



# Universidade Nova de Lisboa Instituto de Higiene e Medicina Tropical

# Comparing two models of massive distribution of mosquito bed nets in rural districts of Mozambique

# Jorge Alexandre Harrison Arroz, MD., MPH.

DISSERTATION FOR OBTAINING THE DEGREE OF DOCTOR OF PHILOSOPHY IN INTERNATIONAL HEALTH IN THE SPECIALTY OF TROPICAL PUBLIC HEALTH

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# Comparing two models of massive distribution of mosquito bed nets in rural districts of Mozambique

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**DOCTORAL ORIENTATION** 

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#### **BIBLIOGRAPHIC ELEMENTS RESULTING FROM DISSERTATION**

This thesis is based on three articles listed bellow, two of them already published in *Malaria Journal*.

I. Arroz J, Mendis C, Pinto L, Candrinho B, Pinto J, and Martins MRO. Implementation strategies to increase access and demand of long-lasting insecticidal nets: a before-and-after study and scale-up process in Mozambique. Malaria Journal 2017; 16:429.

II. Arroz J, Candrinho B, Mendis C, Varela P, Pinto J, and Martins MRO. Effectiveness of a new long long-lasting insecticidal nets delivery model in two rural districts of Mozambique: a before-after study. Malaria Journal 2018; 17:66.

III. Arroz J, Candrinho B, Mendis C, Varela P, Lopez M, Pinto J, and Martins MRO. Cost-effectiveness analysis of two long-lasting insecticidal nets delivery models in mass free campaign in rural Mozambique. Submitted for publication in Acta Tropica.

#### **DEDICATION**

"The greatest enemy of knowledge is not ignorance, it is the illusion of knowledge"

(Stephen Hawking)

This dissertation is dedicated to the memory of my parents: **Ana Harrison** and **Jaime Orlando Lopes Arroz**. Although they were my inspiration to continuously pursue high scholar degrees, they were unable to see my medical doctor graduation, my master in public health graduation, and this doctoral thesis. This is for you mom and dad.

I also dedicate this PhD dissertation to:

#### My sons:

Ameliana Arroz; Sharon Arroz; Jorge Arroz, Jr; Ariel Arroz

My wife:

Naila Soares

#### My brothers and systers:

Cristóvão Harrison, Jaime Arroz, Paulo Harrison, Sérgio Arroz

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They all have been supportive during this phase of my career.

#### And

A collective dedication to all the teachers of the Marien Ngwabi Primary School and Tete Secondary School - the cradle of my education.

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#### RESUMO

Introdução: A disponibilização de redes mosquiteiras impregnadas com insecticida de longa duração (REMILDs) é uma das intervenções principais no controlo vectorial da malária. O uso de REMILDs está associado a uma redução da transmissão da malária. Moçambique disponibiliza as REMILDs através de dois canais: consulta pré natal e em campanhas para a cobertura universal. Este estudo testa novas estratégias de distribuição de REMILDs (intervenção) em campanha e compara os seus resultados com o das estratégias anteriores (controlo). O objetivo geral é o de comparar os dois modelos de distribuição de redes mosquiteiras em distritos rurais de Moçambique.

Métodos: Os distritos de intervenção foram: Gurue e Sussundenga; os distritos de controlo foram: Alto-Molócuè e Machaze. Usando uma abordagem quantitativa, três estudos tiveram lugar: i) antes e depois entre os meses de Outubro e Dezembro de 2015; ii) antes e depois, do tipo observacional e transversal, entre os meses de Junho e Julho de 2016; iii) análise de custo-efectividade entre os meses de Outubro e Dezembro de 2015. Três principais estratégias de implementação foram testadas: uso de cupões durante o registo das famílias (AFs), uso de autocolantes para identificar as casas registadas e um novo critério de atribuição de redes. Os principais indicadores medidos foram: i) percentagem de REMILDs distribuídas; ii) cobertura da posse e uso de REMILDs; iii) percentagem de AFs que alcançaram a cobertura universal; iv) razão incremental de custo-efectividade (RICE); iv) benefício líquido incremental.

Resultados: Cerca de 88% (302.648) de REMILDs foram distribuídas nos distritos de intervenção em comparação com 77% (219.613) nos distritos de controlo [OR: 2.14 (IC 95%: 2,11–2,16)]. Seis meses após a campanha de 2015, dos 760 AFs inqueridos nos distritos de intervenção, 98,8% tinha pelo menos uma REMILD; dos 787 AFs inqueridos nos distritos de control, 89,6% tinha pelo menos uma REMILD [OR: 9,7, (IC 95%: 5,25 – 22,76)]. Cerca de 95% e 87% dos inqueridos que tinham pelo menos uma REMILD reportaram ter dormido debaixo da mesma na noite anterior nos distritos de intervenção e controlo, respectivamente [OR: 3,2; (IC 95%: 2,12-4,69)]; 71% dos AFs inqueridos alcançaram a cobertura universal nos distritos de intervenção contra 59.6% nos distritos de controlo [OR: 1,6; (IC 95%: 1,33 – 2,03)]. A RICE por REMILD distribuída foi de US\$ 0,68. O benefício líquido incremental foi positivo.

Conclusões: Os distritos de intervenção tiveram maior disponibilização de REMILDs, maior cobertura de posse e uso, e um melhor progresso para o alcance de cobertura universal. A nova estratégia foi mais custo-efectiva do que a estratégia anterior. A nova estratégia poderá acelerar o passo no controlo vectorial para a redução da morbimortalidade por malária e alcançe dos objectivos da Estratégia Técnica Global para a Malária 2016 – 2030.

Palavras-chave: Estratégias de implementação; REMILDs; Prevenção; Malária, Moçambique

#### ABSTRACT

Introduction: The provision of long lasting insecticidal nets (LLINs) has been pointed out as one of the core malaria vector control interventions. The use of LLINs is associated with a reduction in malaria transmission. LLINs delivery in Mozambique has been carried out through two delivery channels: prenatal care service and universal coverage campaigns. This study tests new delivery strategies (intervention) in universal coverage campaign and compares its results with previous strategies (control). The general objective of the thesis is to compare two bed nets delivery models in rural districts of Mozambique.

Methods: The intervention districts were: Gurue and Sussundenga; the control districts were: Alto-Molocue and Machaze. Using a quantitative approach, three studies took place: i) before and after study between October and December 2015; ii) before and after, observational and cross-sectional study, between June and July 2016; and iii) cost-effectiveness analysis between October and December 2015. Three core implementation strategies were tested: use of coupons during household (HH) registration, use of stickers to identify registered houses and a new LLINs allocation criterion. The main endpoints measured were: i) percentage of distributed LLINs; ii) LLINs ownership and use coverage; iii) percentage of HHs that achieved universal coverage; iv) incremental cost-effectiveness ratio (ICER); iv) incremental net benefit (INB).

Results: Approximately 88% (302,648) of LLINs were distributed in intervention districts compared to 77% (219,613) in control districts [OR: 2.14 (95% CI: 2.11-2.16)]. Six months after the 2015 campaign, of the 760 HHs surveyed in the intervention districts, 98.8% had at least one LLIN; of the 787 HHs surveyed in the control districts, 89.6% had at least one LLIN [OR: 9.7, (95% CI: 5.25 - 22.76)]. Near 95% and 87% of respondents who had at least one LLIN reported having slept under the LLIN the previous night in the intervention and control districts, respectively [OR: 3.2; (95% CI 2.12-4.69)]; 71% of the HHs surveyed achieved universal coverage in the intervention districts against 59.6% in the control districts [OR: 1.6; (95% CI: 1.33-2.03)]. ICER per distributed LLIN was US\$ 0.68. INB was positive.

Conclusions: Intervention districts had greater LLINs availability, greater LLINs ownership and use coverage, and a better progression toward reaching universal coverage targets. The new strategy was more cost-effective than the previous strategy. The new strategy might well accelerate the pace in vector control for reducing malaria morbidity and mortality and achieving the goals of the Global Technical Strategy for malaria 2016-2030.

Keywords: Implementation strategies; LLINs; Prevention; Malaria, Mozambique

# **TABLE OF CONTENTS**

BIBLIOGRAPHIC ELEMENTS RESULTING FROM DISSERTATIONi
DEDICATIONiii
ACKNOWLEDGEMENTS iv
RESUMOv
ABSTRACTvi
GLOSSARY OF COMMONLY USED TERMSx
LIST OF TABLES AND FIGURES xii
ACRON YMSxiv
CHAPTER 1: GENERAL INTRODUCTION1
PART I1
1.1 Malaria burden in the World, Africa, and Mozambique1
1.1.1 Vectors and etiological agents of malaria1
1.1.2 Malaria burden in the World, Africa, and Mozambique2
1.1.3 Malaria prevention interventions4
PART II5
1.2 Bed nets strategy in the World, Africa, and Mozambique5
1.2.1 Rationale for insecticide-treated nets as malaria prevention tool
1.2.2 Coverage of vector control interventions
1.2.3 Bed nets delivery mechanisms6
1.2.4 Literature review on bed nets ownership and use7
PART III9
<b>1.3 Malaria control efforts and epidemiology in Mozambique</b> 9
1.3.1 Malaria control efforts in Mozambique9
1.3.2 Malaria epidemiology in Mozambique13
PART IV15

1.4 Research question, hypothesis, and objectives15
1.4.1 Research question and hypothesis15
1.4.2 General objective
PART V
1.5 Overview of the studies and methodological approach17
1.5.1 Implementation research: the cornerstone of this thesis
1.5.2 Conceptual framework18
CHAPTER 2: IMPLEMENTATION STRATEGIES TO INCREASE ACCESS AND DEMAND OF LONG-LASTING INSECTICIDAL NETS: A BEFORE-AND-AFTER STUDY AND SCALE-UP PROCESS IN MOZAMBIQUE
2.1 Background27
2.2 Methods
<b>2.3 Results</b>
<b>2.4 Discussion</b>
2.5 Conclusions
CHAPTER 3: EFFECTIVENESS OF A NEW LONG LASTING INSECTICIDAL NETS DELIVERY MODEL IN TWO RURAL DISTRICTS OF MOZAMBIQUE: A BEFORE- AFTER STUDY
3.1 Background
<b>3.2 Methods</b>
<b>3.3 Results</b>
<b>3.4 Discussion</b>
3.5 Conclusions
CHAPTER 4: COST-EFFECTIVENESS ANALYSIS OF TWO LONG-LASTING INSECTICIDAL NETS DELIVERY MODELS IN MASS FREE CAMPAIGN IN RURAL MOZAMBIQUE
4.1 Background53
<b>4.2</b> Methods
4.3 Results
Page   viii

<b>4.4 Discussion</b>
4.5 Conclusions
CHAPTER 5: CONCLUSIONS65
5.1 Summary of the findings
5.2 Limitations of the study65
5.3 Contribution to knowledge and implications
5.4 Recommendations
5.5 Further research directions
5.6 Autobiographical reflection
5.7 Final words
REFERENCES
APPENDIX
Appendix 1: Authorization from the National Committee on Bioethics in Health79
Appendix 2: Authorization from the Instituto de Higiene e Medicina Tropical Scientific Committee

#### **GLOSSARY OF COMMONLY USED TERMS**

Bed nets – are an important form of mosquito control and a major modality for preventing malaria. Bed nets can be treated with an insecticide. The insecticide may be long-lasting (LLINs). If it is not, the net needs regular retreatment with insecticide. An insecticide-treated bed net is called an ITN.

Channel - The route through which the LLINs (or vouchers or coupons) flow to the enduser. Considering the final point at which the user will receive a LLIN is a good way to get a clear idea of the channel.

Health Intervention - The evidence-based practice, programme, policy, process, or guideline recommendation that is being implemented.

Households - All the people who live together or sleep in the same house / yard / plot and share the same food at meal times. When a man has more than one wife or woman, each of them is considered as a separate household.

Implementation fidelity - The degree of adherence to the described implementation strategy and/or the degree to which an intervention is implemented as prescribed in the original protocol.

Implementation science – also called implementation research, is the scientific study of methods to promote the systematic uptake of evidence-based interventions into practice and policy and hence improve health.

Implementation strategies - Methods or techniques used to enhance the adoption, implementation, and sustainability of an under-utilised intervention.

LLINs Ownership - Having possession of a LLIN, whether or not it is used.

LLINs Use - Sleeping under a LLIN at night. As an indicator this is usually measured through surveys asking, for example, whether a specific person slept under a LLIN 'the previous night'.

Long lasting insecticidal net / Long lasting insecticidal nets (LLIN / LLINs) – A factory-treated mosquito net with insecticide incorporated into or bound around the fibers, or a mosquito net treated with a long-lasting insecticidal treatment kit, that retains its biological activity for at least 20 WHO standard washes under laboratory conditions and 3 years of recommended use under field conditions without re-treatment.

Mechanism - The whole delivery system that results in a household getting a net, a channel is part of the mechanism but the whole mechanism includes other aspects such as decisions on pricing, type of LLIN, and procurement.

Pull mechanism - A mechanism that requires the future LLIN owner to take action to get the LLIN. This action must be specific to getting the LLIN (such as going to a retail

outlet) rather than something the person may do anyway (such as attending a prenatal clinic). Most but not all pull mechanisms would involve the LLIN having some cost to the user.

Push mechanism - A mechanism whereby only limited action is need from the future LLIN owner to receive a LLIN, and the LLIN is given at no cost.

Universal coverage – The term 'Universal' suggests a target of 100%. The international consensus, however, is that universal access would be achieved if every household had at least one LLIN for every two people. Pragmatically, it is expected at least 80% of households owning at least one LLIN for every two people.

Vector control - Is any method to limit or eradicate the mammals, birds, insects or other arthropods (here collectively called "vectors") which transmit disease pathogens. The most frequent type of vector control is mosquito control using a variety of strategies. The core vector control interventions are: LLINs and Indoor Residual Spraying (IRS).

# LIST OF TABLES AND FIGURES

Table /	Designation	Daga (a) number		
	Designation	Page (s) number		
Figure		(s)		
Table 1	Estimated malaria cases by WHO region, 2016	2		
Table 2	Main differences between theory and model	19		
Table 3	Description of Social Ecological Model (SEM) Levels	20		
Table 4	Overview of the studies and methodological approach	23		
Table 5	Specifications of the Implementation Strategy	30 - 31		
Table 6	Population, households and coupons delivered and retrieved during Stage II	36		
Table 7	Households composition ( <i>de facto</i> members) and number of 2015 campaign LLINs in intervention and control districts	46		
Table 8	LLIN household ownership, use and universal coverage six month after distribution in intervention and control districts	47		
Table 9	Main differences between the standard (control) and new (intervention) delivery models	55 – 56		
Table 10	Total cost and cost per LLIN delivered (US\$) for each category in the intervention and control districts	59		
Table 11	Comparative cost-effectiveness results in the intervention and control districts	61		
Table 12	Deterministic one-way sensitivity analysis of cost estimates to key assumptions	62		
Figure 1	Estimated malaria cases (millions) by WHO region, 2016	2		
Figure 2	Estimated country share of total malaria cases, 2016	3		

Figure 3	Proportion of estimated malaria deaths attributable	4
	to the 15 countries with nearly 80% of malaria	
	deaths globally in 2016	
Figure 4	Trends in malaria cases and deaths in Mozambique,	13
Ũ	2000 - 2017	
Figure 5	Correlation between malaria prevalence in children	14
	under five years and Human Development Index by	
	province. Mozambique, 2011	
Figure 6	Prevalence of malaria per provinces. Mozambique,	15
	2011 and 2015	
Figure 7	Social Ecological Model	19
Figure 8	Three elements of the theory of social practice	21
		22
Figure 9	Conceptual framework of the thesis	22
Figure 10	Malaria prevalence in Mozambique and	28
Figure 10	1 1	20
	intervention and control districts of the study	
Figure 11	Coupon for household registration	32
	coupon for nousenoid registration	54
Figure 12	Stickers to identify the registered households	32
0		
Figure 13	The coupon-sticker demand effect	48

#### ACRONYMS

ACER – Average Cost-Effectiveness Ratio

ACT – Artemisinin-based Combination Therapy

AL - Artemether-Lumefantrine

AMP – Alliance for Malaria Prevention

AQ – Amodiaquine

CI – Confidence Interval

CQ - Cloroquine

DDT-Dichlorodiphenyl trichloroe than e

HDI - Human Development Index

HH / HHs - Household / Households

HHR – Household Registration

ICER – Incremental Cost-Effectiveness Ratio

INB - Incremental Net Benefit

IPTp – Intermittent Preventive Treatment to pregnant women

IRS - Indoor Residual Spraying

ITN / ITNs – Insecticide Treated Net / Insecticide Treated Nets

LLIN / LLINs – Long-Lasting Insecticidal Net / Long-Lasting Insecticidal Nets

LSDI - Lubombo Spatial Development Initiative

NMCP – National Malaria Control Programme

OR - Odds Ratio

PP – Protected Persons

PPP - Potentially Protected Persons

SD - Standard Deviation

SDOH - Social Determinants of Health

SEM - Social Ecological Model

SP - Sulphadoxine-Pirimetamine

SPT – Social Practice Theory

ToT – Training of Trainers

UCC - Universal Coverage Campaign

WHO - World Health Organization

WHOPES - WHO Pesticides Evaluation Scheme

WTP - Willingness-To-Pay

WVI - World Vision International

#### **CHAPTER 1: GENERAL INTRODUCTION**

# PART I 1.1 Malaria burden in the World, Africa, and Mozambique

#### 1.1.1 Vectors and etiological agents of malaria

Malaria is an infectious vector-borne disease and is caused by single-cell parasite of the genus *Plasmodium* (*P*.), being transmitted from one person to another via the bite of female mosquitoes of the genus *Anopheles* (*An.*) (WHO 2015, MISAU 2012).

Malaria in humans is caused by five species of parasites belonging to the genus *Plasmodium*. Four of these – *P. falciparum*, *P. vivax*, *P. malariae* and *P. ovale* – are human to human vector-borne disease (WHO 2015). There is fifth species, *P. knowlesi*, known since the early 1930 (Knowledges and Das Gupta 1932). In recent years, human cases of malaria due to *P. knowlesi* have been recorded – this species causes malaria among monkeys in certain forested areas of South-East Asia (WHO 2015, Singh *et al.* 2004). This *Plasmodium* species still seems to be under-diagnosed due to diagnostic constraints and possibly also due to a lack of awareness (Sulistyaningsih *et al.* 2010). Current information suggests that *P. knowlesi* malaria is not spread from person to person, but rather occurs in people when an *Anopheles* mosquito infected by a monkey then bites and infects humans (zoonotic transmission) (WHO 2015).

*Plasmodium falciparum* and *P. vivax* malaria pose the greatest public health challenge, accounting for about 96% and 4% of estimated cases globally, respectively (WHO 2017). *Plasmodium falciparum* is most prevalent on the African continent, and is responsible for most deaths from malaria (WHO 2015).

*Plasmodium falciparum* is the most frequent parasite in Mozambique, responsible for approximately 90.0% of all malaria infections, while infections by *Plasmodium malariae* and *Plasmodium ovale* are observed in 9.0% and 1.0%, respectively (MISAU 2012).

There are about 400 different species of *Anopheles* mosquitoes, but only 30 of these are vectors of major importance (WHO 2015). In Africa, *Anopheles (Cellia) arabiensis, An. (Cel.) funestus, An. (Cel.) gambiae, An. (Cel.) melas, An. (Cel.) merus, An. (Cel.) moucheti and An. (Cel.) nili are the dominant vector species (Sinka <i>et al.* 2010). The main vectors of malaria in Mozambique belong to groups *An. funestus* and *An. gambiae* (Arroz 2014; MISAU 2012).

#### 1.1.2 Malaria burden in the World, Africa, and Mozambique

Malaria remains an important public health problem worldwide. Globally an estimated 3.3 million inhabitants are at-risk of being infected and developing the disease (WHO 2014). In 2016, an estimated 216 million cases of malaria occurred worldwide, compared with 237 million cases in 2010 and 211 million cases in 2015 (WHO 2017). Most malaria cases in 2016 were in the WHO African Region (*ca.* 90%). In 2016, there were an estimated 445,000 deaths from malaria globally, compared to 446,000 estimated deaths in 2015. Likewise, the WHO African Region accounted for 91% of all malaria deaths in 2016 (WHO 2017) – Table 1 and Figure 1.

	Number of cases (000)					
	African	Americas	Eastern Mediterranean	South-East Asia	Western Pacific	World
Lower 95% CI	176 000	665	3 600	10 900	1 200	196 000
Estimated total	194 000	875	4 300	14 600	1 600	216 000
Upper 95% Cl	242 000	1 190	5 900	19 800	2 100	263 000
Estimated P. vivax						
Lower 95% Cl	182	405	1 360	3 280	214	6 430
Estimated total	859	556	1 790	4 960	385	8 550
Upper 95% Cl	2 090	786	2 340	7 234	592	11 140
Proportion of P. vivax cases	0.4%	64%	42%	34%	24%	4%

Table 1: Estimated malaria cases by WHO region, 2016

Estimated cases are shown with 95% upper and lower confidence intervals (CI). Source: WHO estimates (World Malaria Report 2017).

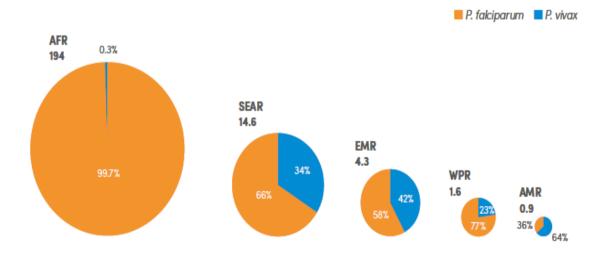


Figure 1: Estimated malaria cases (millions) by WHO region, 2016. The area of the circles are proportional to the estimated number of cases in each region. Source: WHO

estimates (World Malaria Report 2017). Legend: AFR, WHO African Region; AMR, WHO Region of the Americas; EMR, WHO Eastern Mediterranean Region; SEAR, WHO South-East Asia Region; WPR, WHO Western Pacific Region

Of the 91 countries reporting indigenous malaria cases in 2016, 15 countries – all in sub-Saharan Africa, except India – carried 80% of the global malaria burden. Nigeria accounted for the highest proportion of cases globally (27%), followed by the Democratic Republic of the Congo (10%), India (6%) and Mozambique (4%) (WHO 2017). The same fifteen countries also accounted for 80% of global malaria deaths in 2016 (WHO 2017). Nigeria accounted for the highest proportion of deaths globally (30%), followed by the Democratic Republic of the Congo (14%); Mozambique occupied the 8<sup>th</sup> higher position with 4% of malaria global deaths (WHO 2017) – Figure 2 and 3.

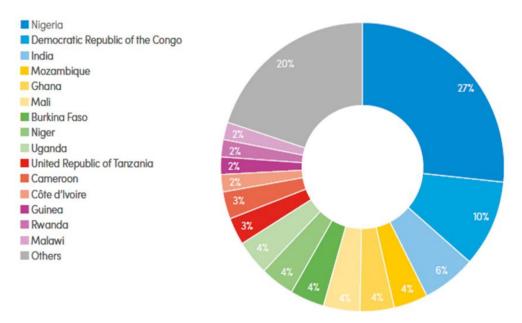


Figure 2: Estimated country share of total malaria cases, 2016. Source: WHO estimates (World Malaria Report 2017)

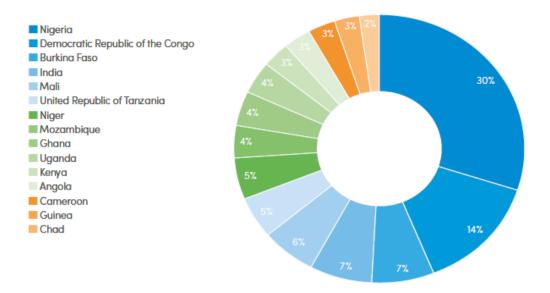


Figure 3: Proportion of estimated malaria deaths attributable to the 15 countries with nearly 80% of malaria deaths globally in 2016. Source: WHO estimates (World Malaria Report 2017)

In Mozambique, malaria accounts for 40.2% of parasite prevalence among children under five years-old (IMASIDA 2015). Transmission dynamics and endemicity in Mozambique are highly variable and strongly influenced by geography and climate, being most intense in the central and north regions, and in coastal areas. The number of suspected malaria cases increased from 6,097,263 in 2010 to 15,453,655 in 2016. *Plasmodium falciparum* reported cases increased from 878,009 in 2010 to 8,520,376 in 2016 (WHO 2017). However, mortality attributed to malaria seems to be decreasing. In 2010, Mozambique reported 3,354 malaria related deaths. In 2016 this number dropped to 1,685 which represent a 50% decrease in malaria related deaths (WHO 2017).

#### 1.1.3 Malaria prevention interventions

World Health Organization (WHO) recommends a package of core interventions – namely quality-assured vector control, chemoprevention, diagnostic testing and treatment – to reduce malaria morbidity and mortality (WHOa 2015). In areas of moderate-to-high transmission (such as Mozambique), ensuring universal access of populations at risk to interventions should be a principal objective of national malaria programmes. The metrics of success are the reductions in malaria case incidence and malaria mortality rates (WHOa 2015). WHO recommends implementing two sets of interventions in a complementary way: (1) prevention strategies based on vector control, and, in certain settings and in some population groups (e.g. pregnant women), administration of chemoprevention, and (2) universal diagnosis and prompt effective treatment of malaria in public and private health facilities and at community level

(WHOa 2015). Structuring programmes in response to stratification of malaria by disease burden and including an analysis of past malaria incidence data, risk determinants related to the human host, parasites, vectors and the environment that together with an analysis of access to services will enable the tailoring of interventions to the local context and ensure efficient use of resources (WHOa 2015).

Insecticide-treated nets (ITNs) and/or indoor residual spraying (IRS), associated with the appropriate management of malaria cases with appropriate antimalarial drugs, are the best practice and can contribute to the significant reduction in the malaria basic reproductive rate (*Ro*) (WHO 2017; Killeen 2014; Lengeler 2004). *Ro* is the potential number of secondary cases that may originate from a primary case, during the entire period of the disease (OMS 2014; Arroz 2017). The higher *Ro* means high malaria prevalence in a given region (Arroz 2017; Killen 2014; OMS 2014). However, this is not linear and other factors should be considered. Arroz (2017) consider that "such key interventions must consider the social determinants of health (SDOH), the socioecological model, and the social and behavior change communication". Vector control interventions involving community actors and associated with social and behaviour change communication might well lead to better outcomes and impact measures (Arroz 2017).

#### PART II

#### 1.2 Bed nets strategy in the World, Africa, and Mozambique

#### 1.2.1 Rationale for insectic ide-treated nets as malaria prevention tool

An insecticide-treated net (ITN) is a mosquito net that repels, disables and/or kills mosquitoes coming into contact with insecticide on the netting material (WHO n.d.). There are two categories of ITNs: conventionally treated nets and long-lasting insecticidal nets (WHO n.d.).

A conventionally treated net is a mosquito net that has been treated by dipping in a WHO-recommended insecticide. To ensure its continued insecticidal effect, the net should be re-treated after three washes, or at least once a year. A long-lasting insecticidal net (LLIN) is a factory-treated mosquito net made with netting material that has insecticide incorporated within or bound around the fibres. The net must retain its effective biological activity without re-treatment for at least 20 WHO standard washes under laboratory conditions and three years of recommended use under field conditions (WHO n.d.). LLINs were developed in the 1990s and first approved by the WHO Pesticides Evaluation Scheme (WHOPES) in 2003 (Pulkki-Brännström A-M *et al.* 2012). The advantage of LLINs through ITNs lies in the needs of re-treatment. LLINs do not need re-treatment for at least three years; ITNs needs re-treatment in a year base.

All mosquito nets (ITNs or LLINs) act as a physical barrier, preventing access by vector mosquitoes and thus providing personal protection against malaria to the individual(s) using the nets (Hawley *et al.* 2003; Binka *et al.* 1998). Pyrethroid insecticides, which are used to treat nets (ITNs or LLINs), have an excito-repellent effect that adds a chemical barrier to the physical one, further reducing human–vector contact and increasing the protective efficacy of the mosquito nets. Most commonly, the insecticide kills the malaria vectors that come into contact with the ITN. By reducing the vector population in this way, ITNs or LLINs, when used by a majority of the target population, provide protection for all people in the community, including those who do not themselves sleep under nets (Hawley *et al.* 2003; Binka *et al.* 1998).

The effective use of long-lasting insecticidal nets (LLINs) can reduce all-cause child mortality (by 22%) and malaria morbidity (Lengeler 2004; Gamble et al. 2009), and is also associated with a community-wide decrease in malaria transmission (Hawley *et al.* 2003). The current challenge is to ensure access and ownership of LLINs in order for at least 80% of the population (and households) to be covered, and make appropriate use of them (Roll Back Malaria Partnership 2005).

### 1.2.2 Coverage of vector control interventions

The coverage of vector control interventions substantially increased in the last six years (2010 – 2016), particularly in sub-Saharan African countries. Across sub-Saharan Africa, household ownership of at least one insecticide treated net (ITN) increased from 50% in 2010 to 80% in 2016. In 2016, 54% of the population was protected by this intervention, an increase from 30% in 2010 (WHO 2017). However, the proportion of households with sufficient nets to reach universal coverage (i.e. one net for every two people) remains inadequate (minimum target 80%), only 43% in 2016 (WHO 2017).

In 2015, only 66% of Mozambican households had at least one long lasting insecticidal nets (LLINs), and only 38.9% of the households had sufficient LLINs for universal coverage (IMASIDA 2015). The scenario was similar for children's under five and pregnant women, with only 48% of the children's under five and 52% of pregnant women slept under a LLINs, respectively (IMASIDA 2015).

The use of ITNs as a malaria vector control strategy began in 1994 through a pilot in Boane district of Maputo province (MISAU 2015). After this pilot study several initiatives of free ITNs distribution took place in some districts. The first free mass bed nets distribution campaign was piloted in 2009 in the central province of Sofala (MISAU 2015). In 2009 the pre natal health services was used to deliver nearly 5.2 million bed nets at national scale (MISAU 2015).

Two bed nets delivery mechanisms are described in the literature: *push* and *pull* (Roll Back Malaria, Vector Control Working Group, Continuous LLIN Distribution Systems Work Stream, 2011):

- In the *push* mechanism beneficiaries are passive, i.e., it is a mechanism whereby only limited action is needed from the future LLIN owner to receive a LLIN, and the LLIN is given at no cost (e.g. free delivery of LLINs through pre-natal health service when LLINs are available for all pregnant women that attend the service);
- In the *pull* mechanism beneficiaries are active, i.e., it is a mechanism that requires the future LLIN owner to take action to get the LLIN. This action must be specific to getting the LLIN (such as going to a retail outlet) rather than something the person may do anyway (such as attending a pre-natal health service). Most but not all pull mechanisms would involve the LLIN having some cost to the user;

Some systems can be considered as a combination of push and pull mechanisms, where LLINs are pushed part of the way. For example:

- A voucher system, whereby vouchers are given (pushed) to beneficiaries. These vouchers entitle beneficiaries to a reduced price when they go and buy an LLIN from a commercial outlet. Acquisition of the LLIN thus requires effort and some payment from the individual (the pull component);
- A coupon system similar to the push-pull voucher system. A coupon is pushed to the beneficiary; the coupon can then be exchanged by the beneficiary for a free LLIN at a specified, likely non-commercial, outlet. Acquisition of the LLIN requires effort from the beneficiary (the pull component). Note that the difference between this and a voucher system is the lack of cost to the user and, likely, the lack of choice of LLIN type;

The "standard" delivery model of free mass LLINs delivery in campaigns in Mozambique makes uses of *push-pull* mechanism, i.e., after household registration (*push*), households are given information about the distribution points and days of the LLINs distribution. The head (or a representative member) of the household should go to the distribution point at the scheduled days to retrieve the free LLINs (*pull*).

#### 1.2.4 Literature review on bed nets ownership and use

Several studies related to ownership and/or use of LLINs has been carried out in order to assess the results from the beneficiaries' point of view. For Mozambique, the study conducted by Biedron *et al.* (2010) concluded that in 2007, none of the provinces had reached LLIN household coverage of 70%. Similar results were obtained in the studies

by Quive *et al.* (2015) and Moon et al. (2016) who found that in 2013 and 2014, estimated household coverage was 62.5% and 64.3%, respectively.

Therefore, low LLINs ownership and use coverage is here identified as a consequence of several bottlenecks during free bed nets campaign implementation. A brainstorm-like situation analysis has been carried out by the researchers and health institutions (between June and July 2015) to evaluate why health interventions using the current delivery model do not lead to the desired results in Mozambique. The following bottlenecks were identified:

- Some households were not registered during the household registration phase and others might have been registered several times;
- The ascription of LLIN per household was made based on a complex formula, depending on too many parameters (age, gender, kinship, and sleeping patterns);
- There were long queues to obtain LLINs because of identification problems related to the household registration method.

Studies carried out in different African countries, where vouchers or coupons have been used for LLIN distribution, have shown high coverage of LLIN ownership and use. A study by Krezanoski *et al.* (2010) carried out in Madagascar in 2007/2008, showed ownership coverage above 70%. Similar results were obtained in Senegal (Thwing *et al.* 2011), Sierra Leone (Bennet *et al.* 2012), Togo (Stevens *et al.* 2013), Tanzania (Renggli *et al.* 2013; West *et al.* 2012) and Benin (Tokponoon *et al.* 2013).

A systematic review of 32 articles and 20 studies (for Burkina Faso, Eritrea, Uganda, Zambia, Kenya, Ghana, Malawi, Tanzania, Madagascar, Togo, Zambia, Niger, and Nigeria between 1997 and 2007) concluded that campaigns fully subsidized with the involvement of community actors, increase the ownership and use of LLIN (as compared to partially subsidized campaigns and carried out in health centers). There is also evidence from the literature that successful registration of households is a determinant factor for receiving at least one LLIN, which in turn depended on the ability of community registers to reach each household (Zegers de Beyl *et al.* 2016).

The above-identified bottlenecks and the findings of the literature review on the use of vouchers/coupons lead to the design of three implementation strategies for the household registration phase of the LLINs campaign in Mozambique, namely:

- Use of coupons during household registration phase;
- Use of stickers to identify the registered households;
- Use of a new ascription criterion based on universal coverage principle (one bed net for every two persons).

These three strategies are the core components of the new delivery model that is currently under implementation in Mozambique.

### PART III

#### 1.3 Malaria control efforts and epidemiology in Mozambique

#### 1.3.1 Malaria control efforts in Mozambique

Structured malaria control in Mozambique began in the late 1930s when the *Estação antimalárica de Lourenço Marques* (the anti-malaria station) was formed in what is now Maputo city (PNCM INFORM and LSHTM 2015). The focus was vector control based on larval control methods. Malaria control continued to focus on vector control activities up to 1970, with the continued use of larviciding and the introduction of indoor residual spraying (IRS) using Dichlorodiphenyltrichloroethane, commonly known as DDT, gammexane and dieldrin (PNCM INFORM and LSHTM 2015). Between the mid-1940s and the late 1970s, there were also reports of the national use of chloroquine (CQ) or proguanil as prophylaxis in school children as documented by Schwalbach and De la Maza (1985).

With the advent of the civil war, malaria control in Mozambique came to a halt between the mid-1970s and early 1990s. In 1982, the National Malaria Control Programme (NMCP) was re-established and limited malaria control activities were carried out within Maputo city. Efforts to control malaria expanded in the 1990s, with trials of various insecticides for IRS (lambda-cyhalothrin, cyfluthrin), the first trials of ITNs in Mozambique and the documentation of cloroquine failures, which ran between 15% and 40% (PNCM INFORM and LSHTM 2015).

The Lubombo Spatial Development Initiative (LSDI), a tri-lateral initiative between the governments of South Africa, Swaziland and Mozambique, started in Mozambique in 2000 with a focus on four project zones within Maputo province (PNCM INFORM and LSHTM 2015). The purpose of the project was to address cross border issues of population, parasite and vector movements, as well as the development and spread of vector and parasite resistance. The need for a regional, inter-country approach to fight malaria was driven by the loss of productivity associated with malaria morbidity and mortality, in conjunction with the high cost of treatment and control of the parasite and its vectors; these contributed to economic and social declines and a lack of development in the region (PNCM INFORM and LSHTM 2015). The LSDI project was a show-case for successful public private partnerships (PPP) in malaria control, and expanded to cover all of Maputo province and Gaza province in 2006 (PNCM INFORM and LSHTM 2015). The 12-year period of the LSDI showed a substantial decrease in

disease burden amongst the three countries involved when compared to the baseline year of 2000. The decrease in malaria cases was 99 % in South Africa and 98 % in Swaziland. Malaria prevalence in Mozambique decreased by 85 % over the same period (Maharaj *et al.* 2016).

In 2000, with support from a range of partners, Mozambique developed its first malaria strategic plan, covering the period 2001-2005. The same year saw a number of other collaborative projects take off, including the *Vurhongha* project, which used community aids to distribute ITNs in three districts (Guija, Mabalane and Chokwe) of Gaza Province (PNCM INFORM and LSHTM 2015).

Within this period (2001 – 2010), Mozambique changed the first line treatment, moving from sulphadoxine-pirimetamine (SP) monotherapy to amodiaquine (AQ)-sulphadoxine-pirimetamine (SP) as the interim policy in 2002, followed by artesunate (AS)-SP as first line in 2006 and to Artemether-lumefantrine (AL) in 2009 (PNCM INFORM and LSHTM 2015). Also within this period, the country successfully secured two Global Fund to fight Aids, Tuberculosis and Malaria grants that facilitated phased distribution of free LLINs across the country, and the second National Malaria Strategic Plan covering 2006-2009 was developed (PNCM INFORM and LSHTM 2015).

Between 2011 and 2015, the third National Malaria Strategic Plan (2012-2016) was developed. Distribution of LLINs expanded to areas that had previously not received bed nets and bed nets replacement was prioritised. The period 2011-2014 saw large-scale coverage across the country with ITNs, with a total of 12 million bed nets delivered via mass campaigns and another five million distributed through pre natal services. Emerging insecticide resistance was more carefully documented with *An. gambiae s.s.* found to remain pyrethroid sensitive, but *An. funestus s.s.* documented as resistant to all classes of pyrethroids in southern Mozambique (PNCM INFORM and LSHTM 2015). The first implementation strategies to increase access and demand of long-lasting insecticidal nets were piloted in 2015 (Arroz *et al.* 2017). In 2016 and 2017, the first national and countrywide bed nets distribution was succeeded conducted, delivering more than 16 million bed nets. In 2017, the fourth National Malaria Strategic plan was developed.

#### Chronological milestones of malaria control in Mozambique

1920 - Possible epidemic with rises in hospital case fatalities;

1937 - Foundation of the Estação anti-malárica de Lourenço Marques;

1946 - Larval control and fogging expanded to Beira city. Beginning of IRS in Mozambique, from 1946 through to 1970; limited use of gammexane IRS and cloroquine or proguanil prophylaxis;

1948 - DDT expanded to Beira City;

1960 - Malaria eradication project started in Southern provinces, south of the Save (Zambezi) River, using DDT IRS, surveillance and treatment;

1970 - IRS programmes come to an end across country;

1975 - Independence of Mozambique;

1975-1978 - Reports of national use of cloroquine prophylaxis among school children;

1977 - Civil war: breakdown of malaria control until 1992;

1980s - Malaria control focused only on Maputo city;

1982 - National Malaria Control Programme re-established;

1983 - Cloroquine resistance detected;

1985-1987 - First trials of bed nets at community level in Boane;

1989-1991 - Field trials of permethrin impregnated wall curtains in Maputo suburbs;

1992 - Civil war ends;

1993 - Trials of Cyfluthrin for IRS in Boane district;

1994 - IRS resumed in provincial capitals following last use in 1970s, and the sugar factories in Mafambisse and Marromeu in Sofala province, and Chinavane in Maputo province. Trials of ITN in Boane district until 1998;

1999 - Cloroquine failures between 15% and 40%; Cross border Lubombo Spatial Development Initiative (LSDI) started in Namaacha, Matutuine & Matola districts in Maputo province, along with Swaziland and South Africa, using bendiocarb for IRS;

2000 - Wide-scale flooding in Gaza and Zambezia provinces led to ITN distribution to contain a potential epidemic. *Vurhonga* project using community health aides to distribute free ITN in Chokwe, Guija and Mabalane districts in Gaza Province;

2001 - First National Malaria Strategy (2001-2006);

2002 - Trial of intermittent presumptive treatment of infants. First-line treatment changed from cloroquine to AQ+SP as interim policy;

2003 - RTS S/AS02A vaccine trial starts in Manhiça with final follow-up in 2006; Phase II trials in infants follow 2005-2007;

2005 - Change in policy from subsidised ITNs for pregnant women to free nets for all. ITN free distribution in some districts in Sofala and Manica provinces. IRS re-started in

Zambézia province using DDT in Quelimane, Nicoadala and Namacurra districts; lamdacyhalothrin in Mocuba and Morrumbala. LSDI project moves to using DDT in all four project zones of Maputo province, following documented resistance to bendiocarb. Introduction of malaria rapid diagnosis tests (mRDTs) in health facilities without laboratory / microscopy facilities;

2006 - Second National Malaria Strategic Plan (2006-2009) begins. ACT (AS-SP) policy implemented to replace AQ+SP as first-line treatment. LSDI expands to include all of Maputo province and Gaza province. *An. funestus* resistance to deltamethrin in Catembe and Bela Vista and lambacyhalothrin in Catembe, Catuane, Benfica. *An gambiae* resistance to deltamthrin in Manjacaze;

2007 - 1.7 million nets distributed in Nampula and Inhambane provinces during 2007-2008 as part of mass Vitamin A and albendazole campaign;

2009 - Free mass distribution for universal ITN coverage piloted in Sofala and Gaza provinces. Artemether-lumfantrine replaced AS-SP as first-line treatment. Phase III RTS S/AS02A vaccine trial start in Manhiça. Near 5 million ITNs distributed nationwide using pre natal services and small-scale distribution campaigns since 2007;

2010 - LSDI cross-border funding reduces subsequently reducing IRS coverage in Maputo and Gaza Provinces;

2011 - LSDI project comes to an end. Free mass ITN campaign expanded to a further 45 districts in six provinces, distributing 2.3 million nets; AL treatment policy rolled out nationwide. Introduction of mRDTs at community level to be used by community health workers (*Agentes Polivalentes Elementares*);

2012 – The third National Malaria Strategic Plan (2012-2016); free mass ITN campaign expanded to additional 21 districts distributing 1.6 million nets; *An. funestus* resistance to lambacyhalothrin in Inhambane city and to bendiocarb in Matola. *An. gambiae* resistance to lambacyhalothrin in Montepuez and Tete city;

2013 - Free ITN distributions campaign expanded to an additional 23 districts distributing 2.8 million nets; introduction of injectable artesunate nationwide; introduction of artesunate suppositories for use by community health workers;

2014 - An. gambiae s.s. remain pyrethroid (deltamethrin) sensitive; however, An funestsus s.s. resistant to all classes of pyrethroids in southern Mozambique. Free ITN distribution of 5.2 million in 36 districts, including replacement of 2011 nets; An. gambiae resistance to lambdacyhalothrin in Dondo and to bendiocarb and deltamethrin in Maputo city. An. funestus resistantane to lambdacyhalothrin in Lichinga;

2015 - Free ITN distribution of 1.8 million in 16 districts, including replacement of 2012 nets; the first implementation strategies to increase access and demand of long-lasting insecticidal nets were piloted in 2015;

2016 - The first national and countrywide LLINs distribution starts in Nampula province and Lichinga district in Niassa province. The implementation strategies piloted in 2015 guided this countrywide LLIN campaign. The launch was on November 6<sup>th</sup>;

2017 – The first national and countrywide LLINs distribution ended on December 6<sup>th</sup>, delivering more than 16 million LLINs. The fourth National Malaria Strategic plan (2017 – 2022) was developed.

#### 1.3.2 Malaria epidemiology in Mozambique

The entire population of Mozambique is at risk of malaria, with the majority living in areas with high risk of malaria infection. Despite significant investment and progress in malaria control over the last ten years, the disease remains a major public health burden in Mozambique. In 2017, there were almost 10 million new cases of malaria. This represents 190% of increase from year 2000 levels (3,446,220 cases). In other hand, deaths reduced in 45% (from 2,039 reported deaths in 2008 to 1,114 deaths in 2017 (NMCP 2017) – Figure 4.

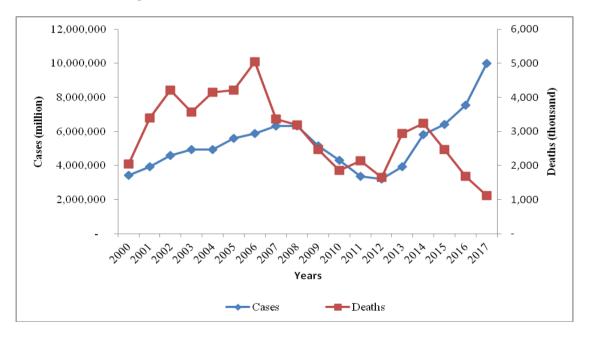


Figure 4: Trends in malaria cases and deaths in Mozambique, 2000 – 2017. Source: NMCP

It is important to remark that in 2006, the peak of malaria deaths (5,038 deaths), was the year in which Mozambique implemented ACT (AS-SP) policy to replace AQ+SP as first-line treatment. In the subsequent years, the deaths substantially reduced.

Malaria is a cause and consequence of poverty. There is a strong negative correlation between the Human Development Index (HDI) and the prevalence of malaria in Mozambique by province, with Pearson coefficient of -0.8 and coefficient of determination of 64.3% (Arroz 2017) - Figure 5.

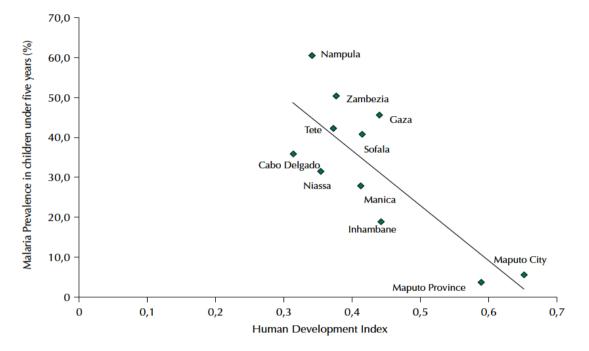
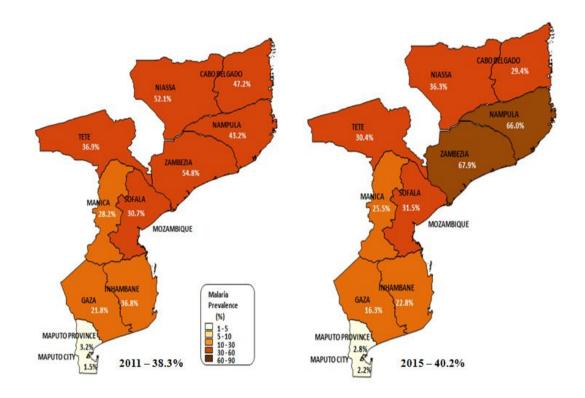
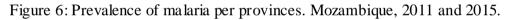


Figure 5: Correlation between malaria prevalence in children under five years and Human Development Index by province. Mozambique, 2011. Source: Arroz 2017.

The malaria prevalence in children aged six to 59 months (using malaria rapid diagnosis test) increased from 38.3% in 2011 to 40.2% in 2015 (IMASIDA 2015). The prevalence of malaria in rural areas (47 percent) is more than double the prevalence found in urban areas (19 percent), with a difference of 28 percentage points. The provinces of Zambezia and Nampula have higher prevalence, 68 and 66 percent, respectively, compared with Maputo, province and city, with the lowest prevalence (three and two percent, respectively) (IMASIDA 2015) – Figure 6. The prevalence of malaria in children aged 6-59 months varies according to the wealth quintile of the mothers, being 61 percent in the children of mothers of the lowest quintile and 7 percent in the children of mothers of the highest quintile, with a difference of 53 percentage points (IMASIDA 2015).





# PART IV

## 1.4 Research question, hypothesis, and objectives

1.4.1 Research question and hypothesis

Research questions and hypothesis more precisely describe what the research findings will inform. Interest in a particular topic usually begins the research process, but it is the familiarity with the subject that helps define an appropriate research question for a study (Haynes 2006). Questions then arise out of a perceived knowledge deficit within a subject area or field of study (Hulley *et al.* 2007). Indeed, Haynes suggests that it is important to know "where the boundary between current knowledge and ignorance lies" (Haynes 2006). The challenge in developing an appropriate research question is in determining which uncertainties could or should be studied and also rationalizing the need for their investigation.

The primary research question should be driven by the hypothesis (Hulley *et al.* 2007; Haynes 2006). Designing a research hypothesis is supported by a good research question and will influence the type of research design for the study. Acting on the principles of appropriate hypothesis development, the study can then confidently proceed to the development of the research objective (Farrugia *et al.* 2009). A two-sided

hypothesis should be used unless there is a good justification for using a one-sided hypothesis (Farrugia *et al.* 2009). A one-sided hypothesis states a specific direction (e.g., there is an improvement in outcomes with the new delivery model). The justification for using one-sided hypothesis for this thesis lays in the fact that improvement in health outcomes is desired with the new delivery model.

The **research question** for this thesis is the following: how the new LLINs delivery model targets the health outcomes (measured in terms of feasibility, ownership and use coverage, and implementation  $cost^{1}$ )?

The following **hypotheses** were assumed: i) null hypothesis: implementation outcomes are the same in districts with the new and standard delivery models; ii) alternative hypotheses: implementation outcomes are better (and statistically significant) with the new delivery model compared with the standard delivery model.

#### 1.4.2 General objective

The primary objective should be coupled with the hypothesis of the study. Study objectives define the specific aims of the study and should be clearly stated (Hanson 2006). The study objective is an active statement about how the study is going to answer the specific research question. Objectives can (and often do) state exactly which outcome measures are going to be used within their statements (Farrugia *et al.* 2009). They are important because they not only help guide the development of the protocol and design of study but also play a role in sample size calculations and determining the power of the study (Hanson 2006). Additionally, they are actionable and provide a bridge between the research problem and research question(s) and/ or hypothesis.

The **general objective** of the thesis is: to compare two bed nets delivery models in rural districts of Mozambique.

In order to achieve the general objective three studies were conducted as **specific objectives**:

Study 1: To describe the intervention and implementation strategies that Mozambique carried out in order to improve access and increase demand for LLINs;

Study 2: To compare the coverage of ownership and use of LLINs in the intervention and control districts in Mozambique;

<sup>&</sup>lt;sup>1</sup> Feasibility – The extent to which an intervention can be carried out in a particular setting;

Coverage – The degree to which the population that is eligible to benefit from an intervention actually receives it;

Implementation  $\cos t$  – The incremental  $\cos t$  of the implementation strategy and incremental net benefit (value for money of the strategies) for decision-makers.

Study 3: To compare the cost-effectiveness of the two-piloted LLIN delivery models in mass free campaigns in rural Mozambique, and establish the most cost-effective delivery model for a country-wide mass free campaign.

### PART V

#### **1.5** Overview of the studies and methodological approach

#### 1.5.1 Implementation research: the cornerstone of this thesis

This thesis was conducted as implementation research. Implementation research (also called implementation science) is the scientific study of methods to promote the systematic transfer of evidence-based interventions into practice and policy and hence improve health (Foy et al. 2015).

Implementation research is mostly needed in low-and middle-income countries, in order to have a greater understanding of how to implement health interventions (Ridde 2016) and thereby overcome bottlenecks detected during the situation analysis. Implementation research can consider any aspect of implementation, including the factors affecting implementation, the processes of implementation, and the results of implementation, including how to introduce potential solutions into a health system or how to promote their large-scale use and sustainability. The intent is to understand what, why, and how interventions work in "real world" settings and to test approaches to improve them (Peters 2013).

Implementation research makes use of implementation strategies. Implementation strategies have unparalleled importance in implementation research, as they constitute the 'how to' component of changing healthcare practice (Proctor 2013). Implementation strategies are methods or techniques used to enhance the adoption, implementation, and sustainability of an under-utilized intervention (Curran et al. 2012).

The complexity of implementation strategies can vary widely. For instance, some implementation efforts may involve a single component strategy. In this case is referred as discrete strategy (Proctor 2013). Most often a number of strategies are combined to form a multifaceted strategy (Proctor 2013).

Strategies must be described clearly in a manner that ensures that they are discussed at a common level of granularity, are rateable across multiple dimensions, and are readily comparable. In short, they must be defined operationally (Proctor 2013). This will make implementation strategies more comparable and evaluable, and ultimately make it easier for researchers and other implementation stakeholders to make decisions about which implementation strategies will be most appropriate for their purposes. Proctor (2013)

proposed seven dimensions that, if detailed adequately, would constitute the adequate operationalization of implementation strategies. This seven dimensions are: (i) the actor(s) – i.e., who delivers the strategy?; (ii) the action(s); (iii) the target(s) of the action – i.e., toward what or whom and at what level?; (iv) temporality – i.e., when or at what phase?; (v) dose – i.e., at what frequency and intensity?; (vi) the implementation outcome(s) affected; and (vii) justification – i.e., based on upon what theoretical, empirical, or pragmatic justification? (Proctor 2013). These seven Proctor dimensions applied into the specific implementation strategies are described in chapter 2.

The first study of this thesis is a genuine implementation research study where the core multifaceted implementation strategies (coupons, sticker, and the new ascription formula) where tested in a pragmatic trail making use of a before-after design study with a control group to see if the implementation outcomes are changing.

Pragmatic trials focus on the effects of the intervention in routine practice. In contrast to explanatory trials, pragmatic trials seek to maximize the variability in the way the intervention is implemented, (e.g., in terms of settings, providers or types of patients), in order to maximize the generalizability of results to other settings (Zwarenstein *et al.* 2008). In this way, pragmatic trials can provide strong evidence of the effectiveness of an implementation strategy in 'real-world' conditions (Zwarenstein *et al.* 2008). The new delivery model was the intervention; the standard delivery model (also herein referred as "old" delivery model) was the control.

The other two studies are based on this first study and aims at:

- Study 2: assessing the effectiveness of the strategies among the beneficiaries 6 months after the pragmatic trial;
- Study 3: assessing the cost-effectiveness of the intervention with the tested implementation strategies.

## 1.5.2 Conceptual framework

Conceptual framework is a network, or "a plane," of interlinked concepts that together provide a comprehensive understanding of a phenomenon or phenomena (Jabareen 2009). A theory and a model are the lens of this thesis conceptual framework. A key difference between the two is that theories are intended to explain phenomena. Models, in contrast, are typically used to frame and represent processes – not explain them – and are often employed to develop study's design and methodological procedures (NCI 2012) – Table 2.

Table 2: Main differences between theory and model (NCI 2012)

Theory	Model
An integrated set of propositions that serves as an explanation for a phenomenon	A subclass of a theory, it provides a plan for investigating and/ or addressing a phenomenon
Introduced after a phenomenon has already revealed a systematic set of uniformities	Does not attempt to explain the processes underlying learning, but only to represent them
A systematic arrangement of fundamental principles that provide a basis for explaining certain happenings of life	Provides the vehicle for applying theories

Models and theories are often characterized by the level of analysis to which they apply: individual, interpersonal, social/community, or multiple (Guest and Namey 2015).

An interpersonal level theory (Social Practice Theory) and multilevel level model (Social Ecological Model) are used.

The Social Ecological Model (SEM) is a multilevel approach for understanding the multifaceted and interactive effects of personal and environmental factors that determine behaviors, and for identifying behavioral and organizational leverage points and intermediaries for health promotion within organizations. There are five nested, hierarchical levels of the SEM: (I) individual, (II) interpersonal, (III) community, (IV) organizational, and (V) policy/enabling environment – Figure 7 and Table 3.



Figure 7: Social Ecological Model

Table 3: Description of Social Ecological Model (SEM) Levels

SEM Level	Description	
Individual	• Characteristics of an individual that influence behaviour change, including knowledge, attitudes, behaviour, self-efficacy, developmental history, gender, age, religious identity, racial/ethnic identity, sexual orientation, economic status, financial resources, values, goals, expectations, literacy, stigma, and others.	
Interpersonal	• Formal (and informal) social networks and social support systems that can influence individual behaviours, including family, friends, peers, co-workers, religious networks, customs or traditions.	
Community	• Relationships among organizations, institutions, and informational networks within defined boundaries, including the built environment, village associations, community leaders, businesses, and transportation.	
Organizational	• Organizations or social institutions with rules and regulations for operations that affect how, or how well.	
Policy/Enabling Environment	• Local, state, national and global laws and policies, including policies regarding the allocation of resources for access to healthcare services, restrictive policies (e.g., high fees or taxes for health services), or lack of policies that require childhood immunizations.	

Source: Adapted from the Centers for Disease Control and Prevention (CDC), The Social Ecological Model: A Framework for Prevention, http://www.cdc.gov/violenceprevention/overview/social-ecologicalmodel.html.

Levels II – IV are used in this thesis as a plan for investigation. Members of a community (interpersonal level) trained for household registration (can influence registration acceptance), interacting with health institutions/organizations (district health authorities and supporting local non-governmental organizations) – community and organizational levels – to build a community-institutional approach for service delivery – LLIN campaign, and influence demand behaviour. Acting at these levels significant influence individuals' attitudes, beliefs, and actions, shaping the community and gender norms and/ or access to, and demand for, community resources and existing services (C-change 2012).

Social practice theory (SPT) is an interpersonal level theory increasingly being applied to the analysis of human behaviour. The central insight of SPT is the recognition that human 'practices' (ways of doing, 'routinized behaviour', habits) are themselves arrangements of various inter-connected 'elements', such as physical and mental activities, norms, meanings, technology use, knowledge, which form peoples actions or

'behaviour' as part of their everyday lives (Reckwitz 2002). The approach particularly emphasises the material contexts (also 'socio-technical infrastructures') within which practices occur, drawing attention to their impact upon behaviour (the production and reproduction of practices).

The theory of social practice presents three elements: materials (the physical objects that permit or facilitate certain activities to be performed in specific ways), meanings (images, interpretations or concepts associated with activities that determine how and when they might be performed), and procedures (skills, know-how or competencies that permit, or lead to activities being undertaken in certain ways) (Reckwitz 2002) – Figure 8.

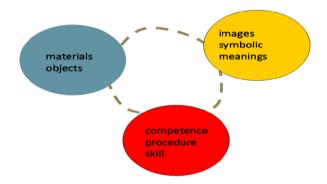


Figure 8: Three elements of the theory of social practice

The coupons and stickers used in the household registration phase of the campign would reflect the material and meaning elements of the SPT, that would lead to the procedure, the action of moving to the place of distribution to exchange the coupon for the LLIN. Additionaly, the sticker identifies the registered houses. Thus, unregistered houses are easily identified during household registration phase and in this way can be registered (ensuring successful and high rates of household registration), leading to more households that can benefit from LLINs. The procedure elements are basic skills, know how given during the trainings of district health authorities and community members, in order to apply the knowledge of how to properly conduct a household registration. Figure 9 schematically represents the conceptual framework of the thesis.

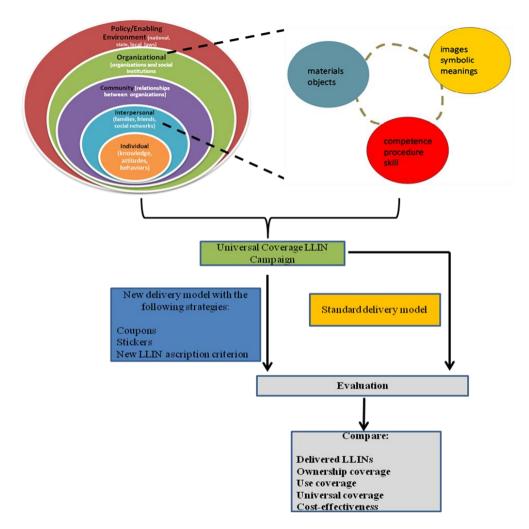


Figure 9: Conceptual framework of the thesis

Based on this conceptual framework and research question, study's design and methodological procedures were developed to accomplish the objectives of each study. Table 4 summarizes the three studies regarding the approach, design, purpose, and main outcomes.

Study and	Design	Purpose	Main outcomes
Approach			
1 - Quantitative	Before-after design – implementation research (the	Feasibility and coverage	<ul><li>1.1 percentage of LLINs</li><li>distributed;</li><li>1.2 percentage of target</li></ul>
2 - Quantitative	pragmatic trial) Before-after design with control group carried out six months after the pragmatic trial (study 1)	Coverage	households benefited 2.1) percentage of households with at least one LLIN in the intervention and control districts; 2.2) percentage of population that slept under an LLIN the previous night; 2.3) percentage of households achieving universal coverage targets (one LLIN for every two persons).
3 - Quantitative	An observational and cross-sectional study with cost- effective analysis component (based on the costs and effects of the 1 <sup>st</sup> study)	Implementation cost Cost- effectiveness	<ul> <li>3.1) ACER<sup>2</sup> per LLIN delivery;</li> <li>3.2) Cost per PPP<sup>3</sup>;</li> <li>3.3) Cost per PP<sup>4</sup>;</li> <li>3.4) Incremental cost- effectiveness ratio (ICER); and</li> <li>3.5) Incremental net be nefit (INB)</li> </ul>

Table 4: Overview of the studies and methodological approach

<sup>&</sup>lt;sup>2</sup> ACER – Average Cost-Effectiveness Ratio <sup>3</sup> PPP – Potentially Protected Persons

<sup>&</sup>lt;sup>4</sup> PP – Protected Persons

# CHAPTER 2: IMPLEMENTATION STRATEGIES TO INCREASE ACCESS AND DEMAND OF LONG-LASTING INSECTICIDAL NETS: A BEFORE-AND-AFTER STUDY AND SCALE-UP PROCESS IN MOZAMBIQUE

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#### RESEARCH

Malaria Journal

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# Implementation strategies to increase access and demand of long-lasting insecticidal nets: a before-and-after study and scale-up process in Mozambique

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#### Abstract

**Background:** The universal coverage bed nets campaign is a proven health intervention promoting increased access, ownership, and use of bed nets to reduce malaria burden. This article describes the intervention and implementation strategies that Mozambique carried out recently in order to improve access and increase demand for long-lasting insecticidal nets (LLINs).

**Methods:** A before-and-after study with a control group was used during Stage I of the implementation process. The following strategies were tested in Stage I: (1) use of coupons during household registration; (2) use of stickers to identify the registered households; (3) new LLIN ascription formula (one LLIN for every two people). In Stage II, the following additional strategies were implemented: (4) mapping and micro-planning; (5) training; and (6) supervision. Odds ratio (OR) and 95% confidence interval (CI) were used to compare and establish differences between intervened and control districts in Stage I. Main outcomes were: percentage of LLINs distributed, percentage of target households benefited.

**Results:** In Stage I, 87.8% (302,648) of planned LLINs were distributed in the intervention districts compared to 77.1% (219,613) in the control districts [OR: 2.14 (95% Cl 2.11–2.16)]. Stage I results also showed that 80.6% (110,453) of households received at least one LLIN in the intervention districts compared to 72.8% (87,636) in the control districts [OR: 1.56 (95% Cl 1.53–1.59)]. In Stage II, 98.4% (3,536,839) of the allocated LLINs were delivered, covering 98.6% (1,353,827) of the registered households.

**Conclusions:** Stage I results achieved better LLINs and household coverage in districts with the newly implemented strategies. The results of stage II were also encouraging. Additional strategies adaptation is required for a wide-country LLIN campaign.

**Keywords:** Before-and-after design, Implementation strategies, Implementation study, Long-lasting insecticidal nets, Universal coverage bed nets campaign, Mozambique

# **Highlights**

#### What is already known about this topic?

- The universal coverage bed nets campaign is a proven health intervention promoting increased access, ownership, and use of bed nets to reduce malaria burden.
- Campaigns that make use of vouchers or coupons have better LLIN ownership outcomes.

#### What are the new findings?

- The use of coupons and stickers during household registration phase of a bed nets campaign might improve registration rates.
- The coupons: (i) ensures the necessary confidence for the households that will in fact receive LLINs; (ii) identifies the distribution point that households should go to in order to obtain LLINs; and (iii) facilitates confirmation that the household was registered, i.e., during LLINs distribution phase, the coupon is exchanged for LLINs. This chain of events, which constitutes a positive gradient of demand behaviour, is here termed as "the coupon effect".
- The sticker ensures that unregistered households can be easily identified and registered, thereby ensuring that more households are registered and can benefit from LLINs. This additional factor is referred to herein as "the sticker effect".
- The combination of these factors (coupon and sticker effect), which encourages the target households to obtain the LLINs and determines their greater ownership, constitute what is herein referred as "the coupon-sticker effect".

#### Contributions of the findings for the literature and policy makers

The added value to the literature is the fact that conducting household registration with coupons and stickers, registration rates might considerable be improved. The improvements on household registration rates will likely result in high chance of obtain a LLIN. Higher proportion of population with LLIN access will likely result in higher proportion of population making appropriate use of LLINs, which might well contribute to malaria burden reduction.

Policy makers are interested in effective (and also cost-effective) implementation of health interventions. At this stage, the findings of this study indicate that the intervention with the tested multifaceted strategies are encouraging, being more effective than the standard delivery model.

# 2.1 Background

In 2015 an estimated 212 million cases of malaria occurred worldwide (uncertainty interval: 148 – 304 million) (WHO 2016). Most of the cases in 2015 were in the African Region (90%) (WHO 2016). In the same year, it was estimated that there were 429,000 deaths from malaria globally (uncertainty interval: 235,000 - 639,000) with an estimated 92% of deaths occurring in the African region (WHO 2016). In Mozambique, malaria is a high burden disease, with a prevalence of 40.2% in children aged 6 to 59 months-old (IMASIDA 2015). The effective use of long-lasting insecticidal nets (LLINs) can reduce all-cause child mortality (by 22%) and malaria morbidity (Lengeler 2004; Gamble et al. 2009), and is also associated with a community-wide decrease in malaria transmission (Hawley et al. 2003). The current challenge is to ensure access and ownership of LLINs in order for at least 80% of the population (and households) to be covered, and make appropriate use of them (Roll Back Malaria Partnership 2005). Universal Coverage Campaigns (hereinafter referred to as UCC) are widely proven to be a health intervention that can rapidly overcome the low LLIN access and ownership coverage (Bennett et al. 2012), and are the most cost-effective malaria intervention (Walker et al 2016; Winskill et al. 2017).

In 2015 66% of households in Mozambique had at least one LLIN, and 39% of households had one LLIN for each two persons (IMASIDA 2015). These figures are considered as low coverage when compared with the target of at least 80% of households with sufficient LLINs to achieve Universal Coverage (*i.e.* one LLIN for every two persons) (Roll Back Malaria Partnership 2005). Therefore, implementation strategies were put in place in campaigns to improve LLIN distribution and reach the desired targets. These strategies were based on the findings that campaigns that make use of vouchers or coupons have better LLIN ownership outcomes (Krezanoski et al. 2010; Renggli et al. 2013; Stevens et al. 2013; Thwing et al. 2011; Tokponnon et al. 2013; West et al. 2012).

This article reports the intervention and implementation strategies that Mozambique carried out in order to improve access and increase demand for LLIN use. A set of implementation strategies is described over two distinct stages: Stage I - a small pilot study in two rural districts; Stage II - a massive pilot in one northeast Mozambican province. The following research questions were addressed: are implementation outcomes changing with the new strategies compared with the old strategies? Which lessons can be learned from the implementation process?

# 2.2 Methods

# 2.2.1 Study design

Stage I was undertaken between October and December 2015. Using a before-after design, the pilot was carried out in four rural districts:

- Intervention districts: Gurue (intervention 1) and Sussundenga (intervention 2), in Zambezia and Manica provinces, respectively;
- Control districts: Alto-Molocue (control 1) and Machaze (control 2), also in Zambezia and Manica provinces, respectively.

This pilot tested a few innovations and adaptations of the model in place for UCC, namely: using coupons to do household registration, using stickers to identify registered households, and a new LLIN ascription criterion – one LLIN for every two persons. These innovations and adaptations led to higher coverage of outcome indicators in Stage I (see results section), guiding a massive pilot of the intervention and strategies in Stage II.

Stage II was carried out in the 23 districts of Nampula province (a northeast province of Mozambique, and the most populated of the country). During this stage complementary components of the strategy were added in order to improve planning and implementation processes. This was done with the technical support of Alliance for Malaria Prevention (AMP). Lessons learned from this massive pilot were used to better understand implementation challenges, and guide the country-wide UCC.

# 2.2.2 Rationale of selection

Malaria is endemic in Mozambique, with a prevalence of 40.2% in children aged 6 to 59 months-old (IMASIDA 2015). The central and northern provinces of Zambezia and Nampula have the highest prevalence (67.9% and 66.0%, respectively), and the southern provinces of Maputo province and Maputo city have the lowest prevalence (2.8% and 2.2%, respectively) (IMASIDA 2015). Manica province has a prevalence of 25.5% (IMASIDA 2015)] – Figure 10.

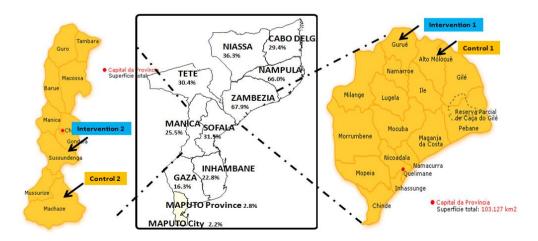


Figure 10: Malaria prevalence in Mozambique and intervention and control districts of the study

The interventions and controls districts were selected based on the following pragmatic and matching criteria: i) they would benefit from the LLIN UCC in the concerned period; ii) have population size similarities (intervention 1 with control 1, and intervention 2 with control 2); iii) they have similar numbers of LLINs allocated for distribution (intervention 1 with control 1, and intervention 2 with control 2); iv) they have rural characteristics; and v) they are districts in provinces with high malaria prevalence.

# 2.2.3 Description of study setting

Mozambique is mostly a rural country, with an estimated 5,058,763 households having an average of 5.0 members per household (IOF 2014/15) resulting in an estimated 25,293,815 inhabitants. The illiteracy rate is 44.9% and most prevalent in the rural area (IOF 2014/15). Sixty-eight percent of the population has easy access to a health facility, *i.e.*, walking less than 30 minutes to reach a health facility. However, this access is lower in rural areas (IOF 2014/15). The major malaria burden in Mozambique is in the central and northern provinces of Zambezia and Nampula (IOF 2014/15; Arroz 2014). Nampula province has an estimated 1,016,455 households with an average 4.8 members per household (IOF 2014/15) resulting in an estimated 4,878,984 inhabitants.

# 2.2.4 Description of the health intervention

The universal coverage LLINs campaign is a proven health intervention promoting increased access, ownership, and use of LLINs to reduce malaria morbidity and mortality (Bennett et al. 2012; Walker et al 2016; Winskill et al. 2017). The current LLIN campaign in Mozambique has several phases related to trainings at provincial and district level, household registration, and LLIN distribution.

# 2.2.5 Description of the implementation strategies

Multifaceted implementation strategies were designed and improved stage-by-stage. These implementation strategies were divided into two components: core/essential components and additional/complementary components.

Three core components were designed and tested in the intervention districts: i) use of coupons during household registration phase; ii) use of stickers to identify the registered households; and iii) a new criterion for LLIN allocation (one LLIN for every two persons). These three implementation strategies were developed and tested in stage I. Household registration in the previous model (control districts) was undertaken without the use of coupons or stickers to identify the registered households, and variables such as name, age, gender, and family relationship of household members were collected and later analysed regarding possible sleeping patterns. The sleeping patterns were the LLIN ascription criteria (Table 5).

Three complementary components were added and implemented: i) mapping and microplanning (improvements added in stage II); ii) training; and iii) support supervisions. Table 5 summarizes the implementation strategies during Stage I and II.

Dimensions	Intervention (after) strategies	Control (before) strategies: previous distribution model
Actor(s)	_	als) and community volunteers t implemented the campaign. Civil
Action(s)	The health intervention: LLINs universal coverage campaign with the following new implementation strategies:	The health intervention: LLINs universal coverage campaign with the following previous implementation strategies:
	Core components: i) coupons; ii) stickers; and iii) one LLIN for every two people ascription criterion.	i) allocation of LLIN is based on sleeping patterns according to data collected during household registration (age, sex, family relationship); ii) number of LLINs per household known
	Complementary components: i) mapping and micro-planning (improvements added in stage II); ii) training; iii) support supervision.	during distribution phase; iii) distribution points known after household registration; iv) training and support supervision during all campaign phases.
Target(s) of the action	Health professionals and conregistrars): know ledge and skills	•
Temporality	Stage I: October - December 2015: Gurue and Sussundenga districts	Stage I: October - December 2015: Alto-Molocue and Machaze districts
	Stage II: August to November 2016 – Nampula province	Stage II: not applicable*

 Table 5: Specifications of the Implementation Strategy

Dose: measured in terms of duration, frequency, and coverage	Trainings duration and coverage: 10 days for micro- planning and training of trainers for implementation (5 members of district team), 8 hours (1 day) for preparation of registrar trainers (1 registrar trainer per 15 household registrar), 16 hours (2 days) for registrar training (assuming 1 registrar can register 20 households per day and 140 households in 7 days), 8 hours (1 day) for training of distribution teams (5 members for each distribution team). Seven (7) days for household registration. Five (5) days for LLIN distribution. Frequency: once.	Trainings: 3 days for micro- planning, 4 hours for preparation of registrar trainers, 4 hours for registrar training (1 registrar trainer per 15 household registrar), 4 hours for training of data analysts, 56 hours (7 days) for analysis of household registration data, 8 hours (1 day) for training of distribution teams. Seven (7) days for household registration. Five (5) days for LLIN distribution. Frequency: once.
Implementation outcomes	Coverage-type: percentage of I target households benefited;	LINs distributed; percentage of
Justification	Programmatic justification: the type of household registration, the complex criteria for LLIN attribution, and the long queues to benefit the LLINs related to the previous campaign strategy made it necessary to design the new implementation strategy. Theoretical justification: Socio- ecological model embedded in social practice theory	Theoretical justification: Socio- ecological model. Working with institutional and community actors to achieve better health outcomes

\*Stage II was implemented only with the new implementation strategies.

# Coupons

The coupons have two parts, the stub, which is for control, and the ticket, which is given to the registered household members. Identical information appears on both the ticket and the stub. The coupon includes a single pre-enumeration area, background image (watermark) of a mosquito net, and information about the province, district, community, name of head of household, name of head of community, number of household members, number of LLIN to benefit, and the name of the distribution points (Figure 11). The coupon is then later exchanged for the corresponding number of LLINs in the distribution phase.

ProvínciaDétito	MINISTÉRIO DA SAÚDE
Número de Série:Data do Registo://	Senha para a recepção de redes mosquiteiras de longa duração
Nome dola Chefelrepresentante da Familia: Comunidade/Pouxado/Bairro Nome do líder Comunitário Neste dia irá receber ( ) redes mosquiteiras; Nº de membros do AF: Nome do Posto de Distribuição	Província Distrito         Número de Série: Pré Enumeração       Data do Registo://         Nome do (a) Chefe/representante da Família:

Figure 11: Coupon for household registration

#### Sticker

The sticker has information about the province, district, town, community, registration date, and the name of the registrar, along with a background image (watermark) of a mosquito net (Figure 12).

Regis	MINISTÉRIO DA SAÚDE to dos Agregados Familiares para a Recepção de Redes Mosquiteiras
Província de:	Distrito de:
Localidade de:	Comunidade:
	CASA REGISTADA
O Registador	Data:/
b	

Figure 12: Stickers to identify the registered households

# Long-lasting insecticidal nets ascription criterion

The LLIN ascription criterion was one LLIN for every two persons (rounded up in case of decimal number) with a maximum (cap) of four LLIN per household, *i.e.*, families with nine or more household members received four LLINs. This LLIN capping criterion was established only in one district in Stage II.

# Mapping and micro-planning

Before mapping and micro-planning each district was given a list of data to be collected. This included population by each locality and administrative post, existing health and school infrastructures, sanctuaries, formal and informal markets, warehouses, distances map, roads, bridges, and remote zones of difficult access. This information is gathered onto a map that allows performing the micro-planning.

The micro-planning process uses a Microsoft office excel® based tool with the following components: i) position micro-plan; ii) household registration plan; iii) transport information; iv) distribution plan; v) transport plan; and vi) crucial materials needed for registration and distribution. It is an iterative tool that allows easily identifying: i) the population in each district by localities and communities; ii) the warehouse that will serve each distribution point; iii) number of LLINs and bales needed for each distribution point; iv) number of household registrars needed for household registration process in a particular set of communities; v) number and type of vehicles needed to transport LLINs from the main district warehouse to satellite warehouses (those located at community level) or distribution point; vi) number of teams needed to distribute the LLINs in five days; and vii) quantities of crucial materials needed for household registration and distribution and distribution phases.

# Training

Two training of trainers (ToT) actions were carried out at the central level. The first and second ToT were conducted between August and September 2016 in order to prepare all National Malaria Control Programme (NMCP) key staff and civil society partners, namely: World Vision International (WVI), Malaria Consortium, Food for the Hungry association, and Foundation for the Community Development.

A cascade of trainings followed the central level ToT, namely: i) micro-planning and implementation ToT; i) training for household registration phase; and iii) training of distribution teams and satellite warehouse keepers. During the micro-planning and implementation ToT (carried out at provincial level) several topics are covered, such as: i) mapping process; ii) micro-planning process; iii) rationale of the new UCC

implementation strategies; iv) logistics (direct and reverse logistics related to LLINs); v) household registration process (including quality control); vi) communication aspects related to UCC; and vii) LLIN distribution organization process.

# Support supervision

Support supervision is a critical implementation strategy that follows the mapping and micro-planning at provincial and district level. One provincial-level supervisor per district was assigned to support the UCC implementation. These supervisors (also called mentors) have the role of ensuring that all processes are carried out as planned (high fidelity) in their district. A structured supervision team was established at the district level and included: i) a coordination group of five elements (district health team trained during micro-planning); and ii) one supervisor for each 15 household registrars. Additionally, an action-checklist was developed in order to ensure appropriate support supervision process by central, provincial, and district supervisor teams.

# 2.2.6 Outcomes and statistical analysis

A coverage-type implementation outcome was used as primary expected outcome in Stages I and II:

Percentage of LLIN distributed calculated as number of distributed LLINs / number of planned LLINs x 100; the planned LLIN was determined by dividing the number of people by 1.78 (rounded up to 1.8) (Kilian et al. 2010);

Percentage of target households benefited calculated as number of households that received LLINs / number of registered households X 100.

All registered households were considered as the denominator for determining household coverage. Since it was a before-and-after design, odds ratio and 95% confidence interval were used to compare and establish differences between intervened and control districts. Implementation effectiveness was also calculated in Stage I to measure the extent of differences between intervention and control districts' implementation outcomes. Implementation effectiveness measure was chosen as it reflects "effectiveness" in implementation studies, *i.e.*, the equivalent of efficacy under "real world" implementation conditions. According to Gupta (1984), implementation effectiveness or effectiveness at strategy implementation should be measured in the form of comparison between actual performance and *a priori* expectations rather than on an absolute scale.

Implementation effectiveness = (outcome proportion with new implementation strategy - outcome proportion with previous implementation strategies) x 100 / outcome proportion with previous implementation strategies.

The WINPEPI (Abramson 2011) version 11.60 computer programs were used for statistical analysis. For all statistical procedures, a 0.05 significance level was adopted for rejecting the null hypothesis.

In stage II (Nampula province LLIN UCC implementation) only administrative data are reported using absolute frequency for registered households and distributed LLINs. Percentage of households benefited, and percentage of distributed LLIN were calculated. There were no control districts or provinces at this stage.

# 2.3 Results

2.3.1 Stage I

Household registration results revealed an existence of 136,985 and 120,446 households in the intervention and control districts, respectively. These household registration results also revealed a need for 344,770 and 284,873 LLINs in the intervention and control districts, respectively.

Nearly 88% (302,648) of planned LLINs were distributed in the intervention districts (Gurue and Sussundenga) compared to 77% (219,613) in the control districts (Alto Molocue and Machaze), with an implementation effectiveness of 12.2% [OR: 2.14 (95% CI: 2.11 - 2.16; p < 0.001)]. Also, Stage I results revealed that 80.6% (110,453) of households received at least one LLIN in the intervention districts compared to 72.8% (87,636) households in the control districts with an implementation effectiveness of 9.8% [OR: 1.56 (95% CI: 1.53 - 1.59); p < 0.001].

2.3.2 Stage II

In Stage II (massive pilot in Nampula province) micro-planning figures revealed a total of 5,638,667 inhabitants and 1,282,512 households. After household registration these figures increased to a total of 7,038,427 inhabitants (24.8% increase) and 1,373,002 households (7.1% increase) (Table 6). During LLIN distribution several districts retrieved more coupons than what had been delivered (fake coupons). The most impressive case of this was in Mossuril district, where 47,231 out of 25,969 delivered coupons were retrieved (Table 6). Despite this, 3,536,839 LLINs (98.4% of the allocated LLINs) were delivered, covering 1,353,827 households (98.6% of the registered households).

Districts	Population		Households	Coupons					
	After micro-planning	After HHR	%	After micro-planning	After HHR	%	Delivered	Retrieved	%
Angoche	446,064	612,491	37.3	83,049	107,960	30.0	107,890	84,049	77.9
Liupo	105,617	140,236	32.8	20,469	24,613	20.2	24,613	26,548	107.9
Mecuburi	197,275	208,387	5.6	46,851	49,001	4.6	49,131	44,942	91.5
Memba	295,251	385,672	30.6	66,504	73,291	10.2	73,341	66,855	91.2
Mogincual	113,717	146,330	28.7	21,220	25,904	22.1	25,953	21,699	83.6
Mogovolas	674,001	491,777	- 27.0	112,011	122,283	9.2	107,387	76,958	71.7
Moma	137,331	276,859	101.6	72,297	51,655	- 28.6	50,146	49,923	99.6
Murrupula	212,692	425,973	100.3	44,261	75,055	69.6	75,914	39,230	51.7
Nacaroa	150,588	206,577	37.2	31,753	41,400	30.4	40,714	33,663	82.7
Rapale	179,362	230,600	28.6	72,889	44,992	- 38.3	44,992	45,229	100.5
Ribaue	314,615	306,341	- 2.6	66,077	59,375	- 10.1	59,108	59,796	101.2
Nampula	746,638	789,361	5.7	159,633	155,854	- 2.4	155,854	160,094	102.7
Erati	329,681	472,101	43.2	79,140	94,714	19.7	94,583	89,977	95.1
Ilha Moz	55,890	94,071	68.3	13,973	15,361	9.9	15,361	14,380	93.6
Lalaua	79,341	149,018	87.8	22,206	27,184	22.4	27,184	27,873	102.5
Larde	83,967	126,257	50.4	20,630	22,504	9.1	22,504	20,806	92.5
Malema	197,836	234,028	18.3	49,459	48,864	- 1.2	48,864	49,630	101.6
Meconta	190,279	253,867	33.4	48,635	52,089	7.1	52,089	49,987	96.0
Monapo	402,534	556,372	38.2	95,612	116,503	21.8	115,197	109,665	95.2
Mossuril	178,671	143,044	- 19.9	35,020	25,969	- 25.8	25,969	47,231	181.9
Muecate	116,606	170,657	46.4	29,002	31,337	8.1	31,337	31,942	101.9
Nacala Porto	293,931	437,379	48.8	60,944	72,889	19.6	72,889	75,236	103.2
NacalaVelha	136,780	181,029	32.4	30,877	34,205	10.8	34,205	35,537	103.9
Total	5,638,667	7,038,427	24.8	1,282,512	1,373,002	7.1	1,355,225	1,261,250	93.1

Table 6: Population, households and coupons delivered and retrieved during Stage II

# 2.4 Discussion

Stage I and II results shows that more LLINs were distributed and more households benefitted as a result of the new implementation strategies. This might be attributed to the coupons and sticker implementation strategy. The coupons seem to have had the desired effect, namely: i) ensured the necessary confidence for the households that will in fact receive LLINs; ii) identified the distribution point that households should go to in order to obtain LLINs; and iii) facilitated confirmation that the household was registered, *i.e.*, during LLINs distribution phase, the coupon was exchanged for LLINs. This chain of events, which constitutes a positive gradient of demand behaviour, is here termed as "the coupon effect". This effect has also been observed in other studies in which coupons or vouchers were used (Krezanoski et al. 2010; Renggli et al. 2013; Stevens et al. 2013; Thwing et al. 2011; Tokponnon et al. 2013; West et al. 2012). Another explanation is that at the time of registering households a sticker was installed to identify registered houses. In this way, unregistered households were easily identified and registered, thereby ensuring that more households are registered and can benefit from LLINs. This additional factor is referred to herein as "the sticker effect". The combination of these factors (coupon and sticker effect), which encourages the target households to obtain the LLINs and determines their greater ownership, constitute what will be called herein "the coupon-sticker effect".

During a wrap up meeting held in early December 2016, with the main stakeholders involved in the stage II massive pilot implementation, several weaknesses were reported, and can be summarized in three critical features: coordination, planning, and some loss of implementation fidelity.

Coordination at provincial and district levels were not well established, leading to incomplete readiness and UCC preparation. The planning process (the micro-planning tool) was not finalized, leading to deficiencies in the implementation process. Not establishing a cap (*i.e.* maximum LLIN per household) also led to inflation in the reporting of number of household members (population increase of 25% between micro-planning and after household registration figures without corresponding increase in households). This happened because the households realized that increasing the number of household members would benefit them with more LLINs. Another factor contributing to this inflation was the poor quality of the coupons, leading to coupon counterfeiting.

Implementation challenges are always present in the "real world". The goal is not to eliminate the implementation challenges (a nearly impossible task) but to reduce them sufficiently to implement the strategy with high fidelity. Only by understanding and measuring whether an intervention has been implemented with fidelity can researchers and practitioners gain a better understanding of how and why an intervention works, and the extent to which outcomes can be improved (Carroll et al. 2007). In fact, some loss of fidelity was noted during the Stage II implementation process, resulting in several constraints, as reported in the results section. However, if a high fidelity level is not achievable, ensuring adequate adaptation of the strategy to fit the local context should at least be attained. In order to ensure effectiveness of the implementation, adaptation may occur with complementary components, but fidelity is mandatory for the core components, *i.e.*, ensuring high quality availability of coupons and stickers, and ensuring application of the new formula (one LLIN for every two people with a cap of four LLINs per household). An additional and required adaptation of the strategies is the introduction of independent monitoring of the household registration, in order to promptly detect errors and correct them during this critical UCC phase.

# 2.5 Conclusions

Stage I results showed greater availability and coverage of target households with LLIN in districts with the newly implemented strategies. The results of Stage II were also encouraging despite some problems related to population inflation and the quality of the coupons produced. Implementation strategies are important for reaching an effective health outcome. The importance of defining core and complementary components of a multifaceted implementation strategy resides in ensuring fidelity of the core components, and eventual adaptation of the complementary components to suit the local context. For the country-wide UCC some adaptation of the strategies is required, such as: ensuring high quality production of the coupons and stickers, capping the number of LLINs per household, and introducing independent monitoring of the household registration.

# CHAPTER 3: EFFECTIVENESS OF A NEW LONG LASTING INSECTICIDAL NETS DELIVERY MODEL IN TWO RURAL DISTRICTS OF MOZAMBIQUE: A BEFORE-AFTER STUDY

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#### RESEARCH

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# Effectiveness of a new long-lasting insecticidal nets delivery model in two rural districts of Mozambique: a before–after study

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#### Abstract

**Background:** In 2015, Mozambique piloted a new model of long-lasting insecticidal nets (LLINs) delivery in a campaign. The new delivery model was used in two rural districts were, and two others were considered as control, maintaining the old delivery model. The aim of this study is to compare the coverage of ownership and use of LLINs in intervention and control districts in Mozambique.

**Methods:** A before-after design with control group was carried out 6 months after LLINs distribution. Using systematic probabilistic sampling, 1547 households were surveyed by means of a questionnaire. To find associations between the district categories (intervention and control) and the main outcomes of the study (LLIN ownership, use, and universal coverage achievement), odds ratio (OR) and respective confidence intervals were calculated.

**Results:** Of the 760 households surveyed in the intervention districts, 98.8% had at least one LLIN; of the 787 households surveyed in the control districts, 89.6% had at least one LLIN [OR: 9.7, 95% (Cl 4.84–19.46)]. Around 95 and 87% of households owning at least one LLIN reported having slept under the LLIN the previous night in the intervention and control districts, respectively [OR: 3.2; 95% (Cl 2.12–4.69)]. Seventy-one percent of the households surveyed achieved universal coverage in the intervention districts against 59.6% in the control districts [OR: 1.6; 95% (Cl 1.33–2.03)].

**Conclusions:** The universal coverage campaign piloted with the new delivery model has increased LLINs ownership, use, and progression for reaching universal coverage targets in the community.

**Keywords:** Long-lasting insecticidal nets campaign, Universal coverage, New and old delivery model, Before-after study, Mozambique

# **Highlights**

#### What is already known about this topic?

- Household registration is a critical phase for a succeeded LLINs distribution.
- Household registration rates proved to be the most important determinant of a household receiving any LLIN from the campaign or for having sufficient LLINs for all household members.
- Access to LLINs is one of the major determinants of their use.

#### What are the new findings?

The "coupon-sticker demand effect" might increase LLIN ownership among households.

The higher LLIN ownership coverage amongst households (due to the "couponsticker demand effect") might well lead to a higher chance of use rates.

# Contributions of the findings for the literature and policy makers

If the study in chapter 2 (Implementation strategies to increase access and demand of long-lasting insecticidal nets: a before-and-after study and scale-up process in Mozambique) considered the "coupon-sticker effect" a determinant of a succeeded household registration, this study confirmed that the new delivery model with the three core multifaceted implementation strategies (coupons, stickers, one LLIN for every two persons ascription criterion) are of paramount importance to increase the pace toward universal coverage targets.

These findings are of great interest for the Global Technical Strategy for Malaria 2016 - 2030 (GTSM). The GTSM established an ambitious goal of by 2020 to reduce at least 40% malaria mortality and morbidity compared with 2015 levels (WHOa). This ambitious goal goes beyond, and by 2030, intends to reach a reduction of at least 90% on malaria mortality and morbidity when compared to 2015 levels (WHOa). The first pillar of this strategy is to ensure universal access to malaria prevention, diagnosis and treatment, and one of the harness supporting elements is innovation.

The effectiveness of the new delivery model is at this stage confirmed, with a high household LLIN ownership and use, and high proportion of households reaching universal coverage targets with the new delivery model.

# 3.1 Background

Using long-lasting insecticidal nets (LLINs) can reduce malaria morbidity and mortality, especially in children and pregnant women (Gamble et al. 2009; Langeler 2004), and the universal coverage LLIN campaign is a proven health intervention toward this goal [Bennett et al. 2012; Walker et al. 2016; Winskill et al. 2017). For countries in sub-Saharan Africa, it is estimated that 60% of at-risk population for malaria infection had access to an LLIN in 2015 and an estimated 53% of the population at risk slept under an LLIN in 2015 (WHO 2016). Ownership and use of LLINs in Mozambique increased between 2011 and 2015, but remain far from the desired targets. Households with at least one LLIN increased from 51% in 2011 to 66% in 2015; the mean LLINs per household increased from 35.7% in 2011 to 47.9% in 2015; the universal coverage goal (one LLIN for every two persons) is still low, with 38.9% of households achieving this target in 2015 against 22.6% in 2011 (IDS 2011; IMASIDA 2015).

Between October and December 2015, Mozambique piloted a new model of LLIN delivery in an intervention campaign. The new LLIN delivery model was used in two rural districts (Gurue and Sussundenga), and two (Alto Molocue and Machaze) were considered as control maintaining the "old" delivery model (Arroz et al. 2017).

Household registration in the control districts ("old" delivery model) was carried out by collecting variables such as name, age, gender, and family relationship of household members, and later analysed regarding possible sleeping patterns. Users' sleeping patterns were the LLIN allocation criteria in the "old" delivery model. Household registration in the intervention districts (new delivery model) was carried out by collecting the number of household members, attributing a coupon to each registered household, and issuing an identification sticker to the household. The number of LLINs allocated to each household was obtained by dividing the number of household members by two (observing the principle of one LLIN for every two persons, rounded up to the next whole number) (Arroz et al. 2017).

The aim of this study is to compare the coverage of ownership and use of LLINs in the intervention and control districts in Mozambique. The specific objectives are: i) to estimate LLIN ownership amongst households in the intervention and control districts; ii) to estimate LLIN use coverage in the intervention and control districts; iii) to estimate the proportion of households reaching universal coverage target (one LLIN for every two person) in the intervention and control districts; and iv) to compare the ownership and use of LLINs in the intervention and control districts.

# 3.2 Methods

3.2.1 Context

The study was conducted in four districts: Gurue, Alto-Molocue, Sussundenga, and Machaze. The districts of Gurue and Alto-Molocue are located in the province of Zambezia and have estimated populations of 403,558 and 375,504 inhabitants in 2015, respectively (INE 2007). The districts of Sussundenga and Machaze are located in the province of Manica and have estimated populations of 165,616 and 134,515 inhabitants in 2015, respectively (INE 2007). All four districts are rural type, with hardship health services access, and low social and economic conditions. In 2015 malaria prevalence in Zambezia and Manica was 67.9% and 25.5%, respectively (IMASIDA 2015).

# 3.2.2 Study Design

A before-after design with control group was carried out six months after LLINs distribution, i.e., between June and July 2016. Two groups were considered: intervention (districts of Gurue and Sussundenga) and control (districts of Alto-Molocue and Machaze). These districts were selected based on the following matching criteria: i) population size similarities; ii) geographical area; iii) similarity in the number of LLINs allocated for distribution; and iv) having rural characteristics (Arroz et al. 2017).

All the localities of these districts were selected for the survey. Within each locality household sample size was calculated by dividing the total sample size of the district by the number of existing localities. After determining the number of households in each locality, households were selected using systematic probabilistic sampling method. For both intervention and control districts the following household definition was assumed: includes all the people who live together or sleep in the same house / yard / plot and share the same food at meal times. When a man has more than one wife or woman, each of them is considered as a separate household.

# 3.2.3 Study Sample Size

For each group, sample size was computed in order to detect a significant difference of 10% between the intervention and control: p1 (intervention) = 80%; p2 (control) = 70%; alpha = 0.05; power = 0.9;  $C_{p,power} = 10.5$ . Therefore, the sample size for each group was 776 households, i.e., each district had 388 households as sample size.

$$n = \frac{[p_1(1 - p_1) + p_2 (1 - p_2)]}{(p_1 - p_2)^2} \times c_{p,power}$$

# 3.2.4 Sampling Strategy

A systematic random sampling was used in which every Nth member of the target population is selected to be included in the study. The sampling unit is the household.

# 3.2.5 Selection of the households

In each locality the households were selected based on the following strategy: first, households list (population frame) was identified and a number assigned to each household; then, the sample interval (number of households divided by sample size) was computed and a random number was chosen to start with; finally, from this first random number, households were systematically selected until the sample size was complete.

# 3.2.6 Data Collection

A semi-structured questionnaire with open and closed questions was used. Before the beginning of the study a pilot study took place by applying the questionnaire to 20 households located in districts that were not part of the study. Some adjustments were made to improve the original version of the questionnaire.

In order to avoid information bias, interviewers were not informed about the expected outcomes of the study, or if the district was from an intervention or a control group.

Additionally, the interviewers used observation techniques to support and validate some the responses given by the households, namely those related to the effective use of LLIN.

As usual, interviewers explained the purpose of the study and obtained authorization and written informed consent; if the household member refused to participate, the questionnaire was applied to the nearest house.

# 3.2.7 Variables

The questionnaire had questions related to the following quantitative and qualitative variables: i) number of *de facto* people living in the household (people living in the same household for at least six months); ii) presence or absence of campaign LLINs; iii) number of campaign LLINs; iv) use of campaign LLIN in the previous night and in the last four nights prior to the survey. All other existing LLINs (e.g., acquired from prenatal care or from campaigns prior to 2015, or from other source) were excluded from data collection during the interview and were considered as households without LLINs. The same approach was applied for those households that had campaign LLINs but slept under LLINs from another source; in this case was considered as owning campaign LLIN, but not sleeping under campaign LLIN. This was important to avoid information bias and effectively evaluate only the outcomes from the pilot.

#### 3.2.8 Households inclusion criteria

The following inclusion criteria were additionally used to select the households to be surveyed: i) households from the selected districts, ii) households living in the district

since July 2015 (period of the beginning of the campaign preparations), iii) interviewee with at least 18 years of age, regardless of gender.

# 3.2.9 Outcomes of interest

The main outcomes are: (i) percentage of households with at least one LLIN in the intervention and control districts; (ii) percentage of population that slept under an LLIN the previous night; (iii) percentage of LLIN owners that slept under an LLIN in the last four nights; and (iv) percentage of households achieving universal coverage targets (one LLIN for every two persons).

# 3.2.10 Statistical analysis

All data were introduced and analysed using SPSS version 23.0. Univariate and bivariate statistical analysis was performed. For quantitative variables descriptive statistics such as mean, median, and standard deviation [*SD*] were used, while absolute frequencies and percentage were calculated for qualitative variables. For universal coverage estimation, the number of LLINs available in each household was divided by the number of *de facto* members from the respective household. Values greater than or equal to 0.5 (meaning that one LLIN is for two persons) were considered as universal coverage target achievement. Subsequently the percentage of households that reached universal coverage was calculated.

In order to analyse associations between the district categories (intervention and control) and the main outcomes of the study (LLIN ownership, use, and universal coverage achievement), odds ratio (OR) and respective 95% confidence intervals (CI) were calculated. For all statistical procedures, a 0.05 significance level was adopted for rejecting the null hypothesis.

# 3.3 Results

4.3.1 Sample characteristics and number of campaign LLINs

There were 1,547 households surveyed, of which 760 were in intervention and 787 in control districts. Both intervention districts have on average more LLINs per household (2.7, 95% CI: 2.6 - 2.8) than control districts (2.3, 95% CI: 2.2 - 2.4). Since the 95% mean confidence intervals between intervention and control districts do not overlap, a plausible mean LLIN difference between intervention and control districts can be considered – Table 7.

Districts	Intervention	Control		
Surveyed households	760 (49.1%)	787 (50.9%)		
	LLINs	LLINS		
Mean	2.7	2.3		
95% CI	2.6-2.8	2.2-2.4		
Median	3.0	2.0		
SD	1.3	1.7		

Table 7: Households composition (*de facto* members) and number of 2015 campaign LLINs in intervention and control districts

Intervention (Gurue and Sussundenga); Control (Alto Molocue and Machaze)

4.3.2 LLINs ownership, use, and universal coverage achievement in intervention and control districts

The percentage of household with LLIN was higher in the intervention districts than in the control districts. There was a significant association between households' ownership of campaign LLIN and the delivery model [OR: 9.7, (95% CI: 4.84 - 19.46)]. Although the use of LLIN in the previous night was above 80% in both the intervention and control districts, the LLIN use was higher in the intervention than in the control districts, and the difference observed was statistically significant [OR: 3.2; (95% CI: 2.12-4.69)] – Table 8.

Amongst LLIN owners, the LLIN use in the last four nights (routine use) was also higher in the intervention than in control districts. There was a statistically significant association between routine use of LLINs and the delivery model [OR: 2.0; (95% CI: 1.29-3.03)]. Of the 760 households surveyed in the intervention districts, 70.8% (95% CI: 67.6 - 74.0) achieved the universal coverage target; of the 787 households surveyed in the control districts, 59.6% (95% CI: 56.2-63.0) achieved the universal coverage target. There was a statistically significant association between percentage of households reaching universal coverage targets and the delivery model [OR: 1.6; (95% CI: 1.33 - 2.03)] - Table 8.

Districts	Households	Households with LLINs				p value
	n	%	95% CI	Total		
Intervention	751	98.8	98.0–99.6	760	9.7	< 0.001
Control	705	89.6	87.5-91.7	787	4.84-19.46	
Total	1456	94.1	92.9-95.3	1547		
	LLIN use in p	revious night (slept (	under LLIN)			
Intervention	725	95.4	93.9-96.9	760	3.2 2.12–4.69	< 0.001
Control	683	86.8	84.4-89.2	787		
Total	1408	91.0	89.6-92.4	1547		
	LLIN use in th	ne last 4 nights amor	ng LLIN owners			
Intervention	716	95.3	93.8-96.8	751	2.0	0.002
Control	643	91.2	89.1-93.3	705	1.29-3.03	
Total	1359	93.3	92.0-94.6	1456		
	Universal cov	verage target achieve	ement (one LLIN for every	two persons)		
Intervention	538	70.8	67.6-74.0	760	1.6	< 0.001
Control	469	59.6	56.2-63.0	787	1.33-2.03	
Total	1007	65.1	62.7-67.5	1547		

Table 8: LLIN household ownership, use and universal coverage six month after distribution in intervention and control districts

Intervention (Gurue and Sussundenga); Control (Alto Molocue and Machaze)

#### 3.4 Discussion

This study shows that there were more households being covered with LLINs in the intervention districts when compared to control ones. The results also show more people using LLINs and better progress toward universal coverage target in the intervention districts. These results are consistent with other published studies and campaigns that used coupons to register households or sleeping spaces in preparation for LLIN campaign (Bennett at al. 2012; Krezanoski et al. 2010; Renggli et al. 2013; Stevens et al. 2013; Thwing et al. 2011).

The average LLINs per household increased when compared with what was observed in the 2015 nationwide survey (average of 1.5 LLINs per household) (IMASIDA 2015). The intervention districts increased 1.2 LLINs per household; the control districts increased 0.8 LLINs per household.

The increased LLIN ownership among households in the intervention districts can be explained by what is herein referred to as the "coupon-sticker demand effect" (Arroz et al. 2017). The coupon effect is characterized by the following: (i) ensures the necessary confidence for the households that they will in fact receive LLINs; (ii) establishes community norms and give a meaning to the community, leading to the action of travelling to the place of distribution to exchange the coupon for LLINs; (iii) identifies the distribution point that households should go to in order to obtain LLINs; and (iv) facilitates confirmation that the household was registered, i.e., during LLINs distribution phase, the coupon is exchanged by LLINs. The sticker effect for LLIN

demand is characterized by easy identification of unregistered households (i.e., households without a sticker), thereby ensuring that more households are registered and can benefit from LLINs. These two effects complement each other and create a positive gradient of demand behaviour, leading to more campaign LLIN access and ownership – Figure 13.

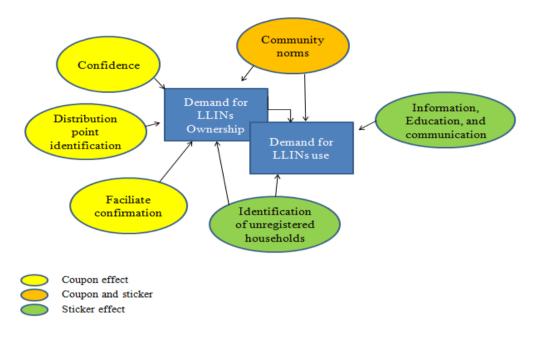


Figure 13 – The coupon-sticker demand effect.

Access to LLINs is one of the major determinants of their use (WHO 2016). LLINs are used by a high proportion of those who have access to them; therefore, the population sleeping under an LLIN closely tracks the proportion with access to an LLIN (WHO 2016). In spite of this, free distribution of LLINs has been shown to contribute to increased coverage and equity in their use (Moon et al. 2016). With this in mind, the higher LLIN ownership coverage amongst households in the intervention districts (due to the "coupon-sticker demand effect") might well lead to a higher chance of use rates. However, the effect of seasonality could also play a role in this high usage rate. The level of LLIN usage can be affected by factors such as temperature, humidity, season, and mosquito density (Rowland et al. 2002), and reported usage levels might therefore be higher or lower depending on whether the survey were conducted in summer and the rainy season. Discomfort during LLIN use (primarily due to heat) might be experienced in summer, leading to low LLIN use rates. Heat was identified as a factor contributing to partial mosquito net use (i.e. use for part of the night, but not all) (Frey et al. 2006). A review conducted by Pulford et al. (2011) also reports discomfort, primarily due to heat, as the most widely identified reason why mosquito net owners chose not to use a mosquito net on one or more nights in the 17 survey-based studies included in the review. On the other hand, in the rainy season with high mosquito density, LLIN use might be higher.

Although the target of universal coverage is difficult to reach and sustain, this study shows that the new delivery model accelerates the pace toward this target. In fact, 71% of households in the intervention districts achieved universal coverage targets against 60% in the control districts. These results were higher than what was observed in nationwide 2011 and 2015 surveys, in which only 22.6% and 38.9% of households reached this target, respectively (IDS 2011; IMASIDA 2015). The higher progression in the intervention districts might be explained by the "coupon-sticker demand effect", the ascription formula used (one LLIN for every two persons), and the fact of no maximum number of LLINs per households being established, i.e., not capping. Another observation to remark upon is the fact that only LLINs distributed by the 2015 campaign were considered in this study. LLINs obtained from other sources, such as from prenatal care, were excluded, which may have underestimated the coverage. Finally, indicators such as ownership and usage rates should also be taken into account in addition to universal coverage for a better prediction of the impact of LLINs in interrupting malaria transmission.

# 3.5 Conclusions

The universal coverage campaign piloted with the new delivery model, based on the use of coupons and stickers, has increased LLINs ownership, use, and progression for universal coverage targets in the community. The authors look forward to seeing the results of other countries' experiences with these two core components during household registration phase. These encouraging results might well help National Malaria Control Programmes to improve the strategies for LLINs delivery model in campaigns, greatly helping to reduce the malaria burden across African countries.

# CHAPTER 4: COST-EFFECTIVENESS ANALYSIS OF TWO LONG-LASTING INSECTICIDAL NETS DELIVERY MODELS IN MASS FREE CAMPAIGN IN RURAL MOZAMBIQUE

#### Manuscript Details

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Order of Authors	Jorge Arroz, Baltazar Candrinho, Chandana Mendis, Pablo Varela, Melanie Lopez, Joao Pinto, Maria Martins

#### Abstract:

**Background:** The international financial crisis poses a significant challenge for malaria vector control. Long-lasting insecticidal nets (LLINs) funding can reduce and is desirable to ensure cost-effective LLINs allocation. In 2015, Mozambique piloted a new outreach model of LLIN delivery. The objective of this study is to compare the cost-effectiveness of two long-lasting insecticidal nets delivery models (standard vs new) in mass campaigns in rural Mozambique.

**Methods:** A cost-effective analysis was retrospectively carried out from different delivery models of LLINs that were undertaken between October and December 2015. Two rural districts were selected as intervention sites (new delivery model) and two served as control (standard delivery model). Costs were calculated using secondary data from the providers' perspective. The following effects endpoints were used: i) number of LLINs delivered; ii) number of potentially protected persons (PPP); and iii) number of protected persons (PP). The average cost-effectiveness ratio (ACER) per LLIN delivery; ACER per PPP; ACER per PP; incremental cost-effectiveness ratio (ICER); and incremental net benefit (INB) were calculated. The ceiling of US\$ 1.32 per LLIN was adopted as willingness-to-pay. Positive values of INB are deemed cost-effective for the new delivery model.

**Results:** The 2015 total financial cost of delivering LLINs was US\$ 231,237.30 and US\$ 174,790.14 in the intervention (302,648 LLINs were delivered) and control districts (219,613 LLINs were delivered), respectively. The ACER per LLIN delivered was US\$ 0.76 in the intervention districts and US\$ 0.80 in the control districts. The ACER per PPP and ACER per PP were lower in the intervention districts. The ICER per LLIN was US\$ 0.68, and the INB was positive.

**Conclusions:** Overall, the newer delivery model was the more cost-effective intervention. However, the long-term sustainability of either delivery models is far from guaranteed in Mozambique's current economic context.

**Keywords:** Long-lasting insecticidal nets campaign; Universal health coverage; New and standard delivery model; cost-effectiveness analysis; Malaria; Mozambique

# Highlights

#### What is already known about this topic?

- As decision-makers and donors face the challenge of balancing increasing health care demand with cost containment, it is crucial to identify cost-effective ways of providing health care.
- Decisions around adoption of implementation of new programs or interventions may be affected by which cost-effectiveness summary measure is reported.
- Incremental Cost-Effectiveness Ratio (ICER) and the Incremental Net Benefit (INB) are preferred ways of reporting a cost-effectiveness analysis, as they consider extra-cost in relation to extra-effect.

# What are the new findings?

- Findings support the conclusion that, from the perspective of a health care provider, the new delivery model is more cost-effective than the standard (control) delivery model.
- The positive incremental net benefit shows that important savings per LLIN delivered could be achieved from adopting the new delivery model (opportunity-cost).
- This study demonstrates that the new delivery model is worthwhile from a programme provider perspective and current donor economic outlook.

# Contributions of the findings for the literature and policy makers

As there are no economic evaluations of LLIN delivery models in mass free campaigns in Mozambique, this study fills this gap and delivers evidence for decision making by the National Malaria Control Programme (NMCP) in Mozambique.

This study also provides an economic evaluation making use of incremental costeffectiveness ratio (ICER) and incremental-net benefit (INB). This two reported cost-effectiveness measures provides guidance for reporting cost-effectiveness evaluation of LLIN campaign implementation in high burden malaria countries.

It is suggested that each country should adopt their own value for money ceiling (willingness-to-pay), or make use of net benefit approach with cost-effectiveness acceptability curve if the ceiling is unknown plotting probability of cost-effectiveness against variation of the ceiling.

If the studies presented in chapter 2 and 3 confirmed the effectiveness of the new delivery model, this study show evidence that the new delivery model is more cost-effective, and there is important cost savings from switching from the standard to the new delivery model. However, the long-term sustainability of either delivery models was called in question in Mozambique's current economic context.

# 4.1 Background

Using long-lasting insecticidal nets (LLINs) can reduce malaria morbidity and mortality, and expanding the LLIN population coverage has been proven to be an effective health intervention toward reducing the incidence of malaria (Bennett *et al.* 2012; Walker *et al.* 2016; Winskill *et al.* 2017). The international financial crisis poses a significant challenge for malaria vector control, and health policy decision-makers (and donors) frequently have to choose between two interventions based on cost-effectiveness analyses. Despite of the considerable international investment made for malaria control over the past 15 years, worldwide funding fell by 8% between 2013 and 2014 (WHO 2015). However, spending on commodities rose 40-fold between 2004 and 2014 and accounted for about 82% of recorded international malaria spending in 2014, whereas LLINs were responsible for 63% of total spending (WHO 2015). Funding for the provision of LLINs can continue to decrease (WHO 2012) and it is necessary to ensure the efficient allocation of LLINs and their appropriate use. Even for existing LLIN delivery models in mass free campaigns, it is necessary to ensure that the existing delivery model is the most cost-effective and sustainable for country-wide campaigns.

Most of the economic evaluation studies compare the distribution of LLINs through various mechanisms (e.g. campaigns through fixed sites and health facilities, campaigns carried out using prenatal care services, and campaigns integrated with immunization) or distribution of LLINs with other malaria control strategies, such as indoor residual spraying (IRS), and intermittent preventive treatment in pregnant women (IPTp), among others. Recently, Ntuku *et al.* (2017) evaluated a fixed delivery strategy and a door-to-door strategy including hang-up activities in Kasaï Occidental Province in Democratic Republic of Congo. Their findings show that the fixed delivery strategy achieved a higher LLIN coverage at lower delivery cost compared with the door-to-door strategy.

In 2015, Mozambique piloted a new model of LLIN delivery in mass free campaign (Arroz *et al.* 2017). The mass free campaigns in Mozambique make use of community channel (defined as the route through which the LLINs flow to the end user), and the LLINs distribution takes place in community distribution centers. Two rural districts were intervened with the new LLIN delivery model, and two served as the control, maintaining the standard delivery model. Immediate results of this pilot showed that 87.8% (302,648/344,770) of planned LLINs were distributed in the intervention districts compared to 77.1% (219,613/284,873) in the control districts [OR: 2.14 (95% CI 2.11–2.16)] (Arroz *et al.* 2017).

As there are no economic evaluations of LLIN delivery models in mass free campaigns in Mozambique, this article fills this gap and delivers evidence for decision making by the National Malaria Control Programme (NMCP) in Mozambique. The objective of this research is to compare the cost-effectiveness of the two delivery models in mass free campaigns in rural Mozambique, and establish the most cost-effective LLIN delivery model.

# 4.2 Methods

4.2.1 Setting and location

The study was conducted in four districts of Mozambique, namely: Gurue and Sussundenga (new delivery model - intervention); and Alto-Molocue and Machaze (standard delivery model - control). These districts were selected based on the following pragmatic criteria: i) they would benefit from the LLIN mass free distribution campaign in the pilot period; ii) they have similar population size; iii) they have similarity in the number of LLINs allocated for distribution; and iv) they have rural characteristics.

The districts of Gurue (intervention 1) and Alto-Molocue (control 1) are located in the province of Zambezia and had estimated populations of 403,558 and 375,504 inhabitants in 2015, respectively. The districts of Sussundenga (intervention 2) and Machaze (control 2) are located in the province of Manica and had estimated populations of 165,616 and 134,515 inhabitants in 2015, respectively (INE 2007). All four districts are rural, with limited access to health services, and low social and economic indicators (INE 2007).

During the household registration phase, carried out in 2015, a total of 136,985 households were registered in the intervention districts, and 120,246 households were registered in the control districts (Arroz *et al.* 2017).

4.2.2 Study Design

An observational and cross-sectional study with cost-effectiveness analysis component was carried out using secondary data from the pilot study on different LLIN mass free distribution models conducted in the intervention and control districts between October and December 2015.

# 4.2.3 Collection of cost data

The costs (expenses) related to the October – December 2015 campaign implementation in the intervention and control districts were retrospectively collected using the financial and accounting systems of the partner organizations supporting the campaign implementation, namely World Vision Mozambique and Foundation for Community Development, i.e., from the programme providers' perspective. The expenses considered were related to training of personnel, allowances (for household registrars, distribution center teams, mobilisers, and health staff perdiem), LLINs warehouse storage, LLIN transportation vehicles rental, and materials production (pamphlets, coupons, stickers, etc).

These expenses were aggregated into the following four activity categories: 1) microplanning costs; 2) LLIN storage costs; 3) costs for LLIN transport from the district warehouse to the warehouses at the localities and distribution centers (satellite warehouses); 4) mobilization and training costs at district level, household registration, and LLIN distribution. The fourth category was subdivided into two: 4.1) Coupons and stickers production costs (only in the intervention districts), and 4.2) Household registration data analysis (only in the control districts).

Percentage costs were calculated for each of these categories. Costs were collected in Mozambican Metical (local currency) and United States Dollars (US\$). In October – December 2015, the exchange rate was: 1 US = 42.00 Meticais. No adjustment for inflation was undertaken since all expenses were paid in 2015. No discount rate was applied since the temporal universe of analysis did not exceed one year.

4.2.4 Comparators: the two delivery models

Standard delivery model – Control districts

Household registration in the control districts was carried out by collecting variables such as name, age, gender, and family relationship of household members, and later analysed regarding possible sleeping patterns. Users' sleeping patterns were the LLIN allocation criteria (Table 9).

New delivery model – Intervention districts

Household registration in the intervention districts was carried out by collecting the number of household members, attributing a coupon to each registered household, and issuing an identification sticker to the household. The number of LLINs allocated to each household was obtained by dividing the number of household members by two (observing the principle of one LLIN for every two persons, rounded up to the next whole number) (Table 9).

Table	9:	Main	differences	between	the	standard	(control)	and	new	(intervention)
delive	ry	models								

Dimensions	Intervention	Control
Actor(s)	Institutional (health professional (household registrars) that imple society partners.	•
Action(s)	The health intervention: LLINs universal coverage campaign with the following new implementation strategies:	The health intervention: LLINs universal coverage campaign with the following previous implementation strategies:
	Core components: i) coupons; ii) stickers; and iii) one LLIN for every two people ascription criterion.	i) allocation of LLIN is based on sleeping patterns according to data collected during household registration (age, sex, family relationship); ii)

	Complementary components:	number of LLINs per
	i) mapping and micro-	household known during
	planning; ii) training; iii)	distribution phase; iii)
	support supervision.	distribution points known after
		household registration; iv)
		training and support
		supervision during all
		campaign phases.
Target(s) of the	Health professionals and con	nmunity volunteers (household
action	-	re teams): knowledge and skills
Temporality	Stage I: October - December	Stage I: October - December
1 5	2015: Gurue and Sussundenga	2015: Alto-Molocue and
	districts.	Machaze districts.
Dose: measured	Trainings duration and	Trainings: 3 days for micro-
in terms of	coverage: 10 days for micro-	planning, 4 hours for
duration,	planning and training of	preparation of registrar
frequency, and	trainers for implementation (5	trainers, 4 hours for registrar
coverage	members of district team), 8	training (1 registrar trainer per
00,010,80	hours (1 day) for preparation	15 household registrar), 4
	of registrar trainers (1 registrar	hours for training of data
	trainer per 15 household	analysts, 56 hours (7 days) for
	registrar), 16 hours (2 days) for	analysis of household
	registrar training (assuming 1	registration data, 8 hours (1
	registrar can register 20	day) for training of distribution
	households per day and 140	teams. Seven (7) days for
	households in 7 days), 8 hours	household registration. Five
	(1 day) for training of	(5) days for LLIN distribution.
	distribution teams (5 members	Frequency: once.
	for each distribution team).	Trequency: once.
	Seven (7) days for household	
	registration. Five (5) days for	
	LLIN distribution.	
Justification	Frequency: once.	Theoretical justification:
JUSTILICATION	Programmatic justification: the	Theoretical justification: Socio-ecological model.
	type of household registration,	e
	the complex criteria for LLIN	Working with institutional and
	attribution, and the long	community actors to achieve
	queues to benefit the LLINs	better health outcomes.
	related to the previous	
	campaign strategy made it	
	necessary to design the new	
	implementation strategy.	
	Theoretical justification:	
	Socio-ecological model	
	embedded in social practice	
	theory.	

## 4.2.5 Measurement of effectiveness

The following effect endpoints were used to measure the effects of the campaign in the intervention and control districts: i) number of LLINs delivered; ii) number of potentially protected persons (PPP); and iii) number of protected persons (PP).

The following assumptions were used to calculate these endpoints:

- Number of LLINs delivered administrative data from the campaign reports, obtained from a tally sheet used during distribution phase; this is the main endpoint from a programme provider perspective;
- Number of potentially protected persons (PPP) this endpoint was estimated in two steps: first, the population access indicator was calculated using the formula proposed by Kilian *et al.* (% population with LLIN access= number of LLIN x (1.6 / target population) x 100 (Kilian *et al.* 2013); then, the result of this formula was multiplied by the estimated population (569,174 inhabitants in the intervention districts and 510,019 inhabitants in the control districts);
- Number of protected persons (PP) this endpoint took into account the proportion of the population who slept under an LLIN the previous night (assuming that one who sleeps under a LLIN is protected). The following formula was used: LLIN use all ages = 0.8133 × LLIN access all ages + 0.0026 (WHO 2017). Then, the LLIN use all age proportion was multiplied by the estimated population to obtained the estimated number of persons protected.

# 4.2.6 Cost-effectiveness analyses

The following cost-effectiveness analyses were calculated: i) average cost-effectiveness ratio (ACER) per LLIN delivery; ii) ACER per PPP; iii) ACER per PP; iv) incremental cost-effectiveness ratio (ICER); and v) incremental net benefit (INB).

The ACER per LLIN delivered was calculated by dividing the total implementation cost (total expenses) by the number of LLINs delivered. ACER per LLIN delivered for each aggregated and standardized cost category was also calculated. ACER per PPP and ACER per PP were calculated by dividing the total expenses by the number of PPP and the number of PP, respectively. These calculations were performed for the intervention and control districts.

The ICER (which indicates the additional amount of money needed to obtain an extra unit of health gain or to prevent an adverse event compared to alternatives) was calculated by dividing the difference between the total expenses in the intervention and control districts by the difference of effects in the intervention and control districts. The ICER was only calculated for the main endpoint, i.e, LLIN delivered because:

- LLINs delivered is directly correlated to population access indicator [coefficient of 1.64 (95% CI: 1.58, 1.69) and R2 = 0.99, p<0.00005] (Kilian *et al.* 2013); therefore, being also directly correlated to the number of potential protected persons; and
- Population access indicator is also directly correlated to LLIN use (LLIN use all ages =  $0.8133 \times$  LLIN access all ages + 0.0026, R2 = 0.773) (WHO 2017); therefore, also being directly correlated to the number of protected persons.

The ICER quantifies the trade-off of interest; however, it does not indicate whether the trade-off is worth it (Hoch and Dewa 2008). The incremental net benefit (INB) approach seeks to address this dilemma. The net benefit approach takes cost-effectiveness analysis one step further by reframing the fundamental economic question. An INB calculation determines whether the net benefit of a new treatment surpasses that of usual care (Hoch and Dewa 2008). In general, the INB is calculated by valuing additional effect ( $\Delta E$ ) in dollars and then subtracting the associated additional cost ( $\Delta C$ ); the exact formula is giving by INB = ( $\Delta E \ge \lambda$ ) -  $\Delta C$ , where  $\lambda$  is willingness to pay (WTP) for a 1-unit gain of effect (Hoch and Dewa 2008). For the same reasons as those already presented for ICER, INB is herein only presented for the main endpoint, LLINs delivered.

# 4.2.7 Decision rule on cost-effectiveness

For defining the decision rule, we need to have a threshold value, i.e, a ceiling that the decision-makers are willing to pay as a good value for money. The ceiling of US\$ 1.32 per LLIN was adopted by the Global Fund for Mozambique in-country mass free campaign budget planning (MISAU and WVM). This ceiling does not include purchase cost. For LLIN distribution plus LLIN purchases cost, a US\$ 9.12 (US\$ 1.32 + US\$ 7.8 which was the maximum inter-quartile purchase cost for the period 2005 – 2012 [Wafula *et al.* 2013]) was assumed as the ceiling.

The decision rule was the following: a positive INB means that the new intervention extra benefits ( $\Delta E \ge \lambda$ ) outweighs its extra costs ( $\Delta C$ ), i.e., the new intervention is deemed cost-effective. Conversely, when INB is less than 0 (negative INB), the extra benefit do not surplus the extra cost, i.e., the new intervention is not cost-effective (Hoch and Dewa 2008).

# 4.2.8 Sensitivity analysis

In order to explore how costs varied according to some parameters, a one-way deterministic sensitivity analysis (i.e. varying one parameter at a time) was performed on the following parameters and assumptions: i) free warehouses for storing LLINs; ii) transport cost ( $\pm$ 50%); and iii) costs of LLINs purchase (-25%, -50%). Base case cost analysis was used to calculate the percentage of deviation in the intervention and control

districts. For the first two parameters, the base case was the ACER and ICER per LLIN delivered. For the third parameter, the base case was also ACER and ICER per LLIN delivered but also included the 2014 purchase cost of US\$ 3.63 per LLIN for the planned 344,770 LLINs in the intervention and 284,873 LLINs in the control districts.

The US\$ 3.63 per LLIN was based on the unit cost for Disease Control Technologies Royal Sentry® rectangular LLINs 190 x 180 x 180 cm of US\$ 3.19; procurement fee 1.50%; outbound transport charges 11.94%; transport insurance charges 0.14%; question and answer charges 0.09%; and pre-shipment inspection charges 0.12%).

These parameters were chosen assuming that they are the most critical for intervention sustainability; negative LLINs purchase variation was considered based on the findings that LLINs' cost trends are not increasing, and shows significantly large reductions (Wafula *et al.* 2013).

# 4.3 Results

4.3.1 Financial costs of the LLIN campaign

The total financial cost of the campaign from the providers' perspective was US\$ 231,237.30 in the intervention districts and US\$ 174,790.14 in the control districts. Cost activity category 4 (mobilization and training costs at district level, household registration, and LLIN distribution) and 3 (costs for LLIN transport from the district warehouse to the warehouses at the localities and distribution centers) comprised around 43% and 38% in the intervention districts and 50% and 41% in the control districts, respectively. Coupons and stickers production (cost category 4.1) comprised around 14%, while household registration data analysis (cost category 4.2) comprised around 3% of total costs. The ACER per LLIN delivered was US\$ 0.76 and US\$ 0.80 in the intervention districts, respectively. LLIN transport was US\$ 0.03/LLIN lower in the intervention districts. District level activities (cost activity category 4) were US\$ 0.06/LLIN higher in the control districts – Table 10.

	Interver	ntion	Control		
LLIN delivered	302,648		219,613		
Aggregated and standardized categories	Expenses	%	Expenses	%	
1. Micro-planning	6,184.85	2.7	5,580.84	3.2	
ACER per LLIN delivered	0.02		0.03		
2. LLIN warehouse storage	6,983.76	3.0	6,880.33	3.9	
ACER per LLIN delivered	0.02		0.03		
3. LLIN transport	86,908.64	37.6	71,007.48	40.6	
ACER per LLIN delivered	0.29		0.32		
4. Mobilization, trainings at district level, household registration, and LLIN distribution	99,105.53	42.9	86,736.97	49.6	
ACER per LLIN delivered	0.33		0.39		
4.1 Coupons and Stickers production	32,054.52	13.9	NA	NA	
ACER per LLIN delivered	0.11		NA		
4.2 Household registration data analysis	NA	NA	4,584.52	2.6	
ACER per LLIN delivered	NA		0.02		
Total cost	231,237.30	100.0	174,790.14	100.0	
ACER per LLIN delivered	0.76		0.80		

Table 10: Total cost and cost per LLIN delivered (US\$) for each category in the intervention and control districts

NA = Not Applicable. Household registration data analyses were not necessary in the intervention districts; coupons and stickers were not used in the control districts.

#### 4.3.2 Cost-effectiveness

The percentage of population with LLIN access and LLIN use in all ages was 16.6% and 13.5% points higher in the intervention districts, respectively. Since both effect endpoint 95% confidence interval between intervention and control do not overlap, a plausible difference between intervention and control districts can be considered (Table 3). The ACER per PPP and ACER per PP was US\$ 0.02 lower in the intervention districts (narrow range with the effect uncertainty). The overall incremental cost to deliver one additional LLIN (ICER<sub>LLIN</sub>) was US\$ 0.68, with a positive (US\$ +53,159.04) INB, i.e., a saving of more than US\$ 50,000 per LLIN delivered would result from switching from the standard to new delivery model (with U\$S 1.32 as willingness-to-pay) – Table 11.

Effects and cost-effectiveness indicators	Intervention	Control			
Delivered LLINs	302,648	219,613			
Target Population	569,174	510,019			
Total cost (expenses)	231,237.30	174,790.14			
% population with LLIN access (95% CI)	87.2% (87.1 - 87.3)	70.6% (70.5 - 70.7)			
PPP (95% CI)	496,343 (495,751 – 496,889)	360,165 (359,563 - 360,583)			
ACER per PPP	0.47 71.2%	0.49 57.7%			
LLIN use all ages (95% CI)	(71.1 - 71.3)	(57.6 - 57.8)			
PP (95% CI)	405,155 (404,683 - 405,821)	294,249 (293,771 - 294,791)			
ACER per PP	0.57	0.59			
ICER for delivered LLIN	0.68				
INB for delivered LLIN	+53,159.04				

Table 11: Comparative cost-effectiveness results in the intervention and control districts

## 4.3.3 Sensitivity analysis

After a sensitivity analysis, the  $ACER_{LLIN}$  remained at a lower rate (less sensitive) in the intervention districts rather than in the control districts, i.e., the results of  $ACER_{LLIN}$  remain robust. The cost-effectiveness of the new delivery model also remained sustained for all the parameters tested (positive INB) – Table 12.

Parameter	Control/ Intervention		ACER	% ACER	ICER	% ICER	
tested	districts	Cost (US\$)	LLIN	deviation	LLIN	deviation	INB <sub>LLIN</sub>
Free	Control	167,909.81	0.76	-4.43			
warehouse	Intervention	224,253.54	0.74	-2.50	0.68	-0.18	53,262.46
Transport cost	Control	210,293.88	0.96	19.70			
(+50%)	Intervention	274,691.63	0.91	19.42	0.78	14.09	45,208.45
Transport cost	Control	139,286.40	0.63	-20.72			
(-50%)	Intervention	187,782.98	0.62	-18.36	0.58	-14.08	61,109.62
LLIN Purchase cost + delivery	Control	1,214,576.59	5.53	591.32		·	
cost	Intervention	1,489,647.80	4.92	547.64	3.31	387.31	482,207.98
Less 25% LLIN Purchase cost + delivery	Control	954,629.98	4.35	443.36			
cost	Intervention	1,175,045.18	3.88	410.86	2.65	290.48	536,864.00
Less 50% LLIN Purchase	Control	694,683.36	3.16	295.40			
cost + delivery cost	Intervention	860,442.55	2.84	274.09	2.00	193.65	591,520.01

Table 12: Deterministic one-way sensitivity analysis of cost estimates to key assumptions

# 4.4 Discussion

This cost-effectiveness study demonstrates that the new delivery model is the more costeffective strategy for the universal coverage campaign. The positive incremental net benefit shows that important savings per LLIN delivered could be achieved from adopting the new delivery model (opportunity-cost). Based on cost-effectiveness analysis, the ACER per LLIN delivered was lower in the intervention districts. This was mainly driven by the low relative contribution of the micro-planning, LLINs transport, and district-level activities costs. Although the ACER of US\$ 0.11/LLIN of the coupons and stickers in the intervention was higher than the ACER of US\$ 0.02/LLIN for data analysis in the control districts, these costs did not sway the total ACER.

These results are in line with the literature on LLINs. Paintain *et al.* (2014) found financial costs for the distribution of LLINs on the order of US\$ 1.19 (ranging from US\$ 1.08 to US\$ 1.41). However, Grabowsky *et al.* (2005) found financial costs of around US\$ 0.32 in Ghana, which is considerably lower than what was found in the present study. As for Mueller *et al's.* (2008) study, they conducted an evaluation in Togo of the cost-effectiveness of an integrated LLINs distribution campaign with a measles vaccination campaign in 2005. Excluding the costs of LLIN acquisition, which were US\$ 3,917,325, they incurred an implementation cost of about US\$ 1.46 million.

The same article reports that 907,500 LLINs were distributed (Mueller *et al.* 2008), which would give an ACER of US\$ 1.6/LLIN. This ACER is higher than what was found in this study, for either the new or standard delivery model.

From a health-financing point of view, the high overall cost found for these interventions casts doubt on their long-term sustainability in low-income contexts. Mozambique allocated US\$ 580.9 million (9% of the National budget) to the health sector in 2015 (UNICEF 2015). For an estimated 25,727,911 inhabitants in 2015 (INE 2007), this budget for the health sector corresponds to US\$ 22.6 per capita [assuming this as Mozambican State willingness-to-pay (WTP) decision rule in the cost-effectiveness decision plan]. Taking into account that the mean cost to distribute one LLIN with the new intervention was US\$ 0.76 in this study, and that one LLIN would be delivered for each two persons, the financial sustainability of the intervention would be guaranteed if a campaign were taken stand-alone by the Mozambican State and the WTP were only for the malaria programme (ICER < WTP).

However, considering that the Ministry of Health does not focus exclusively on LLIN campaigns, and other health programmes exist and require budgetary allocation, the country would not be in a position to guarantee financial sustainability for LLIN distribution. The Mozambique health sector allocated US\$ 4,186,129 to the National Malaria Control Programme in 2014 (WHO 2015). Considering that 100% of the Mozambican population is at risk for malaria, this allocation corresponds to US\$ 0.16 per capita (WTP), i.e., US\$ 0.32 for each two persons (US\$ 0.44 less than the ACER per LLIN in the intervention). This WTP clearly demonstrates the current financial unsustainability of the country in assuming the LLINs campaign. The same conclusion holds even considering free warehouse storage, less 50% transport costs, and 50% reduction of LLINs' purchase cost.

Taking into account that malaria prevention activities also include health promotion (social and behaviour change communication), indoor residual spraying (IRS), intermittent preventive treatment to pregnant women (IPTp), prenatal care LLINs delivery, diagnosis and treatment, and recently a new challenge of immunization with RTS,S malaria vaccine, and mass free LLIN delivery was compared with some of these interventions. Based on literature review, mass free campaign delivery is still more cost-effective than IRS (US\$ 5.41 per person protected) (PMI 2012), RTS,S (US\$ 39.25 per fully vaccinated child) (Penny *et al.* 2016; Galactionova *et al.* 2015), and treatment (US\$ 2.59 per person tested and treated) (Okell *et al.* 2014). This is in line with what Winskill *et al.* (2017) found in their modelling cost-effectiveness study. However, treatment scale-up options should be excluded from the cost-effectiveness analysis based on the principle that diagnosis, and treatment are ethical priorities and equitable access to them is un-debatable (Winskill *et al.* 2017).

This study has some limitations. One of the limitations is the adopted WTP. The value of the maximum a provider is willing to pay for an additional unit of health gain is often estimated through extensive willingness to pay surveys and is not always available to the analysts (Hounton and Newlands 2012). However, the rationale for using the US\$ 1.32 for LLIN delivery and US\$ 9.12 for LLIN delivery plus LLIN purchase cost is not only justifiable, but it is also appropriate to the country context. Therefore, it is suggested that each country should adopt their own value for money ceiling, or make use of net benefit approach with cost-effectiveness acceptability curve if the ceiling is unknown plotting probability of cost-effectiveness against variation of the ceiling. Another limitation is the one-way sensitivity analyses. In the "real-world" more than one parameter varies at a time, and correlation between variations in multiple parameters can overstate uncertainty.

Despite these limitations, this study demonstrates that the new delivery model is worthwhile from a programme provider perspective and current donor economic outlook.

# 4.5 Conclusions

This study compared costs and effectiveness of two delivery models of campaign interventions to increase the uptake of LLINs in rural districts of Mozambique. The new delivery model was the more cost-effective intervention, allowing delivery of more LLINs at a lower cost, potentially protecting more people, and protecting more persons than the standard delivery model. However, the sustainability of both delivery models was called into question given the country's current economic outlook.

# **CHAPTER 5: CONCLUSIONS**

## 5.1 Summary of the findings

The objective of this thesis was to compare two bed nets delivery models in rural districts of Mozambique. The starting point was three core implementation strategies that were tested in a before-after design to see if the bottlenecks identified during the situation analysis could be overcome and, if the implementation outcomes improved with the tested strategies.

This thesis was conducted as an implementation research, starting with an evidencebased intervention (LLINs universal coverage campaign) which is largely proved as an intervention that increase access, ownership and use of LLINs to the poorest at-risk population. However, the bottlenecks identified during the previous implementation process in Mozambique resulted in low ownership and use.

The first study (chapter 2) shows that the new delivery model was feasible and achieved the desired coverage in terms of delivered LLINs and benefited households. However, some implementation constrains were identified, mainly related to implementation fidelity which in turn led to household member inflation. The second study (chapter 3) confirmed the results of study 1 by evaluating the effects (ownership, use, and universal coverage targets progress) of the new delivery model. The third study (chapter 4) concluded that the new delivery model is cost-effective; however, the long-term sustainability of either delivery models is far from guaranteed in Mozambique's current economic context.

# **5.2 Limitations of the study**

It should be borne in mind that the study has a few limitations:

- There was no qualitative interview to the main institutional and community actors involved in the implementation of the intervention and strategies specifically related to the implementation process and perception of the new delivery strategies. While this might be a limitation it does not impact the results because the institutional and community actors actually implemented the intervention with better results in the intervention districts rather in control districts, i.e., the intervention was deemed feasible.
- The second study (chapter 3) used households as sampling unit, and the LLINs use was obtained by only inquiring the interviewers. This is an uncommon approach, since all household members should be asked about the LLINs use. However, only the interviewers were asked because it was difficult to find all household members during the survey. This does not impact on the results of the

study since the same approach was used in the intervention and control district, being comparable with this methodological approach.

• Another important limitation is the fact that no malaria impact indicators (e.g. mortality, incidence, prevalence) have been measured in control and intervention districts. The main reason for this limitation is related to the objective of the study: the objective was to measure if implementation outcomes (LLINs ownership, access and use) were changing with the new strategies. However, this limitation suggests a direction for further research.

## 5.3 Contribution to knowledge and implications

The major contribution of this thesis is that it offers a new framework to implement LLINs universal coverage campaigns in low-and-middle income countries. This was the first universal coverage campaign that tested the use of stickers during household registration phase.

It is known that household registration is a critical phase for a succeeded LLINs distribution (Zegers de Beyl *et al.* 2016). Household registration rates proved to be the most important determinant of a household receiving any LLIN from the campaign or for having sufficient LLINs for all household members (Zegers de Beyl et al. 2016). As discussed in chapters 2 and 3, the coupon-sticker effect might well be an important and positive gradient of LLINs demand because of a higher household registration rate when conducted with coupons and stickers. Since the population sleeping under an LLIN closely tracks the proportion of people with access to an LLIN (WHO 2016), the higher household registration rates leads to a higher chance of LLINs access, ownership, and use, therefore with potential implication on malaria morbidity reduction.

## 5.4 Recommendations

The results here presented indicate that the implementation of the new LLIN delivery model is a cost-effective intervention for a countrywide campaign. However, it is recommended that:

Capping LLINs per household should be applied in order to reduce household member's inflation; In Mozambique context a cap of four LLINs per household is herein suggested. The rationale for a cap of four is based on the fact that the average number of household members in Mozambique is five (IOF 2014/15). With the universal coverage ascription formula (one LLINs for every two persons), this leads to an average of three LLINs per household. Capping at four gives an acceptable margin for those households with up to 8 members, which cover the majority of households in Mozambique (IOF 2014/15).

- Establishing a core coordination group (at all levels national, provincial and district level) and a strong support supervision during preparation and implementation of LLINs universal coverage campaign may help increasing implementation fidelity of the campaign.
- Since behaviour is a process. change long-term advocacy education/communication activities should be implemented before, during and after LLIN universal coverage campaigns. This would lead to higher chance of LLINs ownership, and systematical and appropriate LLINs use, which in turn would result in a higher probability of achieving the goal of reduce malaria morbidity and mortality (Desrochers et al. 2014). Using local community structures and resources (e.g. radios, teachers, volunteers, private institutions and authorities) sensitization can be continuously carried out to encourage systematical and appropriate use of LLINs (Arroz 2017).
- Willingness to pay should be addressed in the future and explored by the National Malaria Control Programme with appropriate government entities in order to gradually make the intervention financially sustainable for the Ministry of Health.

## 5.5 Further research directions

The results of this thesis pose reflections on the following thematic areas:

- Impact on malaria morbidity and mortality
  - The ultimate goal of vector control is to reduce the malaria morbidity and mortality. In this context the following research questions should be addressed: Is this intervention contributing to a reduction in malaria morbidity and mortality?
  - If not, what is failing? Which bottlenecks should be additionally addressed?
  - If yes, is the reduction sufficient to allow a transition from a malaria control to elimination phase?
- Misuse and/or repurposing of LLINs

There are a number of reported misuses of LLINs in African countries, such as:

- For fishing (Eisele *et al.* 2011; Koenker HM *et al.* 2013; Loll DK *et al.* 2013; McLean KA *et al.* 2014; Kibe LW *et al.* 2015);
- For farming activities (Loll DK et al. 2013; Kibe LW et al. 2015);

- For making ropes, swings, footballs (Kibe LW et al. 2015);
- Fencing for livestock, stuffing pillows, filtration of water, wash cloth (Loll DK *et al.* 2013).

In this context, further research should be implemented to address the following questions:

- There is misuse and/or repurposing of LLINs in Mozambique? At what magnitude?
- If yes, which factors influence misuse and/or repurposing of LLINs?

# 5.6 Autobiographical reflection

Undertaking these research studies has been an invaluable learning experience. I have gained understanding on the nature of research and the cyclical nature of the research process. I have learned that research can be frustrating and sometimes tedious, yet at other times immensely rewarding and even exhilarating.

Building the thesis plan was particularly challenging and I had to adopt a step-by-step approach with my advisor which led me to: first, reach consensus about the research questions and general objective; second, to be in agreement about the three aligned studies; and then, to build the methodological approach presented in section 1.6 of chapter 1. My self-training (with a strong support from my advisor) in the field of implementation science/research was of most value during this thesis construction.

This doctoral thesis has also provided some key ideas that have helped me examine my own professional values and weakness for future improvement, and guidelines for possible changes to my own future practice. I intend to explore further the impact of the universal coverage campaign with these strategies in other countries with which I may be involved, as well as to dedicate time to the teaching and planning process of universal coverage campaigns in different settings.

# 5.7 Final words

The new delivery model with the following core strategies: coupons, stickers, and the new LLINs ascription formula (and the complementary strategies described in subheading 2.2.5 in chapter 2) is a cost-effective strategy for delivery LLINs in universal coverage campaign. These promising results should be more explored in terms of impact, and three-year universal coverage campaigns should be continuously carried out in order to contribute to the achievement of the goals of the Global Technical Strategy for malaria 2016-2030.

In fact, Mozambique did carry out in 2016/2017 a countrywide LLIN campaign with these strategies. Immediate results showed that a total of 7,049,894 households were registered (98% of the planned households). A total of 16,557,818 LLINs were distributed between November 2016 and December 2017, corresponding to 97% of LLINs needs based on household registration, and covering 95% of the registered households (6,708,585 households), resulting in an estimated 85% of the total Mozambican population with LLIN access.

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# **APPENDIX Appendix 1:** Authorization from the National Committee on Bioethics in Health



#### MINISTÉRIO DA SAÚDE COMITÉ NACIONAL DE BIOÉTICA PARA A SAÚDE IRB00002657

Exmo Senhor Dr. Jorge Arroz

#### Ref: 383/CNBS/16

#### Data 07 de Novembro de 2016

. 1

Assunto: Parecer do Comité Nacional de Bioética para Saúde (CNBS) sobre o estudo: "Avalação da Eficiência e Eficácia de dois modalos da Distribuição Massiva de Redes Mosquiteiras Impregnadas com Insecticida de Longa Duração em Moçambique"

O Combi Nacional de Bioética para Saúde (CN8S) analisou as correcções efectuadas no protocolo intituíado: "Avaliação da Eficiência e Eficácia de dois modelos de Distribuição Massiva de Redes Mosquiteiras Impregnadas com Insecticida de Longa Duração em Moçambique"

Registado no CNBS com o número 112/CNBS/2015, conforme os requisitos da Declaração de Helsinquia. Não havendo nenhum inconveniente de ordem ética que impeça a realização do estudio, o CNBS dá a sua devida aprovação aos seguintes documentos:

- Protocolo de estudo, versão 2.0
- Instrumentos de Recolha de Dados versão 02
- Consentimento informado versão 02
- Todavia, o CNBS informa que:
- Qualquer alteração que for introducida no protocolo, incluindo os seus anexos deve ser submetida ao CNBS para aprovação.
- 2- A presente aprovação não substitui a autorização administrativa.
- 3- Não houve declaração de conflitos de interesse por nonhum dos membros do CNBS.
- 4 A aprovação terá a validade de um ano, terminando esta a 07 de Novembro de 2017. Os exvestigadores deverão submeter o pedido de renovação da aprovação um mês antes de terminar o peazo.
- 5- Recomenda-se aos investigadores qué mantenham o CNBS informado do decurso do estudo.
- 6 A lista actualizada dos membros do CNBS esta disponível na secretaria do Comité.

Com as nossas mais cordiais saudações.



# Appendix 2: Authorization from the Instituto de Higiene e Medicina Tropical Scientific Committee



#### **Conselho Cientifico**

Ex.ma Senhora Professora Doutora Maria do Rosário Fraga de Oliveira Martins Orientadora do aluno

089 /CC /2017

#### Assunto: 3.º Ciclo de Estudos Superiores em Saúde Internacional – Comissão Tutorial e Plano de Tese – Jorge Alexandre Harrison Arroz.

Informamos que o Conselho Científico (CC) do Instituto de Higiene e Medicina Tropical reunido no dia 08 de março de 2017, aprovou a Orientação, coorientação e composição da Comissão Tutorial do aluno de doutoramento *Jorge Alexandre Harrison Arroz* que passará a ter a seguinte constituição:

- Doutora Maria do Rosário Fraga de Oliveira Martins, orientadora. Professora Catedrática do IHMT-UNL;
- Doutor João Pedro Soares da Silva Pinto, coorientador. Professor Auxiliar do IHMT-UNL;
- Doutor Chandana Mendis, Especialista na área em que se insere a tese e Diretor do Projeto Malaria – World Vision, Maputo, Moçambique;
- Doutor Henrique Manuel Condinho da Silveira, Professor Catedrático do IHMT-UNL.

<u>O aluno deverá agora, proceder ao registo da tese de doutoramento no Conselho</u> <u>Científico</u>, em cumprimento do estipulado pelo Artigo 10.º do Regulamento n.º 474/2012 de 19 de Novembro – Regulamento Geral do 3.º Ciclo de Estudos Superiores Conducentes à Obtenção do Grau de Doutor pelo IHMT/UNL.

Para os devidos efeitos, junto se devolve à Divisão Acadêmica a documentação que sobre o assunto, foi submetida a este Conselho Científico.

Com os melhores cumprimentos,

Lisboa, IHMT, 08 de março de 2017

A PRESIDENTE DO CONSELHO CIENTÍFICO

Lenea Campino, MD, Prof.ª Catedrática

C/conhecimento: - Prof.<sup>a</sup> Doutora Sónia Maria Ferreira Dias. Coordenadora do 3.º Cielo de Estudos de SI; - Doutorando Jorge Alexandre Harrison Arroz; - Divisão Académica.