The desk review and interview results are organised according to the seven analytical framework themes. Table 11 presents all *a priori* themes and sub-themes that emerged from analysis. Within each theme, barriers and opportunities for accelerated global access to PBO LLINs are highlighted.

Table 11. A Priori Themes and Emergent Sub themes Global Policy Analysis

	A Priori Themes from thesis analytical framework	Emergent Sub-themes
1	Context	Lessons from artemisinin resistance ⁵
2	Content	-
3	Actors	-
4	Power	Shifting balance of power
5	Adoption	Evidence Data on failure of current tools Evidence of Effectiveness Independent and clearly communicated evidence Lengthy and unclear global policy adoption process Developing an effective tool Availability of a product champion
6	Availability	Forecasting the PBO LLIN size of the market Affordability of PBO LLINs Fostering innovation Ability to meet global demand Clarity on the process and the evidence base required to convince policymakers
7	Affordability	Scientific and economic evidence; (presented under Evidence) WHO recommendation (presented under Adoption) Price

6.3.1 Policymaking Context

In sub-Saharan Africa, the proportion of the population with access to an ITN in their household increased dramatically from 3% in 2004 to 49% in 2013 (43). Ninety countries (42 of which are in the Africa region) have adopted IRS for vector control, although its implementation and coverage to date have been relatively low (43, 211). As of 2013, 4% of the global population at risk of malaria were protected by IRS (43).

⁵ Emerged from KI interviews even though they were not specifically asked about context

The number of African countries reporting resistance to the pyrethroid insecticides used to treat LLINs has increased as a result of large scale distribution campaigns across countries (5). While there is limited evidence on the epidemiological impact of insecticide resistance on the effectiveness of vector control interventions, at least five countries (Mozambique, South Africa, Senegal, Benin and Burkina Faso) have linked insecticide resistance to reduced effectiveness of vector control tools, leading to an increase in recorded malaria cases (37, 45, 46). However, the lack of adequate insecticide resistance monitoring at country level likely disguises the full extent of the problem (232).

6.3.1.1 Lessons from Artemisinin Resistance

All KIs drew parallels between insecticide and drug resistance, specifically artemisinin. There was a consensus that the vector control community could learn lessons from the manner in which the threat of artemisinin resistance was handled as a global issue. This resulted in World Health Assembly declaration that this malaria drug should never be used as a monotherapy (233). The proponents of artemisinin resistance containment are seen to be particularly skilled at communicating the drug resistance issue and advocating for solutions.

“I think that the pharmacologists and the medics and the doctors in the malaria world have done a much better job of making the case for drug resistance. ... if you listen to the people who have been making the case for managing artemisinin resistance, their presentation of the information, their ability to influence the key stakeholders, their ability to get investment in those things has far exceeded the ability of the vector control community in that sense. And they have done a much, much better job of advocacy for those issues, which is entirely proper, they’re not cheating, it’s just that they’ve seen a problem that relates to their area of expertise and they’ve done a very good job of advocating that set of issues.... we need the key individuals in the vector control community to coalesce and to drive this as a community” (Private sector)

6.3.2 Global Vector Control Policy Content

From a global perspective, LLINs and IRS are considered the two core vector control methods (232). WHO recommends “*full coverage of all people at risk of malaria in areas targeted for malaria prevention with LLINs*” (31). It is recommended that LLINs should be considered a public good for people living in endemic areas and should be provided free of charge or highly subsidised to achieve and sustain full coverage in all transmission settings (31). In 2014, the WHO VCAG, whose remit is to advise WHO on new forms of vector control, recognised that PermaNet® 3.0 has “*increased bio-efficacy*” compared to pyrethroid-only LLINs in areas of insecticide resistance (62). In December 2015 WHO issued a recommendation recognising that PBO LLINs may provide increased efficacy in some settings, but that they should be used only where universal coverage with LLINs and/or IRS will not be compromised. The 2015 recommendation also calls for accelerated deployment of PBO LLINs for evaluation purposes (63).

6.3.3 Policymaking Actors

Four groups of actors were identified through the desk review and KIs as being involved in accelerating access to PBO LLINs.

- i. Product developers/manufacturers: These are actors involved in the research, development and manufacture of PBO LLINs. All KIs recognised that, without the actions of these actors, there would be no development or production of PBO LLINs.
- ii. Policymakers/policy advisors: WHO, through its GMP, is responsible for the setting, communicating and promoting the adoption of evidence-based norms, standards, policies and guidelines to malaria endemic countries with support from technical expert committees which include the MPAC, Evidence Review Groups (ERGs), VCTEG and WHOPES (232). VCAG is an advisory group jointly established by the GMP and the Department of Control of Neglected Tropical Diseases to review and assess the public health value, ‘proof of principle’ (epidemiological impact) of new tools, approaches and technologies (232).

VCTEG is charged with making recommendations to MPAC on the “*effectiveness and appropriate mix of vector control interventions, including the adoption of new forms of vector control following the ‘proof of principle’ from the Vector Control Advisory Group*” (234). WHOPEs plays a role in the adoption of new tools as it is responsible for evaluating the safety, efficacy and operational acceptability of pesticides for public health use (235). It also sets standards, promotes and coordinates the testing and evaluation of pesticides, including those used to treat LLINs (235). ERGs are time limited bodies set up to review a clearly defined area of work, and to provide evidence-based recommendations to the MPAC (234).

- iii. Researchers: Studies and the results of the KI interviews show that researchers have a critical role in gathering evidence to capture the extent of the insecticide resistance problem (37), demonstrate the failure of current tools (45) and test the effectiveness (or lack thereof) of new tools, e.g., PBO LLINs (65). This type of evidence provided by researchers was viewed by all KIs as a key facilitator of policy adoption.
- iv. Donors: All KIs listed donors like GFATM, USAID/President’s Malaria Initiative (PMI), DfID as vital to ensuring access to PBO LLINs, particularly as their willingness to invest in new tools (affordability) is a key determinant of access. Issues of affordability are considered in greater detail below. In addition to traditional donors, one KI from the private sector highlighted the importance of donors such as UNITAID who provide catalytic funding or high-level subsidies for new malaria diagnosis, treatment and vector control interventions as being important in facilitating access.

6.3.4 Perceptions of Power

When asked about which actor wielded the most influence in ensuring access to new malaria vector control tools, all KIs described what can be viewed as a shifting balance of relative influence, i.e., different actors were seen to be ‘most influential’ at different points. Figure 11 is a simple illustration of the shifting balance of influence at various

stages of the process. The figure aims to show the most influential actor at a particular point in time, recognising that all actors wield a level of influence at all stages. Manufacturers were viewed as being particularly influential at the product development stage of access to PBO LLINs as they were responsible for decisions around investing in innovation and implementing product development initiatives.

“So let’s start with the product development process and the first step is clearly they have the product developed, so the first set of first key players is the industry who are developing the products” (Private sector)

At the product evaluation stage, the evidence generated by independent researchers is crucial, conferring significant influence on the actions of researchers at this stage in developing, synthesizing and communicating evidence.

“There is then a slightly softer group who influence it [policy] very strongly, by softer I mean they don’t have a direct decision making role, but they have a very strongly influencing role which is the people who create the evidence about the impact of those products” (Private sector)

At the policy adoption stage and beyond, WHO and donors were seen to wield the most influence, respectively; see Section 3.7 on the financial influence wielded by donors.

“Then when you do have a new product, which will hopefully happen in the near future, I think there is a massive role that organisations such as ours have to play in making sure that these new products are funded so that we create a market for them” (Donor)

“And you need, WHO, WHOPES, they have to be heavily involved because we would look to them for guidance, so it would be a quite powerful thing if they say all countries should be investing in these particular nets; that’s quite influential” (Donor)

“I guess it is WHO because they are the ones that in the end say, yes, they should be used and there should be a recommendation on it, or not so in that first decision-making

point it will be them. I mean later on the balance of the influence would possibly change” (Policy Advisor)

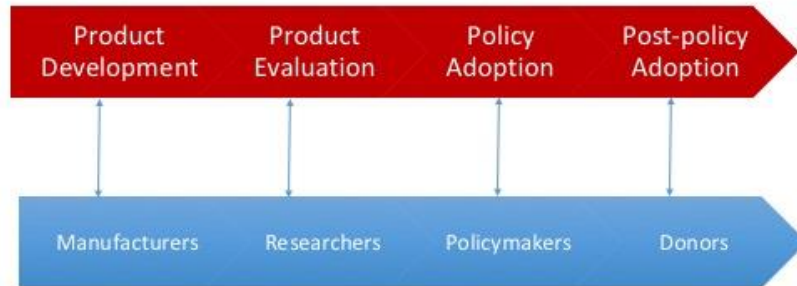


Figure 11 Actors involved in access to new malaria vector control tools and the stages at which they are most influential

6.3.5 Global Policy Adoption Process

The results of the document review show that global malaria policy adoption is a non linear iterative process between the primary policy setting organisation (WHO) and advisory groups with defined roles and a, Figure 12 (234).

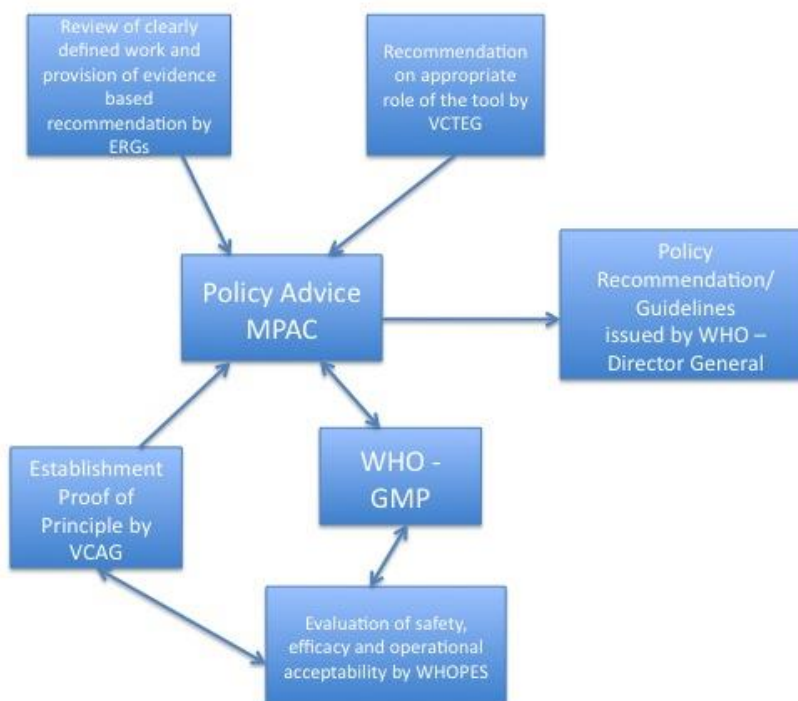


Figure 12. A schematic of the key WHO policymaking process [224]

ERG, Evidence review groups; VCTEG, Vector control Technical Expert Group; MPAC, Malaria Policy Advisory Committee; VCTAG, Vector Control Advisory Group; WHOPES, WHO Pesticide Evaluation Scheme

In 2011, WHO established the MPAC to provide independent advice on key malaria topics to the WHO Director General, who has the mandate to make WHO malaria policy recommendations and guidelines. MPAC develops this advice based on data from malaria endemic countries (232) and input from VCAG, VCTEG, WHOPES and ERGs (Figure 12). In relation to new vector control tools, VCAG assesses whether the tool's concept works, WHOPES sets the standards, which the tool must meet, and VCTEG

determines the tool's role in vector control in relation to other tools. MPAC advises WHO, which makes policy recommendations. The establishment of MPAC was intended to improve the timeliness, transparency, independence and relevance of WHO's recommendations (236). Some KIs, particularly those from the donor and researcher categories were unable to comment on the effect of the reorganisation on the global vector control policymaking process.

"I think everybody is a bit confused about what the role of VCAG is to be honest and VCTEG you know everybody out there is going like, so how does this link to WHOPES etc. and I don't have the answer to that either, I'm probably as confused as everybody else and I think it's an area that requires a lot more clarity about how these different bits are joined together" (Donor)

Furthermore, there is no clarity around instances when recommendations from different groups within the process seemingly contradict one another, as is suggested by some actors (particularly those in the private sector) in response to the PBO LLIN recommendation issued in December 2015 (237). In contrast to the confusion expressed by donors and researchers at least one KI (a policy advisor) was able to vividly describe how the VCAG, WHOPES and VCTEG executed their relative roles in relation to vector control policymaking.

"What does it [the new tool] do? How does it work? Does it really work? For that you need [those] who are going to ...test it to distraction, for me that's VCAG's task. Having established that, there are two further tasks; one is for WHOPES and one is for vector control TEG [VCTEG]. So one is 'okay, we're going to put out our tender for our companies to produce contraptions like these. What should our tender say? What are the standards that we should be looking for in such a thing when they produce them? ... we need some set of minimum standards, that is WHOPES job. And then for VCTEG, its, what's their role? In which battles do we want them? Where should we put them? Should we bring them into the beginning of the battle or the end of the battle, or what?" (Policy Advisor)

The synthesis of KI responses on the factors that facilitated the adoption of new vector control tools into policy resulted in broad consensus under four sub-themes.

6.3.5.1 Evidence

All KIs agreed that evidence was a key-determining factor for the adoption of PBO LLINs. However, in describing the evidence base required, there were nuances to the issue, which are categorised into three sub-themes as follows.

6.3.5.1.1 Data on Failure of Current Tools

KIs from all categories identified the need for robust data to show the operational impact of insecticide resistance and that current insecticide-based vector control interventions are failing. However, this was said to be hindered both by the fact that it is technically difficult to link insecticide resistance to intervention failure and that national insecticide resistance surveillance systems generally lack the resources/capacity to carry out the monitoring.

“Well I mean if there was compelling epidemiological evidence that what we are currently doing, not just nets but all insecticidal interventions were beginning to fail, then I think that will help” (Private sector)

6.3.5.1.2 Evidence of Effectiveness

All KIs recognised that robust evidence on the effectiveness of PBO LLINs was important for policy adoption.

“The consensus that having a good strong evidence base to show that it’s effective ... I would say the most important thing is the evidence and then everything else would flow from that” (Donor)

Two KIs cited the need for evidence to show that PBO LLINs are more effective than LLINs from both an entomological standpoint, i.e., more effective at interrupting blood feeding and/or killing malaria transmitting mosquitoes, and an epidemiological

standpoint, i.e., a reduction in malaria morbidity and mortality. Further, all KIs highlighted the lack of data in terms of quality and quantity as an existing barrier to the adoption of PBO LLIN.

“I think the other thing that is an enormous barrier is the quality of experimental evidence that comes forward.... One of the sets of combination nets is being delayed in this process because there are a number of poor quality trials associated with it that confused the data set” (Private sector)

Poor data quality is exacerbated by a lack of clarity on the data requirements needed to effect a policy change.

“It does need both a clear definition of what the data requirements are for creating a policy decision and what the nature of the trials, quality standards of trials that we need to execute in order to deliver that data” (Private sector)

Data on cost-effectiveness was viewed as an essential component of the evidence package required to influence adoption.

“I think the thing that would drive adoption in the first instance is the primary cost effectiveness question” (Private sector)

6.3.5.1.3 Independent and Clearly Communicated Evidence

Whilst all KIs agreed a package of evidence was required to positively influence policy, there was also a recognition that such a package regarding PBO LLINs was currently lacking. One KI cited two possible reasons for this: the trustworthiness of the evidence (given that manufacturers fund the studies) and a lack of consensus, resulting in evidence that is equivocal and not clearly communicated.

“And independence, I suppose is another thing because that’s what is really lacking from the debate at the momentOn one hand you expect the company to pay because

they're going to make all the profits if it goes well, but on the other hand there'll be a trust issue if they do pay" (Researcher)

"Well, that's the point we need consensus on it. There's no use one doing it and the other not agreeing and yes it's a difficult job because anything that WHO suggests, Dr X will disagree with. Anything that Dr Y suggests.... Dr Y will disagree and that's the end. Well, but somehow, we have to gradually move towards consensus" (Researcher)

6.3.5.2 Lengthy and Unclear Global Policy Adoption Process

KIs from the researcher, donor and private sector categories stated that the process is lengthy and that the relative roles of the numerous policymakers/advisors were unclear.

"The main barrier I would argue is that it's [the adoption process] not well defined and so nobody knows exactly what place they have to go, how long it's going to take, who's going to make critical decisions, etc. And that's really where things are seriously not good at the moment in the world of vector control" (Researcher)

The recent recommendation by the WHO on conditions of use of PBO LLINS was an important attempt to resolve this bottleneck. However, KIs contacted after the recommendations were published stated that the recommendations do not indicate where and under what conditions countries might consider deployment. Furthermore, the KIs stated that the recommendations emphasise that universal coverage of LLINs and/or IRS should not be compromised and call for robust evaluation – the nature and parameters of which are not clearly defined.

The December 2015 PBO LLIN recommendation has been openly criticised by members of the private sector as demonstrating a poorly defined scope and lack of transparency around the approval processes for new tools within WHO (237). This is in stark contrast to the picture some KIs (particularly policy advisors) and the WHO documents present

on the relative roles of the policymaking process being clearly defined and relatively straightforward.

6.3.5.3 Developing an Effective Tool

KIs identified in the donor and private sector categories recognised that developing a truly novel tool was very difficult. Currently, the PBO LLINs undergoing evaluation still incorporate pyrethroids, with one KI describing them as an interim/stopgap measure until LLINs treated with two or more non-pyrethroid-based insecticides become available on the market. Donor and private sector KIs viewed the absence of a truly novel product as a barrier to global adoption of tools like the PBO LLINs.

“I think it will be easier to do when there are completely novel insecticide coming into this moment when we talk about combination nets it’s a pyrethroid plus something else but may or may not work very well or we are talking about nets with a synergist in but I wouldn’t necessarily call nets with synergist combination nets” (Private sector)

6.3.5.4 Availability of a Product Champion

All KIs recognised the role that prominent figures have played in promoting access to LLINs and artemisin-combination therapies (ACTs), corroborating studies that cite the need for a high profile product champion (120). However, two KIs cited the lack of an advocate for the adoption of PBO LLINs.

“You need product champions that are not the manufacturers of the nets. I know there were a group of people there that synthesised the evidence [on LLINs] and said look at all these trials they are showing the same thing and really pushed it. I think the same is happening a bit with repellents at the moment now. So I think it needs somebody, a group of people preferably multi-disciplinary, to really start pushing it forward and I can’t really see that happening at the moment” (Researcher)

While the ability to champion vector control solutions was considered by KIs to be somewhat hindered by the lack of robust evidence, a clear process, an innovative tool, and/or a product/group of product champion(s), KIs cited a number of opportunities to facilitate the global policy adoption of PBO LLINs.

Firstly, the existence of the relatively newly created WHO advisory bodies, such as VCAG, is viewed by KIs as a positive step in facilitating global adoption of PBO LLIN. While the uncertainty about relative roles with other policy influencing bodies exist amongst some categories of KIs, the very existence of a body tasked with making recommendations on the 'proof of principle' of new vector control tools was viewed by all KIs, particularly policy advisors, as a positive step.

“Well, I think that the primary barrier in the last five years has been non-existence of the vector control advisory group. And now that that exists and is in a position, before VCAG there was nothing and when one said who do I go to, to have a policy about this, there’s nothing. So, now that VCAG exists, now there is the right place to go to, and as I was saying before, it’s not perfect realistic yet but they are still learning. But they are at least empowered to make those decisions and make those recommendations; so I think that primary thing has been overcome. I think there is still some uncertainty about the relationship between VCAG and WHOPES and how those two things interact and how products move from one to the other and what’s their relative part of the process is and I think that would get sorted out by people actually bringing things forward and trying and presenting them to the process” (Private sector)

“I think that actually the existence of the VCAG, Vector Control TEG [VCTEG] have already assisted, accelerated the process of policy development” (Policy Advisor)

In June 2014, when interviews were conducted, KIs expressed a need for a clear WHO recommendation, on the utility of next generation LLIN, as well as when and where they would be appropriate, would have a direct and significant impact on their availability and affordability.

“I mean if I was a manufacturer, which obviously I’m not, I wouldn’t scale-up significantly of course until I’ve got my WHOPES approval and the WHO policy position in place” (Policy advisor)

“It’s not just that you have a net out there but this net’s going to give more bang for the buck. Having it in a separate category is important because when we procure nets basically, right now all nets are the same.... Because there’s no global standard that says any of them are different from the other, they all go into one batch and then the price basically drives which net you procure. So obviously, these need to have been endorsed in some way that they are in a separate category because otherwise you are just going to have price driving the procurement” (Donor)

Based on the private sector response and follow up communication from Donors, it would appear that the December 2015 WHO recommendation does not provide the clarity needed.

At the time of the interviews (June-July 2014) one KI was optimistic about the future of the adoption process and expressed that solutions to this barrier were eminent.

“There’s a sense that that whole area of the strange special things that happen around vector control regulatory process is on the verge of getting resolved and it’s not something that we worry about terribly much at the moment because there seems to be some good solution proposals outside there, and the [Gates] Foundation is putting a lot of effort into addressing those” (Private sector)

It appears that though not expressly stated some of the solutions this KI alluded to was the launch of the I2I partnership.

6.3.6 Availability

The availability of PBO LLINs was predicated on five factors cited by KIs, which convinced manufacturers to engage in their development and manufacture.

6.3.6.1 Forecasting the PBO LLIN Market Size

All KIs viewed the ability to forecast the PBO LLIN market size as the biggest motivator for manufacturers to develop and produce them.

“The positive thing would be if the manufactures were confident that there was a market, I think that’s quite important and that they won’t produce unless they think they can sell it” (Policy advisor)

KIs reported that forecasting the size of the market is hindered by limited data on where current LLINs are failing and no recommendations on the context in which PBO LLINs should be used. These limitations make it virtually impossible to estimate the market share that PBO LLINs will have when rolled out.

“So, there isn’t a clear market today, you can’t point to a clear market today and say 30% of the bed net market is combinations nets and it’s going to grow to 50% in five years, there’s just no data that would support anything like that. And it would be very interesting to understand of the two PBO nets, ... just how much market share they were taking” (Private sector)

The inability to predict the market share of PBO LLINs was viewed by all categories of KIs to be aggravated by fluctuations in demand for any type of LLINs as a result of funding uncertainties and the tendency to distribute LLINs through mass campaigns every 3 years, resulting in high demand during a year followed by relatively low demand in subsequent years (238).

“The predictability of financing, we’re in a bit of an unpredictable period at the moment, that would be one of the things would potentially be putting me off as a manufacturer” (Policy advisor)

In addition to the direct resolution of the issues around improved data on LLIN failure and clarity around normative guidelines on where and when PBO LLINs would be

appropriate, most KIs recognised that improving the global tendering and procurement processes around LLINs is vital to facilitating the availability of PBO LLINs.

“We should look at the procurement process and somehow try and get away from the problems associated with tenders. I would promote a multiple year tender, the tender wouldn’t just be for 500,000 nets, 20 tons of it or IRS spray, it would be for the resistance management program. ...It’s all part of the long-term tendency. I think it will ease out the uncertainty, commercial companies would have more confidence therefore they will be more willing to invest” (Private sector)

It was also recognised that changing the tendering/procurement process and providing predictability would require concerted effort on the part of all actors and particularly donors.

“In effect pooled procurement by the three agencies [GFATM, PMI and DfID] I think would also be very helpful in that context so that the manufacturers know when the product will be needed, how much of it will be needed, and they can manufacture according to that and by doing that they can cut down on cost” (Donor)

6.3.6.2 Affordability of PBO LLINs

All KIs viewed the affordability of a PBO LLIN as a critical factor in determining its availability.

“For the manufacturers it’s the money. If they see a product in their class being bought, it’s pump money into our product and if there’s a reason why they bought some other product in this class instead of ours, fix it” (Policy advisor)

The factors that were reported to influence the affordability of PBO LLINs are considered in the detail in the section on affordability.

6.3.6.3 Fostering Innovation

KIs from the researcher, donor and, most strongly, from the private sector categories cited the limited protection of innovation, as a direct result of the nature of the WHOPES registration process, as a barrier to availability. In particular, the 'equivalence process', where new LLIN brands are able to receive WHOPES recommendation if they are chemically equivalent to an original product that has received WHOPES recommendation, is viewed as a disincentive to innovate.

"They also have to have some sort of protection for their innovation; which seems to be a major issue that's coming up now that if they develop these nets, especially for something quite innovative, spend millions developing and then marketing them, and then the generic comes along and has the same idea and then they've lost all their market" (Researcher)

The protection of innovation is vitally important, particularly in light of the fact that KIs recognised the technical difficulty inherent in developing a truly innovative product.

6.3.6.4 Ability to Meet Global Demand

Two manufactures (Sumitomo and Vestergaard Frandsen) currently have PBO LLINs on the market, giving rise to concerns from two KIs from the researcher and policy advisor categories, regarding the ability of manufactures to meet global demand.

"There are some issues like if it were to be only one manufacturer whereas now there is some diversity, still not a lot but there are a number of WHOPES approved long lasting nets. So what is going to happen to those companies that were making the ones that aren't the combination ones? Are we gonna lose those players cos if you say that you shouldn't be using a mono-therapy net then what's going to happen to them" (Policy advisor)

6.3.6.5 Clarity on the Process and the Evidence Base Required to Convince Policymakers

Researchers, private sector and donors all cited a need for clarity on the policy adoption process as well as the package of evidence required to convince policymakers as a current barrier to the availability of PBO LLINs.

“I think there needs to be a clear process for evaluating the products. A clear understanding of how you measure if one of these products is better than a current standard LLIN and then be able to communicate with people who are procuring this net that this is better than a normal net by some standardised level and therefore it is worth paying an extra however much the net is going to be” (Donor)

6.3.7 Affordability

Over the past decade, 80%–90% of vector control has been funded by international donors (32). Thus, when considering the issue of affordability, all but one KI outlined factors that were likely to influence an international donors’ willingness to invest in the purchase and distribution of a PBO LLIN.

“Vector control for malaria is at least 80% if not 90% financed by international funds, so obviously affordability is driven to 80% or 90% by what convinces donors to invest in that. They would be convinced by experts, by academics, by VCAG, by all of the bodies who would review the data, make a judgment on whether that’s good or not, and, if it’s a more expensive product (which is very likely to be the case), whether that increase in whatever it brings is worth the money you have to fork out for it” (Researcher)

One KI highlighted that the lack of local production of LLINs, and the probability that PBO LLINs will also be an external solution, discouraged national funding allocation for vector control.

“To a degree, there is a fatigue amongst African leaders and ministers of health against nets because they’re seen as a product that comes from outside of the continent that’s been pushed by donors. I think if there is an economic development, even if the nets are slightly more expensive, I think it’d be a much more sustainable market if they were actually manufactured within the continent” (Policy advisor)

Three factors were perceived to be critical in influencing the international donor’s willingness to invest in a PBO LLIN: i) scientific and economic evidence, ii) WHO recommendation (see Section 6.3.5), and iii) price.

6.3.7.1 Price

All KIs agreed on the assumption that more effective next generation LLINs (PBO or combination LLINs) are likely to be more expensive. KIs, particularly those from the Donor category, reported that the absence of guidance on when it would be rational to pay more (supported by robust cost effectiveness analysis) and limited resources hinders the affordability of PBO LLINs.

“It’s going to be a difficult prioritisation decision by a country that hasn’t got enough money to sustain universal coverage to buy more expensive nets. And with the new funding model, it’s much more the decision of the country than of the global fund itself but it’s about how you prioritise that resource package” (Policy advisor)

“I think the other big chunk is getting the funders happy with the idea that they’re going to have to pay more for the nets. It’s unrealistic to expect these products to arrive at the same price that the pyrethroid bed nets are today and the intervention funders need to get their minds around that” (Private sector)

However, IRS programmes have been abandoned in the past due to the increased costs of switching to more effective alternatives.

“Well, I mean without knowing the price for it, I think the biggest barrier for it being rolled out would be cost. You know, anything that costs more than what the current pyrethroid LLINs cost will be a problem. And you can see this very nicely at the moment already where with the spraying, I mean the switch to a different carbamate that should be occurring, is not occurring at the rate it should be because actually if you do start rotation....a switch to a carbamate in areas of pyrethroid resistance, you can basically forget about your spray program because the size of it would be so small with the existing funding that uptake of that is going to be very limited and you can see that in the world malaria report where coverage of IRS from 2011 to 2012 it’s come down quite a bit because of this need to switch and, well, if you can’t switch then you may as well not do it at all, that’s sort of the long and short of that. So I think the adoption of the combination nets would be faced by similar challenge unless the cost is somewhat comparable” (Donor)

A number of KIs cited the potential for increased costs to impact the ability to sustain required LLIN coverage levels.

“The change that needs to go on with the investors is about a shift from coverage to impact as their metric. But at the moment, because in effect all the products are the same, it makes sense to have a coverage-focused metric. If you move into a world in which the products aren’t all the same, then coverage is no longer a viable metric and one needs to move to impact as a metric, that’s much more difficult to measure” (Private sector)

While KIs did not consider it likely that donors would abandon LLIN programmes altogether, the ultimate affordability question, as one KI stated, is:

“Can manufacturers produce this [PBO LLINs] at a cost that the market would bear, especially given that there are funding constraints on all sides” (Donor)

Two KIs felt that discussions around LLIN durability have facilitated a shift in conceptualization of cost effectiveness, with some donors moving from price per LLIN to models that consider price per year of effective coverage.

“I think you’d find that for the durability, for example, if you said we’re not doing unit price, these days, they’d be very happy with that. Now, that was definitely not true in 2010, but I think things have changed. And if you said, oh, we’ve got these reasons to suppose that this product is better value for money in terms of dollars per year of coverage even though it’s not the cheapest per unit, if your data is good, they’ll go with that” (Researcher)

KIs cited the potential for catalytic funding and/or high-level subsidies to address the affordability issues and facilitate access to PBO LLINs.

“So I think the adoption of the combination nets would be faced by similar challenge unless the cost is somewhat comparable and yes, you know, somebody can put some catalytic funding in there initially to create the market” (Donor)

6.4 Discussion

This study considers the opportunities and barriers associated with the global vector control policy adoption of PBO LLINs. The study identified three fundamental factors that have a knock on effect on all other areas which when addressed can facilitate increased access to PBO LLINs, namely i) evidence to facilitate global adoption; ii) global adoption which is key to facilitating availability and affordability; and iii) price, which is central to improving affordability in the current resource-constrained context.

The global policymaking context is experiencing a period of rapid changes and since this study was conducted a number of key changes have taken place including the establishment of the I2I partnership and the publication of guidelines for testing new LLIN products (including PBO LLINs) to determine efficacy in areas of high insecticide resistance (240) and recommendations on the conditions for use of PBO LLINs (63). The

impact of these developments on the study outcomes and future directions are highlighted where applicable.

6.4.1 Evidence

This study demonstrates that a package of evidence that is independently developed and clearly communicated comprised of evidence of the problem (failure of current tools), the effectiveness of the new tools, and cost effectiveness data are core requirements for access to new tools. In the policy adoption process for PBO LLINs, evidence constituted a barrier, as policymakers had not clearly articulated the package of evidence required to change policy, leading to recommendations that pose more questions. This lack of clarity impacts on the actions of the manufacturers in their preparation of evidence packages to convince policymakers. The current adoption process, as far as evidence is concerned, is one of trial and error.

In future, if guidance on evidence requirements is pre-issued to manufacturers and evidence dossiers are developed with WHO and expert committees conducting inspections of manufacturing sites, concerns raised by KIs about the lack of clarity around the evidence base required to influence policy are likely to be addressed. These actions could also raise confidence in the independence of the evidence generated as well as promote closer engagement between the manufactures and policymakers and - a strategy seen to promote the appropriate use of evidence in policymaking (112).

The I2I seeks to foster innovation by allowing the review of new vector control tools to be evaluated and recognised for claims superiority (241). This would theoretically encourage developers of new vector control tools to innovate and develop vector control tools that perform beyond minimum safety and efficacy standards on which they are currently assessed.

The issue of evidence is also significant in convincing donors to fund PBO LLINs, given that donors are considered to be evidence driven. This study demonstrates that, though for different reasons, donors, policymakers and manufacturers all require robust

evidence of sufficient quality that supports a clear policy recommendation. This is an instance where the interests of all actors, including researchers, who rely on research publication for promotion (151), are aligned. Therefore, improved coordination across all actor categories may result in generating relevant evidence for policy change.

6.4.2 WHO Recommendations

The lack of WHO recommendations/normative guidance on where and when PBO LLINs should be deployed is a serious obstacle to access. It hinders national adoption, as seen in the Burkina Faso case study (Chapter 5), and causes uncertainties regarding market share and returns on investment, making manufacturers reluctant to venture into development and manufacture (231).

Further, the main donors are unwilling to fund tools that have not been recommended by WHO (242, 243). In instances where PBO LLINs have WHOPES approval as a standard LLIN (PermaNet[®] 3.0 and Olyset[®] Plus), from a funding perspective, they are treated the same as standard LLINs, making it difficult for manufacturers to charge more for any additional benefits they provide. This cycle continues considering that, as shown herein, the willingness of donors to fund a tool (affordability) is directly linked to the manufacturers' willingness to develop and manufacture it (availability). In contrast KIs recognise the need for donors to make a conceptual shift from coverage to impact as their metric making a case for more effective PBO LLINs.

In theory the recent recommendation by WHO gives donors the justification required to fund PBO LLINs, but its emphasis on maintaining universal coverage makes a shift to PBO LLINs virtually impossible in practice given resource constraints and fixed budgetary envelopes. The 2015 PBO recommendation lends some credence to the confusion expressed by KIs around the policy process. While it is clear that in giving advice to the WHO – director general, MPAC receives input from several bodies (Figure 11), it is not clear how differences in opinions and seemingly contradictory positions are resolved. This leads to what the researcher (quoted above) describes as a lack of clarity

on where to go and who has the final word on issues to do with vector control policymaking.

An important development is the establishment of the Innovation to Impact (I2I) partnership in 2015 (after KI interviews were conducted) to support a clear path to market for tools by making the global adoption process transparent and timely (241). The partnership aims at achieving these objectives by:

- i. Ensuring that vector control tools are evaluated based on evidence dossiers (with pre-submission of guidance to developers) (241). This would potentially provide clarity on the specific evidence base required to influence policy.
- ii. Ensuring that evidence is generated in close coordination with WHO (including manufacturing site visits by WHO experts and committees) (241). This would contribute to addressing the concerns around the independence of the evidence generated by product manufactures.
- iii. Ensuring that WHO utilises of a wide range of experts independent of the developers to review product dossiers multiple times a year (241). This would improve the transparency and the timeliness of the review process.
- iv. Ensuring that guidance is provided to funders and countries to facilitate comparative assessments of vector control tools (241), thereby facilitating decision-making on the choice of funding/deploying vector control tools in relation to existing vector control tools.

In future I2I plans to provide guidance to funders and countries that allows comparative assessments of vector control tools. Guidance of this nature would facilitate access to new vector at tools by aiding decisions on where and when the new tools are the most appropriate compared to older tools. However, the extent to which the partnership improves the global adoption process remains to be seen.

6.4.3 Price

The potential cost of PBO LLINs, as with most insecticide resistance management measures, is a major barrier to access (198). International disbursements to malaria-

endemic countries have increased markedly, from less than US\$ 100 million in 2000 to US\$ 1.97 billion in 2013 (211). While this shows a significant increase in international funding, the upward funding trend has slowed since 2009 and it is recognised that the current funding environment, including for vector control, is constrained (211). The recent ERG recommendations may result in donor and countries being dis-incentivised, as purchasing more expensive tools while maintaining universal coverage is difficult within a fixed funding envelope and a resource-constrained environment.

A viable solution to address higher prices includes improved forecasting of demand for PBO LLINs over a number of years and pooled procurement. These practices can result in improved forecasting/predictability of PBO LLIN demand and lead to lower prices (198). This is being used as a strategy to reduce to cost of next generation insecticides for IRS under a UNITAID supported project called NGENIRS (244). This project is a positive precedence, however given the seriousness of the threat of insecticide resistance to vector control and the long-term goal of malaria elimination, an increase in resource commitments and an adjustment to the concept of paying higher prices for more effective tools may be the inevitable cost. This adjustment may be aided by a shift from measuring the coverage (i.e. number of tools distributed) to the measurement of their impact.

While none of the study KIs cited plans to subsidise the cost of PBO LLINs, subsidies, local manufacture and sustained financing were viewed as effective strategies for promoting availability and mitigating cost barriers. These strategies were instrumental in promoting access to ACTs and antiretroviral therapies (141, 224, 245, 246). An important distinction between the access to ACTs and PBO LLINs is that, for ACTs, there was unity behind the concept and a number of different products were available (247). However, without clarity on what package of evidence will result in policy change, solutions to reduce price and advocacy for high-level subsidies of PBO LLINS will be premature.

Studies have shown that policy champions can be powerful in facilitating access to new interventions (120, 151). In the malaria context, this has been pivotal in drawing

attention to the need for increased access to Rapid Diagnostic Tests (RDTs) and ACTs (120, 247, 248). The missing link for vector control tools that address insecticide resistance appears to be policy champions comprised of multi-disciplinary actors coordinated in gathering, packaging and disseminating evidence as part of advocacy to address insecticide resistance in general using tools such as PBO LLINs.

6.5 Conclusions

This study demonstrates that a package of independently developed and clearly communicated evidence that demonstrates the failure of current tools as well as the effectiveness and cost effectiveness the new tool are key facilitators for policy adoption. The case study underscores the need for greater clarity on the relative roles of the key policy advisory bodies. In addition, while the recent 2015 guidance on the use of PBO LLINs is a welcome development, clearer WHO guidance on where and when countries may choose to deploy PBO LLINs is still required to promote donors' willingness to invest in them. In addition, the study highlights that efforts on innovative procurement mechanisms that can support forecasting of demand and facilitate price reductions are needed in order to foster availability and affordability. Finally, this study demonstrates that more effective coordination amongst the vector control stakeholders is urgently required to collect robust and appropriate data and raise the profile of the threat of insecticide resistance as well as advocate short- and long-term solutions.

7 Chapter 7: Synthesis of Findings and Recommendations for Accelerating Access to New Vector Control Tools

7.1 Introduction

The overall aim of this thesis was to explore the factors influencing access to new vector control tools so as to develop recommendations on improving strategies to accelerate access. A synthesis of the findings from the three case studies in Chapters 4–6 is presented, followed by a discussion of the five key areas that must be strengthened in order to accelerate access to new malaria vector control tools.

7.2 Synthesis of Results from the Global and National Case Studies

As stated in Chapter 1, the achievements of SDGs is linked to the elimination of malaria which in turn is dependent on vector control strategies that utilise new and innovative vector control tools. However, these new vector control tools can only be useful if the people who need them can access them (109). People's ability to acquire and use (access) new vector control tools is predicated on a number of factors at the global, national and sub-national levels (152). The aim of this thesis was to gain insight into the factors, at both the global and national levels, that influence access to new malaria vector control tools and to provide recommendations on strategies for accelerated access. This line of enquiry was framed around the two questions:

- What factors influence the adoption of new malaria vector control tools at both the national and global levels?
- What opportunities exist at the national and global levels to accelerate the adoption of new malaria vector control tools?

As detailed in Chapter 3, the synthesising of the findings was an iterative process informed by data from the three case studies and documents reviewed. This process resulted in the identification of eight key policy influencers with the key findings in

relation to each case study summarised in Synthesis of key findings from the three case studies presented in Chapters 4–6 .

Table 12. Synthesis of key findings from the three case studies presented in Chapters 4–6

	Policy influencer	Global Case Study – Policy analysis of next generation LLINs	Nigeria Case Study – Policy analysis of larviciding scale-up	Burkina Faso Case Study – Policy analysis of next generation LLINs
1	Evidence regarding the problem, e.g., insecticide resistance	Evidence of the magnitude, intensity and impact of insecticide resistance is required	Use of insecticide resistance data for decision-making is not routine	Capturing insecticide resistance data was important, but local evidence does not directly impact policy
2	Evidence regarding the tool	The effectiveness of new the tool in multiple settings is required Evidence demonstrating the failure of old tools	WHO recommendation is accepted as evidence of effectiveness	WHO recommendation is accepted as evidence of effectiveness
3	Evidence source and quality	Independent/clearly communicated evidence is required for policy adoption	Local evidence is necessary (even if funded by manufacturers)	International sources of evidence are ideal
4	Data on cost-effectiveness	Data on cost-effectiveness of the new tools is required	Cost-effectiveness is viewed as a donor construct and is an ancillary factor	Unit price rather than cost-effectiveness is important because in the absence of increased resources, actors would rather deploy potentially less effective/cheaper tools than new/more effective and expensive tools
5	Transparent and timely policy adoption process	Lengthy and poorly defined policy process Poor articulation of evidence required to facilitate policy adoption	Well defined national policy process Policy process is disconnected from researchers Policy process can be ignored by high-level politicians to adopt their priorities	Well defined national policy process Strong links between policymakers and researchers National policy adoption is futile without global adoption and donor funding for intervention

6	Availability and source of financing	About 80% from international donors, mainly GFATM	Primarily international donor funds National resources can be committed when intervention is aligned with high-level politician priorities, e.g., economic development through technology transfer	Primarily international donor funds Absence of WHO recommendation impedes donor funding
7	Price of new tools	The price of the new tool can be a barrier, particularly if the expectation is to deploy without losing current coverage levels within a fixed funding envelope	The price of larviciding was not an issue – government prepared to fund/explore alternative funding sources	Unit price of the new vector control tools is paramount in order to achieve universal coverage targets within a fixed funding envelope
8	Product champion	Multiple messages need to be clearly communicated -the scale of the insecticide resistance problem, the appropriate tools and the appropriate context to address insecticide resistance Confusion as to the advocacy/policy champion mandate of the actors and partnerships aimed at facilitating access to new vector control tools	High-level regional and national actors pushing the scale up of larviciding	The emphasis in Burkina Faso was less about policy champions at the national level but more on the need for the global adoption and funding of new vector control tools

7.3 Accelerating Sustained Access to New Malaria Vector Control Tools

In order to leverage on the potential for the 8 policy influencers, identified in table 10, to accelerate access to new vector control tools, five areas need to be addressed:

- i. Increased availability of high quality, robust, appropriate and independent evidence that demonstrates the magnitude, intensity and impact of insecticide resistance, the effectiveness and cost effectiveness of new tools;
- ii. A transparent and timely global adoption process that facilitates national adoption and international funding;
- iii. Diversified funding sources for procuring new vector control tools at the global and national level;
- iv. Innovative mechanisms to address the price of new vector control tools at the global and national level; and
- v. Strengthened coordination among global, regional and national actors to clearly communicate the issue of insecticide resistance and champion appropriate vector control policies and tools.

The following sections present a discussion on these five areas using evidence from the three case studies and document review to support the recommended courses of action.

7.3.1 Increased Availability of High Quality, Robust and Appropriate Evidence

The three case studies corroborate previous reports that demonstrate that evidence often has a role in policymaking (81, 130, 151, 249, 250). However, the case studies also show that, in relation to new vector control tools in the context of insecticide resistance, the ability for evidence to influence access is nuanced and what is required varies by policy level. The package of evidence currently required to facilitate global policy adoption needs to better demonstrate the full extent of the insecticide resistance problem at country level as well as the relationship between the various insecticide

resistance mechanisms and malaria vector control tool failure, linking the entomological effects of insecticide resistance to epidemiological impact. More conclusive evidence of this nature is required, but difficult to develop (37, 251). The evidence related issues are the most immediate priority to be addressed as in the absence of this package of evidence, policy support for adoption of new vector control tools to tackle insecticide resistance, particularly at the global level, will continue to be slow. However, to date, the development of robust and appropriate evidence in relation to new vector control tools has been slow, indicating that while this recommendation is key the feasibility of its operationalisation will be affected if not supported by i) a transparent and timely global adoption system (section 7.3.2) and ii) a strengthened coordination among global, regional and national actors (section 7.3.5). The impact of the absence of evidence appears to be less significant at the national level, where data was either not routinely collected (Nigeria) or lacked the power to directly influence national policy (Burkina Faso).

Evidence regarding the effectiveness and cost-effectiveness of the tool was confirmed as a significant policy facilitator. In both national settings, WHO recommendations were accepted as sufficient evidence of the tool's effectiveness. However, in Nigeria, but not in Burkina Faso, local data was an additional requirement for adoption, confirming studies that argue that the role of local evidence is dictated by the national policy context (222, 252). At the global level, the availability of independent, clearly communicated, robust evidence to demonstrate the effectiveness of the tool in multiple settings was required to influence policy, and cost-effectiveness data was regarded as an important element of the package of evidence. However, at the national level, it was viewed as ancillary because it was considered a donor construct (Nigeria). In Burkina Faso, price rather than cost-effectiveness was viewed as being more central to achieving universal LLIN coverage targets, which currently emphasise universal coverage of tools rather than impact on malaria transmission. Whilst universal coverage targets should not be discarded, the role of new vector control tools in reducing malaria transmission in areas of insecticide resistance while not necessarily achieving universal coverage needs to be explored.

The recent WHO recommendation on the use of PBO LLINs calls for the phased roll-out of new tools for evaluative purposes (63). On the one hand this is a valid means of developing policy relevant evidence that considers the nuances inherent in the evidence requirements at the global and national levels. However, this strategy should have been implemented earlier in the PBO LLIN adoption process in order not to further delay their wide scale access. Furthermore, these evaluations require human and financial resources to be implemented. A resource option would be for national policymakers, particularly in countries that require local evidence for national adoption, to prioritise these evaluations and include them in applications to donors like the GFATM and the President's Malaria Initiative (PMI), which in the past have been predisposed to supporting pilot-based deployment of new tools in the context of robust entomological data gathering (253). These actions need to be underpinned by the development of national capacity to carry out routine data collection and large-scale trials, a recommendation that is extremely difficult to implement given the recognised shortages in key expertise such as entomologists (254). In addition, the use of the evidence at national level to directly influence policymaking needs to be enhanced using strategies that have demonstrated to be effective (111).

In future, pre-issued guidance to manufacturers should facilitate the early development of policy relevant evidence and avoid delays in access due to a lack clarity around the evidence needed to influence policy (241). In addition, in order to accelerate access, global policymakers may consider options like issuing interim recommendations based on minimum standards of safety and efficacy in order for vector control tools to act as a stopgap while evidence or more effective options are being developed (139).

Finally, future analyses need to explore the potential for regional level evidence to be developed and used to influence policy across multiple national contexts, taking in account the unique malaria transmission settings, a viable option would be the implementation of multicentre trial sites. Additionally, initiatives such as Elimination 8 – a coalition of eight southern African countries aimed at aligning policies and strengthening regional surveillance and analysis – can be explored as a template for regional cooperation in relation to developing a robust evidence base.

7.3.2 A Transparent and Timely Global Adoption Process

The global and Burkina Faso case studies show that a transparent and timely global adoption process can facilitate access to new vector control tools, particularly as global adoption significantly impacts on international funding. In the absence of this, product innovation and development is potentially stifled, and national adoption and international financing is hindered. Conversely, the national level policy process appeared to be well defined, though it was undermined by high-level politicians in Nigeria and futile in the absence of funding in Burkina Faso.

Some commentators hold the opinion that the recent WHO recommendation on PBO LLINs has exacerbated the confusion in malaria vector control policymaking, lengthened the PBO LLIN access timeline and further discouraged innovation in the development of new vector control tools (237). Further, it remains unclear whether new vector control tools manufactured with completely novel insecticides will require additional regulatory approvals and the required timeframe for this, since, to date, all insecticides being employed for public health purposes were repurposed from agricultural use (255). This may add a further layer of regulatory approval steps that the public health community currently has little experience in tackling, as well as further time.

Furthermore, KIs from the global study held the view that innovation for the development of novel vector control tools is potentially stifled, firstly, due to the public health market being less profitable than the agricultural insecticide market (256) and, secondly, due to the WHOPES equivalence process conferring an unfair advantage on the manufacturers of generic tools. However, the harm to industry may be overstated given that two innovating manufacturers (Sumitomo Chemical and Vestergaard Frandsen) still account for 75% of the GFATM- and PMI-financed LLINs (257).

At the global level, there is optimism that the lack of transparency in the malaria policy process is being addressed by the creation of the WHO MPAC, the VCAG and the strategic use of the VCTEG (80, 236). While some of this optimism may have been

eroded by the view that the recent PBO LLIN recommendation was not transparent, the plans articulated by the I2I partnership to make the global adoption process more timely and transparent are positive steps. These establishment of these bodies and partnership suggest that addressing issues in relation to the transparency and timeliness of global policy adoption is both imminent and feasible. (241). This partnership, in conjunction with the existing WHO mechanisms, is potentially a very powerful instrument for imminently addressing the shortcomings of the global adoption process (257, 258). Whilst recognising that the I2I partnership is relatively new, a potential weakness in its current approach to national adoption of new vector control tools is the disproportionate emphasis on the national registration of tools at the expense of addressing the drivers of national policy adoption. Although registration can prove to be a barrier, and the process involved in the registration of vector control tools in countries needs to be accounted for in the access timeline, registration did not emerge in the Nigeria or Burkina Faso case studies as a major barrier or facilitator to access. However, this may be due to fact that both larviciding and PBO LLINs utilize chemicals that have long been registered and in use at national level.

It is noteworthy that, if the difficulties around the required evidence base discussed above are not addressed, the likelihood for the global adoption process to be transparent and timely will continue to be hindered, thereby hampering the success of any mechanisms established to accelerate access to new vector control tools. In future, the system needs to be more timely than has been exemplified by the case of PBO LLINs, i.e., the evidence required to facilitate policy adoption needs to be clearly defined and the process needs to be shorter and more transparent, particularly with regards to the relative roles and inputs of the various global policymaking/advisory bodies. The extent to which the plans of MPAC, VCAG and VCTEG, as well as the I2I partnership, will improve the global adoption process for vector control tools and navigate any additional regulatory approvals, and the extent to which these may result in additional delays, remains to be seen.

7.3.3 Diversified Funding Sources for Procuring Vector Control Tools

The potential for the availability of funding to positively and powerfully impact the adoption of a tool was confirmed in the national case studies. Specifically, the source of the funding created a significant impact on adoption of new tools. Indeed, the underlying assumption at the inception of this thesis was that unlocking international donor funding was at the core of facilitating access to new vector control tools. This assumption was valid given that, between 2005 and 2013, approximately 80% of the funds spent on malaria control were from international donors (32). However, the Nigeria case study showed surprising results, whereby the potential for national funding facilitated policy change, while the Burkina Faso case study demonstrated the dangers inherent in the overreliance on international funding, particularly as they are highly influenced by a global adoption process that is still in the process of being improved.

Furthermore, history has demonstrated the devastating impact that donor fatigue has had on countries unable to fund malaria control themselves (4). Indeed, the failure of the previous global eradication efforts and malaria resurgence in a number of countries has been attributed, at least in part, to a lack of sustained donor support. A diversified funding base that includes national funding streams is the only way to ensure rapid and sustained access to vector control tools in countries that need them until malaria elimination is achieved. Thus, any efforts to promote access to new vector control tools as a means of eliminating malaria that do not incorporate strategies to diversify the funding base and include national funding sources, where possible, are likely to fail (2).

Considering donor fatigue and the attractiveness of 'African solutions for African problems' (222, 259), the local manufacture of new vector control tools, supported by technology transfer, offers the potential for national economic development and is a powerful strategy for facilitating national funding (138, 260). For example, the lack of adequate technological transfer has been a problem in promoting access to vaccines and this strategy is now being actively promoted as a means to accelerated access (261). These examples should serve as a sign that national governments can invest a significant amount of time and human resources in interventions that serve economic

and health interests. However, the feasibility of increased government funding in relatively poor countries like Burkina Faso remains slim. National governments, international donors, RBM and WHO, along with partnerships such as I2I and IVCC need to work together to make diversified funding for new vector control tools feasible by incentivising countries like Nigeria, which are potentially able to commit funds to vector control tools, to do so.

The potential for funding to influence policymaking is arguably evident at the global level, where studies have demonstrated the potential of the Bill and Melinda Gates Foundation (BMGF) spending patterns to influence the direction of global malaria policy (262). In 2007, Bill and Melinda Gates called for the renewed focus on eradicating malaria (263). In 2008, the Director-General of WHO credited the BMGF for “*taking that very brave step to challenge us [to aim for malaria elimination]*” (264). Critics suggest that the BMGF places too much emphasis on biomedical interventions like vaccines, diverting focus from interventions that do not fit into the BMGF’s priorities such as the building of resilient public health systems (262). At the global level, diversification of the funding base will ensure that, where one actor does not support a particular tool due to delays in WHO guidance or as a result of institutional priorities, access is not jeopardised because other funding sources are inadequate or do not exist.

It is not recommended that WHO’s central function of promoting the adoption of evidence-based policies be by-passed, because while the Nigeria case study has been cited in this thesis as an example of policy adoption being facilitated as a result of national commitment and resources, it is a situation that can be abused, leading to policies based on political interests rather than evidence. However, it is unsuitable for inefficiencies at the global level to constrain national policy adoption as was the case in the Burkina Faso analysis.

7.3.4 Innovative Mechanisms Reducing the Costs of New Vector Control Tools

The high cost of an intervention is potentially a powerful obstacle to its access (152). The perspectives of the KIs in the global and national analysis show that this can particularly be true when there are cheaper alternatives to the new vector control tool in question, even if these alternatives are less effective. For example, the price of insecticides was cited as a major factor in the discontinuation of the IRS programme in Burkina Faso (Chapter 5). The global and Burkina Faso analyses established that global and national stakeholders assume that PBO LLINs and subsequent next generation LLINs will cost more than standard LLINs. Indeed there is some evidence of relatively large price differentials between standard and PBO LLINs (199) (265) (266), but at the same time there is evidence gathered during this research and others of much smaller price differentials (199). While, the determinants and extent of this additional cost remains unclear and are beyond scope of this thesis, it is clear that there are opportunities for countries to negotiate the reduction of the price of a new vector control tool. Future research should explore market analysis to identify strategies to reduce prices taking into consideration some of the suggestions by KIs in the global case study. One suggestion was the development of longer-term flexible vector control strategies that incorporate a mix of cheaper and more expensive vector control interventions, deployed in-country as appropriate local evidence of transmission and insecticide resistance setting. This provides a level of upfront predictability and transparency that can promote better price negotiations.

The global case study found that the availability of a new vector control is influenced by the sustainability and predictability of the market, i.e., the manufacturer's ability to forecast key elements of the market, including price, market size and demand over multiple years. The global study, like other analyses on expanding access to new vector control tools, calls for improved procurement procedures as a means of overcoming the forecasting issues around market size, demand and price. These coordinated procurement practices already exist for standard LLINs, with some extent of collaboration occurring between donor agencies such as GFATM, PMI and UNICEF (256,

265, 266). The feasibility of a recommendation for coordinated procurement in relation to any new vector control will be impacted by the ability to quantify its market share, and the main donors' willingness to competitively procure the new tool. However, KI in the global analysis expressed a willingness to develop consolidated, longer term procurement plans which include multi country gap analysis and multi year donor funding commitments. The predisposition of major vector control funders (GFATM, PMI and UNICEF) to work together in this way indicates that this recommended course of action in relation to a new vector control tool is feasible. It is noteworthy that such willingness to commit to funding a new vector control tool in such large scales over multiple years will be dependent on the resolution of the evidence, global policy adoption and funding issues discussed in sections 7.3.1 and 7.3.2 above and is therefore unlikely to be as immediate as the other recommendations above.

Access to new vector control tools may be impeded if high costs deter funders from investing; however, it was clear from the global case study and discussions around IRS and LLINs that donors are predisposed to taking into consideration the cost effectiveness the tool in question and not just the purchase price (257). Taking into account the impact of the new vector control tool will improve its cost-effectiveness, provided it is more effective in areas of insecticide resistance.

If a new malaria control intervention is more effective there is precedent for establishing global subsidy mechanism such as the Affordable Medicines Facility–malaria (AMFm). The AMFm was designed to increase access to ACTs by subsidising their costs, increasing demand and ensuring a sustainable predictable market. Evaluations of the AMFm mechanism have shown that the subsidy, along with initiatives such as pooled procurement, can be successful in improving ACT price and availability (224, 267). With regards to vector control, a promising example is the UNITAID and IVCC initiative, which has established a partnership (NgenIRS) to provide co-payments to bring down the cost of the next generation IRS insecticides, such as Actellic 300CS[®], and make them available to countries at lower prices (58).

It is important to note that national adoption and affordability does not automatically translate into national availability. Lessons from ACTs show that, after national policy adoption and financing, it took up to 2 years to import drugs due to procurement-related delays (138). For example, there are 16 WHOPES-approved LLINs (235) and the lead-time from order to delivery is of approximately 6 months (199). The number of manufacturers with the capacity to manufacture and supply PBO LLINs will (at least in the early stages) be significantly less than those supplying standard LLINs, thus severely limiting the available quantities at least until more manufacturers develop new or equivalent products. Once PBO LLINs are recommended, the benefits of the WHOPES equivalence process arguably come into play by allowing manufactures of generic LLINs (seen to be equivalent to an approved LLIN) a shorter path to market, thereby accelerating access. For new malaria vector control paradigms, where only one or two products are being tested, it is clear that the ability to meet global demand if the tools demonstrate effectiveness will be a factor that has a significant impact on the availability of the tools and, therefore, access. Again technology transfer for these new paradigms, particularly those with simple technological requirements, will be a significant, albeit, longer term strategy for accelerating their sustained access.

7.3.5 Strengthened Coordination among a Network of Global, Regional and National Actors

7.3.5.1 Coordinated Network of Policy Champions for Insecticide Resistance and Malaria Elimination

There are numerous studies in the health policy and access to health interventions fields that demonstrate the central role that actors, particularly policy champions, play in facilitating policy change and access to new health interventions. For example, the results of the global case study along with malaria literature show the pivotal role that policy champions played in artemisinin resistance (Professor Nick White (247)), the roll out of rapid diagnostic tests (the Foundation for Innovative New Diagnostics (120)), and the scale-up of ITNs (Professor Christian Lengeler) (120).

However, the need to develop new vector control tools, as shown in Figure 1, goes beyond addressing insecticide resistance as it encompasses the need for a comprehensive vector control response that will contribute to the elimination of malaria. This requires an access architecture that involves a coalition of individuals and organisations at the global, regional and national levels with technical competence, knowledge of the context (i.e., the disease, the product and product market), energy/time and the ability to take strategic action to facilitate access (268). A model for these activities could mirror that used for coordinating access to rapid diagnostic tests, with a focal point based in WHO coordinating affiliations with relevant institutions (120). This coordinated architecture is akin to policy networks, which have the capacity to determine policy success (269) and would be instrumental to strengthening the four areas discussed above.

The IVCC, a product development partnership aimed at developing innovative vector control tools to address insecticide resistance (270). The IVCC, UNITAID and other partners in the NgenIRS project have been supporting access to a new insecticide (Actellic 300CS®) for malaria control programmes (271). The IVCC is also involved in the I2I partnership, which is aimed at achieving appropriate use for health impact, i.e., beyond bringing a product to market (241). Within the limitations of I2I noted in Section 7.3.2, the partnership is potentially a very significant step towards a globally coordinated approach to facilitating accelerated access to new vector control tools.

Partnerships like the IVCC, NgenIRS and I2I, along with manufacturers, researchers, funders and WHO and its advisory committees (such as MPAC, VCAG and VCTEG) are important global initiatives for facilitating access to new tools. However, clarity is needed on the relative roles of the WHO advisory committees in relation to new vector control tools. Furthermore, given the confusion expressed by specific categories of KIs in the global case study, the manner in which the various partnerships work with the WHO mechanisms in order to align and achieve objectives, needs to be clarified. This will result in strengthened coordination of the global actors and allow for:

- i. A comprehensive view of the global architecture (actors and their roles in relation to new vector control tools) and mechanisms to coordinate activities.
- ii. A comprehensive understanding of how the activities of individual actors complement one another and contribute to the goal of access to new vector control tools in the context of both insecticide resistance and malaria elimination.
- iii. The joint priority setting for research, development, resource mobilisation and resource allocation in relation to facilitating access to new vector control tools in the context of both insecticide resistance and malaria elimination.

7.3.5.2 Strengthened Coordination between the Global, Regional and National Levels

In 2012, ECOWAS articulated the regional goal of malaria elimination. This goal is a potential vehicle to facilitate the national adoption and funding of new vector control tools, as in the Nigeria case study, where the national decision to scale-up larviciding was linked to the ECOWAS malaria elimination agenda (169). Demonstrating the centrality of new vector control tools to the wider malaria elimination agenda leverages a key lesson from the findings of the Nigeria case study, i.e., of the power of framing new vector control tools within wider goals as a means to unlocking resources and facilitating access. However, in relation to PBO LLINs, there is no evidence that regional engagement was or is taking place to facilitate access. Hence, there is a need to strengthen links between the global and regional architecture in relation to adoption of specific new vector control tools in the context of insecticide resistance and malaria elimination.

The recent reorganisation of the RBM partnership is potentially a significant opportunity to facilitate increased global, regional and national coordination in relation to access to new vector control tools. The RBM maintains that its strength lays in its ability to form partnerships nationally and globally through networks at the global, regional and national levels (272). The strength of the RBM partnership was evident at the national level in Burkina Faso and Nigeria. However, the influence of its regional

structure was not observed particularly in relation to the contentious issue of larviciding promoted by another regional body, suggesting room for improved regional coordination and influence. The recent reorganisation of the RBM, which included the appointment of a new executive board, aims to provide more emphasis on providing country support, financing, advocacy and resource mobilisation (273). The reorganisation is nascent and its impact on the vector control policy architecture remains to be seen. A recommended priority for the new RBM would be the increased engagement with regional bodies like ECOWAS, which have made malaria elimination a priority.

7.3.5.3 Increased Engagement of High-level National Policymakers

Increased engagement of high-level national policymakers is the final component needed for strengthening the global, regional and national architecture. Members of national vector control policy advisory committees provide a useful entry point for developing support at the national level to facilitate access to new vector control tools (131). In addition, as seen in the Nigeria case study high-level actors, who may not be readily identified may have significant power in effecting policy change that other traditional actors may be powerless to stop (222). This underscores the importance of increased engagement at the highest national and regional policymaking levels as a crucial strategy for facilitating access to new vector control tools. A caveat is that engaging high-level politicians will require the malaria community to actively frame the contributions of new vector control tools in the context of malaria elimination and the wider national socioeconomic goals.

A potentially important vehicle for reaching high-level national politicians on the African continent is (currently) the African Leaders Malaria Alliance (ALMA). ALMA is the coalition of 49 African Heads of State and Government working together to eliminate malaria by 2030 (274). ALMA is currently the only organisation with the aim of actively engaging the highest level of policymakers in sub-Saharan Africa specifically in response to malaria control and elimination. The Nigeria case study shows how high-level regional influence from ECOWAS set the context for the national adoption a vector

control tool for malaria elimination in advance of the WHO Action and Investment to Defeat Malaria in 2015. Despite this, regional bodies, such as ECOWAS, ALMA and the RBM, currently appear to be underutilised as they were not identified by the KIs in the national cases studies as being part of the normal policy actors; facilitating and sustaining access to new vector control tools in the context of malaria elimination will require engagement of such regional bodies to facilitate regional commitment and national action.

Strengthened coordination among a network of global, regional and national actors in order to facilitate access to new vector control tools in the context of insecticide resistance and malaria elimination is not an easy recommendation to implement given the number of organisations and potentially diverse range of interests involved. Nevertheless, until such a network of actors takes a coordinated and prominent stand at the global, regional and national levels, progress towards access to new vector control tools will be slow.

7.4 Conclusions

This chapter reaffirms the notion that without concerted effort to accelerate access to new/innovative vector control tools it will be impossible to achieve the 2030 malaria elimination goals. A synthesis of results from the three case studies are presented here. The chapter outlines the 8 key policy influencers identified from the three case studies, that can facilitate policy adoption at the global and national level. The chapter concludes by presenting a discussion on the 5 areas that need to be addressed in order to leverage on the key policy influencers and accelerate access to new vector control tools.

8 Chapter 8: Conclusions and Future Research

8.1 Thesis Conclusions

The modified analytical framework used in this thesis, based on the Walt and Gilson (77) and Frost and Reich (120) frameworks, provides a novel way to examine and facilitate access to new health interventions. The case study results provide insight into the adoption of new vector control tools at both the global and national levels, addressing knowledge gaps regarding the need for robust policy analysis in relation to malaria control in general, and to new vector control tools in particular (124, 126). The research presents policy analyses that demonstrate the interrelation of global and national policymaking in relation to malaria vector control. The synthesis of the results of the case studies identify 8 key policy influencers that facilitate policy adoption and presents five areas that need to be strengthened in order to accelerate access to new vector control tools.

The findings of this thesis are of particular importance given the pivotal role that vector control has played in malaria control and in the elimination goals set for 2030 (2), as well as the insights it provides regarding the routes to accelerate access to these tools. The synthesised findings of the three case studies show that the national and global level factors that facilitate access to new vector control tools include evidence, a transparent and timely global adoption process, a diversified funding base, price, and a coordinated group of policy champions.

The importance of evidence in policymaking at the global and the national levels (108, 109, 179) is demonstrated by the fact that five of the eight key findings in this thesis relate to evidence. It was demonstrated herein that, in relation to new vector control tools, evidence-based policies in the context of insecticide resistance are nuanced. Further, robust and appropriate evidence that demonstrates the problem as well as the solution is required to effect policy change; such evidence needs to be context specific and its use can be what Weiss (110) classifies as strategic, i.e., choosing evidence that supports pre-established positions or ignoring evidence in favour of other policy influencing factors such as economic development. These findings reaffirm the view

that policymaking is a political exercise characterised by compromise (275). This thesis demonstrates that, even if the policy process in a given context is well defined, appears to be evidence based and is rational, it has the potential to be circumvented by the politics inherent in policymaking. In addition, that the policy process at the national level is linked to the global policy process and that weaknesses at the global level can significantly impact on national policy processes have also been shown.

This thesis corroborates previous findings that highlight the centrality of financial considerations in the access to new vector control tools (128, 141, 142) and uniquely demonstrates how national decision-making powers are constrained by global funding and policy mechanisms, an interconnectedness that was underemphasized in the literature on malaria vector control. Furthermore, it shows that, at the national level, price rather than cost-effectiveness is the determining financial variable, thus affirming the need for interventions that facilitate price reductions, including innovative procurement mechanisms and global subsidies (74, 142). The potential for national funding for malaria control, facilitated by initiatives such as technology transfer, is demonstrated herein to be a powerful factor in determining access to new vector control tools.

Finally, the present work demonstrates that a well-coordinated community of champions is needed to respond to the multi-faceted issue of facilitating accelerated access to new vector control tools in the context of insecticide resistance, thereby echoing political analyses and studies that highlight the importance of a group of actors involved in policymaking to share decision-making and exchange resources in order to achieve a common policy objective (75, 128).

8.2 Future Research

This research reiterates that robust evidence is key to the adoption of new vector control tools and poses a number of critical questions that need to be addressed.

- i. What is the feasibility of developing and using regional level evidence to influence national vector control policymaking, taking into account the multiple malaria transmission settings?
- ii. What factors facilitate increased levels of national funding for malaria control interventions?
- iii. What role can regional bodies like RBM, ECOWAS and ALMA play in coordinating research, resource mobilisation and national policy adoption for malaria elimination?
- iv. What is the feasibility of long-term national vector control procurement plans in reducing the cost of vector control interventions?

These questions will progress from the findings of this thesis by further investigating the economic and policy-related questions required to facilitate access to new vector control tools and ultimately malaria elimination.

8.3 Study Limitations

The study focused on national and global policy adoption, thereby missing the important perspectives of healthcare providers and beneficiaries, which may have added an important angle and provided particularly valuable community-level insight, potentially supporting elements of the decision to scale-up larviciding in Nigeria. However, as stated in the introductory chapter, data on community perspectives have been collected through other aspects of the AvecNet project.

Another potential limitation is the absence of the perspective of regional policymaking institutions and actors who emerged as influential at the KI interview stage. However, the regional perspective was provided during interviews at the national and global level and this was supplemented with document reviews of the relevant regional bodies, including ECOWAS, RBM and ALMA.

For the Nigeria case study, a number of potential limitations must be noted. Firstly, as only 14 people were interviewed, inevitably some categories of stakeholders were

under-represented. Secondly, the study had limited access to what Shiffman terms policy elites, a recognised limitation of policy analysis at this level (276). The researcher's inability to gain access to representatives from ECOWAS, the office of the presidency, and the Minister of Health, all of whom were identified as key actors in the decision to scale-up larviciding but not in the desk review of normal policy actors, denies the study a perspective that would have been valuable and enriching.

The researcher had spent time working closely with the NMCP and therefore had some insider status, potentially allowing for greater insight into the policy analysis (75). In this instance, it allowed the researcher increased access to respondents, the opportunity to investigate a sensitive issue, and an in-depth knowledge and understanding of the culture aiding in the interpretation of non-verbal cues.

In Burkina Faso, participants did not identify the private sector as key to national decision-making. However, it may have been beneficial to have included a perspective from a manufacturer of a next generation LLIN as opposed to directing specific questions to a representative of this sector after the interviews had been completed. The problem of counterfeit nets in Burkina Faso, confirmed after the interviews had been conducted, could have limited the willingness of respondents to openly discuss LLIN procurement; however, some respondents alluded to this and hence these perspectives were captured. Finally, the main researcher's ability to be the primary data collector was limited due to language barriers and the reduced access given to researchers considered outsiders (75). However, this limitation provided an advantage in the data analysis process, where an outsider status conferred objectivity in the interpretation of results. Mr Traore is a Burkinabe working at CNRFP and therefore has some level of insider status (75), allowing for additional insight into the cultural context and helping establish rapport with KIs during data collection.

8.4 Researcher Reflexivity and Positionality

Researcher reflexivity involves *“laying open pre-conceptions and becoming aware of situational dynamics”* (277) in the research process. The section below reports (in the first person) on researcher pre-conceptions that may have shaped the research results.

8.4.1 Nigeria

There was a mutuality of understanding that was inherent in the interviews in Nigeria born by the fact that I am Nigerian and had spent a number of years working as an advisor within the NMCP. A quote by Johnson-Bailey (278) resonates with my experience of conducting the interviews in Nigeria, *“There were silent understandings, culture-bound phrases that did not need interpretation, and non-verbalized answers conveyed with culture-specific hand gestures and facial expressions laced throughout the dialogue”*.

This insider status also allowed me access to KIs that may not have been as open with an outsider. Even in situations where an individual was approached and declined to formally take part in the study, they spent considerable time providing background information that was then followed up through independent sources.

Having worked with the majority of the KIs, I had pre-conceptions of their positions and their bias and their technical orientation, i.e., in many instances I was aware of the underlining organisational dynamics that influenced a KI's responses. In analysing the interviews from Nigeria, I approached the data by analysing every single line of the interviews, suspending judgement, i.e., not drawing any conclusions based on previous knowledge, but constantly asking myself 'what is this person saying in relation to the research question at hand?' A comprehensive record of methods used, triangulation of KI data with document review and review of findings with my supervisors were strategies used to mitigate bias (279). A possible limitation of my insider position, was the preconceptions held by the interviewees in providing responses based on assumptions they had in relation to my views as a result of my work history with the

interviewees. In order to reduce this bias information elicited was triangulated across interviewee categories and through document reviews.

8.4.2 Burkina Faso

My role as a researcher in Burkina Faso was perhaps the inverse of my role in Nigeria. I was in a foreign country, with limited language skills and was, for all intents and purposes, an outsider. For example, when one of the organisations declined to participate in the interviews, unlike in Nigeria where they gave off the record comments, in Burkina Faso I was directed to the organisation's website for information.

Mr Traore (my Burkinabe colleague), a social scientist from the AvecNet project, conducted the majority of the interviews in French, thereby overcoming the language barrier. Mr Traore is an insider to the Burkinabe system and was cognisant of cultural norms and protocols that facilitated the introduction of the research to KIs. However, he was relatively new to the malaria vector policymaking field and his role was largely limited to data collection. What I lacked in insider status in Burkina Faso, I gained in added objectivity when analysing the data captured, indexed and charted as described in the data analysis section.

8.4.3 Global

My position in the global study was based on a mix of being both an insider and an outsider. I had met most of the KIs and had a fair amount of access – aided by introductions from my supervisors. The common ground at the global level was not cultural but rather recognition by the KIs that the research question was important and timely. Furthermore, there was a general desire to find evidence-based solutions to the vector control challenges collectively faced by the global community that has invested heavily in fighting malaria. This made people generous with their time and open with their responses – as a contribution to finding solutions to the problem of access to new vector control tools.

In general, I believe that my thoughts and preconceptions have evolved over the course of the research, lending credence to views that argue the fluidity of a researcher's positionality in relation to research (280). As a result, the preconceptions I held when I conducted the Nigeria study had somewhat evolved by the time I carried out the global study 18 months later. Initially, I leaned quite heavily toward rational model of policymaking, unwittingly believing in the pre-eminence of evidence-based policymaking. However, over the course of the research, I became more aware of the politics involved in policymaking and the reality that other factors, can be, whether I like it or not, considered more important than evidence. As Walt and Gilson put it, the reality of what policymaking is, as opposed to the aspiration of what it should be (75).

I believe that my status in each context, as well as my intellectual evolution as a product of the research, lends credibility to the discussions and recommendations I provide in Chapter 7. This is because the synthesis and recommendations of the case studies provide novel and nuanced insight into five areas that can bridge the gap between the development of new vector control tools and their adoption into policy by capitalising on both the rational (evidence based) and political nature of policymaking.

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ANNEXES

Annex 1 WHOPEs Recommended LLINs

Updated: 2 March 2015

WHO recommended insecticides for indoor residual spraying against malaria vectors

<i>Insecticide compounds and formulations</i> ¹	<i>Class group</i> ²	<i>Dosage (g a.i./m²)</i>	<i>Mode of action</i>	<i>Duration of effective action (months)</i>
<i>DDT WP</i>	OC	1-2	contact	>6
<i>Malathion WP</i>	OP	2	contact	2–3
<i>Fenitrothion WP</i>	OP	2	contact & airborne	3–6
<i>Pirimiphos-methyl WP, EC</i>	OP	1-2	contact & airborne	2–3
<i>Pirimiphos-methyl CS</i>	OP	1	contact & airborne	4–6
<i>Bendiocarb WP, WP-SB</i>	C	0.1–0.4	contact & airborne	2–6
<i>Propoxur WP</i>	C	1–2	contact & airborne	3–6
<i>Alpha-cypermethrin WP, SC</i>	PY	0.02–0.03	contact	4–6
<i>Alpha-cypermethrin WG-SB</i>	PY	0.02–0.03	contact	up to 4
<i>Bifenthrin WP</i>	PY	0.025–0.05	contact	3–6
<i>Cyfluthrin WP</i>	PY	0.02–0.05	contact	3–6
<i>Deltamethrin SC-PE</i>	PY	0.02–0.025	contact	6
<i>Deltamethrin WP, WG, WG-SB</i>	PY	0.02–0.025	contact	3–6
<i>Etofenprox WP</i>	PY	0.1–0.3	contact	3–6
<i>Lambda-cyhalothrin WP, CS</i>	PY	0.02–0.03	contact	3–6

Chlorfenapyr 240 SC: The current assessments of Chlorfenapyr SC (class group: pyrrole) are available in the report of the 16th WHOPEs Working Group meeting, 22–30 July 2013 and the report of the 17th WHOPEs Working Group meeting, 15–19 September 2014 (both reports available at: <http://who.int/whopes/resources/en/>).

Note: WHO recommendations on the use of pesticides in public health are valid ONLY if linked to WHO specifications for their quality control. WHO specifications for public health pesticides are available on the WHO homepage on the Internet at <http://www.who.int/whopes/quality/en/>.

¹ CS = capsule suspension; EC = emulsifiable concentrate; SC = suspension concentrate; SC-PE = polymer enhanced suspension concentrate; WG = water dispersible granules; WG-SB = water dispersible granules in sealed water soluble bags; WP = wettable powder; WP-SB = wettable powder in sealed water soluble bags.

² OC = organochlorines; OP = organophosphates; C = carbamates; PY = pyrethroids.

Annex 2 WHOPES Recommended LLINs

Updated 1 April 2016

WHO recommended long-lasting insecticidal nets

<i>Product name</i>	<i>Product type</i>	<i>Status of WHO recommendation</i>	<i>Status of publication of WHO specification</i>
DawaPlus 2.0	Deltamethrin coated on polyester	Interim	Published
Duranet	Alpha-cypermethrin incorporated into polyethylene	Full	Published
Interceptor	Alpha-cypermethrin coated on polyester	Full	Published
LifeNet	Deltamethrin incorporated into polypropylene	Interim	Published
MAGNet	Alpha-cypermethrin incorporated into polyethylene	Full	Published
MiraNet	Alpha-cypermethrin incorporated into polyethylene	Interim	Published
Olyset Net	Permethrin incorporated into polyethylene	Full	Published
Olyset Plus	Permethrin and PBO incorporated into polyethylene	Interim	Published
Panda Net 2.0	Deltamethrin incorporated into polyethylene	Interim	Published
PermaNet 2.0	Deltamethrin coated on polyester	Full	Published
PermaNet 3.0	Combination of deltamethrin coated on polyester with strengthened border (side panels), and deltamethrin and PBO incorporated into polyethylene (roof)	Interim	Published
Royal Sentry	Alpha-cypermethrin incorporated into polyethylene	Full	Published
SafeNet	Alpha-cypermethrin coated on polyester	Full	Published
Veeralin	Alpha-cypermethrin and PBO incorporated into polyethylene	Interim	Published
Yahe	Deltamethrin coated on polyester	Interim	Published
Yorkool	Deltamethrin coated on polyester	Full	Published

Notes:

1. Reports of the WHOPES Working Group Meetings should be consulted for detailed guidance on use and recommendations. These reports are available on the WHO homepage on the Internet at <http://www.who.int/whopes/recommendations/wgm/en/>;

Annex 3 WHOPES Recommended Compound for Mosquito Larvae

Updated 18 March 2016

WHOPES-recommended compounds and formulations for control of mosquito larvae

Insecticide compounds and formulation(s) ¹	Class group ²	Dosage (active ingredient)		
		General (open water bodies)		Container-breeding (mg/L)
		(g/ha)	(mg/m ²)	
<i>Bacillus thuringiensis israelensis</i> , strain AM65-52 (3000 ITU/mg), WG	BL	125–750 ³	12.5–75 ³	1–5 ³
<i>Bacillus thuringiensis israelensis</i> , strain AM65-52 (200 ITU/mg), GR	BL	5,000–20,000 ³	500–2000 ³	-
<i>Bacillus thuringiensis israelensis</i> (strain AM65-52 + <i>B. sphaericus</i> strain ABTS-1743; 50 BspH ITU/mg), GR	BL	5,000–20,000 ³	500–2000 ³	60–80 ³
<i>Bacillus thuringiensis israelensis</i> , strain 266/2 (≥ 1200 ITU/mg), SC	BL	30–50L ³	3–5 mL ³	0.01–0.04mL ³
Chlorpyrifos EC	OP	11–25	1.1–2.5	-
Diflubenzuron DT, GR, WP	BU	25–100	2.5–10	0.02–0.25
Novaluron EC	BU	10–100	1–10	0.01–0.05
Pyriproxyfen GR	JH	10–50	1–5	0.01
Fenthion EC	OP	22–112	2.2–11.2	-
Pirimiphos-methyl EC	OP	50–500	5–50	1
Temephos EC, GR	OP	56–112	5.6–11.2	1
Spinosad DT, EC, GR, SC	SP	20–500	2–50	0.1–0.5
Spinosad 83.3 monolayer DT	SP	250–500	25–50	-
Spinosad 25 extended release GR	SP	250–400	25–40	-
<i>Open bodies of water</i>	SP	1000–1500	100–150	-
<i>Control of Culex quinquefasciatus in open bodies of water with high organic matter</i>	SP	1000–1500	100–150	-

¹ DT = tablet for direct application; GR = granule; EC = emulsifiable concentrate; WG = water-dispersible granule; WP = wettable powder.

² BL = Bacterial larvicide; BU = Benzoylureas; JH = Juvenile hormone mimics; OP = Organophosphates; SP = Spinosyns.

³ Formulated product.

Notes:

1. Reports of the WHOPES Working Group Meetings (available at: <http://www.who.int/whopes/recommendations/en/>) and the WHOPES publication "*Pesticides and their application for control of vectors and pests of public health importance*" (available at http://whqlibdoc.who.int/hq/2006/WHO_CDS_NTD_WHOPES_GCDPP_2006.1_eng.pdf) should be consulted for guidance on use and recommendations;
2. The WHO Guidelines for drinking-water quality (http://www.who.int/water_sanitation_health/dwg/gdwq3rev/en/) provides authoritative guidance and should be consulted for application of insecticides in potable water for mosquito larviciding; and
3. WHO recommendations on the use of pesticides in public health are valid ONLY if linked to WHO specifications for their quality control (available at: <http://www.who.int/whopes/quality/en/>).

Annex 4: New Paradigms for Malaria Vector Control

Parameter*	New Paradigms for Malaria Vector Control						
	Insecticide-treated bednets against resistant vector populations	Insecticide-treated walls against resistant vector populations	Attract and kill baits	Spatial repellents interrupting human-vector contact	Insecticide-treated materials for specific risk groups	Vector traps for disease management	Lethal house lures
Generic exemplars	LLINs controlling IR populations for defined IR mechanism	IRS/ wall hanging controlling IR populations for defined IR mechanism	Attractive toxic sugar bait	Passive emanator	Insecticide – treated material	Traps with lures	Eave tubes
Prototype	PermaNet® 3.0, Interceptor® G2	To date, no valid prototype with an explicit claim for IR populations has been reviewed	Bait station	Metofluthrin or transfluthrin emanators	Blanket clothes	ALOT IN2TRAP	Eave tubes
Indoor against adult mosquitoes	√	√	√	√	√	√	√
Outdoors against adult mosquitoes	CP and PP	CP	√	√	√	√	√
Outdoors against immature mosquito stages	WHOPES for long lasting effect VCAG for IR claims	WHOPES for long lasting effect VCAG for IR claims				√	
CLAIM: personal protection	PP and/or CP; see notes 1 and 2 below	CP	NO	YES	YES for specific risk groups	NO	NO

CLAIM: community protection	Review and assessment of public health value	TBD	YES	YES	NO	YES	YES
WHOPES/V CAG			VCAG	VCAG	VCAG	VCAG	VCAG
VCAG epidemiolo gical end- point -personal protection (PP) -community protection			CP	PP & CP	PP	CP	CP
Progress of paradigm (VCAG step)			Initial interaction on data needs.	Review and assessment of public health value	Early notification of intervention concepts	Review and assessment of public health value	Initial interaction on data needs.

*CP, community protection; IR, insecticide-resistant; IRS, indoor residual spraying; LLIN, long-lasting insecticide-treated net; PP, personal protection; TBD, to be determined; VCAG, Vector Control Advisory Group; WHOPES, WHO Pesticide Evaluation Scheme

Annex 5 – Search Strategy

A: Policy analysis Search Strategy

Databases	Underlying Questions	First review – March-November 2012	Second review – August - October 2015	Inclusions
PubMed-Medline Google Scholar Google Organisational Websites	What is health policy? How is health policy made? What factors influence its development and adoption? What is the role of evidence in policymaking? What facilitates the use of evidence in policymaking? What are the barriers to the use of evidence in policymaking?	Policy Policymaking Policy Analysis Policy Development Policy process Health Policy Health Policymaking Health policy analysis Health policy development Health policy process Decision-making Evidence-based policy Barriers Evidence and policy Policy framework Policymaking theories Evidence and the policy process Evidence-based health policy Evidence-informed health policy	Policy Policymaking Policy Analysis Policy Development Policy process Health Policy Health Policymaking Health policy analysis Health policy development Health policy process Decision-making Evidence-based policy Barriers Evidence and policy Policy framework Policymaking theories Evidence and the policy process	Titles and abstract were read all articles related to: Published in English Full article accessible Health policy focus Policy processes Policy change Factors influencing policy processes Frameworks and theories on policymaking Studies in developed and developing countries

Annex 5B: Nigeria Search Strategy

Database	Underlying Questions	First review – February 2013	Second review April 2016	Inclusions
Pubmed- Medline Google Scholar	<p>What is the national policymaking context in Nigeria?</p> <p>What is malaria vector control policy in Nigeria?</p> <p>Who are the key malaria vector control policy actors in Nigeria?</p>	<p>Search Terms – using a combination of AND/OR</p> <ol style="list-style-type: none"> 1. Malaria 2. Malaria Control 3. Malaria Prevention 4. Vector Control 5. Integrated Vector Management 6. Insecticide Resistance 7. 1 or 2 or 3 or 4 or 5 or 6 8. Policy 9. Policymaking 10. Policy analysis 11. Policy development 12. Policy process 13. Decision-making 14. 8 or 9 or 10 or 11 or 12 or 13 15. Evidence-based health policy 16. Evidence-based health policy – Nigeria 17. 15 or 16 18. Evidence-informed health policy 19. Evidence-informed health policy- Nigeria 20. 18 or 19 21. Access to vector control tools 22. 21 AND 14 23. Larviciding 24. Malaria Control in Nigeria 25. Vector control in Nigeria 26. Policymaking in Nigeria 27. 7 AND 14 28. 7 AND 17 29. 7 AND 21 	<p>Search Terms – using a combination of AND/OR</p> <ol style="list-style-type: none"> 1. ECOWAS Malaria Elimination 2. Larviciding 3. Onchocerciasis elimination 4. 1 and 2 	<p>Titles and abstract were read and articles were included that were published between 1990-2016 and related to:</p> <p>Published between 1990-2016</p> <p>Published in English</p> <p>Full article accessible</p> <p>Policy adoption of malaria vector control tools</p> <p>Policy adoption and/or recommendation of malaria control tools (drugs, diagnostics and vaccines)</p> <p>Policy adoption of vaccines (not restricted to malaria)</p> <p>Availability of new vector</p>

				control tools The development of new malaria vector control tools The procurement of new malaria vector control tools
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Annex 5 C: Burkina Faso Search Strategy

Databases	Underlying Questions	First review - March 2014	Second review March 2015	Inclusions
PubMed-Medline Google Scholar Web of Science Global Health Jstor, Taylor & Francis	<p>What is the national policymaking context in Burkina Faso?</p> <p>What is malaria vector control policy in Burkina Faso?</p> <p>Who are the key malaria vector control policy actors in Burkina Faso</p>	<p>Search Terms – using a combination of AND/OR</p> <ol style="list-style-type: none"> 1. Malaria 2. Malaria Control 3. Malaria Prevention 4. Vector Control 5. Integrated Vector Management 6. 1 or 2 or 3 or 4 or 5 7. Insecticide Resistance 8. 6 AND 7 9. Policymaking 10. Policy Analysis 11. Policy Development 12. Policy process 13. 9 or 10 or 11 or 12 14. Decision-making 15. Evidence-based health policy 16. Evidence-based health policy – Burkina Faso 17. Evidence-informed health policy 18. Evidence-informed health policy- Burkina Faso 19. Burkina Faso 20. 14 or 15 or 16 or 17 or 18 21. 6 AND 19 22. Access to vector control tools 23. 19 AND 22 AND 6 24. PBO LLINs 25. PermaNet® 3.0 26. Malaria Control in Burkina Faso 27. 26 AND 13 28. Vector control in Burkina Faso 29. 28 AND 13 	<p>Search Terms – using a combination of AND/OR</p> <ol style="list-style-type: none"> 1. PBO LLINs 2. PermaNet® 3.0 3. 1 or 2 4. Actellic® 3CS 5. VCAG Recommendations 6. 3 AND 5 7. WHO Recommendations on PBO LLINs 8. 3 AND 7 9. Innovation to Impact 10. Artemisinin Resistance 11. ACT policy/introduction 	<p>Titles and abstract were read and articles were included that were published between 1990-2016 and related to:</p> <p>Published between 1990-2016 Full article accessible Policy adoption of malaria vector control tools Policy adoption and/or recommendation of malaria control tools (drugs, diagnostics and vaccines) Policy adoption of vaccines (not restricted to malaria) Availability of new vector control tools The development of new malaria vector control tools The procurement of new malaria vector control tools</p>

Annex 5D: Global Search Strategy

Databases	Underlying Questions	First review - March 2014	Second review May 2015	Inclusions
Pubmed- Medline Google Scholar Google Organisation al Websites	What is the global policymakin g context? What are the global malaria vector control policies? Who are the key malaria vector control policy actors at the global level?	Search Terms – using a combination of AND/OR 1. Malaria 2. Malaria Control 3. Malaria Prevention 4. Vector Control 5. 1 or 2 or 3 or 4 6. Bednets 7. Long-lasting insecticidal nets LLINs 8. Insecticide- treated nets 9. 6 or 7 or 8 10. Integrated vector management 11. Insecticide resistance 12. Policy 13. Policymaking 14. Policy analysis 15. Policy Development 16. Policy process 17. 12 or 13 or 14 or 15 or 16 18. Decision- making 19. Evidence- based health policy 20. Evidence- informed health policy 21. 18 or 19 or 20 22. Access to vector control tools 23. PBO LLINs 24. PermaNet® 3.0	Search Terms – using a combination of AND/OR 1. PBO LLINs 2. PermaNet® 3.0 3. 1 or 2 4. Actellic® 3CS 5. VCAG Recommend ations 6. WHO Recommend ation PBO LLINs 7. Innovation to Impact 8. Artemisinin Resistance 9. ACTs policy/introd uction	Titles and abstract were read and articles were included Published between 1990- 2016 Published in English Full article accessible Policy adoption of malaria vector control tools Policy adoption and/or recommendati on of malaria control tools (drugs, diagnostics and vaccines) Policy adoption of vaccines (not restricted to malaria) Availability of new vector

		25. 5 AND 9 26. 17 AND 9 AND 5 27. 21 AND 5 28. 22 AND 17		control tools The development of new malaria vector control tools The procurement of new malaria vector control tools
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Annex 6: Sample – Framework for Organisation Identification

Framework Theme	Definition	Rationale	Organisations identified through document review
Availability	Involves the logistics of making, ordering, shipping, storing, distributing, and delivering a new health technology to ensure it reaches the hands (or mouth) of the end-user.	Availability and those organisations who are central to determining the availability of vector control tools are a set of critical set of stakeholders who form part of the network of organisations who facilitate access. These include, researchers that contribute to the product development and testing process, manufacturers and public private partnerships that facilitate the availability of new vector control tools.	Vesteergaard, Sumitomo, Innovative Vector Control Consortium (IVCC), Insecticide Resistance Action Committee, Researchers with vector control and insecticide resistance expertise
Affordability	Affordability depends on the technology's price, cost of services (such as user fees) related to accessing the technology, and the availability of funds for purchasing (which depends on the purchaser's available resources and perceptions of expected benefits and costs, including side effects, and other factors such as social acceptance).	Given that vector control tools are primarily funded by international donors and to a lesser extent national governments. The concept of affordability in this study will focus on resources and perceptions of expected benefits and costs of international donors. For example according to the World Malaria report 2013 the Global Fund to fight AIDS, Tuberculosis and malaria funds 40% of malaria control globally. Other major funders include DfID, PMI/USAID, World Bank CIDA, AUSAID, etc. UNICEF is also cited as a major procurer of LLINs.	Global Fund, DfID, PMI/USAID, UNICEF

Adoption	Involves gaining acceptance and creating demand for IRMS by global organizations, government actors	<p>The WHO – Global Malaria Programme (GMP) is being responsible for setting, communicating and promoting the adoption of evidence based norms, standards, policies, and guidelines. To fulfil this policymaking function WHO GMP relies on structures such as the Malaria Policy Advisory Committee (MPAC), Vector Control Advisory Group (VCAG), the Vector control Technical Expert Group (VCTEG) and the WHO Pesticide Evaluation Scheme (WHOPES) whose key mandate is to ‘collect, consolidate, evaluate and disseminate information on the use of pesticides for public health. In prominent umbrella group is the African Leaders Malaria Alliance (ALMA) which was set up by African Heads of State to utilize their individual and collective power across country and regional borders. One of the mandates of the organisation is the Provide a forum for high-level, collective advocacy to ensure an timely global procurement system with an emphasis on funding manufacturing and distribution; and provide a forum to share best practices and to review progress and address challenges in meeting the malaria targets. The perspective of stakeholders within this organisation will be pertinent in understanding some of the factors that contribute to national governments adoption of new vector control tools.</p>	<p>WHO-GMP. MPAC, VCAG, VCTEG, WHOPES, ALMA</p>
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Annex 6B: Sample – Framework for Key Informant Identification

Potential perspectives	Name KII NAME	Institution	Area Expertise	Thesis perspective
Adoption/Researcher	Left blank to preserve anonymity	Left blank to preserve anonymity	Vector Control Insecticide resistance	Researcher
Donor	Left blank to preserve anonymity	Left blank to preserve anonymity	Vector control	Donor

Annex 7: Glossary of Research Terms

SN	Term	Definition
1	Access	For the purposes of this study - the ability to consistently obtain and appropriately deploy/ use good quality vector control tools when and where they are needed
2	Adoption	Involves gaining acceptance and creating demand for Insecticide resistance management strategies (IRMS). These constitute global organizations and national government actors. While providers/ dispensers, and individual patients are a crucial stakeholder group to consider in the adoption of a new tool, this study is restricting its scope to adoption (policy endorsement and demand for tools) by global organisations and national governments
3	Affordability	Affordability depends on the technology's price, cost of services (such as user fees) related to accessing the technology, and the availability of funds for purchasing (which depends on the purchaser's available resources and perceptions of expected benefits and costs, including side effects, and other factors such as social acceptance). Given that vector control tools are primarily funded by international donors and to a lesser extent national governments. The concept of affordability in this study will focus on resources and perceptions of expected benefits and costs of international donors
4	Architecture	The organizational structure and relationships that coordinates availability, affordability, and adoption activities, i.e., the network of stakeholders involved in ensuring the availability, affordability and adoption of IRMS
5	Availability	Involves the logistics of making, ordering, shipping, storing, distributing, and delivering new/novel vector control tools
6	Combination LLIN	Long lasting insecticidal nets that use a combination of two insecticides (for the purposes of this study these do not include LLINs that utilize an insecticide and a synergist)
7	Funders	Actors involved in the financing vector control, e.g., GFATM, Dfid, USAID
8	Implementers	Actors involved in the deployment of vector control tools, e.g., Malaria consortium
9	Insecticide resistance monitoring programmes (IRMP)	National insecticide resistance monitoring programmes that seek to collect routine data to inform decisions on the resistance management strategies
10	Insecticide resistance management strategies (IRMS)	The deployment of a set of strategies (vector control tools and complementary practices such as IRMPs) to tackle insecticide resistance
	Insecticide resistance management? tools (IRMT)	Vector control tools deployed in order to/in a manner that addresses insecticide resistance, e.g., the rotation of insecticides in Insecticide spraying programmes
11	LLIN	LLINs with a single insecticide
12	Policymakers	Actors/bodies involved in the making Vector, e.g., WHO, MPAC control policy
13	Private sector	Commercial for profit organisations/ groups of involved in the development and manufacture of vector control tools, e.g., Sumitomo, vestergaard. Product development partnerships such as IVCC whose mandate is to accelerate the development and delivery of new vector control products and tools will also be

		considered as providing perspectives on private sector issues
14	Researcher	Actors involved in carrying out scientific research on Vector control, e.g., academics, research organisations
15	Translation	The 'translation' of a new/novel tool is said to be achieved once a product demonstrates both efficacy in the research environment as well as demonstrated sustainable effectiveness in implementation settings, i.e., turning early-stage innovations into new deliverable health products Components of the translation pathway include basic science, intervention concept, target product profile, proof of concept, product development and implementation

Annex 8: Semi-structured interview guide – Burkina Faso

Framework Themes ^a	SSI questions in English	SSI questions in French
National architecture for coordinating access to combination LLINs (Themes: actors, power and processes)	National architecture for coordinating access to combination LLINs	
Actors	Who are the key actors involved in coordinating access to insecticide resistance management tools like combination LLINs? (Prompt: key policymakers, financiers, manufacturers)	Qui sont les principaux acteurs impliqués dans la coordination de l'accès aux outils de gestion de la résistance aux insecticides comme combinaison MILDA (: les principaux décideurs, les financiers, les fabricants)
Power	Which player / players would you say carries the most influence? Why?	Quel joueur/joueurs diriez-vous porte le plus d'influence? Pourquoi?
Process	Please describe the process of making policies in vector control	S'il vous plaît décrire le processus de rendre les politiques dans la lutte antivectorielle
National availability of combination LLINs (Theme Availability)	National availability of combination LLINs	
	Please describe the factors that led to the adoption/distribution of PermaNet [®] 3) Prompts for factors: Solution to a perceived problem, availability of funding, evidence (local/international) of efficacy, political will from superior officers.	S'il vous plaît décrire les facteurs qui ont conduit à l'adoption / distribution de PermaNet 3 Aller facteurs: Solution à un problème perçu, la disponibilité du financement, la preuve (local / international) de l'efficacité, la volonté politique des officiers supérieurs.
	What would you describe as barriers to the availability of IRMT like combination LLINs?	Que feriez-vous décrire comme des obstacles à la disponibilité de la combinaison de MILDA

	What/if any opportunities exist for overcoming the barriers you described?	Qu'est / si des possibilités existent pour surmonter les obstacles que vous avez décrits?
National affordability of combination LLINs (Themes: Affordability)	National affordability of combination LLINs	
	What factors in your view positively influenced the affordability of PermaNet® 3.0	Quels sont les facteurs dans votre vue influence positive sur l'abordabilité des PermaNet 3.0
	What would you describe as barriers to the affordability of LLINs that seek to tackle resistance (prompts: budget/finance constraints, competing demands/priorities, perceived value compared to alternative products/interventions)	Que feriez-vous décrire comme des obstacles à l'accessibilité des moustiquaires imprégnées qui cherchent à lutter contre la résistance (invites: contraintes de budget / finances, des demandes concurrentes / priorités, la valeur perçue par rapport aux produits / interventions alternatives)
	What/if any opportunities existing for overcoming the barriers you described?	
National adoption of Combination LLINs (Theme: Adoption)	National adoption of combination LLINs	
	What would you describe as barriers to the adoption of LLINs that seek to tackle resistance	Que feriez-vous décrire comme des obstacles à l'adoption de MILDA qui cherchent à attaquer la résistance
	What/if any opportunities existing for overcoming the barriers you described?	Qu'est / si des opportunités existantes pour surmonter les obstacles que vous avez décrits?
	Could you prioritize the top 3 issues which in your view need to be addressed in order to accelerate access to IRMT like combination LLINs at the national level	Pourriez-vous prioriser le top 3 des questions qui, à votre avis, doivent être abordés afin d'accélérer l'accès de combinaison de MILDA au niveau national

^a Information on the 7th framework theme (context) is gathered from desk review

Annex 9: Stakeholder Interview Guide Nigeria

Name:

Gender:

Position:

Type of institution you work for?

Tell me a bit about your background and the work you do in malaria control

What is your role in policymaking processes in malaria vector control?

Vector Control Policymaking in General

Can you describe to me the process by which national vector control policies are meant to be developed and agreed?

Can you describe to me how you are engaged in the policymaking process?

Do you see any barriers to things being taken up as policy?

Which institutions/individuals play the biggest role and, in general who carries the most weight in influencing the decision making process?

Thinking now about the role of evidence in the policymaking process.....

The Role of Evidence in the Process

In what ways, if any, do you use the outputs of research to engage in the policy process?

What kind of evidence do you find useful or most likely to influence policy?

Aside from these sources of evidence, what other factors do you think come into play in decision about a new policy (e.g., donations from foreign governments, lobbying from interest groups (e.g., farmers), concerns about community acceptability/implementability etc.). How?

If you think there is an important research finding that needs to get into policy, what institution would you speak to?

What individuals/institutions ask you for information when they need to make decisions?

Thinking now about a recent change in policy relating to a malaria vector control tool

Recent Malaria Vector Control Policy Change

Can we use the example of larviciding to discuss why policy changes?

In your view, which of these factors played the most important role in

(i) prompting the policy change discussion and

Did the evidence for scientific research play and role and, if so, then in what way?

Which institutions/individuals were instrumental/influential in the policy change process larviciding,?

Overall which three factors do you think have the greatest influence on decisions to change policy and adopt a new intervention strategy?

Thank you for your time and do you have any questions to ask me?

Annex 10: Stakeholder Interview Guide: Global

Name:

Gender:

Position:

Inter start time: Interview end time:

Type of institution you work for?

Global Architecture for Coordinating Access to Insecticide Resistance Management Tools (IRMT) like Next Generation LLINs

Who are the key actors involved in coordinating access to insecticide resistance management tools like combination LLINs? (Prompt: key policymakers, financiers, manufacturers)

Which player / players would you say carries the most influence? Why?

What would be the process for obtaining policy adoption to a new insecticide resistance management tool like combination LLINs?

Global Availability of IRMTs like PBO LLINs

What factors in your view positively influence the availability of IRMT like combination LLINs? (prompts: Product development pipeline, manufacturing, forecasting, procurement, distribution, delivery)

What would you describe as barriers to the availability of IRMT like combination LLINs?

What/if any opportunities exist for overcoming the barriers you described?

Global Affordability of IRMTs like PBO LLINs

What factors in your view positively influence the global affordability of IRMT like combination LLINs?

What would you describe as barriers to the global affordability of IRMT like combination LLINs? (prompts: budget/finance constraints, competing demands/priorities, perceived value compared to alternative products/interventions)

What/if any opportunities existing for overcoming the barriers you described?

Global Adoption of IRMTs like PBO LLINs

What factors in your view positively influence the global adoption (policy endorsement and generating demand for the tools) of IRMT like combination LLINs? (prompts: what kind of evidence base, standards, policies, guidelines)

What would you describe as barriers to the global adoption of IRMT like combination LLINs?

What/if any opportunities existing for overcoming the barriers you described?

Could you prioritize the top 3 issues which in your view need to be addressed in order to accelerate access to IRMT like combination LLINs at the global level?

Insecticide Resistance Management Programmes

What factors are likely to facilitate increased availability of IRMP at national level? (prompts: Capacity and scientific know-how, infrastructure)

What factors do you think positively influence the affordability of IRMPs? (prompts: budget/finance constraints, competing demands/priorities, perceived value compared to alternative products/interventions, perceived threat)

What in your view are the top 3 barriers to the implementation of national IRMPs?

What opportunities exist at the global level, in your view, for increasing access to national IRMPs?

Annex 11: Sample Coding Matrix- Data Analysis

Coding Reference	2	2.1	2.2	2.3
	Availability of PBO LLINs	Positive influencers	Barriers to availability	Opportunities for acceleration
	001	<p>Reference 1 - 0.90% Coverage</p> <p>Okay, so I think the availability will be very much influenced by the manufacturers and they can be quite aggressive in marketing their nets and especially where there are known pockets of high resistance. I've heard of cases where the manufacturers will in and really persuade people that this is the only solution and go in and manufacture it that way. So, the manufacturers can positively influence, (well I don't know if this is positive), but they can influence availability by making them available,</p> <p>Reference 2 - 0.95% Coverage</p> <p>And again availability will be affected by how much, what the pricing mechanism is; if you've got fixed budgets, does that mean lower coverage targets, so, those sorts of decision should be taken by donors but presumably in the case of Global fund, the countries will have to be making those recommendations as part of their Global fund application that they</p>	<p>Reference 1 - 0.72% Coverage</p> <p>but then also there may be issues in the other direction in that they are not manufacturing these at scale at the moment because there is no agreed process on which they are adopted. So if all of a sudden countries did want to or funders did decide to adopt this on a large scale, would they be available? So, I think the manufacturing side is a big challenge there; supply and demand. And again availability</p> <p>Reference 2 - 0.17% Coverage</p> <p>So I can start with the manufacturer's side, they've got to see that there is a demand for these,</p> <p>Reference 3 - 0.15% Coverage</p> <p>they've got to see that there are processes in place for global level endorsement.</p> <p>Reference 4 - 0.80% Coverage</p> <p>And they also have to have some sort of protection for their innovation; which seems</p>	<p>Reference 1 - 0.80% Coverage</p> <p>And, I mean if we are thinking about this as a long term solution, we need much more innovation because the two nets that actually you can go off and order now are both nets that have pyrethroids and a synergist in. And they work okay, but even the manufacturers would acknowledge that these are sort of stop gap, so we need more new nets coming forward so the people trying to accelerate the development of the market, and I think its gained momentum;</p> <p>Reference 2 - 0.68% Coverage</p> <p>I received before and I think this is something where they could play a major role is helping with overcoming these issues of protecting intellectual property and all these sorts of things may be barriers to getting new nets. But I think actually perhaps a bigger barrier is we've spent years now trying to convince countries and it's deep in to documents to put a combination of these;</p> <p>Reference 3 - 1.01% Coverage</p> <p>it's really important to monitor for resistance.</p>

		<p>want to put these nets in these areas. So, the countries will also influence (I'm not sure they'll influence the availability), but they will influence the demand for these.</p>	<p>to be a major issue that's coming up now that what if they develop these nets, especially for something quite innovative, spend millions developing and then marketing them, and then the generic comes along and has the same idea and then they've lost all their market; I have no idea how you tackle that, but that is something that's been raised by the industry partners</p>	<p>We tell everybody to monitor resistance using a very standard methodology and then we offer no interpretation of what the results of that mean in terms of what strategy you should adopt. So I think where we could really accelerate things now is by saying okay if we accept that these nets are going to be developed and are going to be evaluated, there will be evidence that they work better against resistant mosquitoes, let's work with the countries for them to be able to map out where they've got problems with resistance</p>
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Annex 12: Nigeria Ethic Approval



National Health Research Ethics Committee of Nigeria (NHREC)

Promoting Highest Ethical and Scientific Standards
for Health Research in Nigeria



Federal Ministry of Health

NHREC Protocol Number NHREC/01/01/2007-28/01/2013
NHREC Approval Number NHREC/01/01/2007-02/02/2013
Date: February 8, 2013

**Re: Maximising the translation potential of new malaria control tools
through the application of health economics and policy analysis**

Health Research Ethics Committee (HREC) assigned number: NHREC/01/01/2007

Name of Student Investigator: Kemi Tesfazghi

Name of Student Supervisor: Hillary Ranson

Student Contact Address: Liverpool School of Hygiene and Tropical Medicine
Phone +44 785 2175 820 (mobile), +44 1375 377 867 (home), E-mail: o.tesfazghi@liv.ac.uk

Date of receipt of valid application: 28-01-2013

Date when final determination of research was made: 02-02-2013

Notice of Expedited Review and Approval

This is to inform you that the research described in the submitted protocol, questionnaires, the consent forms and other participant information materials have been reviewed and *given expedited committee approval by the National Health Research Ethics Committee*.

This approval dates from 02/02/2013 to 01/02/2014. If there is delay in starting the research, please inform the HREC so that the dates of approval can be adjusted accordingly. Note that no participant accrual or activity related to this research may be conducted outside of these dates. *All informed consent forms used in this study must carry the HREC assigned number and duration of HREC approval of the study*. In multiyear research, endeavour to submit your annual report to the HREC early, in order to obtain renewal of your approval and avoid disruption of your research.

The National Code for Health Research Ethics requires you to comply with all institutional guidelines, rules and regulations and with the tenets of the Code including ensuring that all adverse events are reported promptly to the HREC. No changes are permitted in the research without prior approval by the HREC except in circumstances outlined in the Code. The HREC reserves the right to conduct compliance visit your research site without previous notification.

Signed

Clement Adebamowo BMChB Hons (Jos), FWACS, FACS, DSc (Harvard)
Honorary Consultant Surgeon, Director, West African Center for Bioethics and
Chairman, National Health Research Ethics Committee of Nigeria (NHREC)

Department of Health Planning, Research & Statistics
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Annex 13: Ethics Approval Burkina Faso

MINISTERE DE LA SANTE

MINISTERE DE LA RECHERCHE
SCIENTIFIQUE ET DE L'INNOVATION

COMITE D'ETHIQUE POUR
LA RECHERCHE EN SANTE

BURKINA FASO
Unité - Progrès - Justice

*Reçu le 21-10-13
N° 1*

DELIBERATION N° 2013-10-091

1. TITRE DE LA RECHERCHE

« Maximisation du potentiel d'application de nouveaux outils de lutte contre les vecteurs du paludisme à travers l'application d'économie de la santé et l'analyse des politiques » (version 2.0 de septembre 2013).

2. REFERENCE DU PROTOCOLE

Version 2.0 du 19 septembre 2013

3. DOCUMENTATION

La version 2.0 en français du projet de recherche datée du 19 septembre 2013 ;
La version 2.0 en français de la Fiche d'information des participants pour les Entretiens Individuels Approfondis datée du 19 septembre 2013 ;
La version 2.0 en français du consentement éclairé datée du 19 septembre 2013 ;
Le guide d'entretien (Interview des décideurs) ;
Les CVs des investigateurs ;
Une copie de la délibération N°2013-6-48 du 20 juin 2013.

4. REFERENCE DU DEMANDEUR

Co-investigateur principal : Dr SAGNON N'Falé (CNRFP)

5. SITE DE LA RECHERCHE

Burkina Faso

6. DATE DE LA DELIBERATION

08 octobre 2013

7. ELEMENTS EXAMINES

- conception scientifique et conduite de la recherche ;
- soins et protection des participants à la recherche ;
- protection de la confidentialité des données du participant à la recherche ;
- processus de consentement éclairé ;
- budget de la recherche ;
- CVs.

Annex 14: Ethics Approval Burkina Faso



Centre National de Recherche et de Formation sur le Paludisme
01 BP 2208 Ouagadougou 01
Burkina Faso

Ouagadougou, le 19/09/2013

Dr. Sagnon N'Falé, Entomologiste médicale
Tel /Fax: 50 32 46 95/96; 50 30 52 20
Tel. Mobile : 70 23 91 09
E-mail : n.fale.cnlp@fasonet.bf

A
Monsieur le Président du
Comité d'Ethique pour la
Recherche en Santé du
Burkina

Lettre N° : AvecNet/2013/013

Objet: Soumission d'un amendement au protocole

Monsieur le Président,

Par délibération N°2013-6-48 du 20 juin 2013, nous avons obtenu un avis non favorable pour la mise en œuvre du projet de recherche de l'étude en sciences sociales intitulé : «**Optimiser l'adoption de potentiels nouveaux outils de contrôle du paludisme par une approche fondée sur l'analyse économique de la politique de santé**» (version 1.0 du 26 mars 2013).

Par la présente, nous venons soumettre le protocole revu ainsi que ses annexes (fiche d'information, consentement, questionnaire). Ledit protocole est à présent intitulé «**Maximisation du potentiel d'application de nouveaux outils de lutte contre les vecteurs du paludisme à travers l'application d'économie de la santé et l'analyse des politiques**» (version 2.0 de septembre 2013).

Annex 15: Ethics Approval Liverpool School of Tropical Medicine for Nigeria and Burkina Faso Case Studies



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Ms Dluwakemi Mesfazghi
Liverpool School of Tropical Medicine
Pembroke Place
Liverpool
L3 5QA

Tuesday, 26 February 2013

Dear Ms Mesfazghi,

Re: Research Protocol 13.07) Maximising the translation potential of new malaria control tools through the application of health economics and policy analysis

Thank you for your letter dated 21st February 2013 responding to the action points requested by the Research Ethics Committee. The protocol now has formal ethical approval from the Chair of LSTM Research Ethics Committee.

The approval is for a fixed period of three years, renewable annually thereafter. The committee may suspend or withdraw ethical approval at any time if appropriate.

Approval is conditional upon:

- Submission of ethical approval from other ethics committees.
- Notification of all amendments to the protocol for approval before implementation.
- Notification of when the project actually starts.
- Provision of an annual update to the Committee. Failure to do so could result in suspension of the study without further notice.
- Reporting of all severe/unexpected adverse events to the Committee.
- Reporting of new information relevant to patient safety to the Committee.
- Provision of Data Monitoring Committee reports (if applicable) to the Committee.

Failure to comply with these requirements will result in withdrawal of approval. The Committee would also like to receive copies of the final report once the study is completed.

Yours sincerely,

A handwritten signature in black ink that reads 'Angela Obasi'. The signature is written in a cursive style and is positioned above a horizontal line.

Dr Angela Obasi
Chair, Research Ethics Committee

Annex 15B: Ethics Approval Liverpool School of Tropical Medicine for Global Case Study



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Ms Oluwakemi Tesfazghi
Liverpool School of Tropical Medicine
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Liverpool
L3 5QA

Monday, 12 May 2014

Dear Ms Tesfazghi,

Research Protocol (14.006R5) Global adoption of a new combination long lasting insecticidal net: Process, barriers and opportunities for accelerated access

Thank you for your correspondence of the 15/04/2014 repsonding to the action points set by the committee. As this project will not require in-country approval I can confirm that the protocol now has formal ethical approval from the Chair of LSTM Research Ethics Committee.

The approval is for a fixed period of three years and will therefore expire on 11/05/2017. The committee may suspend or withdraw ethical approval at any time if appropriate. Approval is conditional upon:

- Continued adherence to all in-country ethical requirements.
- Notification of all amendments to the protocol for approval before implementation.
- Notification of when the project actually starts.
- Provision of an annual update to the Committee. Failure to do so could result in suspension of the study without further notice.
- Reporting of new information relevant to patient safety to the Committee
- Provision of Data Monitoring Committee reports (if applicable) to the Committee

Failure to comply with these requirements is a breach of the LSTM Research Code of Conduct and will result in withdrawal of approval and may lead to disciplinary action. The Committee would also like to receive copies of the final report once the study is completed.

Please quote your Ethics Reference number with all correspondence.

Yours sincerely


Dr Brian Paraghes,
Co-Chair, LSTM Research Ethics Committee

Annex 16: Participant Information Sheet for all Case Studies

Adoption and support for combination long lasting insecticidal net: Process, barriers and opportunities for accelerated access

Information Sheet for In-depth interviews (APPENDIX 2)

Institution	Individuals
Liverpool School of Tropical Medicine Pembroke Place, Liverpool L3 5QA	Ms Kemi Tesfazghi o.tesfazghi@liv.ac.uk +44 785 2175 820

What is this research about?

My PhD project is part of an EU funded project AvecNet and seeks to accelerate the availability of new Insecticide Resistance Management Strategies (IRMS). This qualitative study forms part of my PhD and aims to contribute to accelerated access to IRMS (which comprises of Insecticide Resistance Management Tools (IRMT) and Insecticide Resistance Management Programmes (IRMPs)) by understanding the process for the global policy adoption of IRMTs such as combination Long lasting insecticidal nets (CLLNs) and IRMPs, the potential barriers in the identified process and opportunities to accelerate access. This will be achieved by obtaining KI's perspectives on five areas: global organizations and structures important for ensuring access to new IRMS; availability, affordability and adoption⁶ as well as opportunities and threats to accelerated access.

How will the information be collected?

Documents have been reviewed to identify institutions involved in ensuring the availability, affordability and adoption of IRMS, elicit policymaking processes and structures, as well as to identify key stakeholders. In addition to the document reviews, key informant interviews will be carried out with global level stakeholders involved in malaria vector control policy making, research, financing and implementation.

Why do you want to talk to us and what does it involve?

I would like to talk to you in order to gain your perspective on the global adoption of IRMS, the process, barriers and opportunities for accelerated access.

⁶ Adoption encompasses policy adoption and generating global demand

What will you be talking to us about?

I would like to talk to you about the process of adopting new IRMS: the key stakeholders involved and factors that influence issues like their availability and affordability. I would also like to talk to you about potential opportunities to accelerate access to these new tools.

If you would like to see a copy of the topic guide in advance of the interview please feel free to contact Ms Tesfazghi on the address provided above.

Are there any advantages or disadvantages to me of taking part?

The interview should take a maximum of 90 minutes, however you can halt the process at any point in time. There are no individual benefits to taking part, but in answering our questions you will help us improve our understanding accelerating the access to life saving IRMS.

Who will have access to the information I give?

We will not share individual information about you with anyone beyond myself and the study team at LSTM, who are closely concerned with the research. Information shared with funders will be anonymized. All of our documents/recordings are stored securely in locked cabinets and on password protected computers. Tapes will be destroyed as soon as they have been transcribed (usually within two weeks) and the transcripts will contain no information that will allow for the identification of individual participants.

The knowledge gained from this research will be shared in summary form, without revealing individuals' identities. With your agreement, anonymous quotes may be used to illustrate general points, but if they are used they will not contain any information that will allow identification of individuals.

What will happen if I refuse to participate?

All participation in research is voluntary. You are free to decide if you want to take part or not. If you do agree you can change your mind at any time without any consequences.

What if I have any questions?

You are free to ask me any question about this research. If you have any further information or points for clarification regarding the interview at a later date or if you have any further questions about the study, you are free to contact the research team using the contacts provided above.

Annex 17: Interview Consent Form for all Case Studies: Accelerating Access to New Vector Control Tools: Policy Analysis

Study title: Global adoption and support for combination Long lasting insecticidal nets: Process, barriers and opportunities for accelerated access

CONFIDENTIAL

Participant Identification Number for this Study:

The purpose of this form is to allow the use of your interview for research purposes. Please sign below if you have read the information sheet and agree to take part in this research study.

I have been read the information sheet dated _____ that explains the reasons for this study [or have understood the verbal explanation] and I understand what will be required of me and what will happen to me if I take part in it.

All the questions I had about this study have been answered.

I understand that at any time I may withdraw from this study without giving a reason.

I hereby declare that I have not been subjected to any form of coercion in giving this consent.

I am aware that all the information that I give will be kept confidential, and will only be seen by the study investigators.

I agree to quotes arising from my participation in the study being included anonymously the study report.

Yes/No

If yes:

I would like to see and approve the use of any such quote before submission of the report to (name of host organization) or any other third party.

Yes/No

I do not need to see and approve the use of any such quote before submission of the report to (name of host organization) or any other third party.

Yes/No

Annex 18: Chapter 6 Global Analysis Supplementary Quotes

	Analytical Framework	Subtheme Theme	Additional illustrative quote
1	Global Adoption Process	Data on failure of current tools	<i>'I think everyone understands that resistance has become more of a challenge but as of yet there is really not a lot of documented data on the [operational] impact of resistance.'</i> (Funder)
			<i>'The main limitation is of course the national capacity to do this [insecticide resistance monitoring]. The resources I think are available in almost every country through PMI, through Global fund ... So, the question is do they have the human capacity and lab capacity to look up all these things...The question is not resources, it's (1) to see the importance of it, (2) to have the resources, human and technical resources to do it.'</i> (Researcher)
2	Global Adoption Process	Evidence of effectiveness of new tool	<i>That if you see a significant difference in disease impact with the combination LLIN in comparison with the pyrethroid, that's the thing that will motivate people and drive people in that direction</i> (Private sector TM)
3	Global Adoption Process	Lengthy and unclear global policy adoption process	<i>'...because there is not one final approval agency like there is for drugs. In drugs, when you develop a drug it's very clear who in the end is going to make a final decision. And by and large only that agency is relevant for the decision you want to make. In vector control, there are at least three different players, you have the national approval agencies, there's WHOPEs and there's VCAG. And how they interact, what the prerogatives are etc is absolutely not defined and that's part of the problem.'</i> (Researcher)
4	Global Adoption Process	Developing an effective tool	<i>'I think it depends on which, generation of the combinations LLINs cause there are going to be several different generations. I think my current view, is that the LLINs that are on the immediate horizon that are likely to be approved in the next 3 or 4 years as combination LLINs are not ideal and I would use them as effectively emergency response; if you have some problem with the pyrethroid LLINs in a particular place.'</i> (Researcher)

6	Availability	Forecasting the size of the market	<i>'So, there isn't a clear market today, you can't point to a clear market today and say 30% of the bed net market is combinations nets and it's going to grow to 50% in five years, there's just no data that would support anything like that. And it would be very interesting to understand of the two PBO nets, ... just how much market share they were taking. I suspect it's really not very much. So there isn't an established market that we can point the manufacturers to and say 'there it is, that's what you ought to go after', there are still some really substantial policy and regulatory risks attached to these manufacturers, so they're trying to work out what the right way to approach it is.'</i> (Private sector)
7	Availability	The ability to predict market share	<i>'I think nowadays you can at the same time while looking at the product obviously a shift in the way people are thinking about distributions, away from just campaigns to continuous distributions and potentially with campaigns at such a time when the campaigns are needed so that would perhaps or could be an enabler for increasing access because if it meant that the demand was steady all over the year, rather than intermittent very large requirements then that would help to make it available.'</i> (Policy advisor)
8	Availability	Affordability of PBO LLINs	<i>'I think, is the predictability of a market for the manufacturer, otherwise the manufacturer would be reluctant to invest into a new product and we've seen that ...I think already. And so knowing about the demand for....or potential demand for a specific product from the key donors, I think is going to be a huge catalytic factor in this process.'</i> (Donor)
9	Availability	Fostering innovation	<i>'The other piece I think is definitely the intellectual property protection for some of this new nets, I've heard that some of the manufacturers are not going to be submitting products until the intellectual property issues that WHOPES has, are sorted ... unless that gets sorted out that also touches our getting new products into the market place.'</i> (Donor)
10	Availability	Ability to meet global demand	<i>If all of a sudden countries did want to or funders did decide to adopt this [next generation LLINs] on a large scale, would they be available? So, I think the manufacturing side is a big challenge there.</i> (Researcher)
11	Availability	WHO recommendation	<i>'I mean if I was a manufacturer, which obviously I'm not, I wouldn't scale up significantly of course until I've got my WHOPES approval and the WHO policy position in place.'</i> (Policy advisor)
12	Availability	Clarity on the process and the	<i>'I think there needs to be a clear process for evaluating the products. A clear understanding of</i>

		evidence base required to convince policymakers	<i>how you measure if one of these products is better than a current standard LLIN and then be able to communicate with people who are procuring this net that this is better than a normal net by some standardized level and therefore it is worth paying an extra however much the net is going to be. Otherwise, it will just look like a more expensive net to people who are going to procuring the net without that standard measure of how much better it is against resistant mosquitoes or for resistance prevention.'</i> (Donor)
13	Affordability	Price	<i>'I think the other big chunk is getting the funders happy with the idea that they're going to have to pay more for the nets. It's unrealistic to expect these products to arrive at the same price that the pyrethroid bed nets are today and the intervention funders need to get their minds around that.'</i> (Private sector)

Annex 19: Chapter 5 Burkina Faso Analysis Supplementary Quotes

SN	Research Finding	Supplementary illustrative quote
1	The PNLP drafts the policy document and politicians at the highest level endorse it	<i>"To summarise, ... it is up to the politicians to decide, especially those who are at the ministry level, at the National Assembly (Parliament), it is up to them to decide; yes we are going for a particular strategy, no we do not go." (NGO)</i>
2	Policies are developed by PNLP with input from partners	<i>"It is at the development stage that the technical department in charge of the issue will consult the other partners like us, the WHO, the UNICEF, all these partners are already involved in the development of the draft." (NGO)</i>
3	Policymakers as technicians	<i>"There are technicians first who work in the shade. I mean the national program for malaria control (PNLP). These technicians draft all... strategies about malaria control." (NGO)</i>
4	Power as to influence opinion	<i>In different countries they [WHO] act as a Special Advisor to the Ministry of Health, and most of the strategies put into practice to counter lots of diseases are, to a certain extent, dictated by the WHO, who conducts countless studies and offers solutions to countries....And in general, WHO is also the organisation that provides guidance to various donors." (Donor)</i>
5	Financial power	<i>Global Fund is providing a very significant financial support, [compared to] the other partners provide [who provide] very little financial support." (Multilateral)</i>
6	Financial resources influence policy adoption	<i>"When it [research] is confirmed at the international level, now the funding bodies now adopt that strategy and now come to the country and suggest activities to the country saying 'these are the new strategy that we have resources to support...if you are interested'. So based on that also, the Comité de Pilotage decides to go with that new strategy" (Researcher)</i>
7	National research indirectly influences national policymaking	<i>"I say that this is nice, you need to produce nice result, but you will change the situation not directly but indirectly." (Researcher)</i>
8	The decision to procure PBO LLINs was not made nationally.	<i>'I didn't buy myself.... when they [the procurement agency] buy, they come with PermaNet 3.0' (Policymaker)</i>
9	Individual interests can affect choice of vector control tool	<i>"Do you think this decision maker will let you popularise your new technique that will prevent him from importing mosquito nets and therefore lose his contract percentage" (NGO)</i>
10	WHO recommendations influences donor	<i>"Donors will fund, if you use a method that has been proven, which has been recognised by the WHO as a valid mandate' (Donor)</i>

11	The need to meet set target is jeopardised if the new tool is more expensive and the resource envelope is fixed.	<i>"I think the first priority should be letting everybody have access first of all as a minimum and now start improving it."</i> (Researcher)
12	National funding is a way to improve affordability and availability of new tools.	<i>"Poor availability of nets can be caused by the political commitment. It is also the absence of a national budget line; if we count only on the partners to acquire it."</i> (NGO)



National malaria vector control policy: an analysis of the decision to scale-up larviciding in Nigeria

Kemi Tesfazghi,¹ Jenny Hill,² Caroline Jones,^{3,4} Hilary Ranson,¹ and Eve Worrall^{1,*}

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Accepted on 9 May 2015

Abstract

Background: New vector control tools are needed to combat insecticide resistance and reduce malaria transmission. The World Health Organization (WHO) endorses larviciding as a supplementary vector control intervention using larvicides recommended by the WHO Pesticides Evaluation Scheme (WHOPES). The decision to scale-up larviciding in Nigeria provided an opportunity to investigate the factors influencing policy adoption and assess the role that actors and evidence play in the policymaking process, in order to draw lessons that help accelerate the uptake of new methods for vector control.

Methods: A retrospective policy analysis was carried out using in-depth interviews with national level policy stakeholders to establish normative national vector control policy or strategy decision-making processes and compare these with the process that led to the decision to scale-up larviciding. The interviews were transcribed, then coded and analyzed using NVivo10. Data were coded according to pre-defined themes from an analytical policy framework developed *a priori*.

Results: Stakeholders reported that the larviciding decision-making process deviated from the normative vector control decision-making process. National malaria policy is normally strongly influenced by WHO recommendations, but the potential of larviciding to contribute to national economic development objectives through larvicide production in Nigeria was cited as a key factor shaping the decision. The larviciding decision involved a restricted range of policy actors, and notably excluded actors that usually play advisory, consultative and evidence generation roles. Powerful actors limited the access of some actors to the policy processes and content. This may have limited the influence of scientific evidence in this policy decision.

Conclusions: This study demonstrates that national vector control policy change can be facilitated by linking malaria control objectives to wider socioeconomic considerations and through engaging powerful policy champions to drive policy change and thereby accelerate access to new vector control tools.

Key words: Larviciding, larval source management, malaria, policy analysis, vector control