A Comparative Analysis of Malaria Control Programmes Targeting Delivery of Over-the counter Antimalarial Drugs in Kenya

Thesis

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A Comparative Analysis of Malaria Control Programmes Targeting Delivery of Over-the counter Anti-malarial Drugs in Kenya

Timothy Osebe Abuya
B.Ed (Science), MPH

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University of Cape Town, Cape Town, South Africa.

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ABSTRACT

Background: The retail sector is an important channel for increasing access to adequate treatment of fevers in Africa. The objectives of the thesis were to assess the performance of three malaria control programmes targeting private medicine retailers (PMRs) by addressing coverage, utilisation, impact on PMRs' knowledge, practices and implementation processes in Kisii central, Kwale and Bungoma districts of Kenya.

Methods: The thesis used mixed methods including retail audits, surrogate client surveys based on post intervention cross sectional surveys in intervention and controls and mapping of outlets in intervention areas. Qualitative methods including record reviews, in-depth interviews and focus group discussions with programme stakeholders were analysed using thematic framework and policy analysis.

Results: There was a significant impact on PMR knowledge and practice of an NGO-led participatory training programme in Kisii-central district with 60.5% of trained PMRs selling AQ medicines adequately compared to 2.8% in the untrained ones (OR; 53.5: 95% CI 6.7, 428.3). There was some evidence of a limited impact for the MoH-led participatory training programme in the Kwale district, where 18.8% of trained PMRs sold AQ medicines adequately compared to 2.3% of control PMRs (OR; 9.4: 95% CI 1.1, 83.7). This study was unable to show evidence of impact in the social marketing programme in Bungoma district. In terms of coverage, Kisii central covered 27.1% of all outlets in the study sites, compared to 14.1% and 16.7% in Kwale and Bungoma districts, respectively. Policy analysis indicated that, deliberate and careful management of the implementation process, actors involved and establishing a transparent management system with a flexible decision-making processes, is key to successful uptake and impact at retailer level.

Conclusions: PMR interventions operationalised through various institutions in the district level settings at moderate scale are likely to impact on PMR knowledge and practices and lead to increased coverage of appropriate treatment to target populations. Implementation management play a major role in determining programme impact, and should be areas of focus in planning and managing public health programmes.

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DEDICATION

To my wife Veena

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List of acronyms and abbreviations

AQ	Amodiaquine
AIE	Authority to Incur Expenditure
ACT	Artemesinin based Combination Therapy
ADDO	Accredited Drug Dispensing Drug Outlets
AFRO	African Regional Office
AL	Artemether Lumefantrine
AMREF	African Medical Research Foundation
BDMI	Bungoma District Malaria Initiative
CBO	Community Based Organisations
CBS	Central Bureau of Statistics
CHW	Community Health Workers
CFW	Cry for the World Foundation
CCM	Country Coordinating Committee
CQ	Chloroquine
CDC	Centre for Disease Control
CORPS	Community Owned Resource Persons
CI	Confidence Interval
DDP	District Demonstration Programme
DHMT	District Health Management Team
DHMB	District Health Management Board
DN	District Nutritonist
DVBD	Division of Vector Borne Diseases
DDT	Dichloro-Diphenyl-Trichloroethane
DoMC	Division of Malaria Control
DFID	Department for International Development
DMOH	District Medical Officer of Health
DPHO	District Public Health Officer
DHEO	District Health Education Officer
EA	Enumeration areas
FGD	Focus Group Discussions
GFTAM	Global Fund to Fight AIDS, TB and Malaria
GLLAMM	Generalised Linear Latent and Mixed Model
GoK	Government of Kenya
GPS	Global Positioning Systems
GIS	Geographical Information systems
HMM	Home Management of Malaria
HIV/AIDS	Human Immuno Virus/Acquired Immunity Deficiency Syndrome
IMCI	Integrated Management of Childhood Illnesses
IEC	Information Education and Communication
ITN	Insecticide Treated Nets
IQR	Inter Quartile Range
ICIPE	International Centre for Insect Physiology
JKJ	Jirani Kwa Jirani
KNMS	Kenya National Malaria Strategy
KES	Kenya Shillings
KEHP	Kenya Essential Health Package
KeNAAM	Kenya NGO Alliance Against Malaria
KEMRI-CGMRC	Kenya Medical Research Institute/Centre for Geographic Medicine Research Coast
KPMG	Klynveld Peat Marwick and Goerdeler
KHPF	Kenya Health Policy Framework

LMIC	Low and Middle Income Countries
MDG	Millennium Development Goals
MoH	Ministry of Health
M & E	Monitoring and Evaluation
MoU	Memorandum of Understanding
Merlin	Medical Emergency Relief International
MSW	Medical Social Worker
MRO	Medical Records Officer
NHSSP	National Health Sector Strategic Plan
NMCP	National Malaria Control Programme
NGO	Non Governmental Organisations
OR	Odds Ratio
OTC	Over the Counter
PSI	Population Services International
PHO	Public Health Officers
PHT	Public Health Technician
PC	Project Coordinator
PM	Project Manager
PO	Project Officer
PO-M&E	Project officer Monitoring and Evaluation
PT	Pharmaceutical Technologist
PMR	Private Medicine retailers
PMV	Private Medicine Vendors
QAP	Quality Assurance Project
RBM	Roll Back Malaria
SPO	Senior Project Officer
SP	Sulphadoxine-Pyrimethamine
SSA	Sub Saharan Africa
TB	Tuberculosis
TP	Thiessen Polygons
TBA	Traditional Birth Attendants
TDR	Tropical Diseases Research
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
US	United States
USAID	United States Agency for International Development
USD	United States Dollars
UR	Utilisation rate
VHM	Village Health Monitors
VTV	Vendor to Vendor
WHO	World Health Organisation

CHAPTER 1:

Introduction and Literature Review

1.1 Introduction

Malaria remains a major public health challenge worldwide with most malaria illnesses and deaths caused by the *Plasmodium falciparum* parasite (Greenwood et al., 2008). Malaria has been estimated to account for 515 (range 300–660) million clinical attacks, with about 2.2 billion people exposed to the threat of *Plasmodium falciparum* malaria (Snow et al., 2005). Recent estimates using spatial analysis of populations at risk indicate similar estimates with 2.37 billion people being at risk of *P. falciparum* in 2007. 26% live in the World Health Organization (WHO) African region and 62% in the combined South East Asia region and Western Pacific region (Guerra et al., 2008). The burden of malaria is greatest among children under five and pregnant women. For example, in 2000, there were about 116 million malaria episodes in children under five years of age, with 545000 children being admitted with severe malaria and 3.6 per 1000 per annum episodes of severe malarial anaemia (Roca-Fletrer et al., 2008).

Against this background, the study described in this thesis set out to evaluate three malaria control interventions in Kenya, all based on addressing the role of the private retail sector in optimising malaria home care. Based on a conceptual framework drawn from the literature on evaluating public health interventions, the study used mixed methodologies to evaluate three key areas of programme performance: retailer knowledge and practices; programme utilisation and coverage; and implementation processes.

This chapter presents an introduction to this thesis. It begins by describing current global malaria control strategies and aims at situating retail sector interventions within broader malaria control efforts (section 1.2). Thereafter, drawing on literature reviews, the current understanding of care seeking practices for fever and malaria in Sub-Saharan Africa (SSA) is presented to illustrate the importance of retail sector in the

treatment of fevers and malaria (section 1.3). Based on the evidence from care seeking studies, the development of the concept of Home Management of Malaria (HMM) as a control strategy is presented in section 1.4. Section 1.5 outlines the objectives of the study while section 1.6 provides a description of the conceptual approaches to evaluating public health interventions and the way they have been used to inform the conceptual framework for this study. This framework is further developed in the second half of chapter 2. Section 1.6 also provides background information on the methods used in this study. This chapter ends with the aims and scope of the thesis (1.7).

1.2 Malaria control strategies

1.2.1 Historical overview of global control efforts

Historically, malaria control efforts have led to success in some parts of the world. For example, malaria occurred in the United States (US) and Western Europe until it was eliminated in the US between 1947-1951 due to economic development and public health measures (Greenwood et al., 2008). In 1955 the Global Malaria Eradication Campaign based on indoor and outdoor spraying with dichloro-diphenyl-trichloroethane (DDT) and use of choloroquine (CQ) medicines was launched focusing on malarious regions of the world but not the majority of SSA countries (Trigg and Kondrachine, 1998). Global eradication efforts were not pursued in SSA countries due to transport problems, water shortages, different habits of populations in Africa, lack of a well developed public health-oriented infrastructure, the emergence of resistance to DDT and CQ, and lack of political will (Trigg and Kondrachine, 1998; Greenwood et al., 2008). The development of primary health care renewed optimism for malaria control efforts in the 1980s. But problems of interpretation of the primary health care strategy and reluctance to move away from practices used in the eradication era led to increased malaria burden in the 1980s and 1990s (Trigg and Kondrachine, 1998).

Since the late 1990s, there has been progress on expanded programmes, funding, technology and advocacy for malaria (Bates and Herrington, 2007). Coordinated malaria control efforts gave rise to initiatives such as Roll Back Malaria (RBM) launched by WHO, the United Nations Children's fund (UNICEF) and the United Nations Development Fund (UNDP) in 1998 (Teklehaimanot et al., 2001; Bates and Herrington, 2007). There has also been increased funding and commitment by governments and other private organisations towards malaria and other diseases such as Tuberculosis (TB) and Human Immunodeficiency Virus–Acquired Immune Deficiency Syndrome (HIV-AIDS). In 2002 the Global Fund to Fight AIDS, TB and Malaria (GFTAM) was formed to attract and manage funds for the three diseases (Bates and Herrington, 2007; Glass and Fauci, 2007; Snow et al., 2008). Initiatives such as the Multilateral Initiative on Malaria started in 1997 have enhanced scientific and research capacity for malaria (Teklehaimanot et al., 2001; Glass and Fauci, 2007). Other initiatives include the Malaria Vaccine Initiative under the Bill and Melinda Gates Foundation, the World Bank's Malaria Global Strategy and Booster programme (World Bank, 2007), and the US President's Malaria Initiative, working with the United States Agency for International Aid (USAID) and the Centres for Disease Control (CDC) among other agencies (President Malaria Initiative, 2008).

Such a wide range of contributors and efforts has led to recent calls for the re-adoption of global eradication of malaria, although this has been presented as a long-term vision rather than a near-term goal (Roberts and Enserink, 2007; Feachem and Sabot, 2008). Calls for eradication are partly due to reductions in malaria morbidity and mortality in some countries and progress in the development of new drugs (Bhattarai et al., 2007; Fegan et al., 2007). Although the debate on its feasibility continues, contemporary approaches to malaria control under the RBM initiative remain key to the reduction of malaria mortality and morbidity in SSA.

1.2.2 Roll Back Malaria initiative

RBM's global strategic plans 2005-2015 are in line with the Millennium Development Goals (MDGs) and continue to guide malaria control efforts in Africa (RBM, 2005). In 2000 world leaders committed to a global partnership to reduce extreme poverty, hunger, disease and lack of adequate shelter, and promote gender equality, education and environmental sustainability. They set out a series of time-bound targets known as the MDGs with eight goals, 18 targets and a deadline of 2015. The sixth goal focuses on control of HIV/AIDS, malaria and other diseases. The target for malaria disease is "to have halted by 2015 and begun to reverse the incidence of malaria and other major diseases"(http://www.unmillenniumproject.org/goals/gti.htm). To ensure that MDGs related goals are achieved, RBM's strategic plan aims to reduce malaria morbidity and mortality by 75% by the year 2015 and ensure universal and equitable coverage of effective interventions (RBM, 2005).

To attain this target, four core strategic approaches have been identified: rapid, effective treatment of persons with malaria as close to home as possible within the first 24 hours of illness onset; increased use of insecticide treated nets (ITNs) to limit human-mosquito contact; prevention of malaria in pregnancy; and better epidemic preparedness and appropriate response to epidemics (http://www.rbm.who.int/). The first strategic approach is relevant in this thesis since retail sector interventions aim to improve case management of malaria and fevers at home as part of HMM strategy.

Most national malaria control programmes have adopted RBM's strategic approaches and developed a plan of action and targets. For example a meeting of African Heads of State in 2002 ratified an action-oriented document named the Abuja Declaration which set targets to halve malaria mortality for Africa's people by 2010. The leaders resolved that by 2005:

- 60% of those with malaria have prompt and effective treatment of malaria within 24 hours of onset of symptoms
- 60% of under five and pregnant women have access to protective measures such as ITNs
- 60% of pregnant women at risk of malaria have access to chemoprophylaxis (RBM, 2003).

Although many SSA countries have not attained these targets (Amin et al., 2003; Monasch et al., 2004; Nsungwa-Sabiiti et al., 2005; Ahorlu et al., 2006; Oresanya et al., 2008), malaria control efforts remain a priority.

Access to appropriate and effective treatment for malaria in endemic regions remains important for positive outcomes since there is evidence that many deaths occur within 48 hours of onset of illness (Greenwood et al., 1987). Effective case management depends on correct diagnosis, prescription and availability of effective treatment (Font et al., 2001). However, case management in most SSA countries is characterised by several challenges. First, most rural populations in many endemic countries live far from health facilities, limiting physical access to treatment (Atting and Egwu, 1991; Diop et al., 1998; Baume et al., 2000; Bour, 2003; Dzator and Asafu-Adjaye, 2004; Mbagaya et al., 2005). Secondly, health facility level factors such as the availability of drugs and equipment, poor staff attitudes, cost and opening hours limit access to adequate care (Williams and Jones, 2004). Thirdly, the symptoms of malaria are difficult to distinguish from other illnesses or may co-exist with other illnesses (Greenwood, 1997; Berkley et al., 1999; Kallander et al., 2004), making it difficult to diagnose. Even in cases where diagnostic facilities are available, malaria test results are sometimes not used by clinicians. There are also potential inaccuracies of test results due to capacity and equipment constraints (Reyburn et al., 2004; Zurovac et al., 2006; Greenwood et al., 2008).

A fourth challenge associated with case management is the spread of *P. falciparum* resistance to former first line drugs such as CQ and sulphadoxine-pyrimethamine (SP) medicines (White, 2004; Greenwood et al., 2008). This has led to the development and deployment of new drugs with emphasis on Artemesinin-based combination therapies (ACT) due to their high cure rates, potential to decrease transmission and the limited resistance of malaria parasites to these drugs (Greenwood and Mutabingwa, 2002; White, 2004; Bosman and Mendis, 2007; Rosenthal, 2008). Although use of ACT is likely to reduce the global burden of malaria (Greenwood et al., 2008), deployment, access, implementing costs, and rational use of the drug remain a challenge (Malenga et al., 2005; Zurovac et al., 2005; Bosman and Mendis, 2007; Gitonga et al., 2008; Njau et al., 2008; Wasunna et al., 2008; Zurovac et al., 2008).

In the light of all these challenges, clinical diagnosis in malaria endemic areas, although imprecise, remains the basis of treatment for most febrile patients (Wongsrichanalai et al., 2007). International guidelines recommend that fevers in children under five years in endemic countries be treated presumptively as malaria (WHO, 2000a). The next section reviews the existing evidence on fever and malaria treatment practices in SSA, and points to the rationale for developing and implementing retail sector interventions.

1.3 Care seeking for fevers and malaria in Sub-Saharan Africa

1.3.1 Literature review for care seeking behaviour

There are two recent systematic reviews that have summarised care seeking for fevers and malaria. McCombie's paper, published in 2002, builds on an earlier WHO review on malaria care seeking behaviour. This earlier review examined published and unpublished literature between 1985 and 1993. It aimed at identifying potential determinants of care seeking patterns and assessing what was known about adequacy

of the treatments used (McCombie, 1996). The later review updated the evidence to April 2002, with a focus on methodological issues around the classification, definition and treatment of illnesses (McCombie, 2002).

The second review used is that by Williams and Jones, published in 2004 (Williams and Jones, 2004). This summarised behavioural issue related to malaria control, building from McCombie's 1996 review, and attempted to see whether methodological rigour had increased or knowledge from the 1996 review had been applied programmatically. The review considered both published and unpublished work between 1994 to 2002 (Williams and Jones, 2004).

This section draws on these reviews to illustrate the main features of care seeking patterns for fevers and malarial illness in both adults and children, with emphasis on the role of the retail sector. In addition to directly reviewing the published articles cited in these articles, a separate search was made in PubMed to identify more recent relevant publications. Three sets of search words were used: care seeking, malaria or fever and Sub-Saharan Africa; treatment seeking, malaria or fever and sub Saharan Africa; and self-treatment, malaria or fever and Sub Saharan Africa. The inclusion criteria were papers that: describe care seeking patterns qualitatively or quantitatively; were conducted in SSA between 1978-2008; reported on childhood illnesses/fever, malarial or acute illnesses in adults or children; and were either a descriptive study or part of ongoing or planned intervention.

Before summarising the outcome of this process, limitations, methodological challenges and operational definitions of terms are discussed. The review in this chapter has two main caveats. First, no grey literature was used to update the published reviews. Secondly, research published in other languages other than English were

difficult to access and extract information. Methodological challenges included differences between studies in the type of questions asked (for example, the use of hypothetical versus actual illness episodes), the classification of sources of care, analysis and presentation of data. In addition, there were variations in the use of terms such as "home" management or self treatment, reported time to treatment, and the extent to which switching patterns of care were reported (McCombie, 2002; Nyamongo, 2002; Williams and Jones, 2004). These factors made a quantitative summary on resort to care difficult to extract.

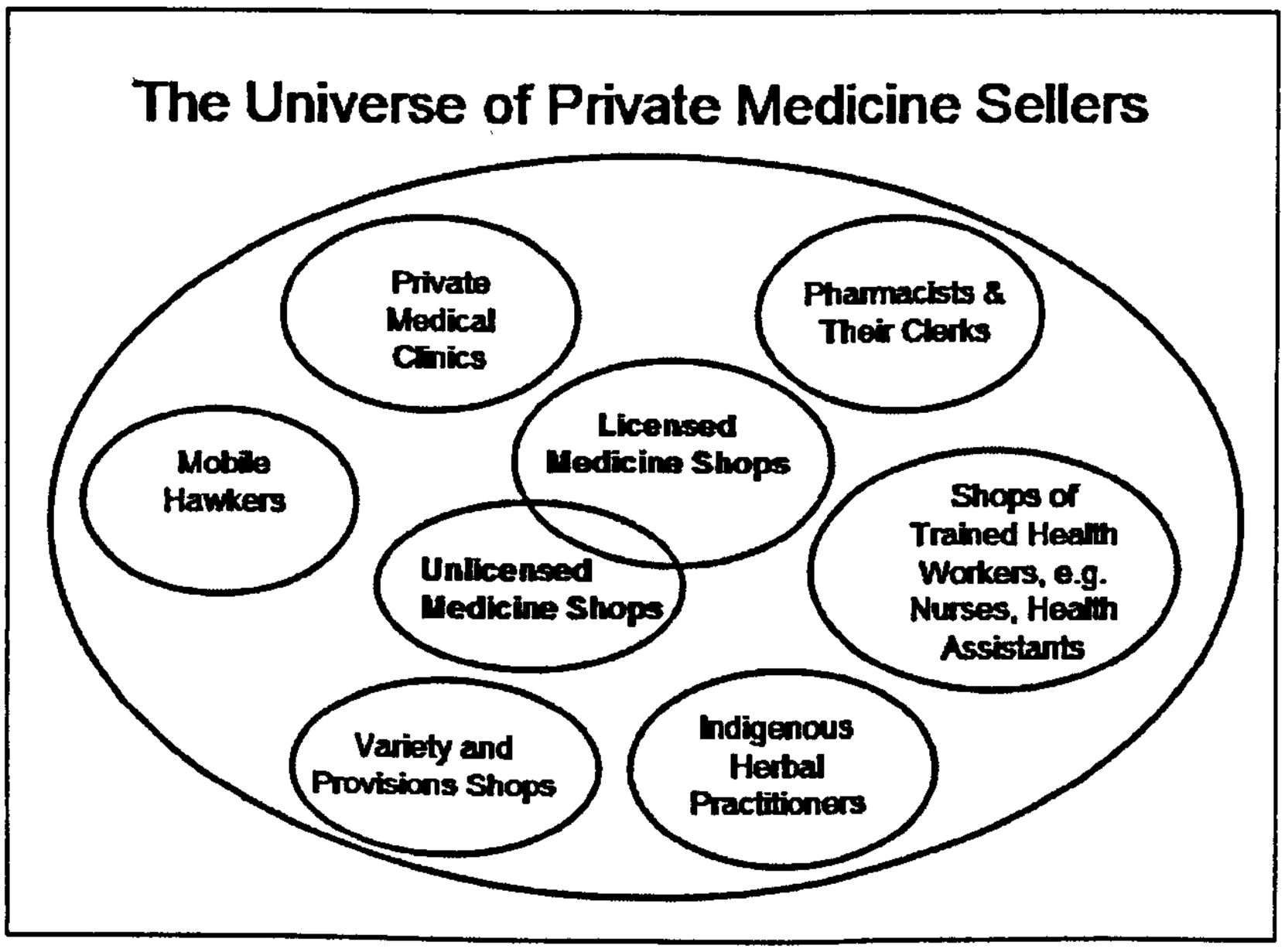
In terms of operational definitions, the term "home" in this context is used to refer to any action taken without contact with formal health practitioners (government/mission, non-governmental organisation (NGOs) or private health facilities). It includes use of drugs kept at home (left over medicines from previous episodes), purchase of medicines from any kind of medicine sellers, use of herbal remedies and consultation with traditional healers.

There are considerable variations in the type of medicine sellers described in different settings and the laws that regulate them, with each country having its own procedures and categories of licenses across SSA (Goodman et al., 2007a). Medicine sellers operate from specialist drug shops, general retail outlets, kiosks and market stalls, or as itinerant hawkers. In some of these situations, they may also sell a variety of other household goods (Goodman et al., 2004). Under national legislation, there are categories of medicines that can be sold over the counter (OTC) from general outlets, and these vary from country to country. OTC medicines often include aspirin, paracetamol, cough medicines and, in some countries, anti-malarial medicines. Other medicines are restricted to sales with a prescription and are sold through outlets

registered as pharmacies. However, PMRs have been reported to sell prescription medicines, such as antibiotics (WHO/RBM, 2005; Goodman et al., 2007a).

Similarly the terms used to describe medicine sellers varies, including drug sellers, shopkeepers, chemical sellers or patent medicine vendors (PMVs). An RBM technical advisory group recommended use of the term "medicine sellers" to capture the disparate groups of providers available in many settings. They used the term "universe of private sector providers" illustrated in figure 1.1 which includes a wide range of providers (WHO/RBM, 2005). The group of sellers who commercially retail medicines to communities with or without a prescription are referred to as private medicine retailers (PMRs) throughout this thesis.

Figure 1.1 Universe of private medicine sellers; Source: (WHO/RBM, 2005)



1.3.2 Studies reviewed and variables of interest

From the combination of the search strategy described earlier, 111 articles and three reviews were found relevant. Of these 102 full text articles and 12 abstracts were obtained and reviewed. Information extracted included country, location and year of

study, objectives and design, methods, setting (health facility or community based, urban or rural), recall period, type of illness, malaria transmission patterns and age of participants. Other variables included the proportion treated through PMRs or health facilities, given anti-malarial at home and given adequate malaria medicines by PMRs. Relevant data was used to construct table 1.1. The table contains 93 studies where quanitiatve outcomes of interest as well as qualitative information on care sekeing patterns of the above variables were provided. The proportion of illnesses first treated through PMRs refers to cases where use of PMR was reported. The proportion treated through health facilities includes where the first actions reported were the use of public, private, NGO or mission facilities. The proportion using any type of anti-malarial medicines at home includes those that were either purchased from PMRs or were kept at home, (including drugs sourced from health facilities from previous visits). The proportion that used anti-malarial medicines adequately from PMRs includes studies that reported use of anti-malarial medicines. Adequacy is based on a definition of each study.

1.3.3 Descriptive summary of the review

This section describes the geographical distribution, study design, methods, setting, transmission patterns, and types of illnesses, recall periods and the age groups included for all studies reviewed. The studies represented all the regions of Africa except North Africa. Only 16 studies from French speaking countries were reviewed, illustrating a potential limitation of generalising findings to the African region. Overall, 52 studies were based in West Africa, 48 in East Africa, 10 from South Africa and three from Central Africa. One study used demographic health survey data from 23 SSA countries.

Most studies (99/114) were descriptive cross-sectional surveys. Seven studies were longitudinal, three were retrospective, and two used demographic health survey data and ethnographic methods, respectively. 67/114 studies used quantitative data collection techniques, 12 were qualitative and 29 used both methods. Six studies involved blood sampling. Most studies were community based (95/114), 17 were based at a health facility while two included both. A majority (77) were conducted in rural areas, 15 were urban and another 15 compared urban and rural patterns of care seeking. This information was not available in 12 studies. Care seeking studies for fever or malaria have been conducted in almost all types of malaria transmission settings. Of those that reported transmission settings (62), 23 were conducted in endemic areas, nine each in holo-endemic and seasonal transmission areas, six in meso-endemic, three in epidemic type settings and four compared areas with different transmissions patterns.

Many studies focussed on febrile illnesses alone or as a proxy for malaria. For those that mentioned malaria (31), many of them did not define it. 28 studies described care seeking for acute illnesses. One study in Tanzania focussed on fatal illnesses (de Savigny et al., 2004). In addition to the type of illnesses, studies either reported treatment of actual illness or hypothetical situations, or both. For studies that focussed on actual episodes, information on recall periods was available in 62 studies. 35/62 studies used a two week recall period, 12 studies reported a one week period, while 3 studies reported a three week period. Three studies used three months, five used one month while two studies used 6 months and 5 years recall periods, respectively. These variations make inferences on the variables of interest difficult. Finally, most studies focussed on study participants below five years of age (56/114). 28 studies included adults and children, five studies considered pregnant women and four studies considered adults only.

Table 1.1: Care seeking patterns for fevers and malaria in sub-Saharan African countries

Country/Location/year of study	Recall period	Malaria transmission patterns	Age (years)	% first treated by PMRs *	% first treated in health facilities†	% given anti-malarial at home‡	% given adequate anti-malarial by PMRs	Reference
23 SSA countries	2 weeks	na	<3	11.3%	46.9%	na§	na	(Filmer, 2005)
Benin	2 weeks	na	<5	na	6%	na	na	(Fourn et al., 2001)
Burkina Faso: Tougan, Nouna, Solenzo 1994-1995	4 weeks	Holo-endemic	all	na	21%	na	na	(Krause and Sauerborn, 2000)
Burkina Faso: Nouna 1999	na	Holo endemic	<5	13%	17.1%	na	na	(Muller et al., 2003)
Cameroon: Bolifamba	2 weeks	Endemic	<5	Pre: 50.3%§ Post: 17.5%	Pre: 30.3% Post: 100%	na	na	(Nkuo Akenji et al., 2005)
Chad: Walia 2003	1 week	na	all	68.1%	28.9%	na	na	(Leonard, 2005)
Congo: Brazzaville 1997	2 weeks	na	<5	na	na	66%	na	(Talani et al., 2003)
Ethiopia: Adis Ababa 1991-1992	na	na	<10	45.1%	41%	na	na	(Yeneneh et al., 1993)
Ethiopia: Jimna town 2000	na	na	all	52.4%	66.6%	na	na	(Worku and Abebe, 2003)
Ethiopia: Butajira 1999	6 months	Seasonal	all	na	33.3%	92%	na	(Deressa et al., 2003a)
Ethiopia: Adami Tulu 2003	2 weeks	Seasonal	<5	na	52.9%	6.4%	na	(Deressa et al., 2007)
Ethiopia: Shewa, Oromio 2000	na	na	>15	40%	87%	78.8%	na	(Deressa et al., 2003b)
Gambia: 1996-1997	4 weeks	Seasonal	<5	na	na	na	na	(Clarke et al., 2003)
Ghana: Duffo, Dagme 1992-1993	na	na	<5	na	na	na	na	(Agyepong and Manderson, 1994)
Ghana: Keta 2002 -2004	2 weeks	Endemic	<5	67%	na	na	na	(Ahorlu et al., 2006)
Ghana: Kintampo 2004	na	1 day	<1	na	39%	na	na	(Bazzano et al., 2008)
Ghana: Chokor, Latebiokorshie 1998-1999	1 week	na	<5	27%	31.7%	na	na	(Biritwum et al., 2000)
Ghana: Ashanti 2002	2 weeks	na	all	71%	9%	91%	na	(Buabeng et al., 2007)
Ghana: Ablekuma, Berekuso 1978	na	na	all	na	na	na	na	(Gardner et al., 1984)
Ghana: Wassa , Kassena 1998-2001	na	Hyper-endemic	<10	na	na	95%	na	(Abuaku et al., 2004)
Ghana: Kassena-Nankana 2000-2003	2 weeks	Endemic	<5	24.3%	36.7%	na	na	(Owusu-Agyei et al., 2007)
Guinea : Conakry 1986	2 weeks	na	<5	na	4.4%	59%	na	(Dabis et al., 1989)

**Care sought through general retail shops, drug shops or other medicine sellers as defined by each study*
†includes both private and public health facilities
‡any action at home including, drugs from shops, traditional healers left over drugs from various sources, herbs
§Na- not given,
§ for studies with pre and post data only pre intervention data was used, for studies done in either urban and rural or wet and dry, the average was used for the estimations of median proportion

Table 1.1 continued

Country/Location/year of study	Recall period	Malaria transmission patterns	Age (years)	% first treated by PMRs	% first treated in health facilities	% given anti-malarial at home	% given adequate anti-malarial by PMRs	Reference
Guinea: Telimele, Kindia 1988	na	Endemic	Adults	na	Rural:33% Urban :69%	na	na	(Glik et al., 1989)
Guinea: Mafe`rinyah 1999	1 day	Meso-endemic	<5	na	13.1%	18%	na	(Diallo et al., 2001)
Kenya: Kwale, Makueni, Busia 2004	2 weeks	Varying	all	47.1%	na	22.7%	12.1%	(Abuya et al., 2007)
Kenya: Kwale, Makueni, Bondo, Kisii 2001	2 weeks	Varying	<5	26.1%	38.7%	na	na	(Amin et al., 2003)
Kenya: Ganze 2003-2004	2 weeks	Endemic	all	Wet: 47.9% Dry: 43.9%	Wet: 22.5% Dry: 12%	na	na	(Chuma et al., 2006)
Kenya: Kilifi 2003-2004	2 weeks	Endemic	all	Rural: 54.7% Urban: 50.1%	na	na	na	(Chuma et al., 2007)
Kenya: Ugingo village, Usigu	1 week	na	children	na	na	na	na	(Geissler et al., 2000)
Kenya: Kwale, Makueni, Bondo, Kisii 2006	2 weeks	Varying	<5	47.1%	35.3%	30.9%	na	(Gitonga et al., 2008)
Kenya: Gucha 2000	2 weeks	Unstable	all	47%	26%	na	na	(Guyatt and Snow, 2004)
Kenya: ,Bungoma 1996	2 weeks	Endemic	<5	na	43%	32%	na	(Hamel et al., 2001)
Kenya: Makunga 1997/98	1 week	Endemic	pre school	32.4%	30.4%	na	na	(Mbagaya et al., 2005)
Kenya: Kilifi	2 weeks	Endemic	<10	Rural: 47% Urban: 46%	Rural : 25.1% Urban: 14.4%	na	na	(Molyneux et al., 1999)
Kenya: Kilifi	2 weeks	endemic	<10	Rural: 48.9% Urban: 45.7%	Rural : 36.1% Urban: 33.1%	na	na	(Molyneux et al., 2002)
Kenya: Baringo 1992	2 weeks	na	all	4.8%	88.2%	na	na	(Munguti, 1998)
Kenya: Kilifi	2 weeks	Endemic	<5	58.0%	25.4%	na	na	(Mwenesi et al., 1995)
Kenya: Suneka 1997	na	Epidemic	all	na	14.3%	na	na	(Nyamongo, 2002)
Kenya: East Asembo Kisumu 1990-1991	1 week	Holo-endemic	<6	47.2%	18%	na	na	(Ruebush et al., 1995)
Liberia: Bomi, Granb Cape 1984	na	na	7	21.8%	24.0%	na	na	(Foster et al., 1993)
Malawi: Blantyre 2003	2 weeks	na	<5	78%	58%	66.5%	4.9%	(Holtz et al., 2003)
Malawi: National 2000	2 weeks	na	<5	35%	27.5%	na	na	(Kazembe et al., 2007)
Malawi: Nationwide	2 weeks	na	children	na	52%	56%	na	(Slutsker et al., 1994)
Mali: Bandiagara, Sikasso 2002/03	2 weeks	na	<16	na	8.50%	na	na	(Diallo et al., 2006)
Mali: Yanfolia 1998	5 months	na	<5	na	7.6%	na	na	(Thera et al., 2000)

Table 1.1 continued

Country/Location/year of study	Recall period	Malaria transmission patterns	Age (years)	% first treated by PMRs	% first treated in health facilities	% given anti-malarial at home	% given adequate anti-malarial by PMRs	Reference
Niger: Niamey, 1992 Karma 1994	na	Endemic	na	na	81.9%	na	na	(Julvez et al., 1995)
Nigeria: Lagos State	na	na	<5	na	na	na	na	(Adegboyega et al., 2005)
Nigeria: Masseey hospital,Lagos 1996	na	na	Children	na	na	30%	na	(Afolabi et al., 2004)
Nigeria :University college Ibadan	na	na	<10	87.7%	na	36.5%	15.2%	(Ajayi and Falade, 2006)
Nigeria: Ibadan, maternity hospital	1 week	na	pregnant women	na	na	na	na	(Akanbi et al., 2005)
Nigeria: Benue valley, Adamawa 1999	na	na	<5	29%	10.7%	na	na	(Akogun and John, 2005)
Nigeria: Abeokuta health facilities 2001/2002	na	na	<5	na	17%	90%	na	(Dada and Omokhodion, 2007)
Nigeria: Aboh Mbaise 1988	2 weeks	na	<5	na	40.9%	70.3%	na	(Ejezie et al., 1990)
Nigeria: South West	na	na	all	na	na	na	na	(Falade et al., 2005)
Nigeria	2 days	na	<5	na	na	na	na	(Fawole and Onadeko, 2001)
Nigeria: Abia, Anambra	3 months	na	<5	na	na	na	na	(Ibeh et al., 2005)
Nigeria:Ijegemo, Ogun	na	na	<5	na	28%	na	na	(Ibidapo, 2005)
Nigeria: Enugu 2002	na	Holo-endemic	<5	46%	24%	na	na	(Oguonu et al., 2005)
Nigeria: Imesi-Ile 1990	2 weeks	Endemic	Pregnant women	na	na	na	na	(Okonofua et al., 1992)
Nigeria: Idere, ukehe, mbaugwu	2 weeks	na	<5	46.3%	46.3%	na	na	(Salako et al., 2001)
Nigeria: Osun state hospital 2004	na	na	<14	na	na	83.2%	26.6%	(Senbanjo et al., 2006)
Nigeria: Ihiala, Nwewi, Isi, Oji	1 month	na	all	36%	49.3%	na	na	(Uzochukwu and Onwujekwe, 2004)
Nigeria: Modakeke, Ile-Ife 2002	na	na	<5	na	13.5%	61.2%	na	Olaogun et al 2005
Nigeria: Enugu, Udi ,Inyi, Oji in Oji-River	na	Endemic	all	45.3%	27.1%	na	na	(Onwujekwe et al., 2008)
Nigeria: Enugu 2002	na	Holo-endemic	<5	46%	24%	na	na	(Olaogun et al., 2005)
Senegal: M'Backe	na	na	all	na	72.6%	na	na	(Faye et al., 2007)
Senegal: Fatick 2001	7-18 days	Endemic	<5	na	75%	18.2%	na	(Franckel and Lalou, 2008)
Senegal: Dakar 2003	na	na	all	na	na	na	84%	(Ndiaye et al., 2006)
Senegal: Gossas 2005	na	na	all	na	na	13%	na	(Ndour et al., 2006)
Sudan: Gezira 1995	1 week	na	all	na	na	na	na	(Abdel-Hameed, 2001)

Table 1.1 continued

Country/Location/year of study	Recall period	Malaria transmission patterns	Age (years)	% first treated by PMRs	% first treated in health facilities	% given anti-malarial at home	% given adequate anti-malarial by PMRs	Reference
Sudan: Kordofan/Umadara	na	Meso to hyper-endemic	<5	na	84.4%	na	na	(Malik et al., 2006a)
Tanzania: Rufiji, Kilombero 1991	na	endemic	<5	8.1%	44.7%	na	na	(de Savigny et al., 2004)
Tanzania: Kagera, Mwanza , Mara	3 months	na	<5	na	73%	na	na	(Kaatano et al., 2006)
Tanzania: Mnazi Moja dispensary	na	na	all	na	na	na	na	(Mnyika et al., 1995)
Tanzania: Kilombero, Ulanga, Rufiji	2 weeks	Perennial	<5	56.4%	28%	na	na	(Njau et al., 2006)
Tanzania: Kabaha 1997	na	Perennial	<5	na	21%	22%	na	(Nsimba et al., 2002)
Tanzania: Kibaha	na	na	<5	75%	na	22%	na	(Nsimba and Rimoy, 2005)
Tanzania: Kibaha 1995	3 months	Holo-endemic	<5	na	75%	na	na	(Tarimo et al., 1998)
Togo: Plateux region 1984	3 weeks	na	<5	na	20%	94%	na	(Deming et al., 1989)
Uganda: Rakai	na	na	all	na	Child: 32% Adult: 49%	na	na	(Amuge et al., 2004)
Uganda: Mulago parish 2004	2 weeks	Meso-endemic	<10	55%	34.8%	57.1%	61.1%	(Kemble et al., 2006)
Uganda: Kabale Town	na	Epidemic	all	adults: 27.2% Child: 25.4%	Adults: 64.8% Child: 61.8%	na	na	(Lindblade et al., 2000)
Uganda: Mulago Hospital 1992	7 days	na	<5	na	na	50%	na	(Lubanga et al., 1997)
Uganda: Sembabule	na	na	<2	na	na	na	na	(Mbonye, 2003)
Uganda: Mukono 2002-2003	2 weeks	Hyper-endemic	all	38.3%	32.8%	na	na	(Mbonye et al., 2006)
Uganda: Kogoborya Hoima,	na	na	pregnant women	56%	60.6%	na	na	(Ndyomugyenyi et al., 1998b)
Uganda: Kamwezi in Kabale 2001/03	1 day	Low unstable	all	87.3%	10.9%	na	na	(Ndyomugyenyi et al., 2007)
Uganda: Tororo and Busia	na	na	<5	75%	na	40%	na	(Nshakira et al., 2002)
Uganda: Kasese 2002	2 weeks	Meso-hyper-endemic	<5	43%	53%	na	na	(Nsungwa-Sabiiti et al., 2005)
Uganda: Mbarara	na	Meso-endemic	<5	22.8%	75.4%	na	na	(Nuwaha, 2002)
Zambia: Kitwe, Lufwanyama 1997	3 weeks	na	<5	na	70%	na	na	(Baume et al., 2000)
Zambia: Mporokoso, Choma,	na	Endemic	Adults	na	59.5%	na	na	(Kaona et al., 2000)
Zimbabwe: Uzumba Maramba Pfungwe , Hurungwe, Mount Darwin, Bulilimamangwe, Chipinge	na	na	all	na	85.4%	na	na	(Tsuyuoka et al., 2001)

1.3.4 Use of PMRs for treatment of fevers and malarial illnesses

The literature on care seeking for fevers and malaria illustrates that the types and sources of care available vary between countries and with urban/rural areas. Care seeking occurs in a pluralistic health system with complex patterns involved. Both quantitative and qualitative evidence exist to show the importance of PMRs as a first source of treatment for childhood and adult illness before visiting a health facility, and as a major source of anti-malarial medicines (Williams and Jones, 2004). This section reviews evidence on patterns of use of PMRs compared to health facilities, reasons behind their popularity and the quality of care given.

Patterns of use of PMRs are drawn from the use of PMRs in table 1.1 and the conclusions of the authors in the reviews used. Regardless of type of illnesses, age, urban or rural settings or malaria transmission patterns, use of PMRs is common in many parts of SSA. The proportion using PMRs before visiting a health facility ranged from 4.8% in an area of low transmission in Kenya (Munguti, 1998) to 87.7% in heath facility-based survey among children in an endemic area of Nigeria (Ajayi and Falade, 2006). A high proportion of use (87.3%) was also reported in a field-based survey among pregnant women in Uganda (Ndyomugyenyi et al., 1998a). The proportion of illnesses treated through PMRs as a first action did not vary with studies conducted among children or adults recall periods, health facility or community based surveys. However, it appeared to vary with urban or rural settings. Seven studies reported use of PMRs in urban areas and 29 in rural settings. One study reported similar proportions of use amongst urban and rural residents (Molyneux et al., 1999; Chuma et al., 2006). Also one study showed that most poor respondents used PMRs, traditional healers and community health workers (CHWs) more often than other treatment options, while the

least poor used private clinics (Uzochukwu and Onwujekwe, 2004). But overall, PMRs are used by all socio-economic groups.

Use of PMRs as a source of care is often done promptly after symptoms are recognised (Deming et al., 1989; Molyneux et al., 1999; Amin et al., 2003; Holtz et al., 2003; Ahorlu et al., 2006; Gitonga et al., 2008). PMRs are patronised for a variety of reasons including physical proximity compared to health facilities (Glik et al., 1989; Yeneah et al., 1993; Mwenesi et al., 1995; Baume et al., 2000; Muller et al., 2003). PMRs are also used if carers perceive the illness to be less severe or because outlets are thought to have a reliable drug supply (Mwenesi et al., 1995; Afolabi et al., 2004; Ibeh et al., 2005). Other reasons include their ability to respond to community pressures by selling drugs in accordance to clients needs (Okeke et al., 2006), they are friendly, offer credit to clients, and are often cheaper than health facilities (Glik et al., 1989).

Despite their popularity, there are concerns on the quality of care given, especially on the type of medicines and the way they are administered. Most studies do not report clearly the proportion that obtained anti-malarials from PMRs for fever or malaria (McCombie, 2002). For studies that reported types of drugs sourced from PMRs, the most frequently reported drugs bought were anti-pyretics (Agyepong, 1992; Snow et al., 1992; Agyepong and Manderson, 1994; Slutsker et al., 1994; Mwenesi et al., 1995; Baume et al., 2000; Tarimo et al., 2000; Thera et al., 2000; Amin et al., 2003; Ajayi and Falade, 2006). Given that many fevers in malarious areas may be due to malaria (Kachur et al., 2006), and since WHO recommends presumptive treatment of childhood fevers as malaria in endemic settings, this common use of anti-pyretics for childhood fevers is likely to contribute to perceived burden of disease.

A few studies reporting on the use of anti-malarials purchased from PMRs included information on dosage patterns (Krause and Sauerborn, 2000; Thera et al., 2000; Holtz et al., 2003; Marsh et al., 2004; Ajayi and Falade, 2006; Senbanjo et al., 2006; Abuya et al., 2007). From table 1.1 only six studies had information on dosing with anti-malarial medicines sourced from PMRs. Measures of adequacy varied between studies, influencing interpretation of the summary statistic and making it difficult to compare across studies (McCombie, 1996; McCombie, 2002). The highest proportion (61.1%) was recorded in a hospital based study in Uganda (Kemble et al., 2006) and the lowest (4.9%) in a community survey in Malawi (Holtz et al., 2003).

In summary, key lessons learned from this review include:

- Many fevers are first treated at home with OTC medicines in the majority of sites where this has been studied. This occurs in both rural and urban areas, and where use of OTC anti-malarials at home is common (Williams and Jones, 2004). It also illustrates that this occurs in different malaria transmission settings.
- There are numerous descriptive studies on care seeking patterns for fever or malaria covering almost all regions of Africa. However, differences in the methods used make comparisons across studies difficult. There is therefore need for improved methodological rigour, including defining terminologies, to allow for cross site comparison (McCombie, 2002; Williams and Jones, 2004).
- The evidence around the use of PMRs as a source of care generates an understanding of the importance of strategies to improve management of fevers and malaria at home.

The next section describes interventions that sought to address the problems of quality of care given for febrile or malarial illnesses at home.

1.4 Home Management of Malaria

1.4.1 Historical overview of HMM

HMM is an integral part of malaria case management within the RBM strategy and includes services offered by the community and the formal and informal private health sectors. It aims to ensure effective care for non-immune persons such as young children (under five years) and pregnant women. It may be applicable to both adults and children in low to moderate transmission areas (WHO, 2005a). WHO defines HMM, as "...early recognition of and prompt and appropriate response (treatment) to malarial illness in children under 5 years of age outside the health facility setting within the home or community"
(http://www.who.int/malaria/homemanagement.html accessed 24 July 2008).

The history of HMM can be traced back to recognition of the need for interventions to improve care sought outside formal health care settings (section 1.3). Although community based approaches to malaria and other illness control existed, renewed efforts to fight malaria through community involvement gained momentum in 1997 through a meeting of Heads of State from the then Organization of African Unity. An outcome of this meeting was the formation of Africa Initiative for Malaria in April 1998, which later merged with the RBM initiative to advance malaria control efforts for the African region.

Meanwhile, in early 2000, a working group in the WHO-African Regional Office (AFRO) was formed to develop strategies for community-based interventions. In April

2000, a meeting brought in several WHO-AFRO departments, including RBM, and the Integrated Management of Childhood illnesses (IMCI), to develop a framework for community based interventions. In August 2000, a draft document on the framework was developed (WHO, 2000b). This was followed by two regional workshops, which marked the first steps towards scaling up experiences on the role of communities in the implementation of curative and preventive malaria activities. These meetings brought together participants working with communities to share experiences and develop country specific action plans for the promotion of community-based interventions for malaria control.

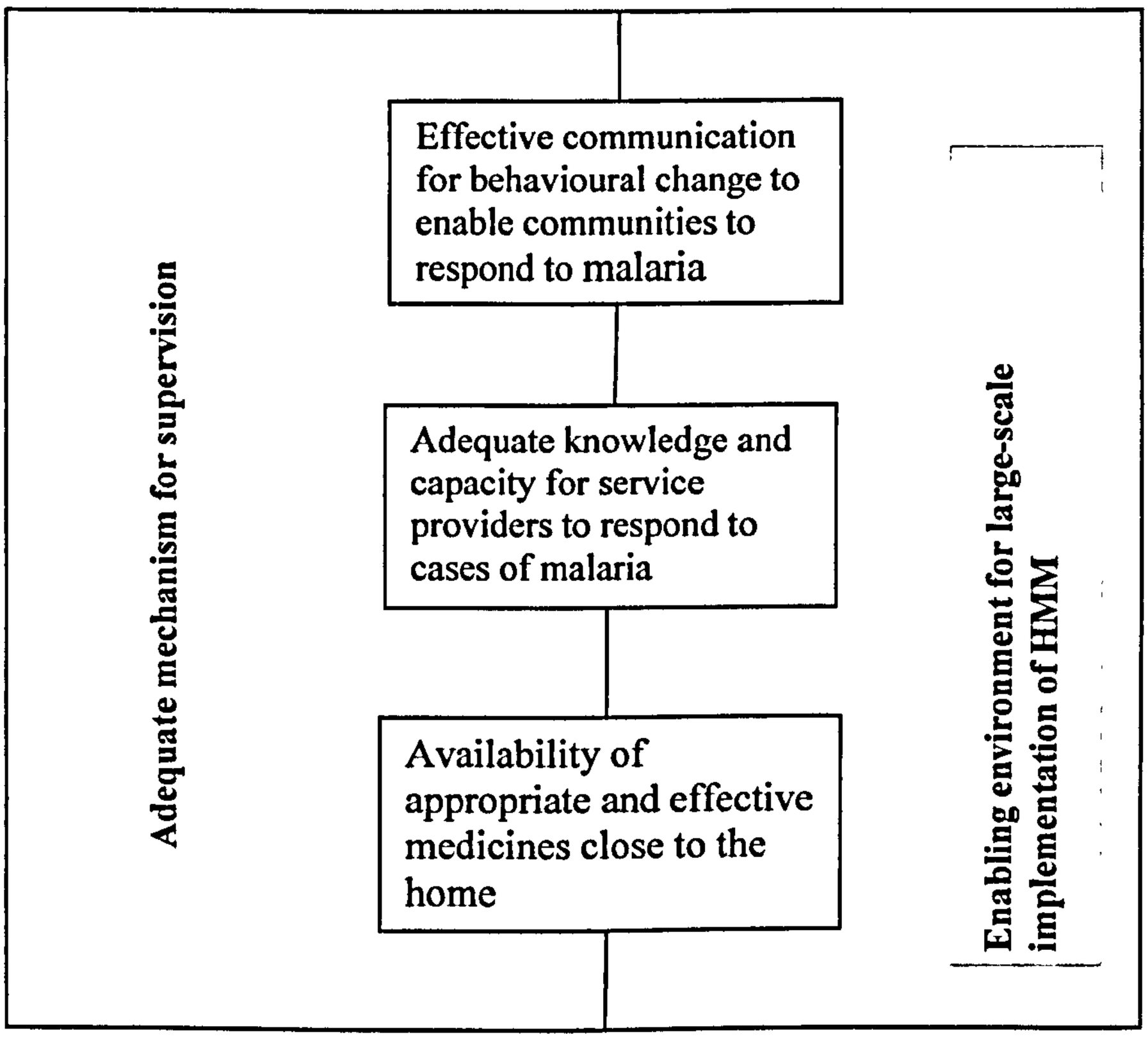
In the global arena, RBM continued to develop the HMM strategy. In 2000 WHO set up a task force on HMM to make an assessment of priorities and needs, and to update the HMM research agenda. The research agenda was presented in the Tropical Disease Research (TDR) division of WHO to shape the work plans for 2001 (WHO/TDR, 2000). Based on these efforts and given the evidence on the importance of the approach, a workshop was held in Geneva in 2002 to develop a framework for scaling up HMM, and an action plan to support HMM in African countries (WHO, 2004a). In 2004, a WHO technical team on HMM met in Zimbabwe to develop a generic strategy of HMM, defined the key components and set goals and objectives (WHO, 2005a). WHO adopted the HMM strategy which was subsequently included in the national control strategies of more than 22 African countries (WHO, 2004a; WHO, 2004b; WHO, 2005b). The implementation of HMM in Kenya is presented in chapter two.

1.4.2 Objectives and strategic components of HMM

The main objective of the HMM strategy is to reduce severe malaria morbidity and mortality among children under five. Specifically, the strategy seeks to increase the capacity of caregivers to recognize malaria illness promptly and take early appropriate

action; to empower service providers by imparting adequate knowledge, skills and capacity to respond to malaria illness appropriately; and to create an enabling environment for implementation (WHO, 2005a). The strategic components of HMM are presented in figure 1.2. National control programmes are encouraged to implement HMM as a package to achieve the strategy's main objectives. This thesis aimed to contribute to the current understanding of the strategic component that focuses on imparting skills and knowledge to PMRs (WHO, 2005a).

Figure 1.2 Strategic components of HMM (WHO, 2005a)



1.4.3 Interventions to improve HMM using PMRs in SSA

Based on the strategic approaches for HMM (figure 1.2), this section describes interventions aimed at improving PMRs knowledge as part of HMM in SSA (WHO, 2004a; WHO, 2005a). A recent review on medicine sellers in SSA was used to summarise existing evidence on these interventions (Goodman et al., 2007a). This review was updated by a further search in PubMed using the following search terms:

medicine sellers, drug shops, retail sector, chemical sellers, general shops, patent medicines vendors, with Sub Saharan Africa and malaria. In addition, websites of organisations included in Goodman's review with projects focusing on PMRs and malaria control were accessed for any recent reports on PMR interventions. These sites included Population Services International (PSI), the Clinton Foundation, WHO/TDR and Cry for the Word Foundation (CFW^{TM}). Other contacts or actors involved in developing or supporting HMM initiatives in SSA were also consulted for information on ongoing PMR activities.

From the search strategy, 66 articles were identified. 61 articles had information on PMRs describing the role, characteristics of retail sector, regulatory mechanisms, and behaviour of PMRs and patterns of use of the sector by community members in different geographical settings. Five described PMR interventions in SSA. By accessing the websites described above, three reports describing on-going interventions were identified. One publication reporting outcomes of PMR interventions to improve access to ACT medicines in Tanzania was identified through contacts. A summary of these studies is presented in table 1.2. The table was adapted from Goodman's review by restructuring and adding one column to describe key outcomes and evaluation methods.

There were 19 interventions identified that aimed to improve treatment of malaria through PMRs in SSA. Geographically, five were based in Nigeria, six in Kenya, two each in Uganda, Ghana and Tanzania, and one each in Madagascar and Zambia. Some studies in Kenya and Uganda were implemented as part of scaling up PMR interventions within a national HMM strategy. The interventions were implemented in areas of different malaria transmission areas ranging from holo-endemic, seasonal transmission and epidemic type settings, mostly in rural areas. The number and type of

PMRs involved in the interventions varied as did their distribution, the size of the interventions and their regulatory frameworks.

1.4.4 Nature of interventions involving PMRs

All the interventions involved some form of training, demand generation or consumer information. Three studies used franchise or accreditation networks, and almost all interventions (except one) involved working with existing PMRs (Goodman et al., 2007a). In addition, all interventions except one (piloting use of ACT in Tanzania), involved improving knowledge in the use of SP, CQ or AQ anti-malarial medicines.

The major intervention components identified were training or capacity building, demand generation, quality assurance, and creating an enabling environment (Goodman et al., 2007a). Training was through 2 to 4 day participatory workshops or peer education at the shop (PSI Nigeria; Health communication project, 2003; Kaona and Tuba, 2003; Tavrow et al., 2003). Training content covered malaria causes and treatment, drug use, communication, referral, safety, regulatory law, management skills, and franchising principles (Goodman et al., 2007a). One intervention in Uganda used negotiation sessions to identify achievable behaviour changes targets (Tawfik et al., 2006).

Demand generation was accomplished through mass media or public information activities (PSI Madagscar; PSI Nigeria; Muturi, 2001; Brieger et al., 2002; Health communication project, 2003; Ndomondo-Sigonda et al., 2003; Tavrow et al., 2003; Marsh et al., 2004; ACCESS Programme, 2005). Messages on product information and malaria treatment were communicated using channels such as television, radio, mobile video units, posters, billboards, leaflets, flyers, point of sale stickers, promotional material, and special events (Goodman et al., 2007a). Other projects trained community volunteers to promote appropriate medicines and use of trained PMRs

(Brieger and Ogulande, 2001; Brieger et al., 2002; Kaona and Tuba, 2003; Tavrow et al., 2003; Marsh et al., 2004). Subsidies on pre-packaged anti-malarial drugs were promoted in programmes in Tanzania and Nigeria (PSI Madagscar; The steadman Group, 2007).

Table 1.2: PMR interventions to improve malaria related activities in SSA adapted from (Goodman et al., 2007a)

Country: Study/project, Year intervention began, Number and Type of PMRs involved	Nature of Intervention	Evaluation design /Methods	Key Outcomes	References
Kenya: Changing home treatment by training shopkeepers; 1999; General retail shop keepers, n=285	Training and demand generation skill-based participatory 4 day workshops for medicine retailers, provision of job aids, on-going monitoring, and community information activities to promote appropriate sales of anti-malarials	Pre-post with control on community drug use and provider behaviour using surrogate client surveys, household surveys and qualitative studies	% of OTC anti-malarial users receiving adequate dose rose from 8%-33% between 1998 and 1999. % of shop treated fevers within 24 hours rose from 1% to28% by 2001.	(Marsh et al., 1999; Marsh et al., 2004)
Kenya: Vendor-to-vendor (VTV) education in Bungoma; 2003; Wholesale counter attendants, mobile suppliers, retail shops and kiosks, retail pharmacies, private clinics, n=73 wholesalers and over 500 general retails shops reached	Training, Information, Education and Communication (IEC) materials, one day training of wholesalers and mobile vendors as outreach educators. Participants equipped with job aids and posters for distribution to smaller outlets. A neighbour-to-neighbour component, added later to increase demand for anti-malarials	Post hoc evaluation of control and intervention on provider behaviour and knowledge using surrogate clients surveys, retail census and qualitative study	38 % of intervention PMRs selling SP medicines accompanied with information on correct dose compared to 15% in the comparison group	(Tavrov et al., 2002; Tavrow et al., 2003)
Kenya: Training retailers in correct use of OTC anti-malarials; 2001; retail drug shop owners, n=255	Training, IEC materials, job aids, demand generation activities in the community. 2-day training sessions, supportive supervision.	Pre-post on provider knowledge using interviews and review of records	60% of trained PMR treat simple malaria with correct drug amodiaquine (AQ) and give dosage according to age	(Muturi, 2001)

Country: Study/project, Year intervention began, Number and Type of PMRs involved	Nature of Intervention	Evaluation design /Methods	Key Outcomes	References
Kenya: Training PMRs in over 33 districts on correct management of anti-malarials as part of scaling up HMM; 2005, n=747	Training, demand generation, Skill-based participatory 2-day workshop of general retailers, provision of job aids, on-going monitoring, and community information activities to promote appropriate sales of anti-malarials	Post intervention cluster randomised design using surrogate client survey and retail audit in three districts	Outcomes from one district part of this thesis[1]	(Ministry of Health, 2006)
Kenya: Child and Family Wellness Shops (CFWshops™); 2003; CHWs trained by the project operate shops and clinics under franchise, n=42 shops	Quality assurance and training, establish new clinics and shops in underserved areas to provide quality, standardized products, run by trained and supervised CHWs. Manuals provided on diagnosis, treatment and drug management.	na	na	(Ombogo, 2005)
Kenya: Evaluating the introduction of Artemether lumefantrine (AL) into selected clinics operating CFW franchising system in Kirinyanga, Embu and Mbeeere districts, 2005	Involved improving access to ACT medicines	Pre and post using exit interviews, household interviews; qualitative -key informant: studies and focus group discussions (FGDs)	15% claim to have taken AL. 45 respondents (33%), reported taking an adequate dose	(The steadman Group, 2007)
Nigeria: Primary care training for medicine vendors in a rural community; 1992, PMVs and their apprentices, n=37	Training: eight- two hour training sessions on primary care. Designed with a PMV training committee, selected by the local PMV association.	Pre-post with control on provide knowledge using informant interviews, observation and document review	Trained PMV had higher mean score of knowledge 71.6% versus 43.2% pre training	(Oshiname and Brieger, 1992)

[1] Results from two other districts presented as annex

Country: Study/project, Year intervention began, Number and Type of PMRs involved	Nature of Intervention	Evaluation design /Methods	Key Outcomes	References
Nigeria: Promoting pre-packaged drugs for prompt and appropriate treatment of fever in rural, 2002; PMV, Volunteer Village Health Workers, and Auxiliary Health facility Staff, n=12	Training, demand generation and pre-packaged drugs and job aids. Three types of distributors were trained to promote and sell age-specific pre-packaged anti-malarials and cotrimoxazole for preschool-aged children. Community health education also undertaken	Pre and post on community drug use and provider choice		(Brieger et al., 2002)
Nigeria: Improving home based management of fever in Abia State, 2003 Informal retail drug sellers, PMVs/ Catchment Area Planning and Action Committees PMVs; n=1,031	Training, demand creation and pre-packaged drugs. Social marketing, mass media, community mobilization, and PMV training. Master trainers trained for cascade training of fellow PMVs. Supportive materials include shop danglers, stickers, job aids, customer handbills and training handbooks.	Pre and post on provider behaviour and knowledge using surrogate client survey and inventory of providers	A nearly six-fold increase in PMVs "recommending or giving the correct dose" (from 9% to 53%)	(Greer et al., 2004)
Nigeria: Community Partners for Health: urban health coalitions. (1994) BASICS PMVs / community-based organizations (CBOs), n= 49 PMVs	Quality assurance, training building on the successful partnerships between CBOs and private health facilities, attempts were made to encourage PMVs to join the partnership for training and community accountability.	na	na	(Brieger and Ogulande, 2001)

Country: Study/project, Year intervention began, Number and Type of PMRs involved	Nature of Intervention	Evaluation design /Methods	Key Outcomes	References
Madagascar: Pre-packaged malaria treatment for children, 2003; Doctors, pharmacists, wholesalers and retailers in malaria endemic areas n=2800 general retailers	Social marketing of pre-packaged drugs. Subsidised pre-packaged CQ kits for 2 age groups, with clear labelling and instructions, mass media promotion, marketed to doctors, pharmacists, wholesalers and retailers.	na	na	(PSI Madagscar)
Nigeria: Pre-packaged malaria treatment for children, 2003, Hospitals, clinics, pharmacies and PMVs n=3600 PMVs trained; product reaches potential market of 300,000	Social marketing of pre-packaged drugs Pre-packaged CQ kits for two age groups for uncomplicated malaria, with labelling and instructions, mass media promotion, sold through major wholesalers and sub-distributors, job aids for PMVs. Follow up and training of pharmacists and PMVs.	na	na	(PSI Nigeria)
Uganda: Utilizing the Potential of Private Health Practitioners in Child Survival, 2003, Drug sellers: n=9	Training, policy formulation and negotiation sessions with private health practitioners targeting specific practices related to case management of childhood diarrhoea, fever. Two to three moderators conducted negotiation sessions for 20–30 private practitioners, with follow-up monitoring and support visits.	Pre-post on provider knowledge using provider survey	For diarrhoeal % of providers who recommended continued feeding (from 4% to 20%; $P < 0.006$), and increased fluids intake or (from 11% to 45%; $P < 0.001$).	(Tawfik et al., 2006)

Table 1.2 continued

Country: Study/project, Year intervention began, Number and Type of PMRs involved	Nature of Intervention	Evaluation design /Methods	Key Outcomes	References
Uganda: Partnering with traditional healers and drugs sellers, 2001 in Ssembabule, Uganda, *CORE Group* Traditional Birth Attendants (TBAs), traditional Healers and Drug Vendors, n= 50	Training, job aids, awareness-raising events. Part of a district child survival project; TBAs, traditional healers, and drug vendors trained for three days. Calendars and poster produced as communication aids for vendors.	Pre-post on consumer knowledge and provider choice	Mothers' knowledge of appropriate CQ dosage increased from 6% in 1996 to 41 % in 2000.Twice as many mothers knew the correct CQ dosage for children under two years of age in 2000 as compared with 1996.	(The CORE group, 2004)
Zambia: Improving household use of CQ, 2000, Kanoa and Tuba. Village health motivators (VHM) including drug vendors, n=81	Training and community information VHMs and vendors trained for 14 days as communicators of malaria knowledge and correct dose information, and supplied with symptom manual. Vendors provided with dosage guides for distribution to clients.	Pre and post with control on consumer knowledge using interview schedule	There was 60% increase in adequate CQ dosage in all age groups in careers in post intervention wards	(Kaona and Tuba, 2003)
Ghana: Healthy Happy Homes, 2002 *Ghana Health Service / RBM /Kinapharma* Chemical shop owners and shop attendants shop owners: n=1,035 Shop attendants: n=362	Demand generation and training. Radio drama from Home-Based Care initiative communication campaign. Aimed to educate, motivate, and demonstrate issues related to malaria and other childhood illnesses. Pharmaceutical company conducted training. Chemical sellers distributed IEC materials	na	na	(Health communication project, 2003)

Table 1.2 continued

Country: Study/project, Year intervention began, Number and Type of PMRs involved	Nature of Intervention	Evaluation design /Methods	Key Outcomes	References
Ghana: Essential Medicines Franchise, (CAREshops), 2003, Pre-existing licensed chemical sellers n=221	Quality assurance, training and marketing. Conversion of existing chemical sellers shops into network of essential medicines franchises. 5-week training and branding of facilities. Owners had access to pooled procurement of high quality medicines at affordable prices.	Pre-post on provider knowledge	% Asking questions about symptoms form 50% to 59%, % sold anti-malarial 50%-62%	(Idun et al., 2005; Mensah, 2005)
Tanzania: Pilot ACT Subsidy Programme 2007	Training, accrediting, pre-packaging of AL demand generation through community information in ADDO rural areas	Pre and post using surrogate client surveys, exit interviews, retail audits	30% of 400 customers interviewed bought ACT drugs however only 26% of were for under fives	(Clinton Foundation, 2007)
Tanzania: Accredited Drug Dispensing Outlets (ADDOs), 2002. Pre-existing small drug retailers (Duka la dawa baridi)	Quality assurance, accrediting, training, regulatory action and brand marketing Short course formal training of drug retailers. Accreditation of participants and licensing to sell wider variety of essential drugs, including antibiotics and anti-malarials. Creation of new cadre of pharmaceutical outlets combined with marketing and commercial incentives. Regulation decentralized to ward level	Pre-post with control on provider behaviour using surrogate client surveys, exit surveys and retail census	75% of shops reported drug in stock.	(Ndomondo-Sigonda et al., 2003; ACCESS Programme, 2005; Hetzel et al., 2007)

Goodman and colleagues (2007) further identify ways in which quality assurance was implemented, namely, franchising or accreditation, consumer accountability, engaging a medicine seller association, or monitoring and supervision (Goodman et al., 2007a). Franchising or accreditation entailed specific recognition of trained outlets through painted logos, posters, or stickers that identified them as programme outlets. The networks were publicised through identifiable names, brands, and logos. Franchising or accreditation was key in three projects, CFWshops™ in Kenya, ADDOs in Tanzania, and CARE shops in Ghana (ACCESS Programme, 2005; Mensah, 2005; Ombogo, 2005) and in one study pre-packaged anti-malarial drugs were promoted (Greer et al., 2004).

Finally, only five studies addressed creation of an enabling environment through drug policies and regulations (PSI Nigeria; Greer et al., 2004; ACCESS Programme, 2005; Mensah, 2005; Tawfik et al., 2006). Interventions which utilised franchising principles also provided credit facilities to PMRs (http://www.cfwshops.org; Ndomondo-Sigonda et al., 2003; Mensah, 2005). In Tanzania the pilot project on improving access of ACT worked with the national drug board to deregulate ACT use in the programme areas (The steadman Group, 2007). The development of PMR interventions implemented in Kenya and those evaluated in this thesis are described in chapter two.

1.4.5 Impact of interventions on PMR knowledge and practices

Fourteen PMR interventions were evaluated and documented improvements in knowledge and practices of PMRs. Most studies relied on methods such as retail audits, exit surveys, surrogate client surveys and in some cases record reviews to examine an impact on PMR knowledge or practices. Evaluation designs were generally weak, with most relying on pre and post data without a control group (Goodman et al., 2007a).

All the studies evaluated PMR knowledge through a retail audit or by presenting a series of test questions to PMRs. There were variations in reported improvements on PMRs knowledge. For example, in Nigeria, PMRs' scores in a test of appropriate treatment of malaria medicines rose from 46 to 70% (Oshiname and Brieger, 1992). In Kenya, by reviewing PMRs records, there was an increase from 0 to 59% of PMRs with correct knowledge of CQ (Muturi, 2001). Evaluation of a social marketing intervention showed that PMRs receiving job aids from mobile vendors had significantly higher knowledge scores than those receiving job aids from wholesale attendants (Tavrow et al., 2003). Through test questions, the proportion of franchised shops scoring more than 60% in managing simple ailments increased from 35% to 82% in Ghana (Mensah, 2005).

Provider practices were evaluated through surrogate client surveys, with all interventions reporting improvements in PMR practices. Some studies examined drug stocking patterns, while others examined PMR practices while selling medicines including asking questions about the user. In Tanzania, following a subsidized ACT programme, 55% of all intervention outlets stocked ACTs (The steadman Group, 2007). In Kenya, the proportion of sellers stocking recommended anti-malarial drugs was 62% in outlets that had received job aids compared to 23% in controls (Tavrow et al., 2003). In Tanzania, the proportion of drug stores stocking unregistered medicines was 2% in accredited stores compared with 10% in controls (ACCESS Programme, 2005). The proportion of PMRs asking for danger signs (vomiting, diarrhoea and difficulty in breathing) while selling medicines was also measured. Although in some settings asking for danger signs was higher in intervention outlets compared to controls (26% versus 0%) (Marsh et al., 2004), this remained low in other studies (Tavrov et al., 2002; Greer et al., 2004).

There was an indication of the impact of the intervention on PMRs practices while selling anti-malarial medicines. After the intervention, the proportion giving appropriate drugs for uncomplicated malaria increased from 2% to 73% in Luwero, Uganda (Tawfik et al., 2006). In Kilifi, Kenya, training of PMRs led to significant changes in the proportion of OTC anti-malarial drug users receiving an adequate dose from 8% to 33% between 1998 and 1999 in the early implementation area and rose to 64% across the early and late implementation areas with use of SP medicines in 2001 (Marsh et al., 2004). In Nigeria, the proportion of sellers recommending or giving a correct anti-malarial dose also increased from 9% to 53% after training and introduction of pre-packed anti-malarial drugs (Greer et al., 2004).

Studies that evaluated the impact of interventions on educating the community demonstrated increase in caregiver knowledge (Goodman et al., 2007a). In Zambia, training and community mobilization enabled caretakers to identify simple and severe malaria in 32% and 51% respectively (Kaona and Tuba, 2003). Rates of appropriate treatment at community level were examined in Kenya and Nigeria (Goodman et al., 2007a). In rural Nigeria, promotion of pre-packaged anti-malarial drugs through community distributors led to an increase in anti-malarial drug use for reported fevers from 38% to 50% (Brieger et al., 2002). In Kilifi, Kenya, there was an increase in the proportion of shop treated childhood fevers receiving an adequate amount of a recommended anti-malarial drug from 2% to 15% within 24 hours after training on CQ and to 30% after subsequent training on SP (Marsh et al., 2004).

1.4.6 Summary of PMR interventions

In summary, PMR interventions lead to greater knowledge, improved practices of PMRs and a higher rate of appropriate treatment of malaria and other childhood illnesses among communities (Goodman et al., 2007a). However, most of the PMR

interventions were implemented as pilot studies while others were conducted as part of scaling up interventions within the national malaria control programmes. There are plans to scale up these interventions in some countries using ACT. For example, ACT is being introduced in the HMM programme in northern districts of Uganda. A community-based trial of ACT is currently on-going in Burkina Faso (Hopkins et al., 2007). In Kenya, use of ACT is also being piloted with the support of PSI in some Kenyan districts (Goodman -personal communication). Overall, there is a push to piloting ways of delivering ACTs through global subsidies (Institute of Medicine, 2004; Gelband and Seiter, 2007). A draft proposal on piloting subsidised ACT delivery through PMRs has been approved by the WHO/TDR task force (Affordable Medicines-Facility Malaria, 2007). On the basis of this strategy, ACT subsidies have been planned or put in practice in 12 countries in SSA and Asia (Sabot et al., 2008).

On the basis of the existing literature on interventions focussing on increasing knowledge of community level providers, several research gaps have been identified (figure 1.3). This study aimed to address some of these gaps through a comparative analysis of three different PMR programmes in Kenya. Both reviews emphasise an underlying theme of limited evidence on use of ACTs and PMRs in the HMM and sustainability of the programmes discussed in subsequent paragraphs.

Figure 1.3 Research gaps in studies evaluating HMM using PMRs and other community level providers (Goodman et al., 2007a; Hopkins et al., 2007)

- Limited evidence on the distribution of benefits of interventions across socio-economic groups
- Limited evidence of sustained impact and capacity to operate at scale
- Need for evaluation of interventions at scale to include indicators directly related to health outcomes, costs, cost effectiveness including deploying ACTs in HMM
- Need to assess the impact of widespread presumptive use of ACTs in HMM programmes on the development of drug resistance
- Limited understanding of the impact of community-based treatment on malaria-associated morbidity and mortality in different epidemiologic settings, particularly areas with perennial malaria transmission
- Insufficient evidence on whether any approach of working with PMRs is superior in improving malaria treatment
- Limited evidence for long term resources required to sustain supervision required to maintain a comprehensive training programme or accreditation network in settings struggling to provide supervision to primary health care programmes
- Need to expand the geographic coverage of existing studies to cover wide range of locations and capture potential variations in effectiveness across epidemiologic and health system settings and with different types of sellers found across Africa
- Limited evidence on the impact of community level providers such CHWs

The drug policy changes for first line anti-malarial medicines from CQ to SP and, more recently, from SP to ACT has imposed challenges on the implementation of PMRs programmes. These changes require that the curriculum for training or messages for communication be reviewed, which is costly and confusing to the target audience. Since ACT is still a prescription only medicine in many countries, its introduction for use as an OTC generates legal bottle necks. In addition, the high cost of ACTs disproportionably increases the cost of treating malaria. Other problems include the potential for developing parasite resistance especially in settings where indiscriminate use is widespread, given the difficulties in diagnosis (Charlwood, 2004; D'Alessandro et al., 2005; Goodman et al., 2007b; Hetzel et al., 2007). Use of ACT subsidies in the HMM is being piloted with promising impact on costs in Tanzania (Samarasekera, 2008a). However, concerns over sustainability of such programmes remain.

All the evaluations indicate limited evidence around sustainability of the interventions. Little consensus exists in the conceptual and operational definition of sustainability (DeRoeck, 1998; Shediac-Rizkallah and Bone, 1998). Several terms have been used, including "sustainability", "institutionalisation" "incorporation", "integration", and "routinization" (Shediac-Rizkallah and Bone, 1998). Sustainability is defined as the ability of interventions to deliver their intended benefits over a long period of time, when the donor funding and technical assistance is terminated (DeRoeck, 1998; Shediac-Rizkallah and Bone, 1998). The focus of sustainability is continuity of programme benefits (Shediac-Rizkallah and Bone, 1998). Institutionalisation is the long term viability and integration of a new programme, or the process by which new practices become standard activities within an organisation, also called routinization or incorporation (Shediac-Rizkallah and Bone, 1998; Swerissen and Crisp, 2004). The focus of institutionalisation is persistence of the programme activities themselves rather than the benefits. In this context, sustainability encompasses both continuation of programme activities as well as potential benefits at end user or organisational level. Across all PMRs interventions evaluated, given the short period between implementation and evaluation, none of them examined potential sustainability. Sustainability is therefore a critical element to consider if long-term benefits of PMRs interventions are to be realised.

1.5 Study Objectives

The literature that has been discussed so far provides the background to this study by describing the development of home management of malaria and the role of PMRs in malaria control. In order to address some of the research gaps outlined above this section outlines the objective of this study.

1.5.1 General objective

To compare overall performance of three malaria control programmes targeting PMRs by addressing impact on PMR knowledge and practices, population coverage and utilisation, and implementation processes.

1.5.2 Specific objectives

1. To determine the impact of the programme on PMR knowledge and practices (Chapter three).
2. To estimate population geographic coverage and utilisation of programme outlets (Chapter three).
3. To examine programme implementation processes and underlying explanatory factors (Chapter four).

In addition to malaria specific programmes presented in section 1.4, there is a wider literature on evaluating public health interventions in general that was used to inform the evaluation approach used in this thesis. The next section provides an overview of approaches to the evaluation of public health interventions and the background to the methods used in this study.

1.6 Evaluation of public health interventions

This section provides an overview of approaches to evaluating public health interventions and how this was used to develop the conceptual framework for this study. It begins by describing operational definitions used, background literature on quantitative methods used in this study and the approach to describing programme implementation processes.

Before examining the evaluation frameworks, a number of operational definitions are provided. Evaluation is a process that attempts to determine systematically and objectively the relevance, effectiveness and impact of activities in the light of the objectives (Last JM, 2001). An intervention comprises a set of actions that aim to bring about identifiable outcomes, while a public health intervention occurs when these actions are applied to community members with the aim of delivering a health benefit to the communities (Rychetnik et al., 2002; Rychetnik et al., 2004).

There are three primary types of evaluation: process, formative and summative. Process evaluation involves the assessment of programme delivery and the context in which the programme is being conducted, the resources required and implementation process. It is also known as implementation assessment and monitors the activities conducted in relation to the proposed scope and timetable of work. Formative evaluation refers to the activities undertaken to fine tune programme implementation and entails use of data from process evaluation to make necessary adjustments. Summative evaluation measures the extent to which change occurs, consistent with the objectives of the programme. The results are used to make decisions about the value of the programme (Habicht et al., 1999; Rychetnik et al., 2004).

1.6.1 Framework for evaluating public health interventions

Most public health interventions are complex in that they have a number of components which may act both independently and inter-dependently to bring change (Campbell et al., 2000; MRC, 2000). A sequential framework for developing and evaluating complex interventions has been described. This framework is useful in this context since it focuses on both development and evaluation of an intervention (MRC, 2000). It has distinct phases that parallel drug development stages:

- Pre-clinical or theoretical stage

- Defining components of intervention (phase 1)
- Defining intervention design (phase 2)
- Methodological issues (phase 3)
- Promoting effective implementation (phase 4).

Although the framework is presented in stages, the process is iterative and acts as guide to the development or evaluation conducted at any stage of implementation (Campbell et al., 2000; MRC, 2000). The pre-clinical or theoretical phase entails establishing the theoretical basis for an intervention. This may not be necessary in some cases where an intervention is already widely practised or when its mechanisms of action are already understood (MRC, 2000). However, a review of the theoretical basis for an intervention may lead to changes in the hypothesis, improve specification of active components of an intervention (Campbell et al., 2000), and allow for potential to generalize outcomes (Bradley et al., 1999).

The second phase addresses the understanding of how an intervention works (MRC, 2000). This can be done by providing an impact model of the way that different elements inter-relate and lead to the observed effects (Campbell et al., 2000). This may provide an understanding of the anticipated or unanticipated outcomes, as illustrated in the multi-country IMCI evaluations (Bryce et al., 2005). The third stage is linked to the development of an intervention where evidence is gathered around acceptability and feasibility of the intervention. This is also called exploratory phase where different versions of the intervention may be tested to achieve optimal effectiveness (Campbell et al., 2000).

The fourth stage is the main trial that requires comparison with an appropriate alternative using a standard protocol. A randomised controlled trial is considered the

gold standard for evaluating health interventions (Eccles et al., 2003). Attention to design issues such as sample size, inclusion and exclusion criteria, methods of randomisation, appropriate outcome measures and informed consent are essential (MRC, 2000). The final stage is long term implementation of the intervention to determine whether it can reliably be replicated in uncontrolled settings. Particular attention to the rate of uptake, the stability of the intervention, any broadening of subject groups and the possible existence of adverse effects is examined (Campbell et al., 2000).

Embedded in the stages outlined above are a number of issues. The progression from one stage to another is not linear. Depending on the stage at which the intervention is being evaluated, both quantitative and qualitative methods may be necessary for defining and measuring outcomes. In addition, examining implementation process and context are critical to understanding the outcomes (Hawe et al., 2004). Design issues are important in appraising evidence of any evaluation and are described next.

1.6.2 Evaluation design for public health interventions

Habicht and colleagues propose an approach to assessing impact, performance and explanatory factors for public health interventions, presented in the matrix form in figure 1.4 (Habicht et al., 1999). The horizontal axis considers outcomes of interest while evaluating the performance of the intervention or its impact on health or behavioural indicators. Performance is measured through provision, utilisation and coverage. Impact refers to the long-term outcome or the ultimate objective of the programme, such as reduction in morbidity or mortality. It may also refer to immediate, short-term, or intermediate effects of an intervention which provide evidence of progress (Habicht et al., 1999).

The vertical axis focuses on the degree of certainty that the observed effects are due to the programme implemented, and is divided into adequacy, plausibility and probability assessments (Habicht et al., 1999). All types of inference may include impact and performance evaluation. If the level of inference needed is adequacy, then a control group may be unnecessary, and the results are compared against set criteria (Victora et al., 2004). Plausibility assessments, although not randomised, aim to make causal statements linking the intervention and measured outcome(s). To do this a control group is required. Control groups may be historical, that is, measurements are made among target population before and after implementation of the programme. An internal control refers to groups that should have received intervention but did not. A third category is use of an external control group, which refers to comparisons with other geographical areas without the programme. The comparison may be cross sectional, where comparisons are made at a single time point, or longitudinal, where comparisons are made between intervention and control from beginning to end of the cycle. Use of controls strengthens the plausibility of a causative link between interventions and outcomes measured by reducing the potential influence of confounders (Habicht et al., 1999).

Probability assessments are based on randomised control trials and aim to reduce confounders, bias and chance (Kirkwood et al., 1997; MRC, 2000). Randomisation may be done at individual or community level. This becomes the unit of analysis depending on the nature of intervention or target group (Rosi et al., 1999). When the level of delivery of an intervention is a group of people, or communities in a geographic area, then the design is referred to as a cluster randomised design (Kirkwood et al., 1997; Eccles et al., 2003).

Figure 1.4 Evaluation design issues of public health interventions

What do you want measure?

How sure do you want to be?

Type of evaluation /inference	Performance			Impact /Outcome
	Provision	Utilisation	Coverage	
Adequacy (changes occur)	Are services available?	Are services being used?	Is target population being reached?	Were there improvements in disease patterns/behaviours?
Plausibility (effect above and beyond external influence)	Does intervention area appear to perform better?			Are there changes in health/behaviour that appear to be beneficial to intervention compared to control group?
Probability (programme effect)	Is intervention better than control group?			Are changes in behaviour /health more beneficial to intervention than control group?

While randomised designs are regarded as the gold standard, they may not be feasible for assessing effectiveness of large scale interventions (Black, 1996; Habicht et al., 1999; Victora et al., 2004). A randomised trial may be inappropriate because the very act of random allocation may reduce the effectiveness of the intervention or when experiments are impossible due to ethical reasons (Black, 1996; Kirkwood et al., 1997; Rosi et al., 1999; Victora et al., 2004). Randomisation may be unnecessary when the effect of an intervention is dramatic and the likelihood of unknown confounding factors is so small that they can be ignored. In any case, randomisation is rarely large enough to measure accurately infrequent adverse outcomes or prevent rare events, or when the outcomes of interest are far in the future and there are practical difficulties in maintaining prospective studies. Alternative options have been described as non-randomised or quasi-experimental designs. Three common designs are uncontrolled

before and after studies, controlled before and after studies and time series (Black, 1996; Kirkwood et al., 1997; Rosi et al., 1999; Eccles et al., 2003).

Apart from the design issues, the choice of an evaluation design may be influenced by the known efficacy of the intervention, the subject area of intervention, timing and the cost of evaluation (Habicht et al., 1999). In addition, regardless of the design chosen, the implementation processes and the influence of context on the intervention are necessary elements to consider while interpreting the outcomes. IMCI studies for example, have illustrated the importance of examining implementation process (the package of activities conducted) and the context (wider issues around management of health systems or geographical features) (Huicho et al., 2005; Victora et al., 2005). However, in many studies implementation processes are rarely described, and this may limit understanding of the outcome (Bradley et al., 1999). Examining the context of implementation may help understand how the interaction between the context and the intervention components produce observed outcomes (Bradley et al., 1999; Rychetnik et al., 2002). The integration of qualitative and quantitative methods provides plausible explanations of the outcomes or may define relevant components at the design stage (Bradley et al., 1999; Hawe et al., 2004; Victora et al., 2004).

The approaches to evaluating public health interventions described in this chapter were drawn upon to develop the conceptual framework for this thesis, described in chapter 2. To evaluate three PMR interventions implemented in Kenya, three main areas were examined: implementation process, the impact of intervention on PMR knowledge and practices, and coverage and utilisation of the programmes. Quantitative data collection methods used in this thesis addressing the impact of the interventions on PMRs' knowledge and practice were adapted from those used in previous evaluations (table 1.2). The next section describes the background literature to these methods.

1.6.3 Retail audit and surrogate client survey

In a review of methods used to evaluate private sector supply of public health products, Conteh and Hanson describe several quantitative methods, such as structured or semi structured questionnaires, direct observations, surrogate client surveys, and retail audit (Conteh and Hanson, 2003). The last two methods were identified for use in this evaluation since they are suitable for assessing the knowledge and practices of providers such as PMRs.

Retail audits originated as methods used by market research firms to establish volumes of products, brands and stock levels sold by outlets (Conteh and Hanson, 2003). The retail audit has been adapted to establish drugs sold in retail outlets. In this case a census is first conducted of all outlets to allow a representative sample to be taken for a detailed retail audit. A number of studies have used this method to establish drugs sold by PMRs and knowledge gained from interventions (Tavrow et al., 2003; Goodman et al., 2004; Greer et al., 2004; Amin, 2005; Samarasekera, 2008a).

The surrogate client survey is also known as an undercover, mystery shopper or simulated client survey. A researcher poses as a client seeking care from a provider who is unaware of their identity (Madden et al., 1997). The method offers a chance to record actual practice from the client's view in a standardized way (Madden et al., 1997; Conteh and Hanson, 2003). The approach requires a clear definition of case scenarios, adequate recruitment of clients and preparation of field work (Madden et al., 1997). The method has several limitations. First, standardized scenarios only extract information on a small part of a provider's behaviour and give no insight on characteristics and motivations of providers. It is also difficult to know whether the clients represent typical cases (Madden et al., 1997). A further reservation for this approach is the inability to ask providers for consent, which contradicts an important

principle of health research (Madden et al., 1997). It has been used to assess PMRs behaviour while selling medicines in several evaluations (Tavrow et al., 2003; Greer et al., 2004; Marsh et al., 2004; Ministry of Health, 2006; Hetzel et al., 2007; Hetzel et al., 2008).

1.6.4 Assessing coverage and utilisation

Whilst it is important to assess the extent to which practices are improved by an intervention, the overall impact at population level will be affected by programme coverage. Assessing coverage is therefore an important element of evaluating the performance of an intervention (figure 1.4). Coverage is the extent to which a target population in need of programme services is being reached (Habicht et al., 1999). The current study utilised geographical information systems (GIS) techniques to assess coverage, physical accessibility and the population likely to use PMR interventions. The section begins by an overview of the concept of access and its relationship to utilisation, with an aim to situate this component of the study in the wider context of physical accessibility to health care. It then describes studies that have examined physical distance as a barrier to health care and ends with an overview of studies where GIS techniques have been used for assessing coverage of malaria interventions in the Kenyan context.

There have been debates around the concept of health care access since the early 1970s (Penchansky and Thomas, 1981; Goddard and Smith, 2001; Gulliford et al., 2002). A recent framework identifies three dimensions of access: Availability; Affordability and Acceptability referred to as the "A-Frame" (Thiede et al., 2007). Availability is also referred to as physical access and examines whether or not appropriate health services are available in the right place and at the time they are needed. Affordability is viewed as financial access and is the degree of fit between cost of utilising services and

individuals' ability to pay. Acceptability, sometimes seen as cultural access, is the nature of service provision and how this is perceived by individuals and communities (Thiede et al., 2007). Access is therefore a multi dimensional concept with the fundamental element underlying it being the notion of empowerment to allow communities make informed decisions about health service use (Thiede, 2005).

In this evaluation, the access domain of interest concerned availability. Health service is represented by the act of selling anti-malarial medicines by trained PMRs. The trained PMRs are considered service providers; the functioning of the retail sector represents the system factors while household factors are linked to issues around utilisation of PMR services by community members. Since measuring physical access formed a component of this study, the next set of paragraphs describes the relationship between distance and utilisation of services.

There is evidence suggesting that increasing distance to health service points acts as a hindrance to utilisation of available services (Noor, 2005). Distance has been shown to delay access to health service in formal health care settings. For example, in Uganda distance to a health facility was a determinant to delivery at home (Amooti-Kagunaa and Nuwaha, 2000). In another study, those living within 1-2 km of the health centre in Uganda sought treatment within 24 hours compared to those living more than 2 km away (Ndyomugyenyi et al., 2007). In Kenya, lack of money for transport contributed to delay of mothers from accessing health facilities (Mwenesi et al., 1995). In Ethiopia, those further than one hour's walk from the nearest health care facility initiated treatment later than those with less than one hour's walk (Deressa et al., 2003a).

Physical distance has also been shown to decrease attendance rates. For example, in Papua New Guinea, distance decreased use of health services both overall and in

malaria and acute respiratory infections (Muller et al., 1998). Studies in Zambia, Kenya and Nigeria indicated that use of health services either diminished with increased distance to where potential users lived or was an impediment to service use (Atting and Egwu, 1991; Diop et al., 1998; Baume et al., 2000; Hjortsberg and Mwikisa, 2002; Mbagaya et al., 2005). In Ghana, distance had an inverse relationship with utilisation of health services (Bour, 2003; Dzator and Asafu-Adjaye, 2004).

Decreased distance also influences use of preventive services. In Kenya, those living near a market centre were likely to use nets purchased from the retail sector (Noor et al., 2006b), while use of nets among pregnant women was significantly associated with one hour walking distance to clinics (Gikandi et al., 2008). Long distances to health facilities also influenced immunisation coverage (Omutanyi and Mwanthi, 2005). In Burkina Faso 28% of the total cost was used in transport to and from health facilities contributing to increased cost of accessing health care (Sauerborn et al., 1996). In Zambia and Ghana lack of transport limited access to malaria treatment from health facilities (Williams et al., 1999; Bazzano et al., 2008). The World Bank report also shows that affordable access to health services was low contributed largely by long distance to service points (World Bank, 2004).

The relationship between physical accessibility and utilisation is complex. Utilisation is influenced by both demand (physical and financial accessibility and socio-cultural factors) and supply (price, knowledge of technology and management of efficiency factors) (Ensor and Cooper, 2004). Potential utilisation is used to illustrate the relationship between the type and range of services provided by PMRs and the community health needs. Physical access is measured by examining distance between trained PMRs and clients while taking account transportation options examined using GIS techniques.

Recent developments of GIS techniques offer a potentially robust way of measuring physical access (Thiede et al., 2007). GIS techniques have been used to define health worker shortages in developed countries (Luo, 2004; Wang and Luo, 2005). In some contexts they have been used to assess the impact of health sector reforms on equity (Rosero-Bixby, 2004). GIS methods have also been used to understand physical accessibility and utility of primary health care facilities in developing countries (Noor et al., 2003; Gething et al., 2004; Noor et al., 2006a; Tanser et al., 2006).

Recent utility of GIS methods in the Kenyan context include use of the geo-space time model to monitor health service use over time and predict national out patient treatment burden (Gething et al., 2007; Gething et al., 2008). In the context of malaria control interventions in Kenya, GIS modelling has been used to assess determinants of physical accessibility of ITNs and coverage across social economic groups (Noor et al., 2006b; Noor et al., 2007; Gikandi et al., 2008). GIS techniques are used in this thesis to estimate the physical distance covered by community members to access intervention outlets of three PMR programmes in Kenya. The approach is used to model potential utilisation that takes account of physical distance and not other parameters relevant to access.

1.6.5 Assessing implementation process of PMR interventions

This section examines the approach used in this study to assess the implementation process of the programmes evaluated. Theory and empirical work around policy processes, mostly from outside the health sector, considers the importance of implementation processes and their implications for policy achievements (Hill and Hupe, 2002). Going beyond conventional public health understandings, this literature sees the implementation process as full of contestation, negotiation and bargaining among implementing actors (individuals and organisations), leading to decisions that

shape the implementation (Walt and Gilson, 1994). This work indicates that examining the interactions between any intervention and implementing actors and context will generate a richer understanding of the way that outcomes are achieved or constrained. It adds concern for actors and their influence over implementation and a broader understanding of context (including, for example, political and institutional influences) to existing public health evaluation concerns. Examining implementation using this approach enables a deeper understanding of how the intervention works in real life and the factors underlying the outcomes observed.

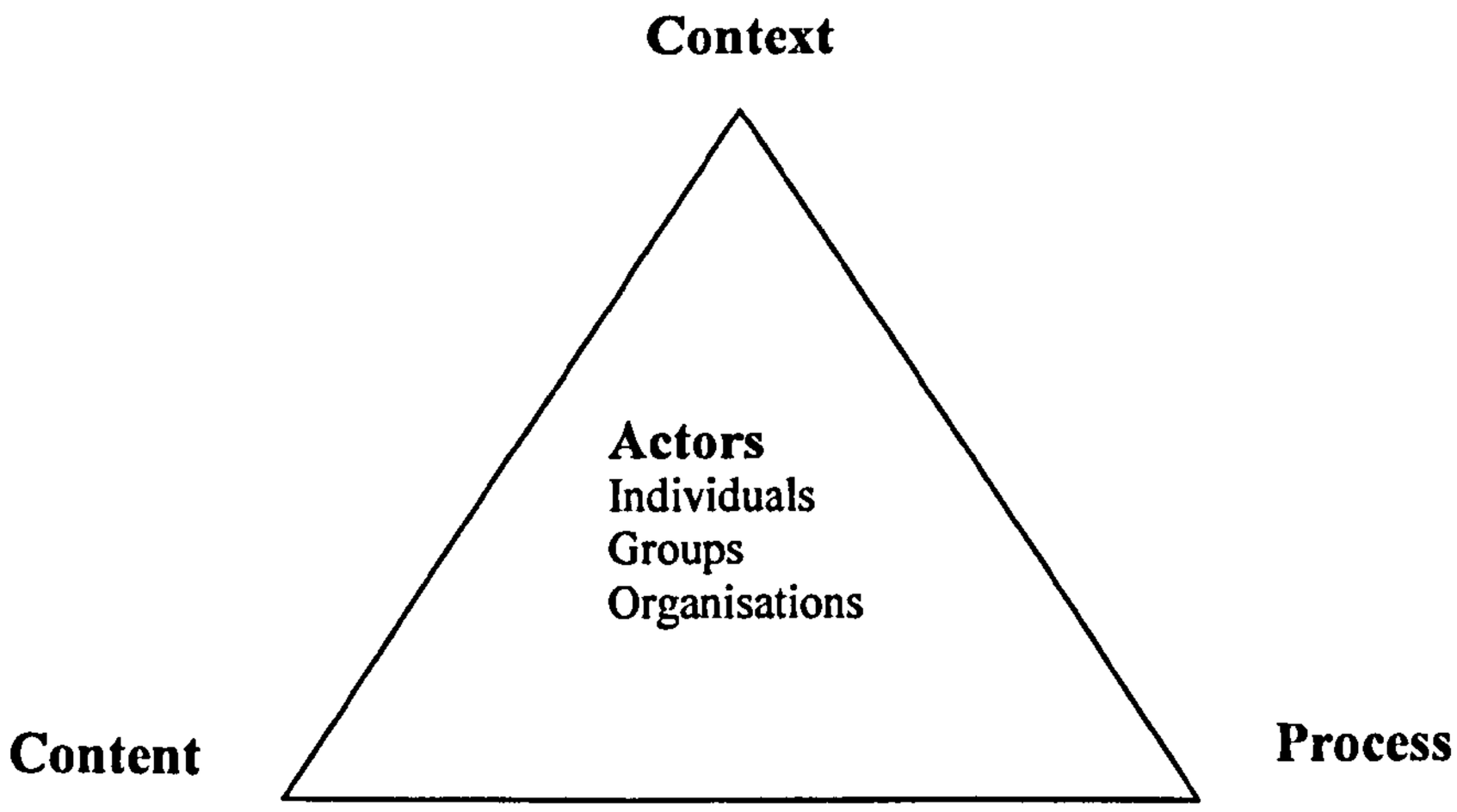
1.6.5.1 Theoretical concepts and policy analysis frameworks

In broad terms, policy analysis seeks to understand and describe processes of policy making and implementation, and use this understanding as a basis for recommendations on how to strengthen policy development and implementation (Walt, 1996). This analysis is useful retrospectively or prospectively in various sectors such as health, education or trade to understand past or future failures and successes (Buse et al., 2005; Walt et al., 2008). Health policy refers to courses of action and inaction that affect institutions, organisations, services and funding arrangements of the health systems. It is expressed both explicitly, in statements, regulations and laws, and implicitly, through people's perceptions, understandings, and practices, which are in turn shaped by other factors such as their values, past experiences, and the wider context (Buse et al., 2005).

There are a number of policy analysis conceptual frameworks, some of which help to understand and describe the policy process. The stages heuristic framework, divides the policy process into four stages; agenda setting (problems reach the attention of decision makers), formulation (policies are designed and enacted), implementation (governments carry out the policies) and evaluation (their impacts are assessed) (Buse

et al., 2005). The policy analysis triangle (figure 1.5), meanwhile, provides a picture of the sets of factors that have influence within any process of policy development and implementation. It emphasises that these processes are always political and need to take account of *who* (actors) and *how* (process) decisions are made, *what* (content) decisions are made and under *what* conditions (context) (Walt, 1994).

Figure 1.5: Policy analysis triangle: source: (Walt and Gilson, 1994)



Actors are central to the policy process and may block or support the process in many ways leading to various outcomes. *Content* is the substance of a particular policy; it is the nature and design of the policy. *Context* refers to systemic factors, political economic social or cultural, which may have an effect on policy either directly or through their influence over other elements of the triangle. *Process* refers to the way in which policy is initiated, developed, or formulated, negotiated, communicated, implemented and evaluated (Buse et al., 2005). As all four elements of the triangle interact to shape policy process, there is always a need for an integrated analysis of their influence.

A wider body of policy analysis theory provides conceptual frameworks focussed on how all or some of these factors interact in influencing decision making. Policy network theory, for example, focuses specifically on systems, interactions and

interconnectedness between actors, including processes of shared decision making and exchange of resources to achieve goals (Walt et al., 2008). Relevant theory specific to implementation broadly encompasses 'top down' theory which is concerned with policy being decided at national level with implementation being conducted by administrative agencies. Bottom up theory is concerned with administrators and local networks shaping implementation (Walt et al., 2008). Innovation theory (Greenhalgh et al., 2004) is a body of work that is coming to be seen as particularly relevant in understanding the early stages of implementing new interventions within health systems. Innovation theory concerns with how set of behaviours or routines are implemented by planned and coordinated actions either passively (diffusion) or actively (dissemination) to improve health outcomes.

1.6.5.2 Policy analysis studies in low and middle income countries

There is limited empirical evidence from studies that have utilized policy analysis in understanding the implementation process in low and middle income countries (LMICs). The bulk of the current evidence describes the technical content of policy rather than the role of actors, power and processes in implementing policy or the context in which decisions are made (Gilson and Raphaely, 2008). A review of health policy analysis work in LMICs between 1994-2007 has been conducted (Gilson and Raphaely, 2008). Empirical studies conducted in SSA were extracted from their review. Since this study addressed implementation of malaria related interventions, additional literature describing implementation process of malaria related policies in SSA countries were included. The studies are categorised according to the focus of the study using the elements of the policy analysis triangle (figure 1.5).

Some studies primarily examine the implementation process of policies. In Ghana, for example, the process of implementing community-based health planning services

illustrates that policies that require large scale organisational change are complex to undertake. This is particularly in settings where internal resources for financing the process of change are lacking. For effective outcomes strategies are required to phase in changes through discrete components in small units. In addition pilot studies during scaling up are important in allowing adaptation to local realities (Nyonator et al., 2005).

The influence of context on implementation process has also been studied. In Kenya, a description of health sector reforms illustrated how some reforms were implemented speedily when research or clear evidence was presented or when political will existed (Mwabu, 1995). Another study, examined the means for, and methods of, interpretation of the policy context and its influence on implementation process. The key contextual factors that influenced implementation were demographic or epidemiological changes; processes of social and economic change; economic and financial policy; politics and the political regime; and ideology (Collins et al., 1999).

Other studies have examined both the implementation processes and the role of actors. In Kenya, an exploration of the introduction of Malarone® donation programme from inception to national level policy showed the political nature of implementation and the influence of national, regional or international actors on the development and implementation of the programme (Shretta et al., 2001). Other studies consider how the understanding of policy content influences actors and implementation processes. In Kenya, Shretta and colleagues reviewed experience on the change in policy from CQ to SP in 1998. This study shows the difficulties of using available evidence to change drug policy where actors perceptions of the credibility of data differed influencing the time taken to implement the new drug policy (Shretta et al., 2000). A recent study on the process of implementation of ACT as first line policy in Kenya showed how the

understanding of the new policy by international and local actors delayed implementation of the new policy. Reasons behind these delays were around lack of clarity on sustainable financing for the drug, funding mechanisms, poor dialogue with pharmaceutical companies with a national interest in anti-malarial drug supply, single sourcing and complex drug ordering, tendering and procurement procedures (Amin et al., 2007). Similar experiences in terms of delay and negotiations by different actors on the choice of best option for the countries have been described in Sudan and Zambia (Malik et al., 2006b; Sipilanyambe et al., 2008).

A study in South Africa on the development of health care financing highlights the importance of actor management strategies by which reform drivers of any policy process could create alliances of support to overcome potential opposition to proposed policy changes (Thomas and Gilson, 2004). A study in a rural area of KwaZulu Natal in South Africa showed that abortion was supported by actors in specific circumstances, such as rape or incest, due to a perception that a child born of rape would be seen as unwanted child. This illustrates the way that community norms can influence actors' implementation of a policy (Harrison et al., 2000). Other studies have shown how a policy is shaped by actors' views and values and the role of front line actors in implementation (Seidel et al., 2000; Kaler and Watkins, 2001; Walker and Gilson, 2004).

The interaction between the role of actors, context and implementation process has also been studied. In a study that examined reasons behind the slow implementation of HIV/AIDS programmes in the first four years in South Africa, authors illustrate the role of political context in shaping the development of the AIDS policy (Schneider and Stein, 2001). The initial policy-making and mobilisation of resources were relatively straightforward but the implementation process was challenged by actors' lack of deep

understanding of the transitional political environment, changes in health system management, funding mechanisms appropriate leadership in facilitating the response to AIDS (Schneider and Stein, 2001).

In Kenya, health sector reforms at the district level indicated that the process was based on several assumptions but the realities presented by the market orientation of the health system and poor governance of the political system led to failure to improve health (Oyaya and Rifkin, 2003). In Uganda, authors used theory to deepen their understanding of implementation processes during a change in information systems from a centralized to a district focussed system. The main challenges were a lack of clarity on the role of medical records officers and the structure within district constraining implementation (Gladwin et al., 2003). In Ghana, a qualitative analysis of the implementation process of an integrated policy on sexually transmitted infections and family planning was done to ascertain how sensitive the policy was to existing contexts and procedures. The study illustrated the way that implementation is influenced by local service contexts, economic and epidemiological factors, and socio-cultural attitudes and behaviours (Mayhew, 2000). In Tanzania, actors' role in the implementation of a new anti-malarial treatment policy (from SP to ACT) was examined to show the way that good intentions can be shaped by actors' role in implementation, leading to new practices that are different to those intended (Mwisongo, 2007).

In summary, empirical evidence from the policy analysis literature highlights the complexity of implementation and that actors are central to these processes. This study utilises policy analysis understanding, and specifically innovation theory, to examine the implementation processes of three different PMR interventions. This component of

the study focuses on the role of actors, the policy-context interaction, the early implementation process and its relationships to the outcomes.

1.7 Scope and role of thesis

This thesis includes a series of inter-related studies measuring the performance and outcome of different PMR programmes aiming to improve HMM in Kenya. As described, the study set out to address several gaps outlined in section 1.4. They included providing evidence of an impact of PMR programmes at scale and in different geographic locations, where the latter aimed to capture variations in effectiveness across different epidemiologic and health system settings and with different types of sellers. The study through assessing the implementation processes hoped to provide further evidence on the role of PMRs in malaria control and continue to inform policy for this sector by assessing the relative advantages of different programmatic approaches implemented in Kenya. Findings of this research may support national strategic planning for involving the retailers in malaria control and assist the Division of Malaria Control (DoMC) in monitoring and evaluating current and planned PMR programmes.

This thesis is structured around five chapters. The current chapter has provided a review of literature relevant to this thesis and forms the introduction to the study. Chapter two describes the context for the thesis by describing the geographical location of Kenya, the organisational structure of the Kenyan health care system and the development of PMR interventions implemented. An overview of the retail sector programmes evaluated in this study is described in addition to the conceptual framework and the study methods. Chapter 3 presents results of the quantitative impact of the interventions on PMR knowledge and practices, and the estimation of population geographic coverage and utilisation of the programme. Chapter 4 utilises

health policy analysis methods to examine the factors influencing programme implementation and its performance. Chapter 5 pulls together a discussion on policy implications of this study by drawing both generic and specific lessons learnt from this evaluation, and provides the conclusion of the study.

Chapter 2:

The Kenyan health system, background to thesis and study methods

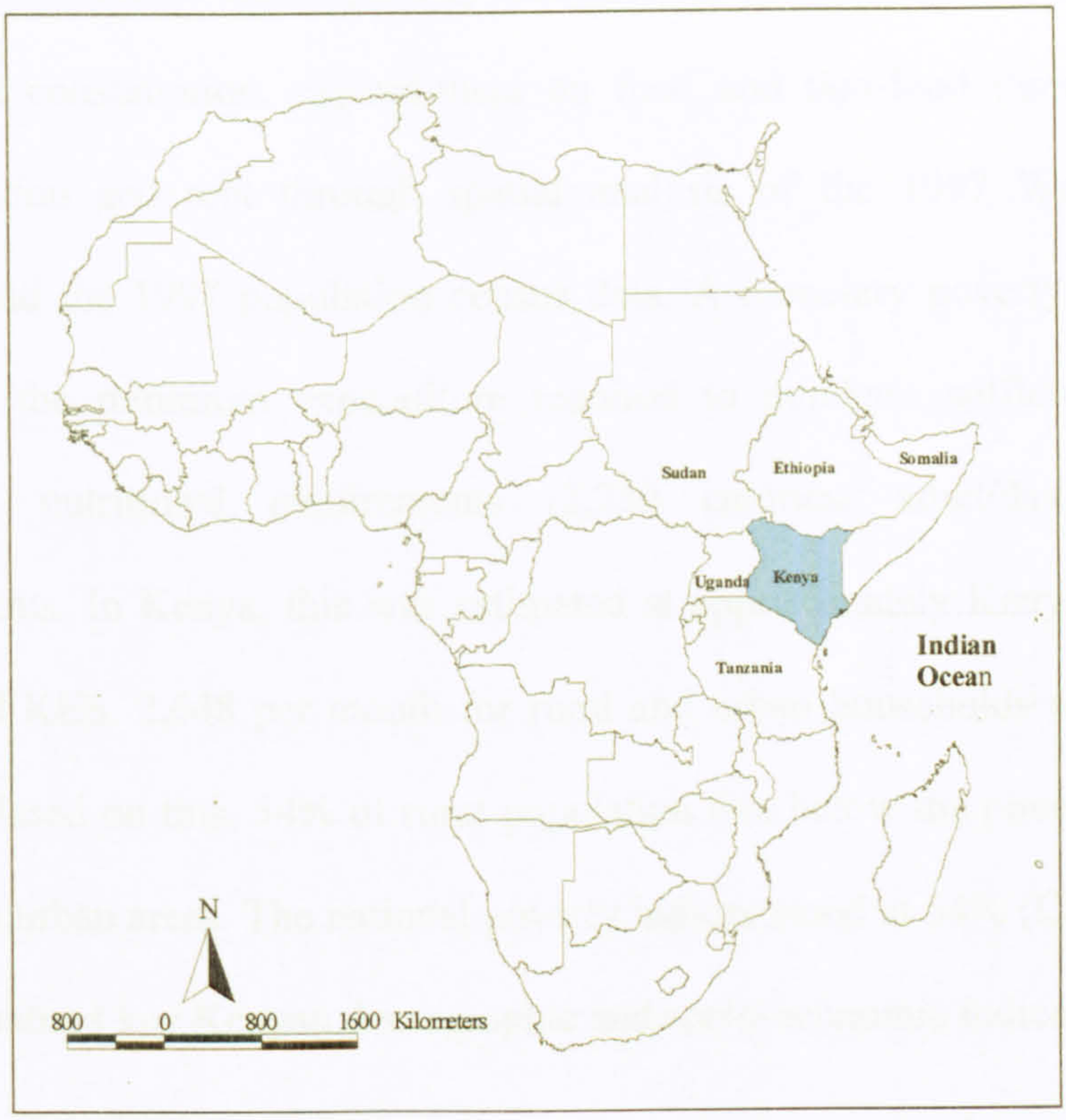
2.1 Introduction

The chapter lays out the country context for the thesis and provides a description of the conceptual framework and methodologies used in the study. It begins with a description of the geographical location of Kenya and describes the organisational structure of the Kenyan health care system and broader health policy environment. It provides an overview of malaria control efforts in Kenya including the development of the Kenya National Malaria Strategy (KNMS), and presents the framework for the development of HMM and the retail sector interventions implemented in Kenya. An overview of the retail sector programmes evaluated in this study is then described. Information on the conceptual framework and the study methods used drawing on the literature described in chapter one (section 1.6) is also presented.

2.2 Geographical location and basic indicators for Kenya

Kenya is situated in the eastern part of the African continent. Uganda borders it to the west, Tanzania to the south, Ethiopia to the north, Sudan to the northwest, Somalia to the northeast and the Indian Ocean to the southeast (figure 2.1). The country is almost bisected by the equator and lies approximately between latitudes 5°00'N and 4°40'S, and between longitudes 33°83'E and 41°76'E. Kenya has five administrative levels for purposes of governance and resource allocation. The first level is the province, of which there are eight: Nairobi, Central, Coast, Eastern, North Eastern, Nyanza, Rift Valley and Western. The provinces are further sub-divided into districts, the second administrative level. Districts are sub-divided into divisions, divisions into locations, and locations into sub-locations (third, fourth and fifth levels, respectively).

Figure 2.1: Map of Africa showing the location of Kenya



The 1999 National Population and Housing Census shows that Kenya's population was approximately 29 million people, concentrated along a corridor through the highlands, around Lake Victoria and along the Coast. Kenya's population is generally young with 44% of Kenyans aged below 15 years. Those between 15 and 64 years were 52% and those aged 65 years and above were 4% (CBS, 2001). A recent estimate of life expectancy at birth is 52.8 years. The Kenya Demographic Health Survey 2003[2] shows that under five mortality has not improved with 110 deaths per 1000 live births in the period 1993-1997 and 115 deaths per 1000 live births for the period 1998-2003 (CBS, 2003a).

[2] There are limitations of the survey particularly on sample size with a small number of households selected from Northern Kenya due to logistics making the sample less self weighting at national level

In terms of economic status, poverty measures have been derived from information on household consumption, expenditures on food and non-food items such as health transportation and rent through spatial analysis of the 1997 Welfare Monitoring surveys and the 1997 population census data. A monetary poverty line was derived based on the minimum expenditure required to purchase sufficient food to meet minimum nutritional requirements (2,250 calories/ adult/day) and non-food requirements. In Kenya, this was estimated at approximately Kenya Shillings (KES) 1,239 and KES. 2,648 per month for rural and urban households respectively (CBS, 2003b). Based on this, 54% of rural population live below the poverty line compared to 52% in urban areas. The national poverty indices stood at 54% (CBS, 2003b). Table 2.1 summarises key Kenyan demographic and socio-economic indices.

Table 2-1 Summary characteristics of the Kenyan demographic indices

Indicator	Value of indicator/units
Demographics*	
Area	582, 646 km^2
Population size (1999)	28, 686, 607
Annual population growth rate	2.9%
Projected population (2006)	35 673 917
Population density	49 per km^2
Under five population	1, 033, 491
Projected under five population (2006)	5 648 449
Health indices †	
Infant mortality	77 per 1000 live births
Under five mortality	115 per 1000 live births
Maternal mortality	0.69/1000 woman years exposure
Life expectancy at birth	52.8 years
Poverty indices ‡	
Percent living below poverty line	54%
Urban poverty incidence	52%
Rural poverty incidence	54%
Literacy rate among men	88.1%
Literacy rate among women	78.5%

*Source: population census of 1999 (CBS, 2001)

† Source: Kenya Demographic and Health Survey(CBS, 2003a)

‡ Source: Poverty mapping exercise(CBS, 2003b)

2.3 Kenyan health care system

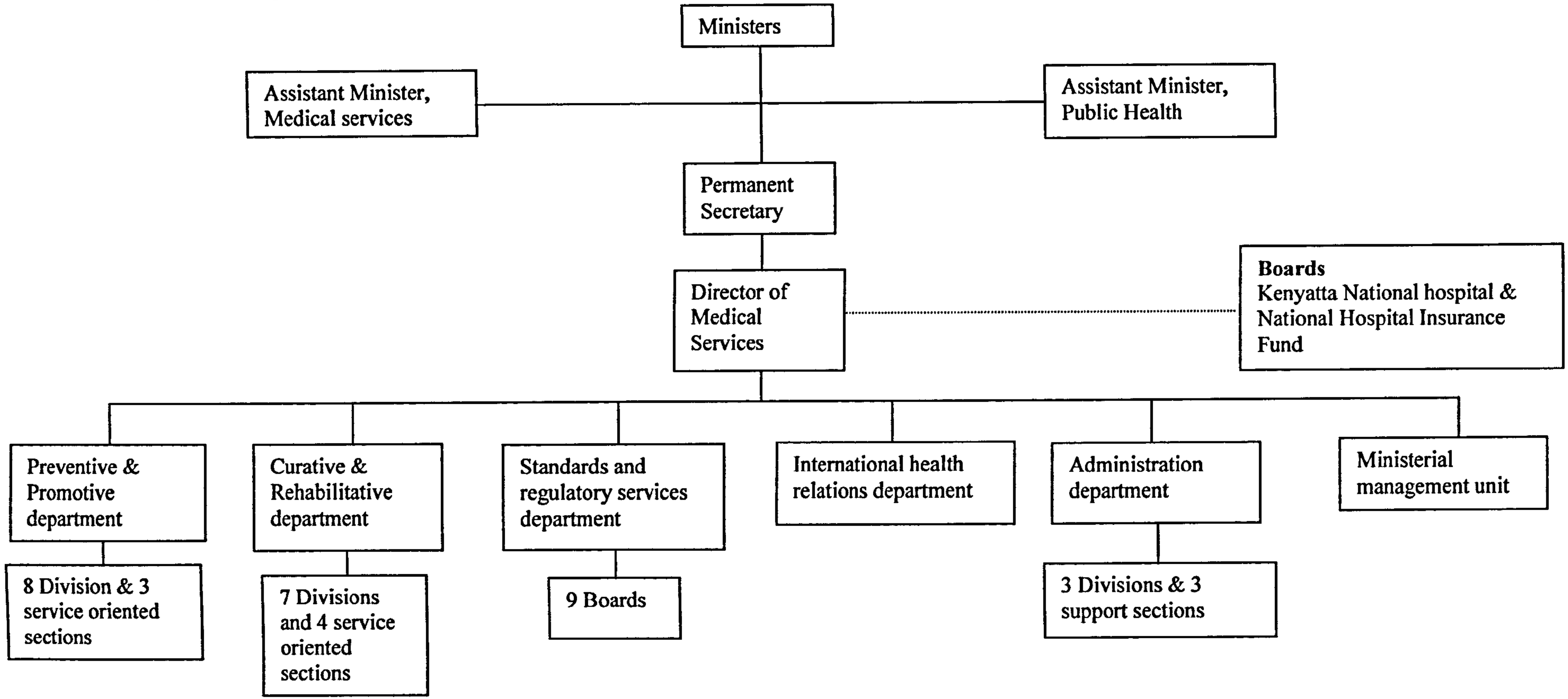
2.3.1 Kenyan Health Policy Framework: An overview

The Ministry of Health (MoH) operates within a policy environment that is subject to internal and external influences. A number of key policy documents have shaped the Kenyan health policy landscape including the Kenya Health Policy Framework (KHPF) of 1994, the National Health Sector Strategic Plan (NHSSP) I: 1999-2004, the NHSSP II: 2005–2010, the National Social Health Insurance Fund of 2004 and the 10/20 policy on cost sharing at government health centres and dispensaries (MoH, 2005a) .The history of health sector reform policies can be traced back to 1994 with the production of Kenya's Health Sector Policy Framework Paper (GoK, 1994). To operationalise this document, the MoH established the Kenya Health Policy Framework Implementation Action Plan and the Health Sector Secretariat in 1996. In 1999, the MoH produced the NHSSP I: 1999-2004, which covered a wide range of areas that needed to be strengthened to deliver better health care to Kenyans. However, these plans were not effectively implemented, prompting the development of the current second five year Strategic Plan II aimed to revitalise the direction of the health sector (NHSSP II) (MoH, 2005a).

2.3.2 Structure of the Kenyan health care system

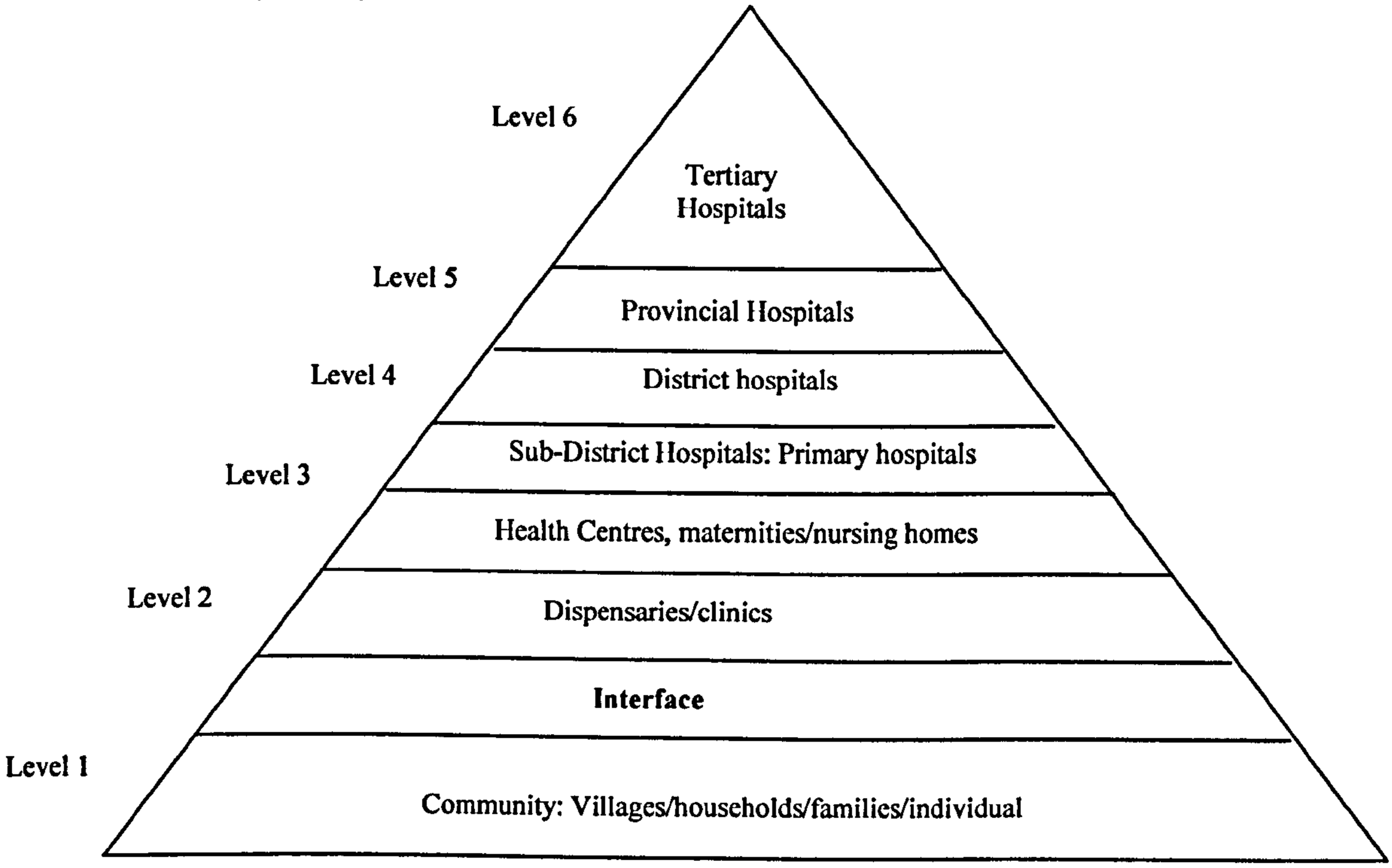
The current Kenyan health sector comprises the public sector, with major players being the MoH, parastatal organisations, local government and the private sector, (MoH, 2005b). Health services are provided by a network of over 7,312 facilities countrywide, with the public sector accounting for 48% of all facilities (Noor, A. personal communication). Figure 2.2 shows the organisational structure of the MoH.

Figure 2-1 Organogram showing the administrative and organisational structure of the Kenyan Ministry of Health (NCAPD, 2004)



In terms of health service provision, services are delivered though facilities at different levels (figure 2.3). The national level comprises national referral hospitals, providing rehabilitative and therapeutic services.

Figure 2-2 Levels of health care delivery within the Kenya Essential Package for Health (KEHP)



The provincial level acts as a referral resource for district hospitals, where the former provide specialised care. They oversee the implementation of policy at district level, maintain quality standards and coordinate health activities. The third level is the district hospital, which delivers services and generates their own expenditure plans and budget based on guidelines from the headquarters. Facilities at this level are managed by the District Health Management Team (DHMTs) and District Health Management Board (DHMBs). The fourth level is a health centre, which provides a wide range of curative and preventive services. The fifth level is the dispensary, which is meant to be the first line of contact with patients but, in some areas, this function falls to the health

centres. Dispensaries provide a wide range of preventive and curative health services (NCAPD, 2004).

The KEHP represents the integration of all health programmes into a single package towards the improvement of health with emphasis on the community level of care. The basic preventive and curative services for minor ailments are being addressed through the community package and synergise with services provided by NGOs, privately owned facilities, community and faith-based organisations (MoH, 2005b). The current number of health personnel for Kenya is presented table 2.2. The enrolled nurses are the largest group of medical personnel contributing 48.3% of the entire health workforce. The health worker: population ratio is lowest for dentists, with one per 42, 418 Kenyans. The doctor: population ratio stands at 1 doctor per 7,112 people.

Table 2-2 Registered medical personnel and provider population ratio for Kenya

Registered medical personnel *	Number of providers	Provider: population ratio †
Doctors	5,016	1:7,112
Dentists	841	1:42, 418
Pharmacists	2,570	1: 13,880
Pharmacy Technologists	1,620	1:22,020
B.Sc Nursing	280	1:12,7406
Registered Nurses	10,210	1:3,494
Enrolled Nurses	30,562	1:1,167
Clinical Officers	4,953	1:7,202
Public Health Officers	1,314	1: 27,149
Public Health Technicians	5,861	1: 6,086

*Number of health service providers was derived from registered medical personnel captured in the health information systems, MoH 2005.

† Ratio calculated on the basis of the 2006 population projection

2.4 Malaria control efforts in Kenya

Global malaria control efforts were presented in chapter 1 section 1.2. In Kenya these efforts can be traced back to the colonial period when these were directed from the central government. Later policies in the first quarter of the 1900s were a direct response to experience and anticipated epidemics (MoH, 1998). In 1926 there was an

increase in malaria epidemics, which affected the European highlands and accelerated concern for the colonial government to control malaria. Epidemics in the late 1930s and early 1940s intensified the need for a nation-wide policy for malaria control (MoH, 1998).

Formal centralised control efforts were established by the creation of the Division of Insect-Borne Diseases in 1947. This was responsible for research and control of communicable diseases, including malaria. From the 1970s to the 1990s, vector control was organised through the Division of Vector Borne Diseases (DVBD) and administered at district level under the MoH. From the 1980s malaria control began to be linked to community-based health care programmes involving CHWs and Community Owned Resource Persons (CORPS). Such programmes were linked to the primary health care approach established after the 1978 Alma Ata conference (WHO, 1978). In response there was significant investment in the Bamako Initiative through a number of NGOs which supported training of CHWs in Kenya (MoH, 1998). The development of guidelines for CHWs and CORPS in 1998 was an important step in the recognition of efforts made at community level to fight malaria (Snow et al., 2001).

The development of a structured system of malaria control began to take shape in 1992 through the establishment of National Plan of Action for Malaria Control (MoH, 1998), which saw the establishment of the Malaria Control Unit in 1994 under the DVBD. This became the operational arm of the National Malaria Control Programme (NMCP) and was later upgraded to the DoMC in 2000 (Snow et al., 2001).

2.4.1 Role of DoMC in malaria control

The DoMC is the operational arm of the NMCP and is responsible for overseeing the implementation of the KNMS. The DoMC has the overall responsibility for planning and coordination of inputs and activities for malaria control at all levels. Donors and

the Kenyan government finance operational activities of the DoMC. Technical activities are supported by inputs of the technical working groups convened when need arises and drawing from implementation partners, consortia and advisers such as Department for International Development (DFID), WHO/AFRO and the Kenya Medical Research Institute (KEMRI).

Through a consultative process, the DoMC embarked on a process of developing a national approach to malaria control that drew on all the existing evidence, experience and knowledge (Snow et al., 2001). The KNMS was launched in April 2001 with the aim of increasing coverage of specific malarial control interventions and to sustain these to 2010 (MoH, 2001). The four strategic approaches were drawn from the RBM initiative (chapter one section 1.2.2). These approaches are supported by two crosscutting strategies: IEC activities to arm the public with preventative and treatment knowledge; and monitoring, evaluation and research to update and inform malaria control strategies. For each of the approaches, the KNMS set targets against which progress could be assessed. Embedded within the KNMS is the recognition of the role of communities and the retail sector in malaria control under the case management strategic approach. As described in chapter one, one of the key targets for case management is that: "...60% of fever cases which are treated at home by family members or caretakers will be managed appropriately".

The case management strategy is also linked to the IMCI initiative. IMCI is a global strategy developed to reduce mortality among children under five. It aims at improving quality of care in first level health facilities through the introduction of standard treatment guidelines and training of health workers. Later it evolved into a broader strategy consisting of improving case management skills of health workers; improving the health system supports required for high quality care for children coming to

facilities; and improving household and community practices related to child health nutrition and development (Lambrechts et al., 1999).

The role of retail sector in the management of malaria is tied to the third IMCI component which focussed on improving household and community practices related to child health nutrition and development (BASICS II, 2001). The programmatic elements in the implementation framework include improving partnerships between health facilities and communities; increasing appropriate accessible care and information from community based providers, including PMRs; and integrated promotion of key family practices for child health and nutrition (BASICS II, 2001).

The role and responsibility of communities in malaria control is well recognised in malaria control programmes and community IMCI. Community IMCI initiatives which focus on malaria have been variously implemented in Kenya over the last three decades. Examples include activities of NGOs such as CARE-Kenya using CHWs in Siaya; Aga Khan foundation in Mombasa supporting distribution of bed nets; and Plan International using CHWs and TBAs in Kwale (MoH, 1998). In order to harmonise such efforts, the KNMS embraced the HMM. One component implemented was PMR programmes aiming to optimise the management of fevers treated through the general retail shops and chemists. Since 1998 these have included participatory skill-based training of PMR in Kilifi; a modified social marketing programme training wholesale attendants and mobile vendors to distribute IEC materials to PMRs in the VTV programme in Bungoma; and the micro-finance and social franchise programme in Kirinaga and Mbeere districts developed by the CFW (Snow et al., 2001).

2.4.2 The role of retailer programmes in the HMM in Kenya

This section describes three main programmes that supported the subsequent development of a national strategy for working with PMRs.

2.4.2.1 The Kilifi shopkeeper training programme

The Kilifi shopkeeper programme began in 1995 to examine the strategic role that shopkeeper training could occupy in malaria control using a main focus of community participation. The pilot project began in a rural division of Kilifi district with formative research to assess the feasibility and potential impact of training PMRs on anti-malarial use. This showed an impact in behaviour of participating PMRs and clients (Marsh et al., 1999) and led to a larger trial in 1999 in Kilifi district. The programme was developed collaboratively by the KEMRI-Centre for Geographic Medicine Research Coast (CGMRC), the Kilifi DHMT and the DoMC (Marsh et al., 2004). The main components of the programme were community selection of programme PMRs, participatory skill-based training workshops for PMRs, and public information activities, including distribution of IEC materials. Overall the study showed a marked improvement the use of recommended OTC anti-malarial medicines (chapter 1 table 1.2).

2.4.2.2 The Bungoma-AMREF programme

The second PMR programme was part of the Bungoma District Malaria Initiative (BDMI) supported by USAID and the African Medical Research Foundation (AMREF). The BDMI aimed at exploring programmatic options for reducing malaria morbidity and mortality among children under the age of five years and pregnant women, and to strengthen local capacity to deliver effective and sustainable integrated malaria control at the health facility level and a component targeting PMRs (BDMI, 1999). The PMR programme used the existing drug distribution channels to promote

better selling practices for anti-malarial medicines and improve the capability of mother and other caretakers to manage fever and anaemia at the household level. The programme was started in 1999 and involved training wholesale attendants, mobile vendors[3] and pharmacy attendants, and the distribution of job aids[4] and posters with sales OTC anti-malarial medicines to PMRs. Training of distributors included information on malaria treatment and prevention, communication skills and use of job aids. Early evaluations suggested differences between intervention and control outlets six months post implementation.

The Bungoma-AMREF programme illustrates a social marketing strategy targeting wholesaler level. Typically, social marketing is the application of commercial tools and concepts of commercial marketing to social health and problems. It intervenes on the demand and supply sides of the market to increase coverage. On the demand side this is achieved by promotional activities of branded products through price subsidies to allow a movement along a certain demand curve. The supply side involves the development of a branded product which is either new or competitive, where the existing product range is narrow and highly priced. In addition, a distribution chain is created or reinforced to ensure availability to meet demand created. Efforts are made to expand the distribution chain to lower socio-economic groups (Kikumbih et al., 2005). The Bungoma-AMREF programme aimed to increase the supply of anti-malarial medicines through strengthening the distribution chain coupled with promotional activities using job aids, training of wholesalers and mobile vendors. However, the programme did not apply price subsidies or over branding of existing anti-malarial products, and involved relatively low levels of mass marketing at the outset.

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[3] they sell general wares and medicines to retail outlets using bicycles
[4] Visual tools that support providers to offer adequate health care.

2.4.2.3 Cry for the World Foundation programme

A third programme targeting PMRs was the CFW™ social franchise project funded through private subscriptions to CFW™ and locally implemented through the NGO Sustainable Healthcare Foundation. The project targeted diseases causing 70-90% morbidity in children and their families in Kirinyaga and Mbeere districts of Central province. The project drew on micro-enterprise principles to enable existing CHWs to own and operate franchised drugs shops. The franchise model included rules that CHWs must follow, such as those concerning diagnosis, treatment, and drug handling, as a condition of maintaining their business opportunity. CFW™ monitored compliance by ensuring that retailer adhered to the franchise rules. Since 2000, the network of outlets has more than quadrupled to 54 locations comprising 28 drug outlets and 26 private medical clinics. In 2004, the network treated 177,256 patients and in 2005, the number of patients was 435,527

(http://www.cfwshops.org/overview.html.).

2.4.2.4 Assembling experiences of PMR interventions in Kenya

On the basis of experiences gathered throughout the implementation of these programmes, the DoMC held a consultation workshop in May 2001 to combine lessons learnt and define common approaches. The workshop involved actors with experience in community-based health care programmes such as NGOs, UNICEF, the social franchising model of the CFW™, the social marketing strategy in Bungoma and the Kilifi shopkeeper training programme. The outcome was the formation of two working groups, one on legislative issues and the other on strategies for working with CORPS and PMRs. Both private and public sector actors were involved in the working groups under the auspices of the DoMC. The temporary working group on the strategies for working with PMRs and CORPs developed guidelines for the implementation of PMR programme at district level in 2002 (MoH, 2003).

The involvement of the retail sector in HMM was further developed through a series of meetings held to facilitate dialogue with the DoMC and WHO in 2001. From these meetings the DoMC adopted a generic strategy that included increasing caregiver and provider knowledge on the use of OTC anti-malarial medicines through training PMRs and communities (MoH, 2003). Following this, an advocacy meeting was held in May 2002 to induct district level managers on the proposed scaling up process. Scaling up was initially planned as a step-wise process starting with five District Demonstration Programmes (DDP) to develop capacity in these core districts, gain experience and provide evidence of effectiveness. With support from the GFTAM, a training of trainers' workshop was held in 2003 to build capacity in the first five districts. The KEMRI-CGMRC partnered with the MoH to provide technical implementation support and evaluation activities in three of the five districts (Kwale, Busia, and Makueni). However, due to pressure to scale up the strategy from international initiatives between 2003-2005, over 33 districts obtained funds through the GFTAM to implement PMR programmes prior to evaluations being completed for the DDP.

2.4.3. Influence of drug policy change in the implementation of HMM in Kenya

Since the late 1990s the MoH has changed its first line drug for the treatment of uncomplicated malaria twice (Shretta et al., 2000; Amin et al., 2007) due to the development of parasite resistance to anti-malarial medicines used. The first change was in 1998 when SP replaced CQ. In 2004 the policy was changed again from SP to ACT.

The evidence gathered on CQ resistance ignited the process of policy change from CQ to SP between 1991 and 1998. Decisions to change were slowed down by confusion on what constituted failure, evidence required to change, lack of cost-benefit analysis data on the cost of change, and political hurdles. SP was initially a prescription only

medicine, and it was not until late 1999 that SP was made an OTC medicine to increase accessibility to communities (Shretta et al., 2000). Subsequent change in first line treatment recommendations from SP to ACT in Kenya in 2004 faced similar challenges. The process of change began by establishing evidence for clinical and parasitological failure rates in accordance with WHO guidelines (WHO, 1999). A number of working groups reviewed this evidence and considered options for change, including AQ, combinations of either SP or AQ with artesunate, or AL (Amin et al., 2007). A number of challenges faced the working group including lack of nationally generated evidence and pressure from WHO to consider a specific product, AL. In 2004, the DoMC recommended a new anti-malarial drug policy to the Kenyan Government thus a shift of first line anti-malarial treatment for uncomplicated malaria from SP to AL (MoH, 2004). This policy was to be implemented in a phased process through experience gained in the public sector, deregulation of ACT status for OTC use, and the development of evidence based operational research to maximise its use in the retail sector (DoMC, 2006). Despite these announcements, there remained several concerns about implementation, around perceived failures in long term predictable financing, procurement and supply. The process was also affected by political issues raised by the national and international pharmaceutical interests regarding single sourcing of AL and regulatory issues concerning widening access to this drug (Amin et al., 2007). The latter was of particular interest in the implementation of the retail sector programmes, given the prescription only status of AL.

Within such an anti-malarial drug policy landscape, programmes involving the retail sector met several implementation challenges. The national policy window for scaling up PMR programmes in Kenya coincided with the period when SP was losing its efficacy. The announcement of the change to ACT as a first line anti-malarial medicine in 2004 threw confusion into the scaling up. In view of the failure rates seen for SP in

many parts of Kenya, and the lack of alternative available OTC anti-malarial, the DoMC identified AQ as the appropriate OTC medicine for first line treatment of malaria in the retail sector. The main evaluation of PMR practices in this study was based on the use of AQ medicines. It is important to note that although AQ was both the second line malaria treatment and officially a prescription only medicine, the drug had been available in the retail sector in Kenya for many years in various branded forms (DoMC, 2005).

2.5 Approach to programme evaluation in this thesis

This thesis aimed to understand how three different PMR initiatives performed and to compare the relative advantages of each in terms of their effect on retailer knowledge and practices; geographic coverage of and utilisation by populations; and implementation processes (section 1.6) This thesis employed quantitative and qualitative methods to assess programme performance. It was designed and conducted between 2005 and 2006 based on a comparative analysis of the Bungoma-AMREF, the Kisii-Merlin and the Kwale-MoH PMR programmes.

2.5.1 Overview of programmes evaluated

This section introduces the implementation experiences of the evaluated interventions in Bungoma, Kisii and Kwale districts. This description provides background information on the key elements of intervention design and the implementation milestones. Across all the sites, as outlined in table 2.3, there were five main elements of the intervention, namely training, demand creation, accreditation, motivation, monitoring and evaluation, and formative research. Although mobile sellers in public health terms are potentially a key group of providers, the focus of these interventions was largely to reach non-mobile medicine sellers in the periphery.

Table 2-3 Summary of the elements of the intervention across all sites

Key elements of innovation	Kisii -Merlin	Kwale-MoH	Bungoma–AMREF
Training activities	Three-day direct PMR training workshop, Recruitment based on selection criteria: remote settings, selling anti-malarial, relatively stable, willingness to be trained. Refresher training planned but dropped. Record keeping emphasised	Two-day direct PMRs training workshop. Recruitment based on selection criteria: remote settings, relatively stable, selling anti-malarial, willingness to be trained. Refresher training planned but not conducted	No direct training of PMRs, one-day orientation of wholesalers, wholesale attendants, mobile vendors. No selection criteria, Refresher training conducted
Demand creation	Initial plan to have public meetings to create awareness but changed to a focused approach through targeted distribution of IEC materials in schools, community groups, churches and health facilities	Public information activities planned through distribution of IEC materials and public meetings though not conducted	Distribution of IEC materials including job aids and posters. Bolstered by contests held in communities to create demand through JKJ strategy However this was not fully implemented
Accreditation	Provision of wooden posters and certificates though a few PMRs were not issued	Provision of paper posters and certificates although the latter was not implemented	Provision of letters to vendors, signing agreement forms to perform according to standards and provision of paper posters.
Motivation	Financial token of about USD 3.7/workshop given to PMRs for lunch and transport and PHOs involved from the user organisation	Financial token of USD 3.7 given to PMRs for transport and lunch and USD 5.2/workshop for PHOs and DHMT members	Deliberate attempts to dialogue between implementers, mobile vendors and PMRs and awards given to exemplary performers in "Malaria Effective Treatment Night". Financial token of USD 7.5/workshop given to mobile vendors and PHOs involved
Monitoring, supervision and follow up	Core team checking PMR records and supportive supervision adopted	Minimal follow up done and monitoring not done	Core team follow up to oversee the retailer practices and collect receipts
Formative research and dissemination of findings	Conducted to provide information for design of IEC materials and assess progress of programme	Baseline household surveys not used for design. Retail audit conducted to assess sources of drugs, provide list of outlets for selection process	Helped design innovation. Dissemination of findings formed an integral part of the implementation process

2.5.1.1 Bungoma-AMREF programme

The BDMI programme was set up in 1999 following a number of baseline surveys and follow up studies conducted in 1998 to inform programme design (figure 2.4). Based on these findings, interventions were developed in malaria case management of children in health facilities and at community level; management of malaria in pregnancy; and use of insecticide treated materials. The VTV strategy was implemented as part of community IMCI and funded by the USAID-Quality Assurance Project (QAP) through contractual agreements between AMREF and other international partners such as CDC and QAP. The implementation process can be viewed as having occurred in three main phases: an initial development phase; the first implementation phase conducted with donor support from AMREF, funding partners, an external technical team and the DHMT; and a subsequent implementation phase following donor withdrawal. Following the withdrawal of the main funding agency in 2002, the implementation process was managed by AMREF and DHMT (phase 3 in figure 2.4). The objective of the intervention was to improve the capability of caretakers to manage fever and anaemia at the household level through training mobile vendors, wholesale, and pharmacy attendants and distributing job aids to PMRs.

As a social marketing approach, the Bungoma-AMREF intervention targeted the whole district, including retail shops, drug shops and private clinics. The key actors involved in the intervention at district level were representatives of the funding agencies and technical partners, the programme manager (AMREF), and the MoH field officers such as public health officers (PHOs), public health technicians (PHTs)[5], wholesalers, mobile vendors and PMRs. The training component targeted a range of wholesale drug suppliers across the district (mobile drug vendors, general wholesalers and suppliers in pharmacies) who were trained to provide information and job aids to

[5] MoH officers who oversee general public health activities

PMRs on the use of OTC anti-malarial medicines. This was preceded by training of wholesale outlet and pharmacy owners for one day to mobilise their support for the programme (Tavrow et al., 2003). Training was conducted between April and June 2000 (figure 2.4 phase 1), and included the signs and symptoms of malaria, dangers of malaria, prevention and treatment of malaria.

Initial demand creation was based on the production of IEC materials such as flyers on malaria control and treatment. Evaluation conducted at the end of phase 1 indicated the need to strengthen demand creation, and a community based programme called the Jirani kwa Jirani (JKJ) [6] which was introduced in phase 2. The JKJ programme was based on a pyramid information dissemination approach. PHTs were trained to pass information and IEC materials to community members who would then pass the same messages to five neighbours. This process of training five others was to be repeated until the entire village was covered. The JKJ component also used song contests to encourage people to internalise five key messages on malaria control. In the early implementation phase of the programme (2000-2003) 1,400 copies of IEC materials were distributed to approximately 500 outlets across the district. 40 mobile vendors, 22 wholesale pharmacy attendants and 11 wholesale shops attendants were trained (Tavrow et al., 2003).

Another element of the intervention was accreditation. Accreditation focused on voluntary adherence to minimal standards to assure public safety and encourage quality service delivery (Smith et al., 2001). Accreditation was broadly meant to strengthen demand from community members and encourage PMRs to adhere to recommended guidelines of selling anti-malarial medicines. In the Bungoma-AMREF site, accreditation was achieved through signing of agreement forms by wholesale and

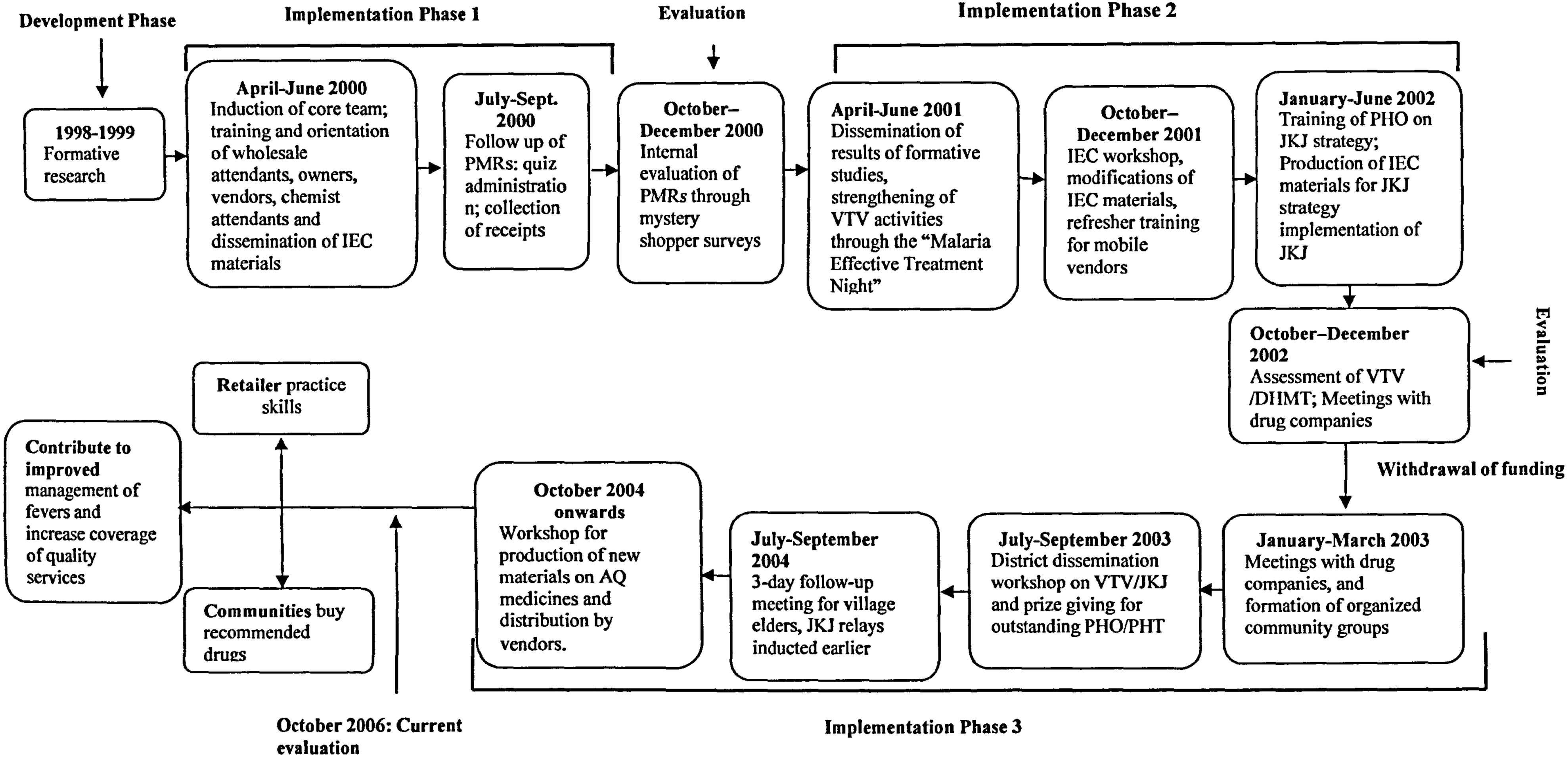
[6] Acronym in Kiswahili meaning neighbour to neighbour

chemist owners, letters of approval and copies of the official government notice on OTC medicines given to mobile vendors by the DHMT.

The fourth element of the intervention covered strategies to motivate the DHMT teams and PMRs to implement the intervention. This was done through financial incentives given as routine allowances. A financial per diem payment of USD 7.5[7] was given to mobile vendors and PHOs and members of DHMT during participation in the workshops. In addition, PHOs, mobile vendors or PMRs who performed well in the intervention activities were awarded with certificates of recognition during public meetings dubbed "Malaria Effective Treatment Nights". Incentives given to all actors generated a range of expectations discussed in chapter four (section 4.4). The final component was monitoring and evaluation. Attendants and mobile vendors were followed up by PHOs, where quizzes were administered and receipts on distributed IEC materials were collected. Operational and empirical research was used to inform programme planning in the Bungoma-AMREF site. This was conducted at different time points and the results were disseminated at district, national and international levels (figure 2.4). Details of the implementation processes are discussed in chapter four.

[7] Exchange rate of 1 US dollar = KES 67

Figure 2.4 Implementation milestones towards achieving intended outcome in the Bungoma-AMREF intervention



2.5.1.2 Kisii-Merlin PMR training programme

Merlin (Medical Emergency Relief International) is a United Kingdom based humanitarian organisation providing health care to populations experiencing crisis (http://www.merlin.org.uk/, 2007). The Merlin malaria control programme in Kisii Central and Gucha districts aimed at reducing morbidity and mortality associated with malaria. This was to be achieved through increasing capacity among formal and informal healthcare providers to diagnose and treat malaria according to the MoH guidelines. The programme was funded by the Government of Finland through a common project with International Centre for Insect Physiology and Ecology (ICIPE) and incorporated partners including the MoH, World Vision, PSI and communities.

The PMR training programme was part of the larger malaria control component of the Merlin project. The underlying approach drew on the Kilifi shopkeeper training programme. The strategy used behaviour change principles of participatory skill-based training, as well as monitoring, supervision and demand creation. The programme described in this study began in 2003 in Kisii Central and Gucha districts (figure 2.5). At the time of this evaluation, the PMR programme was operationalised by Merlin.

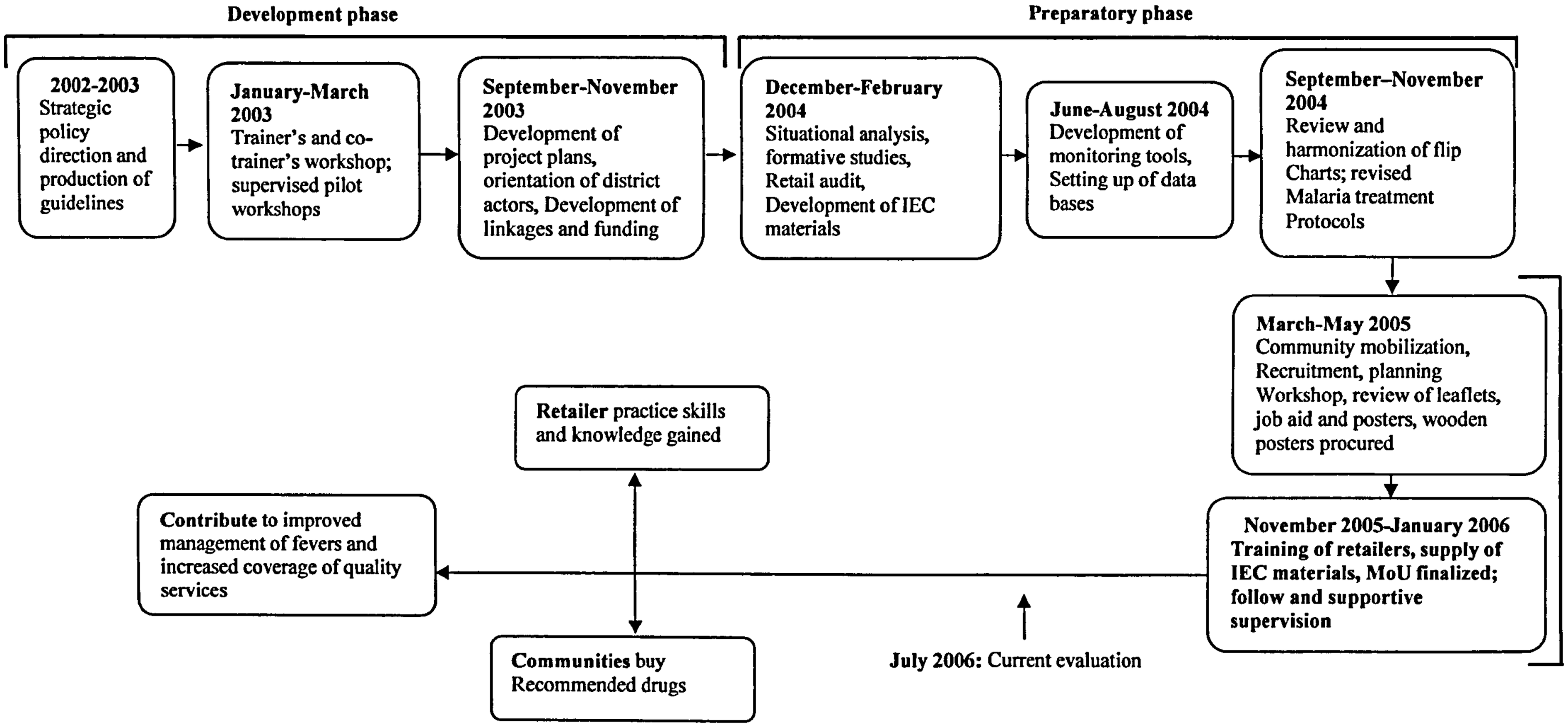
The key actors involved were the NGO programme manager, two NGO trainers, PHOs and PHTs in relevant divisions, PMRs and communities. The programme targeted two divisions in each district where Merlin was involved, that is, Mosocho and Kiamokama divisons of Kisii Central district and Sameta and Ogembo divisions of Gucha district.

Activities in the Kisii-Merlin programmes involved direct training of PMRs in participatory skill based workshops lasting three days. Recruitment of PMRs was based on selection criteria such as remote settings, sale of anti-malarial medicines, relative stability and willingness to be trained. The training covered general information on malaria treatment and control; signs and symptoms of malaria,

including danger signs; communication skills; referral practices; and record keeping. Training activities were conducted between November 2005 and January 2006. The second element of the intervention was demand creation. Initial plans were to create demand through public meetings. Later, several changes were made to inform the communities of the innovation through schools, community leaders and churches. An additional approach was distribution of T-shirts with messages on fever management at community level. Demand creation was supported by accreditation conducted through awarding certificates to PMRs and providing wooden-backed posters to display outside trained outlets. These enabled community members to identify which outlets had been trained.

The fourth element of the intervention was motivation. In the Kisii-Merlin site, PMRs and members of the DHMT who were involved in the implementation process were given allowances during training workshops. Per diem allowances approximating USD 3.7 was given to PMRs, and USD 5.2 for PHOs and DHMT members during participation in the workshops. The fifth component of the intervention was monitoring and evaluation. Follow up monitoring activities, including checking records and administering quizzes were conducted in the majority of outlets. Later, this was supplemented with dialogue to solve problems encountered and on site reminders to promote sustainability of the new knowledge. The final element of the intervention was operational research conducted by the monitoring and evaluation department of the local Merlin office to inform future planning for the intervention. Earlier formative research had been conducted by ICIPE to help target the intervention to areas most affected by malaria. Figure 2.5 summarises the implementation milestones of the Kisii-Merlin intervention.

Figure 2.5 Implementation milestones towards achieving the intended outcome in the Kisii-Merlin intervention



2.5.1.3. Kwale-MoH PMR training programme

Section 2.4.3 outlined the development of the DDP as the first step taken by the DoMC towards scaling up the HMM strategy in Kenya in a coordinated manner. The implementation was funded by the GFTAM and processed through the normal government system under the direction of the DoMC. The KEMRI-CGMRC provided technical support for trainers and conducted baseline surveys in 2003 and programme evaluations in 2005. The initial districts involved were Kwale, Nandi, Busia, Makueni, and Kisii and Gucha. On the basis of the implementation guidelines developed, the research team from KEMRI-CGMRC designed evaluation activities in collaboration with the DoMC and the DHMT of the three districts (Kwale, Makueni and Busia). Of the three districts evaluated in the DDP, quantitative and qualitative data from Kwale have been used for the comparative analysis that forms the main premise of this thesis. Kwale was chosen as a case study to represent the MoH-led programme for two reasons. Firstly, Kwale and Makueni were part of the monitoring and evaluation sites for the DoMC for assessing targets set within the KNMS (DoMC, 2002; Noor et al., 2003). For this reason, data such as geographic positioning of retail outlets and health facilities, and community treatment seeking patterns were available for assessing coverage and modelling utilisation as part of this study. Of these two districts, Kwale was considered more suitable for this evaluation since it experiences a higher malaria burden than Makueni and was therefore likely to serve as a better comparator for programmes in Bungoma and Kisii. Data from the DDP evaluation in Kwale, Makueni and Busia are presented in annex I.

The Kwale-MoH intervention represents a MoH-led large-scale approach that combined PMR workshops and public information activities to address PMR and client behaviour. The programme adapted the Kilifi shopkeeper training approach to the constraints of the government health sector. The main objectives were to train

PMRs to stock MoH recommended anti-malarials; offer appropriate advice on the treatment of simple fevers in children with anti-malarials; and educate community members on fever management through public information activities. The programme initially targeted two divisions that had been randomised before intervention to programme implementation. A further two divisions were similarly allocated to control, allowing for the potential implementation in these areas depending on outcomes seen. Kinango and Matuga divisions were identified as the first implementation sites with Msambweni and Samburu acting as controls. The key actors involved were the district public health officer (DPHO), district health education officer (DHEO[8]), four PHOs in charge of divisions, PMRs, CORPS and community members. At the time of this evaluation the intervention was being implemented by the DHMT.

Like the Kisii-Merlin programme, the main component of the intervention involved participatory skill-based workshop training of selected PMRs and community education activities on malaria treatment and prevention. The selection process was similar to the Kisii-Merlin site. The PMR training workshop lasted two days covering: signs and symptoms of malaria including danger signs; malaria treatment; communication skill and referral of clients to healthy facilities. Prior to PMR training, capacity building workshops were held for the district and divisional level actors (figure 2.6), as for the Kisii-Merlin programme.

In the Kwale-MoH site, plans were made to create demand for the programme and awareness of malaria treatment through public meetings and distribution of leaflets to the communities and PMRs. This involved pre-testing of PMR job aids and

[8] DPHO and DHEO coordinate public health activities in districts supervise and regulate sale of food and drugs in general shops and chemists.

community leaflets which were later produced centrally through the DoMC. As part of the process of demand creation as well as accreditation, PMRs were supplied with posters to display outside their outlets to help community members identify trained outlets.

PMRs and DHMT members involved in the intervention were given per diem allowances during training to facilitate attendance and provide motivation. This was approximately USD 3.7 given to PMRs for transport and lunch and USD 5.2 for DHMT members who participated in the workshops. Other activities such as monitoring were also planned. Finally, baseline research was conducted by the technical team to guide implementation, such as the development of a database of retail outlets selling anti-malarial medicines. The main implementation gaps identified and the reasons behind the gaps are discussed in chapter four. Figure 2.6 presents the implementation milestones for the Kwale-MoH intervention.

Figure 2.6 Implementation milestones towards achieving the intended outcomes in the Kwale-MoH intervention

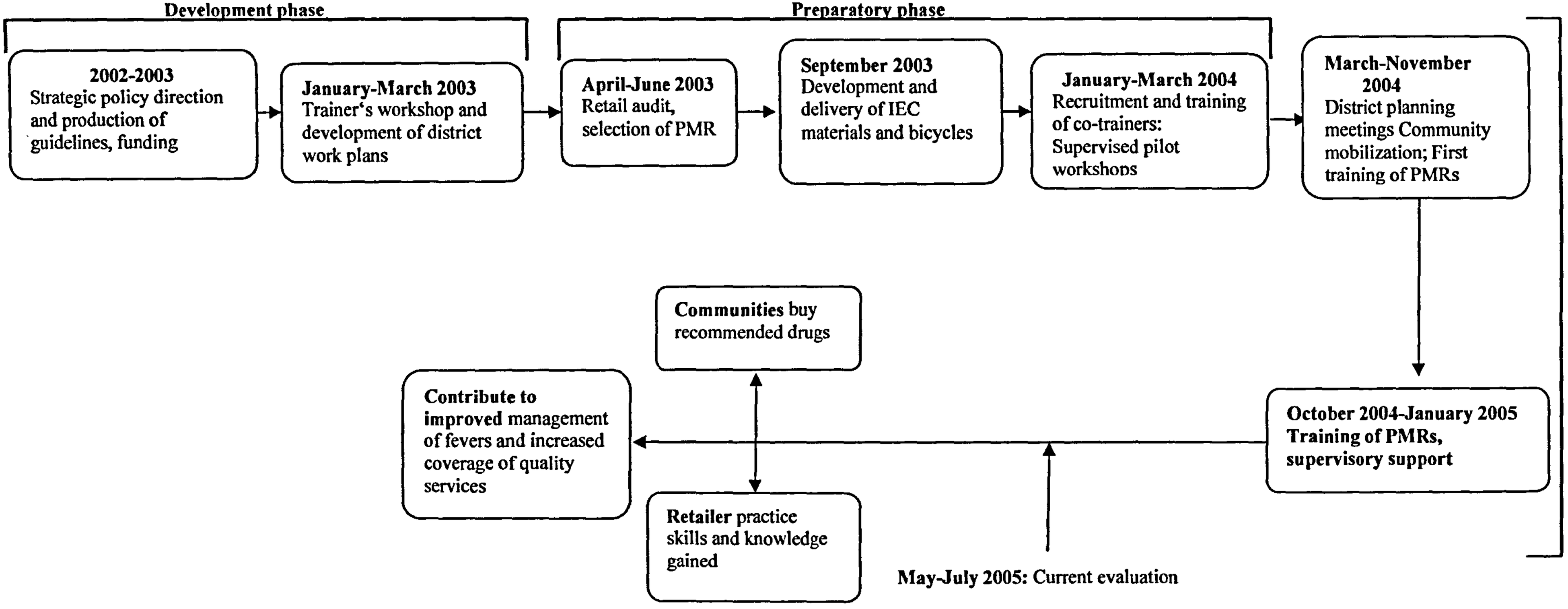
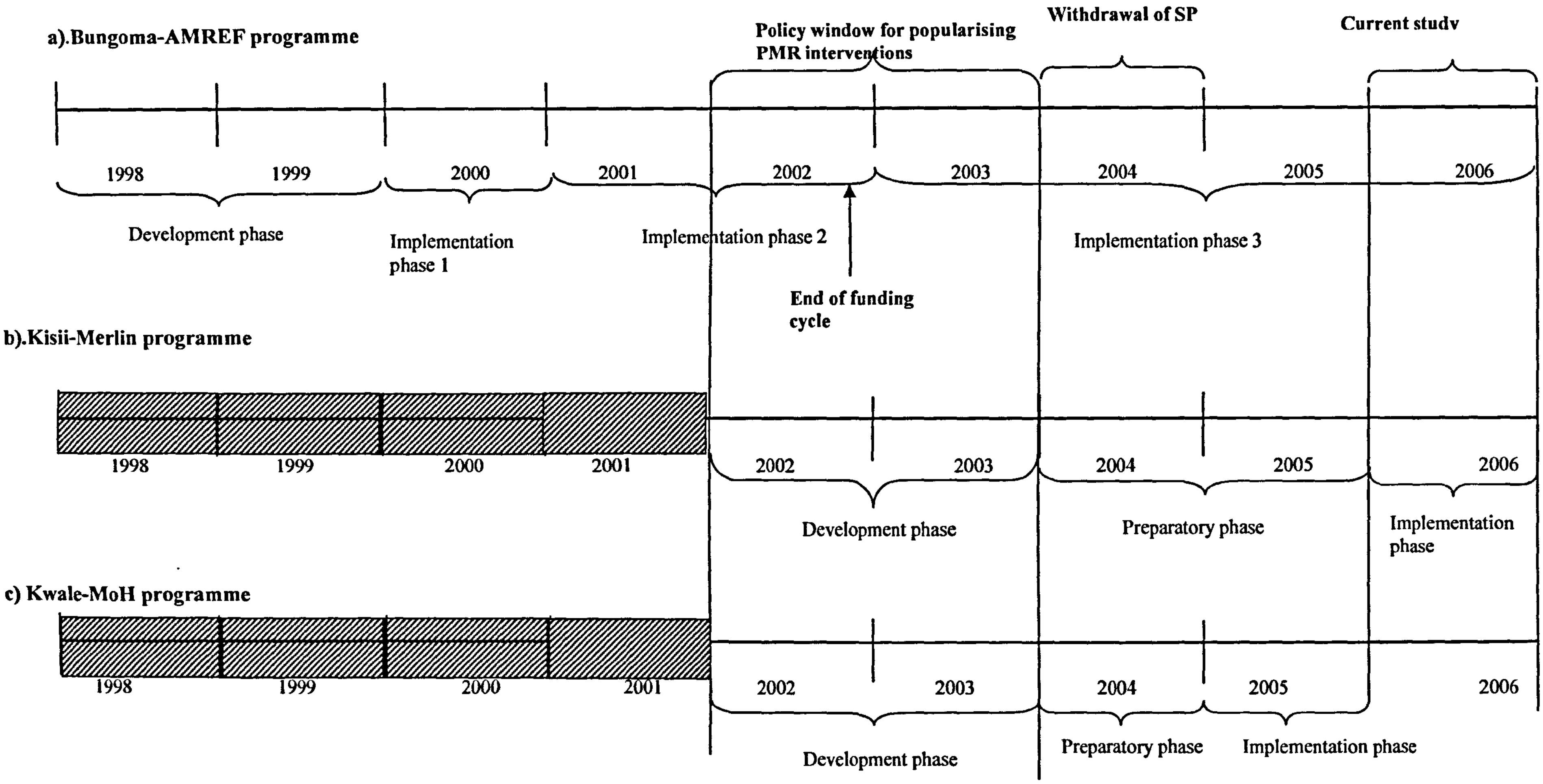


Figure 2.7 presents a simplified timeline of the implementation process across all sites. The development phase of the Kisii-Merlin and Kwale-MoH programmes coincided with a policy window for retail sector interventions in malaria control at international and national levels[9]. However, during the same period (2002-2003), the main funding for the Bungoma-AMREF programme was coming to an end. Although the development phase for all the programmes took two years, the activities in the Bungoma-AMREF sites differed from other sites. The main activity for this site during the development phase was baseline formative research while the other two sites focussed on training trainers and developing work plans. After implementation, Bungoma-AMREF also had two sets of internal evaluations which informed further planning. The current evaluation was conducted three years after withdrawal of funding. In two sites (Kwale and Kisii), the preparatory phase coincided with the period when SP was being withdrawn as the first line OTC medicine, and its successor in the private retail sector was not clear.

[9] Period where national strategy was being developed

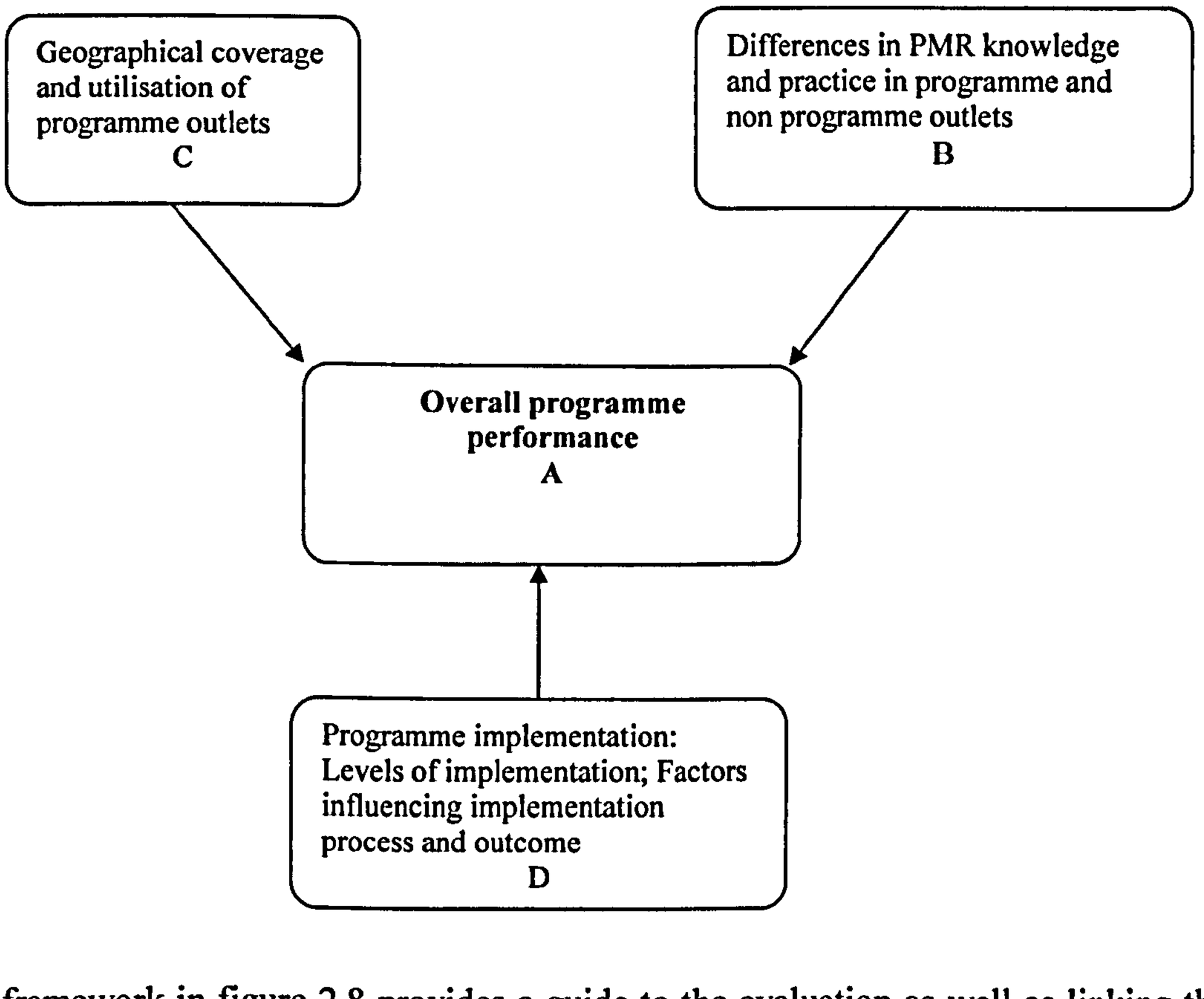
Figure 2.7 Summary of time line of activities across the three sites



2.6 Conceptual framework

This section lays out the conceptual framework for the study presented in this thesis. It outlines the rationale for using this framework, and illustrates the linkages between the framework, objectives and indicators for the evaluation. A review of literature (chapter one section 1.6) indicated that measures of performance include provision, coverage, utilisation and impact (figure 1.4). In addition, implementation processes are necessary elements to consider while interpreting and understanding the outcomes. The conceptual framework for evaluating these interventions is drawn from that literature and covers the measures mentioned above (figure 2.8).

Figure 2.8: Conceptual framework for assessing programme performance



The framework in figure 2.8 provides a guide to the evaluation as well as linking the indicators used in the objectives for this assessment. Overall performance of the intervention (Box A) was measured through: an assessment of programme impact on retailer knowledge and practices; provision (whether activities were implemented),

utilisation (whether trained seller services were used) and coverage (target population reached). The impact of the programme at retailer level was assessed by comparisons between programme and non-programme outlets (Box B), using quantitative indicators to determine the impact on PMR behaviour associated with programme activities. Study methods for this assessment were retail audit and surrogate client surveys described in section 2.8. In order to assess population coverage of trained PMRs (Box C), quantitative indicators were measured using GIS techniques. Potential utilisation of the programme outlets (Box C) was modelled by combining mapping data and treatment seeking behaviour data from previous surveys (Gitonga et al., 2008). Implementation was assessed qualitatively using a health policy analysis framework (Box D).

2.6.1 Indicators for assessing retailer's knowledge and practices

The indicators outlined below were used to assess the impact of the programmes on PMR knowledge and practices, illustrated in Box B, figure 2.8. The primary indicator for assessing the impact of programme on PMR knowledge and practice was:

- The proportion of sales where anti-malarial medicines are sold accompanied with advice in accordance with MoH recommendation

Secondary indicators were:

- The proportion of programme outlets that stock MoH recommended anti-malarial medicines
- The proportion of outlets where the main seller understands MoH recommendations on anti-malarial medicines and can identify appropriate dosages for children.

The primary and secondary indicators aimed to answer objective 1 and were derived from the retail audit and the surrogate client survey.

2.6.2 Indicators for estimating population coverage and utilisation of programme

As described in chapter one, coverage refers to the extent to which population in need of programme services is reached while utilisation is the extent to which the services are being used (Habicht et al., 1999; Shengelia et al., 2005). In line with objective two, indicators for assessing coverage and utilisation (Box C) were grouped into two sets:

Firstly, indicators of coverage defined through spatial access to examine the public health impact:

- Proportion of programme outlets per unit administrative area (division)
- Ratio of outlets with trained PMRs to health facilities per unit programme area (division)
- Retailer-population ratios

Secondly, indicators of potential utilisation were derived by modelling mapping data from previous fever surveys (conducted as part of evaluating RBM targets) to identify:

- Derived threshold distance (the distance within which most caregivers would be likely to access treatment through a given retail outlet)
- % under five population living within the calculated threshold distance of a trained retailer for each specific location

2.6.3 Assessing implementation and factors influencing process

Although achieving stated impacts are the ultimate goals of programmes, tracking the process of implementation is key. As a precursor for medium and long term results (Bryce et al., 1994), they provide evidence for observed impacts, provide lessons on how to adapt programmes in the future and strengthen the internal validity of outcomes. The study employed policy analysis technique in understanding the implementation process and gaps, and exploring factors influencing practice which had a bearing on the outcomes of interest. In this study, the term implementation gap refers

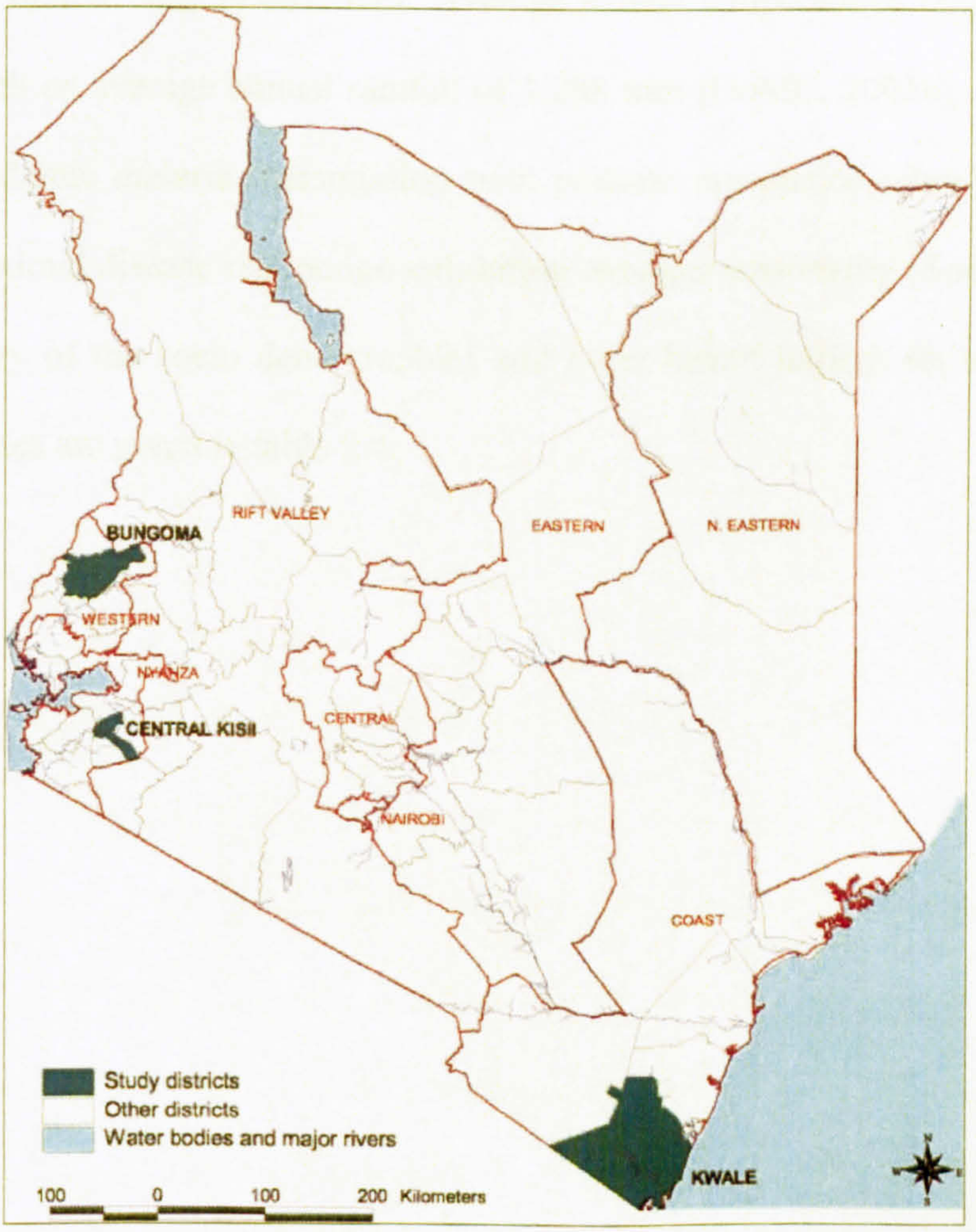
to differences between planned and implemented activities. Key sources of data are described in section 2.9.3 and have been used to achieve objective three: examining programme implementation factors influencing the process.

2.7 Geographical location and characteristics of study districts

2.7.1 Bungoma district

Bungoma is among districts in Western Province lying between longitude 34.38^0 and 35.1^0 east and latitude 0.30^0 and 0.54^0 south (figure 2.9). The mean annual rainfall is 1250-1800 mm and annual temperatures between 21-30°C. Malaria transmission occurs all year round with higher rates during the rainy seasons. The endemic pattern is similar to the lakeside endemic malaria (Snow et al., 2003).

Figure 2.9 Geographic location of the study districts in Kenya



2.7.2 Kisii Central district

Kisii Central district is within Nyanza province and lies between longitude 34.21^0 and 35.3^0 east and latitude 0.25^0 and 0.51^0 north. The average annual rainfall is 1500 mm with temperatures between 14 -27°C (DoMC, 2001a). The district is characterised by a highland/epidemic type of malaria transmission. This is a feature of malaria in highland districts where there is a potential for limited transmission lending itself to an overall low disease risk on an average year, with variations in rainfall and ambient temperatures between years leading to epidemics (Snow et al., 2003).

2.7.3 Kwale district

Kwale district is in the Coast Province between latitude 3.550^0 and 4.667^0 south and longitude 38.450^0 and 39.667^0 east. Average annual temperatures range from 24.6 to 27.5°C with an average annual rainfall of 1,288 mm (DoMC, 2001b). The district has coastal endemic malaria transmission with parasite prevalence often exceeding 50% with a maximal disease risk period exhibiting stronger seasonality (Snow et al., 2003). A summary of the socio demographics and other health indices for the comparative analysis sites are given in table 2.4.

Table 2-4 Demographic, and malariometric indices of the study districts

Indicator	Kwale-MoH	Kisii-Merlin	Bungoma-AMREF
Demographics*			
Area	8295 km^2	649 km^2	2069Km^2
Population size (1999)	496 133	491 786	876 491
Inter-censal population growth rate	2.6%	2.1 %	4.3%
Projected population (2006)	595 168	565 689	1 1184 323
Population density	60 persons /km^2	758 persons/km^2	422 persons/km^2
Population under five	85474	75733	167574
Projected < five population	102 536	87 114	226 428
Altitude	0-842 m	1000-1800 m	1200-2100 m
Health status indices †			
Infant mortality per 1000 live births	91	90	78
Under five mortality per 1000 live births	149	109	126
Number of Health facilities			
Hospitals (NGO/MoH)	3	5	4
Health centres	7	13	7
Dispensaries	54	39	24
Private clinics	35	71	24
Maternity & nursing homes	7	4	2
Private hospitals	2	6	0
Institutional facilities	0	1	0
Specialised facilities	1	1	0
Poverty indices ‡			
% living below poverty line	63%	62%	57%
Malariometric indices			
Malaria risk	Endemic coast	Highland	Lake endemic
P. falciparum prevalence §	67.5%	27.56%	55.9%
Fever prevalence in <5** 、	43.3%	40.8%	64%

**Source: 1999 Population and Housing Census, † Source: Kenya Demographic health survey 2003, ‡ Source: Poverty mapping exercise in 2003 and Kenya Demographic health survey 2003, § Source: Malaria Atlas project based on a number of studies between 1985 to date, ** Source: care-seeking surveys conducted in sentinel Districts 2002-2005, and other studies conducted in Bungoma.*

2.8 Study design and selection of study sites

The overall study design for the comparative analysis was based on cross sectional surveys conducted in each of the three districts. Impact on PMR knowledge and practice (Box B figure 2.8) was assessed through quantitative surveys of programme and non-programme outlets in each district. In the Kwale-MoH site, the surveys were part of a larger cluster randomised trial comparing intervention and control divisions. The other two sites utilised a pragmatic design based on post implementation surveys in programme and non-programme areas. Data on population coverage and utilisation

(Box C) was based on mapping surveys and drew from existing treatment seeking data to model utilisation. Implementation processes were assessed qualitatively using health policy analysis (Box D).

As described earlier, the Kwale-MoH site was part of DDP planned in advance of implementation. The study sites were selected randomly before implementation and the unit of randomisation were divisions. To minimise bias the DHMT in Kwale district identified four divisions they considered similar in socio-economic characteristics, malaria burden, malaria control programmes and access to health care facilities prior to randomisation. In Kwale, 4 out of 6 divisions; (Matuga and Kinango) had been randomly allocated to intervention area (starting 2003), while (Msambweni and Samburu) acted as control divisions.

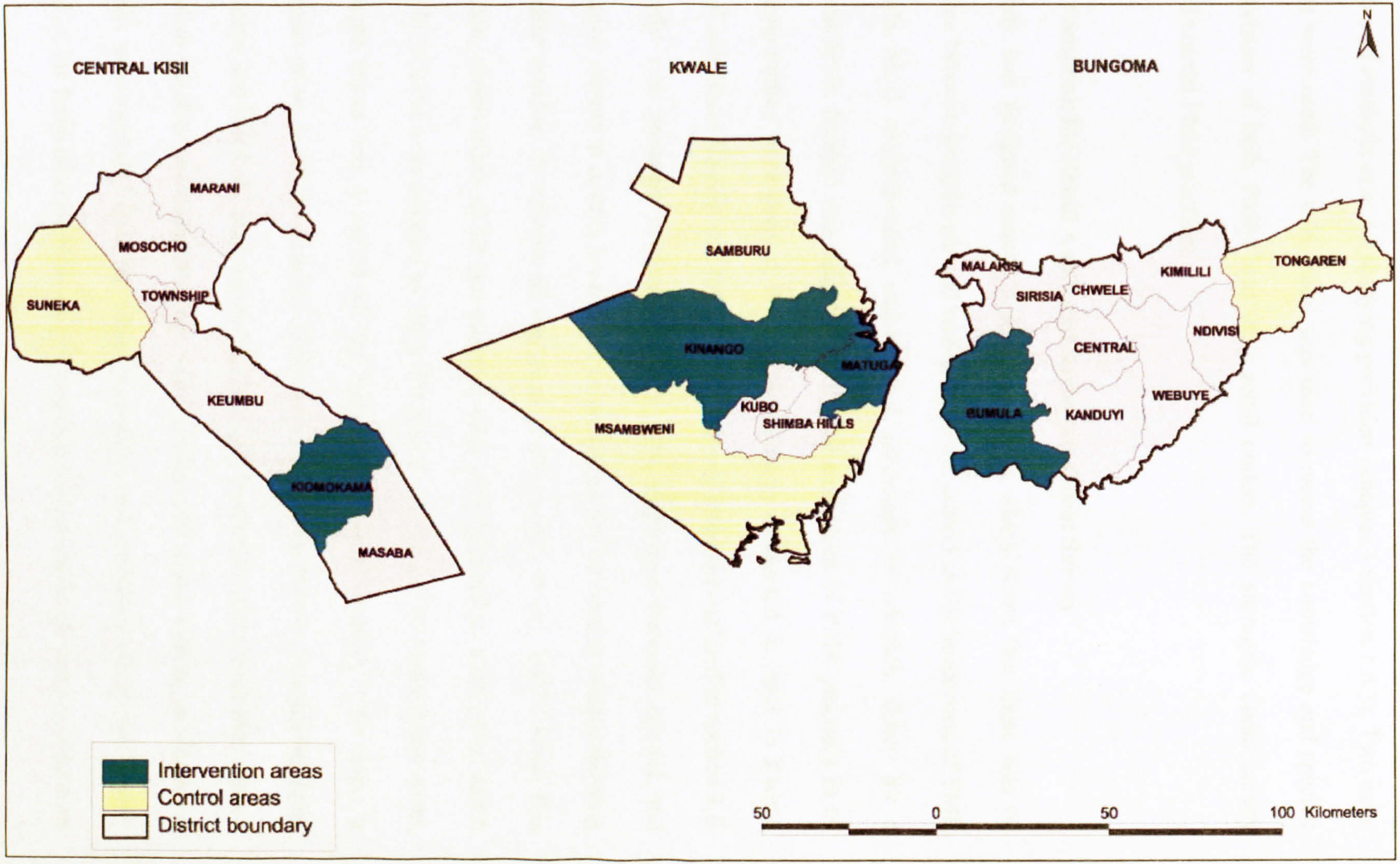
For Bungoma-AMREF and Kisii-Merlin programmes, the evaluations for all aspects of programme performance were designed and conducted post intervention based on purposive selection of study sites. This pragmatic design was necessary because the current study occurred after implementation and pre-intervention data were not available. In order to assess the impact of programme on PMR knowledge and practices, the study adopted a non random allocation of one division to intervention area and one to control, with matching based on DHMT's local knowledge for similarity in geographical features, malariometric indices and other malaria control activities. Indicators for Boxes C and D were assessed in intervention areas only.

The Bungoma-AMREF programme presented unique challenges in identifying intervention and control areas because the intervention design targeted outlets in the whole district. In order to select the intervention area, a meeting with all active mobile vendors identified divisions they frequented most in the last six months. They included

Kanduyi, Webuye, Bumula Ndivisi, Chwele and Malakisi divisions. Chwele, Ndivisi and Malakisi divisions were excluded due to other retailer training activities that had been conducted by AMREF and MoH with GFTAM support. Webuye and Kanduyi divisions have a greater urban concentration making it difficult to match a control area with similar features. Bumula division was therefore identified as the intervention area. To select the control area, a discussion with both the DHMT and AMREF staff led to the section of Tongaren division as the control.

The choice of the intervention area of the Kisii-Merlin was made in consultation with Merlin and MoH staff where the trainings had been conducted in the last six months in Kisii Central district. Of the two divisions where training had been conducted, (Mosocho and Kiamokama), Kiamokama division was selected as the intervention to match the only available division (Suneka as the control). Figure 2.10 shows the geographical location of the study sites in each district.

Figure 2.10 Map showing geographical location of selected study sites in each district



2.9 Study methods

2.9.1 Quantitative studies

A number of methods exist for studying providers (chapter 1 section 1.6.3). Two main methods were used. The retail audit was used to assess the knowledge and specific characteristics of both PMRs and their retail outlets. The surrogate client survey assessed normal PMR practices.

2.9.1.1 Sampling for Retail Audit and Surrogate Client Survey

The study was designed around a null hypothesis which stated that there was no difference between programme and non-programme outlets in the proportion of PMR who sold MoH recommended anti-malarial medicines in adequate doses for a childhood fever. Sample size calculations for the evaluation of PMR practices in all three programmes were derived from earlier surveys conducted in 2003 in Kwale, Makueni and Busia districts and linked to the primary indicator outlined in section 2.6. The study was powered to demonstrate a 20% difference between control and intervention outlets at district level from an estimated 5% of control outlets showing appropriate practice in surveys of untrained PMR (Abuya et al., 2007). From this calculation, observations of 60 anti-malarial sales were required in each group and a total of 80 outlets were targeted to allow for data losses. In all the intervention areas, the sample frame was a list of all the trained or accessed outlets[10]. To select a comparison group in all the districts, PHOs and local administrators, constructed hand drawn maps and listed all retail outlets likely to sell medicines. They were then visited to establish whether anti-malarial drugs were stocked and those without anti-malarial medicines were excluded from the sampling frame since the intervention outlets were selected on the basis of availability of anti-malarial medicines. From this list, a random

[10] Outlets supplied with IEC materials

selection process was conducted without replacements using STATA version 8 (Stata Corp, College Station, Texas, USA.

2.9.1.2 Planning and preparation of surveys

Preparation for the survey involved sensitisation and planning meetings with local leaders from the study areas. In addition a meeting the District Medical Officer of Health (DMOH) was held to introduce planned research activities. In all districts, planning also involved recruitment of field workers through an advertisement put up in every study division two weeks before the survey. Depending on the geographical areas to be covered, 12 to 24 female candidates were selected and an additional six candidates for the mapping exercise in each district. Female candidates were preferred for the surrogate client survey since care for younger children is predominantly a domain of mothers in these settings. All the candidates were trained for three days on the study activities, the importance of how to maintain the covert nature of the survey, communication skills, and obtaining informed consent.

2.9.1.3 Surrogate Client Survey method

As described in chapter one, the surrogate client survey aimed to collect information on the behaviour of PMRs while selling OTC anti-malarial medicines. Six female field workers per division were trained and visited sampled outlets. They visited outlets away from their own homes to avoid recognition by community members. They used a standardised scenario, which entailed asking for an anti-malarial medicine for a child. If asked, they provided standardised responses to questions about the age of the child (three years), the symptoms of the illness (simple fever[11]) and any previous treatment

[11] Defined by the perception of the caregiver and not associated with signs of severity, including diarrhoea and vomiting more than three times a day

given (none). Details of the transaction, questions asked and information given were entered in a simple questionnaire after leaving the outlet.

2.9.1.4 Retail audit method

The survey entailed an audit of outlets to collect information on general characteristics of the outlets and PMRs, drugs stocked; retailers' knowledge and reported practices in selling and advising on malaria medicines stocked; and their referral practices. In contrast to the surrogate client survey, the child in the scenario developed for the retail audit was aged 5 years. This difference arose in response to observations during the surrogate client survey that PMRs were reluctant to sell anti-malarial medicines to children under five. Field workers visited outlets using public transport or by foot in their respective divisions. The supervisor met them after every two days to review their work. Before each interview, the field workers gave a careful explanation of the purpose of the survey and sought verbal consent from the main seller. Any refusals to participate were recorded and the reasons for refusal noted. A pre-tested structured questionnaire was used to collect the information. This survey was conducted after completion of the surrogate client survey.

2.9.1.5 Generating coordinates for assessing coverage

In order to map all outlets in the programme areas and generate coordinates for modelling and assessing coverage of the programme, field workers were trained on the use of the global positioning systems (GPS) hand held receivers (Germin etrex and Trimble 12 band GPS units). Mapping was conducted after the surrogate client and retail audit surveys. Field workers then conducted a short interview on ownership of the outlet and involvement in the retailer programme. Thereafter the field workers took three geographical coordinates of the outlet. Each of the readings was taken when the

accuracy level was below 20 metres. An average was then taken to generate coordinates to mark each outlet.

2.9.2 Quantitative data management

2.9.2.1 Storage and analysis of the surrogate client survey and retail audit data

All the quantitative data from the surrogate client survey and retail audit were checked for errors and coded each day. Assessment of adequateness of advice of anti-malarial medicines was based on the national malaria control drug charts (annex II). Data were double entered using FoxPro Version 6 software (Microsoft Corp, Redmond, USA). Verification, cleaning and analysis was conducted using STATA version 8 (Stata Corp, College Station, Texas, USA). Analysis within each district was done using chi–square tests of association to compare proportions for key outcome indicators. Where differences between the control and intervention areas were observed, a logistic regression model was conducted to measure the magnitude of effect.

2.9.2.2 Generating maps

All the data collected during the mapping exercise was entered in excel sheet (2003) and later transferred to GIS software to generate maps. The average coordinates calculated in excel were exported to Arcview GIS 3.2 (ESRI Inc., USA). The point data was then overlaid with the polygon features of the division surveyed. This helped in validating the geo-positioning of the outlets. The outlets were classified in Arcview GIS software into trained and non-trained. Maps generated are presented in chapter three.

2.9.2.3 Developing models for assessing utilisation

This section provides an overview of the model used to derive threshold distances for estimating utilisation (mean distance travelled by community members in which

utilisation for those outlets begin to decay). The proportion of clients using retail outlets for a fever in a particular locality was derived from a previous household survey. Using the enumeration area (EAs[12]) maps in the programme areas, distance in terms of walking time to visit each treatment source for fever was derived using a surface model allowing for the terrain. The basic inputs for the model were journey time to the nearest retail outlet for fever treatment which was represented by a numeric code (1 for retail outlets and 2 for other options). The reference table was exported to S-Plus for widows 6.1 version (Insightful Corporation, Inc., Basingstoke, Hampshire, UK). The script calculated utilisation rate (UR) at each journey-time interval. UR was smoothened by taking a moving average window of 50 minutes for each point interval. The purpose was to assess the relationship between UR of retail sector users versus all other sources outside home. The following mathematical function is the fit onto the resulting plot (Noor et al., 2006a):

$$UR = \begin{cases} a \exp\left[-\dfrac{(T-c)}{b}\right] & for \quad T > c \\ \\ a & for \quad T <= c \end{cases}$$

UR = Utilisation rate (between 1 and 0, arbitrary units); T = Journey time from facility of interest (minutes); a = parameter value determining initial constant rate of UR; b = parameter value determining rate of decline of UR; c =parameter value determining distance at which UR starts to decline which was considered the threshold distance. This was derived in terms of walking time later transformed into distance in kilometres (km) based on a 5 km per hour for normal walking time.

Once a threshold distance was derived, an under five population surface model was developed using the projected under five population for 2006. In this analysis thiessen polygons (TP) were used to generate the catchment areas for each of the market

[12] Smallest unit for population census

centres. TP assigned each point of the market centre or village with retail outlets and based on straight line distances, (and using the threshold distance), polygon maps of retail outlet catchment areas were generated. A polygon in this context is an area of influence of each market centre or village points with retail outlets. A population surface for children under five covering a grid of 100m by 100m cell generated was used to extract the number of children in each polygon. The under five population of all EAs falling within the centre's catchment area was summed as the potential users of the retail outlets. Copies of all the tools are provided as annex III.

2.9.3 Qualitative study and policy analysis

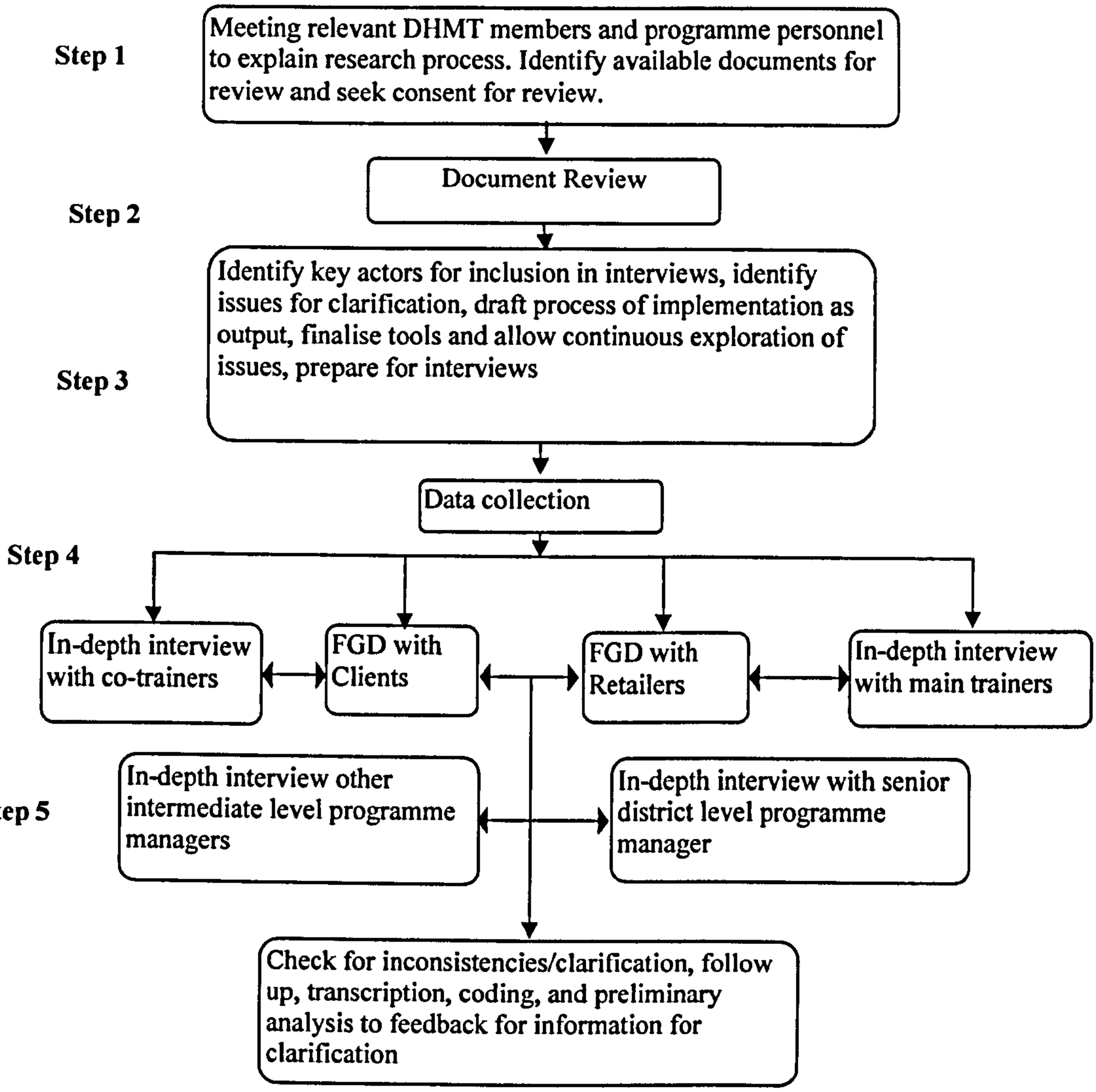
This study employed a retrospective policy analysis approach to describe implementation processes and investigate the factors influencing the outcomes observed. As described in chapter one, policy analysis offers frameworks to understand implementation process (chapter 1 section 1.6.5). The policy analysis triangle was used to guide areas of investigation. The innovation theory allowed an understanding of how specific elements of the policy triangle interacted with each other to influence implementation processes and outcomes of interest (chapter four).The analysis of context drew on documents describing social demographics, local malariometric data, other malaria control programme activities and perceived contextual features as discussed by local actors. Content was examined through interviews with actors, review of training manuals, and relevant policy documents plans and budgets. To examine the process, a chronology of events was drafted from records and triangulated from interviews. In addition, a stakeholder analyses were conducted to deepen understanding of implementation process (Varvasovszky and Brugha, 2000).

A number of data collection methods were employed. These included FGDs, document

reviews, in-depth interviews and field diaries. FGDs are an important tool in qualitative health research (Kitzinger, 1995; Jones, 2000; MacDougall and Fudge, 2001; Duggleby, 2005). They were used to explore perceptions and experiences of clients and PMRs in the implementation of the programmes. In-depth interviews were used to elicit information on key actors' understanding, perspectives and experiences with the programme and underlying reasons for the implementation gaps. Use of a diary of events and interactions with programme actors kept by the principal investigator helped construct a picture of social reality with regard to events (Jones, 2000). Use of a diary supplemented information from interviews, described observations and enhanced reflexivity. Finally, relevant policy documents at district level were reviewed to provide data on implementation process.

All the qualitative data collection tools were developed through preliminary discussions with key actors in study sites. Issues around the role of actors, chronology of implementation, funding processes and overall implementation experiences were then listed and guided the development of policy analysis protocol and tools. The main objective of this exercise was to determine factors that explained implementation experiences and gaps across study sites. Specifically the qualitative study sought; to determine features of expected implementation practice; to examine the actual experience of programme implementation and differences with expected practice; to explain the differences between the expected and actual practices of programme implementation with particular reference to actors and the design of intervention. Tools were pre-tested in Kwale district and modified at each site depending on the context and programme under assessment. Figure 2.11 is a summary of the overall qualitative research strategy.

Figure 2.11: Research strategy for the qualitative and policy analysis study



The arrow designates an iterative approach in which data was collected among actors

2.9.3.1 Sampling technique for the qualitative study

Sampling in qualitative studies differs fundamentally from quantitative approaches. Sampling focussed on key actors, maximised diversity and provided flexibility needed for an iterative process. Purposive sampling (Marshall, 1996), was used to select actors who played key roles in the programme. Identification of primary actors such as PMRs, clients, trainers and managers was done through document reviews and snowballing techniques[13]. A structured tool was used to log all the actors involved, their roles in the programme and their current position within the districts. Actors for

[13] asking respondents interviewed who else was involved in the programme and interviewing them

the in-depth interviews were managers at district level, main trainers, implementing officers at divisional level and co-trainers responsible for operationalising the programme. All programme actors available on site were interviewed. Study participants for FGDs were selected purposively in the implementation divisions. They included trained PMRs and potential clients from the intervention areas. Sampling for FGDs endeavoured to create a homogenous group with similar experiences to facilitate free dialogue (MacDougall and Fudge, 2001). Factors such as gender and age were considered for clients FGDs. Although these varied between groups, gender was less important for the retailers' FGDs than for client groups since the study did not include sensitive questions.

2.9.3.2 Desk review of programme activity

A review of documents was done at various time points. A review of global and national HMM documents was conducted in the preparatory phase of the study to understand the policy framework. Records reviewed include reports of implementation activities, work plans, minutes of planning meetings, letters or memos on programme implementation, financial returns, and IEC materials produced for each programme. Other documents include government reports on poverty levels and demographic health data for study districts. Desk review also enabled tool modification, supported triangulation of experiences and helped to construct a description of the implementation process.

2.9.3.3 Focus group discussions

FGDs were conducted with potential clients and PMRs. Participants were recruited by local administrative leaders using two criteria. For the client FGD the criteria for selection were mothers with children under five and from different the programme areas. Trained PMRs were also recruited from programme areas. The number of

participants varied in each group across the districts, averaging between 8-12 persons per session. All interviews were conducted in convenient venues for the participants. Biographical data of all participants were collected to assess homogeneity of the groups and examine the relationships between findings and these variables. An attempt to capture group interaction was made through recording non-verbal expressions. Two research assistants and the principal investigator supported in note taking and logistics. Two types of recording were used; written notes and tape recording. Written notes were used to provide back up copies in case of mechanical failure or human error and to capture of nonverbal cues. All discussions were done in languages understandable to the participants and recordings were conducted within the boundaries of confidentiality agreed at the time of discussions. The discussions focussed on normal client-PMR interactions, views on programme activities, goals, perceived barriers and facilitating factors.

2.9.3.4 Interviews and informal discussions

The first in-depth interviews were conducted with co-trainers to allow an exploration of implementation experiences at the point of delivery. Issues raised were followed up during interviews with managers for clarification. Thereafter, district level and programme managers were interviewed after conducting FGDs with PMRs (figure 2.11). All the interviews were held at convenient places for the participants. Invitations were made orally through prior contacts with all potential interviewees. Note taking was enhanced through use of two note takers who took notes on alternate days or times. Field notes were counter checked against tape recorded information immediately after each discussion. The focus of the discussion was the role of actors in the programme, views on programme goals, implementation experiences and their perceptions of factors influencing that process.

2.9.3.5 Use of diaries

A field dairy was kept by the principal investigator throughout data collection in all the districts. This documented data from informal discussions with various actors in the study site. Emerging issues and ideas were recorded which enhanced reflexivity. Reflexivity refers to the process of examining the social world and how that influences interpretation. The researcher takes account of their own beliefs, values, knowledge, and biases of data as well as the impact of the researcher on the subject under investigation (Cutcliffe, 2003). This supported transparency in the interpretations and judgement made. Rigour and reflexivity during data collection was enhanced through describing in detail activities for each day and any relevant issues were followed up through informal discussions with the key actors. Information in the diaries was also used as field memos (information that aided in understating the data) during the analysis stage. Table 2.5 summarise all interviews held in each site.

Table 2.5: Types and number of qualitative interviews and discussions

Data collection technique	Category of participants	Kisii-Merlin	Kwale-MoH	Bungoma - AMREF
In-depth Interviews	Main trainers	1	2	1
	Co-trainers	1	4	3
	District level health managers	0	2	2
	Programme Managers	2	na	1
Total in depth interviews		**4**	**8**	**7**
Focus group Discussions	Rural based PMR	2	2	2
	Urban based PMR	2	2	2
	Rural based clients	2	2	2
	Urban based clients	2	2	2
	Vendors	na	na	2
Total FGD s		**8**	**8**	**10**

2.9.4 Managing qualitative data

Qualitative interviews were taped, translated into English, transcribed and typed into Microsoft word software. Debriefing sessions were held by the principal investigator

and the research team after each interview to provide an overview of issues raised. Informal analysis was conducted and summaries of the collected data made after each session for clarification or follow up. Tapes and diaries were kept in locked cabinets and were only accessible to the research team. Copies of transcribed data were stored at the research centre and backed up in the server.

Qualitative data were stored and managed using Nvivo7 (QSR international). Preliminary analysis entailed open coding and progressive categorisation of issues based on inductive (where analytical categories were derived gradually from the data) and deductive approaches (where ideas from the interview schedule shaped the coding scheme) (Pope et al., 2000). These categories (themes) were further modified as more issues were examined from the data. Regular consultations were held with other members of the research team to enhance reflexivity. Categories derived from the data were further analysed through the development of analysis charts, which were guided by the policy analysis triangle (Walt and Gilson, 1994). At this stage, triangulation of data was enhanced through comparisons of analysis charts within and across sites to look for similarities and differences to support identification of key issues around implementation processes. Final analysis was organised around a description of the implementation process and factors underlying gaps. Validity and rigour was enhanced during the interpretative analysis through a series of feedback sessions with members of the research team. A range of analyses were prepared to examine experience within and across sites around key issues. This led to a deeper understanding of the complex interactions of key explanatory factors which are likely to account for the variation in implementation practices and the primary outcome observed across the programmes. Two complementary theoretical frameworks were applied which aided in explaining implementation experiences and its influence over the quantitative outcomes observed.

2.9.5 Ethical considerations

Informed consent is universally recognized as a central component of ethical conduct in research involving people. Informed consent is given when a competent person who has received and understood sufficient information voluntarily decides whether or not to take part in research (Allmark et al., 2003; Marshall, 2005). Informed consent can be obtained in verbal or written form depending on the nature of the study and the setting. In this study verbal consent was sought for retail audit and GPS surveys.

Seeking consent for the surrogate client survey presented a dilemma since this action would have been highly likely to undermine the outcomes and the purpose of the study (Madden et al., 1997). To strike a balance between the social value of this research in assessing provider behaviour and adhering to ethical research principles, an alternative approach of consulting with local leaders on the activities to be conducted was used. The popularity of the retail sector, concerns of widespread inappropriate practices amongst the PMRs, and the lack of alternative methods to assess provider practices support the need for including this covert method in the study. The study was also reviewed and approved by national scientific steering and ethical review committees.

For the participant, the main cost associated with participation in the surveys was the time spent in interviews. As far as possible, data collection was planned around local community timetables and took considerations of events and routine activities. The research aim and processes were explained to all participants as appropriate, and their informed consent was obtained both for participation and for recording of interviews where applicable.

Protecting the identity of participants at the point of data collection and reporting is an important ethical procedure. However, a dilemma recognised in this study is lack of

complete anonymity of data especially during reporting given the small number of actors being interviewed. Attempts were made to minimise these problems and strike a balance between the value of providing information on implementation experiences and anonymising participants. During all FGDs, use of number tags in place of names was used to ease note taking and to anonymise data at the point of collection and reporting when using quotes. Interviewees were also given an option of not using tape recorders during interviews or if they did not want their quotes used during reporting. Another measure used to maintain anonymity in reporting was the use of broad actor groups in relation to quotes, such as 'DHMT members', to indicate the perspective of the information without linking to a particular actor. This was important as certain information provided was considered sensitive but necessary to illustrate challenges of implementation. Copies of the information sheet are attached as annex III.

Chapter 3:

Quantitative Assessment of the Impact of PMR Programmes on Retailer Knowledge, Practices, Coverage and Potential Utilisation

3.1 Introduction

This chapter contributes to the first and second objectives of the thesis. The first objective was to determine the effect of programmes on PMR knowledge and practices while the second one was to estimate population geographic coverage and utilisation of PMR services. It also discusses methodological limitations; assesses the plausibility of a causal relationship between the intervention and the outcomes measured in each site; and examines the generalisability of these findings to other settings.

As discussed in chapter two section 2.6, measures of coverage relate to Habicht's framework of evaluation of "programme performance" (Habicht et al., 1999). They are examined by the proportion of all outlets in the intervention areas reached by the programme and the extent to which programme targets were achieved (the proportion of outlets stocking anti-malarials reached by the programme). Measures of coverage relates to spatial distribution of outlets in relation to population and transport networks. Other non-spatial measures include provider: population ratios, such as trained outlet: population ratio; trained outlet: under five population ratio; health facilities: population ratio and the number of programme outlets per unit area. The second set of measures relate to potential utilisation, including threshold distance and under five population within the threshold distance to generate potential users of the programme outlets. These data were derived from GPS mapping of all outlets in the intervention areas.

Objective one focuses on the impact of programme at retail outlet level (chapter two figure 2.8 box B). The impact of the programmes was measured using intermediate outcomes linked to or reflecting PMR behaviour. They were derived from retail audits and surrogate client surveys. These surveys provided two main types of information. Descriptive information about the outlets and PMRs aimed to assess the extent to

which comparisons of control and interventions were valid, or other factors (confounders or bias) might explain any measured differences; and to indicate the generalisability of these findings to other settings. The second category of information addressed the impact of programmes by comparing the knowledge and practices of PMRs in programme and non programme outlets, and assessing the extent to which differences between them could be attributed to the interventions.

3.2 Measures of coverage and potential utilisation

3.2.1 Spatial distribution of retail outlets in the three sites

Following patterns of programme implementation, GPS coordinates for this assessment were collected from one division in Kisii Central and Bungoma districts, while in Kwale district coordinates were collected from two divisions. Figure 3.1 (a-c) shows the spatial distribution of retail outlets and health facilities of the three sites in relation to the population densities and transport networks. For each site, the first map shows projected population densities for 2006 in each EA. The second map illustrates distribution of retail outlets and health facilities, while the third map combines retail outlets, health facilities and transport networks in the study divisions.

From figure 3.1a and table 3.1, the Kisii-Merlin site had the highest population density (757 people/km^2), which was more evenly distributed than the other sites. In the Bungoma-AMREF site, the population density (508 people/km^2) is in between that of the other two districts, with the population distribution characterised by pockets of high and low densities in different EAs. For the Kwale-MoH site, the population density in Matuga (253 people/km^2) is much higher than that in Kinango (47 people/km^2). The overall population density for Kwale is lower than that of the other two districts.

To assess the overall programme coverage, the second map in figure 3.1a provides a visual illustration of a relatively even distribution of trained outlets in the Kisii-Merlin site compared to the other sites. Overall, Kiamokama division of the Kisii-Merlin site had the highest coverage of all existing outlets, with 83/306 (27.1%) outlets trained (table 3.1). In the Kwale-MoH site, figure 3.1b shows that most of the trained outlets were clustered around the coastal strip and major market centres. The programme covered 96/679 (14.1%) of all existing outlets across two divisions. There were variations in coverage at divisional level with Kinango division covering 18.5% compared to 10.5% in Matuga division. However, the overall coverage in the Kwale-MoH site was generally similar to the Bungoma-AMREF site. The Bungoma-AMREF site (figure 3.1c) had most accessed outlets located along the main road networks coinciding with the population distribution patterns of the division. The overall programme coverage was 73/437 (16.7%).

To assess the extent to which the programme targets were achieved, table 3.1 illustrates the number of trained outlets with anti-malarial medicines. For the Kisii-Merlin and Kwale-MoH sites this was an important recruitment criterion. For the Bungoma-AMREF site, the aim was broad outreach by channelling IEC materials through normal anti-malarial distributors. Availability of anti-malarial medicines in the programme outlets is therefore a measure of how well programmes reached targeted outlets. Table 3.1 shows that most outlets in each of the sites did not generally stock anti-malarials; for example, only 39.4% of all operational outlets in the Kisii-Merlin site stocked anti-malarials. There were a relatively high proportion of outlets (56.1%) which stocked anti-malarial medicines in the Kwale-MoH site, likely to have been influenced by the inclusion of Matuga division which had the highest proportion of outlets with anti-malarial medicines (69.4%) compared to other districts, and to the more rural Kwale

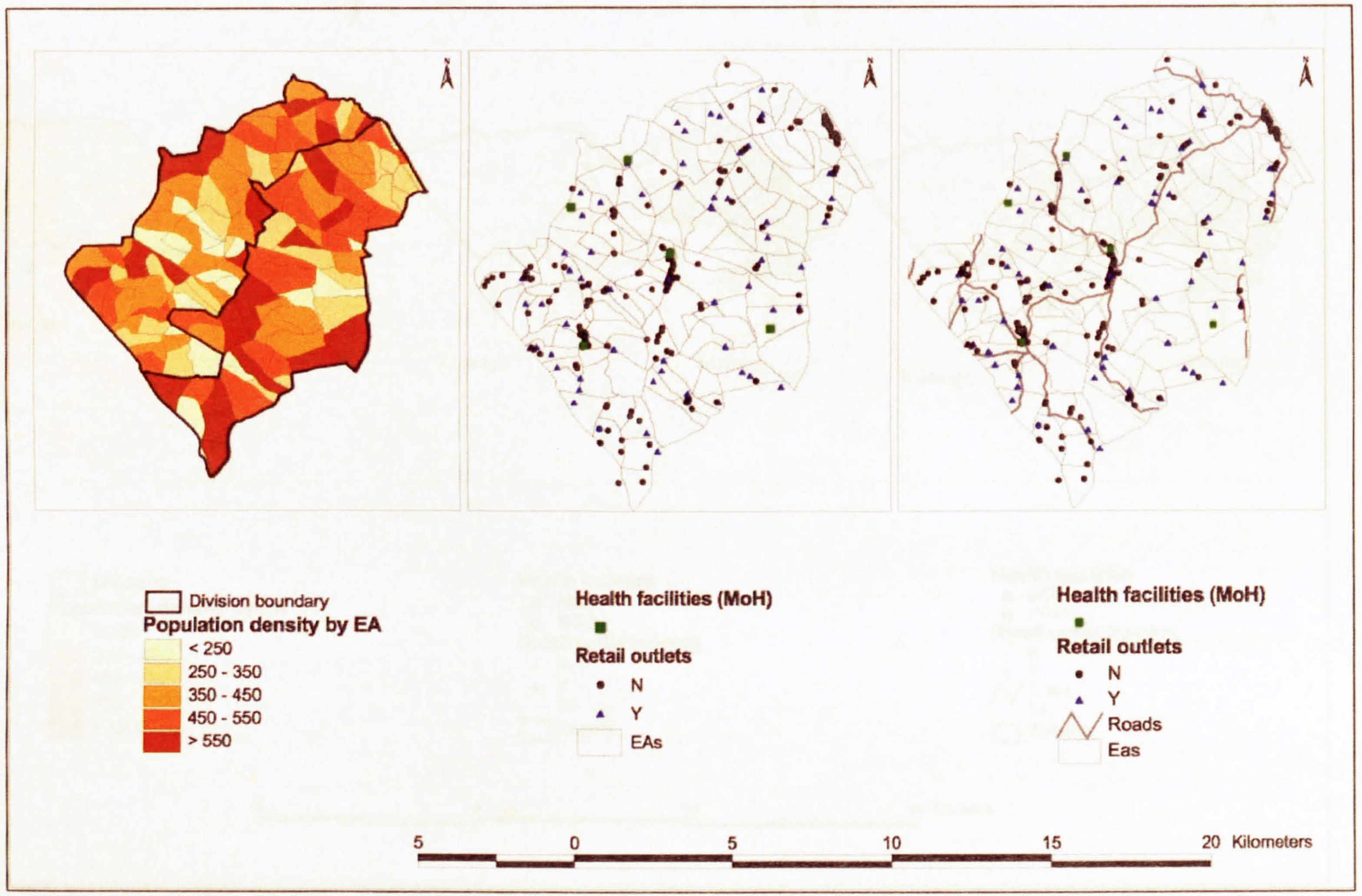
division of Kinango (44.3%). In the Bungoma-AMREF site, only 37.6% of all outlets had anti-malarial medicines. The Kisii-Merlin site reached a higher proportion of outlets stocking anti-malarial medicines (69.7%) than other sites. The Kwale-MoH site reached 25.3% of outlets stocking anti-malarial medicines. Divisional level analysis indicates that Matuga covered 16.7% while of Kinango reached 42.2% of outlets with anti-malarial medicines. The Bungoma-AMREF site covered 44.5% of outlets stocking anti-malarial medicines. Overall, the Kwale-MoH site had the lowest coverage of targeted outlets.

Table 3-1 Retail sector service indices across the programme sites

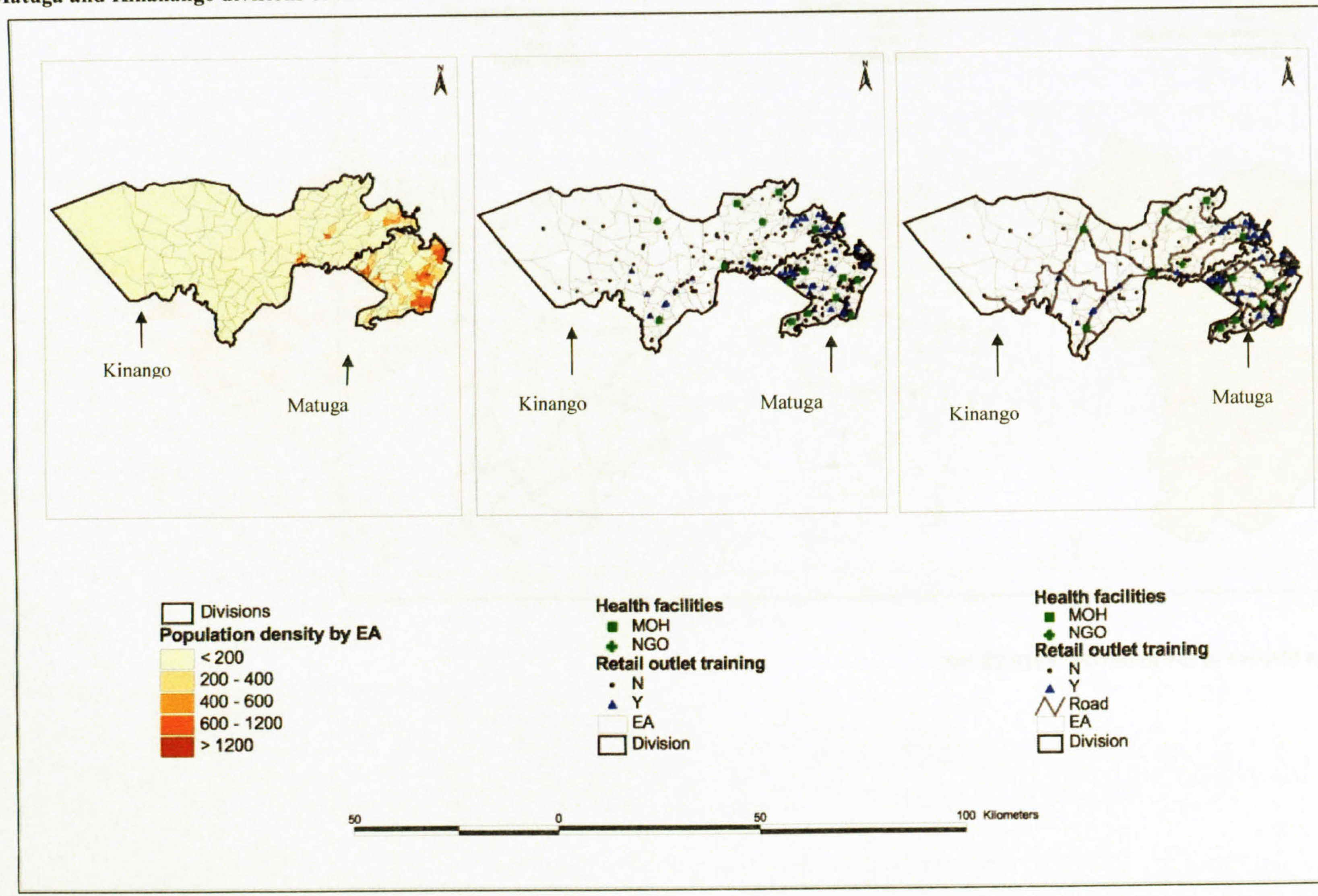
Characteristics	Kisii-Merlin: Kiamokama division	Kwale-MoH			Bungoma-AMREF: Bumula division
		Matuga division	Kinango division	Both divisions	
Coverage of programmes					
Outlets in division	331	391	318	709	462
Open outlets /all outlets	306/331 (92.4%)	387/391 (98.9%)	291/318 (91.8%)	679/709 (95.8%)	440/462 (95.2%)
Trained outlets/all open outlets*	83/306 (27.1%)	42/387 (10.9%)	54/291 (18.5%)	96/679 (14.1%)	73/437 (16.7%)
Outlets with anti-malarial/open outlets †	119/302 (39.4%)	251/387 (64.9%)	128/291 (44.3%)	379/676 (56.1%)	164/436 (37.6%)
Trained outlets /all outlets with anti-malarials	**83/119 (69.7%)**	**42/251 (16.7%)**	**54/128 (42.2%)**	**96/379 (25.3%)**	**73/164 (44.5%)**
Health facilities and population distribution					
Health facilities	9	4	4	8	6
Area	161 Km^2	341 Km^2	1842 Km^2	2183 Km^2	343 Km^2
Population projections by 2006§	121 844	86 284	86 405	172 689	174 321
Population density	757 persons / Km^2	253 persons/Km^2	47 persons/ Km^2	79 persons/ Km^2	508 persons/ Km^2
Projected under five	18 226	12 781	15 897	28 678	34 123
Under five population potentially reached	29876	8260	39575	47785	29475
Population service indices					
PMR: population	1:368	1:220	1:272	1:243	1:377
PMR: under five population	1:56	1:33	1:50	1:40	1:74
Trained PMR: under five population	1:219	1:304	1:294	1:299	1:467
Health facility: population	1:13538	1: 21571	1:10800	1:21608	1:29053
Trained PMR: population	1:1007	1:2054	1:1600	1:1798	1:2387
Health facility: trained PMR	1:9	1:9	1:8	1:12	1:12

**training status of three outlets in Bungoma could not be established; †there were a number of outlets where information on anti-malarial medicines in stock could not be established, ‡Availability of anti-malarial in trained outlets could not be established in 2 outlets in Kisii, and 1 in Kwale and Bungoma districts respective; §population projections for 2006 are based on the 1999 census*

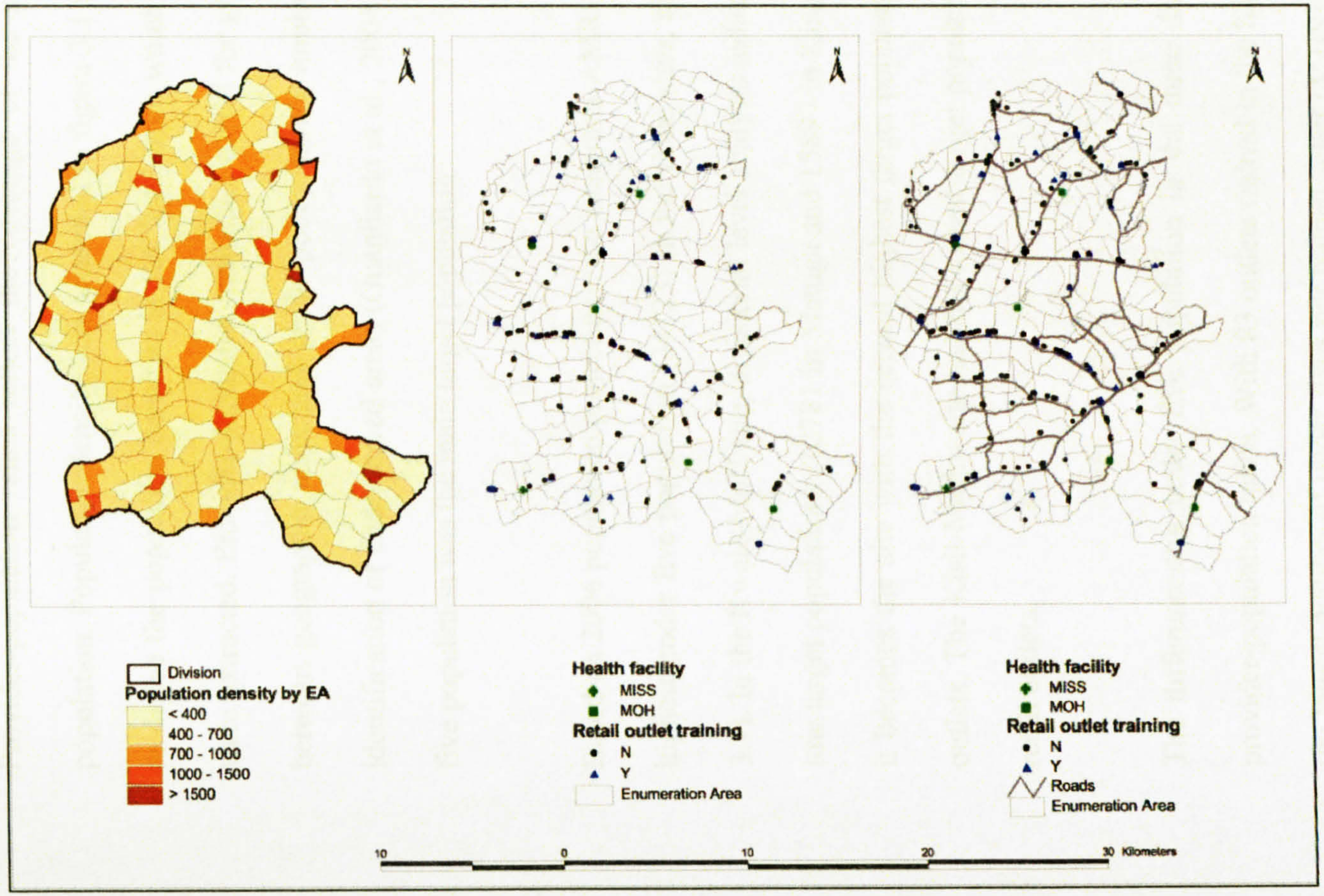
Figure 3.1: (a-c) Maps of study sites showing GIS data on population distribution, retail outlets, health facilities and transport networks
a) Kiamokama division of the Kisii-Merlin site



b) Matuga and Kinanango divisions of the Kwale-MoH site



c) Bumula division of the Bungoma-AMREF site



3.2.2 Provider-population ratios of retail outlets

Provider-population ratios reflect the coverage of the programmes in relation to population. Population density was presented in figure 3.1 a-c. These maps were used to derive the population densities at EA level from which provider-population ratios were extracted. Provider-population ratios are useful for gross comparisons of supply between geographic units and guide policy where minimum standards are set for identification of underserved areas (Guagliardo et al., 2004). In this context, the under five population was the main target population.

Based on 2006 population projections, the Bungoma-AMREF site was the site with the highest under five population (34123) in the three sites, served by 462 outlets (table 3.1). In the Kwale-MoH site, divisional level analysis indicates that both divisions had low target populations (12781 in Matuga and 15897 in Kinango), but, when combined, it becomes the site with the second highest target population (28678) served by 709 outlets. The Kisii-Merlin site had the lowest target population (18226) served by 306 retail outlets.

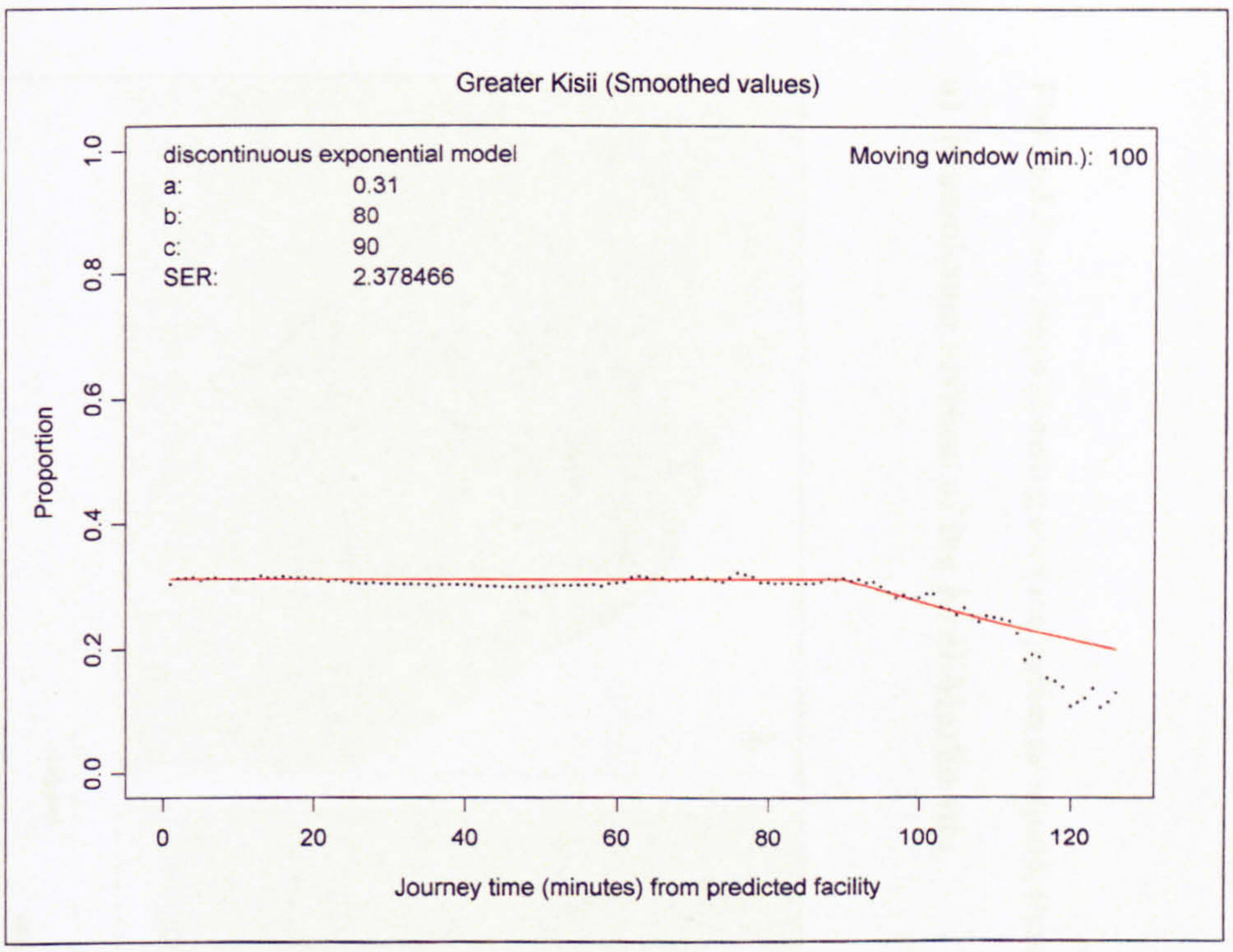
The differences in under five population in the three districts led to variations in provider-population ratios. With 83 outlets trained in the Kisii-Merlin site, the site had the lowest number of under fives per trained seller (1:219). The population density of Matuga was 253 persons/Km^2 compared to 47 persons/Km^2 in Kinango. However, the provider population ratios were relatively similar, with Matuga having a ratio of 1:304 compared to 1:294 in Kinango. The Bungoma-AMREF site had the highest number of under fives per trained seller (1:467).

3.2.3 Threshold distance for using retail sector services.

Results in this section were derived from modelling utilisation rates of retail outlets for fever treatment against all other treatment sources. Utilisation enabled a critical assessment of physical access beyond the gross provider: population ratios. This included examining the surface factors such as road networks and existence of geographical features that may influence physical access.

Figure 3.2 illustrates the output of the analysis of threshold distance (considered as the minimum distance a care giver is likely to travel to access PMRs services). The y-axis shows the proportion of patients (under five) who used retail outlets at each interval while the x-axis shows predicted travel times in minutes to the outlets. Due to lack of fever data from the Bungoma-AMREF site and insufficient data from EAs that fell within any of the intervention areas of the Kwale-MoH site, fever survey data from four EAs of the Kisii-Merlin site was used to derive threshold distance. The parameter C in figure 3.2 represents the distance within which most caregivers would use the retail outlets. This parameter was 90 minutes, translating to a travel distance of 7.5 km (assuming a walking rate of 5km/hour). The 7.5 km threshold distance was then used to estimate the underlying under five population likely to use trained retail outlets.

Figure 3.2: Graph showing utilization rates of retail sector services for treatment of fevers in the Kisii-Merlin site

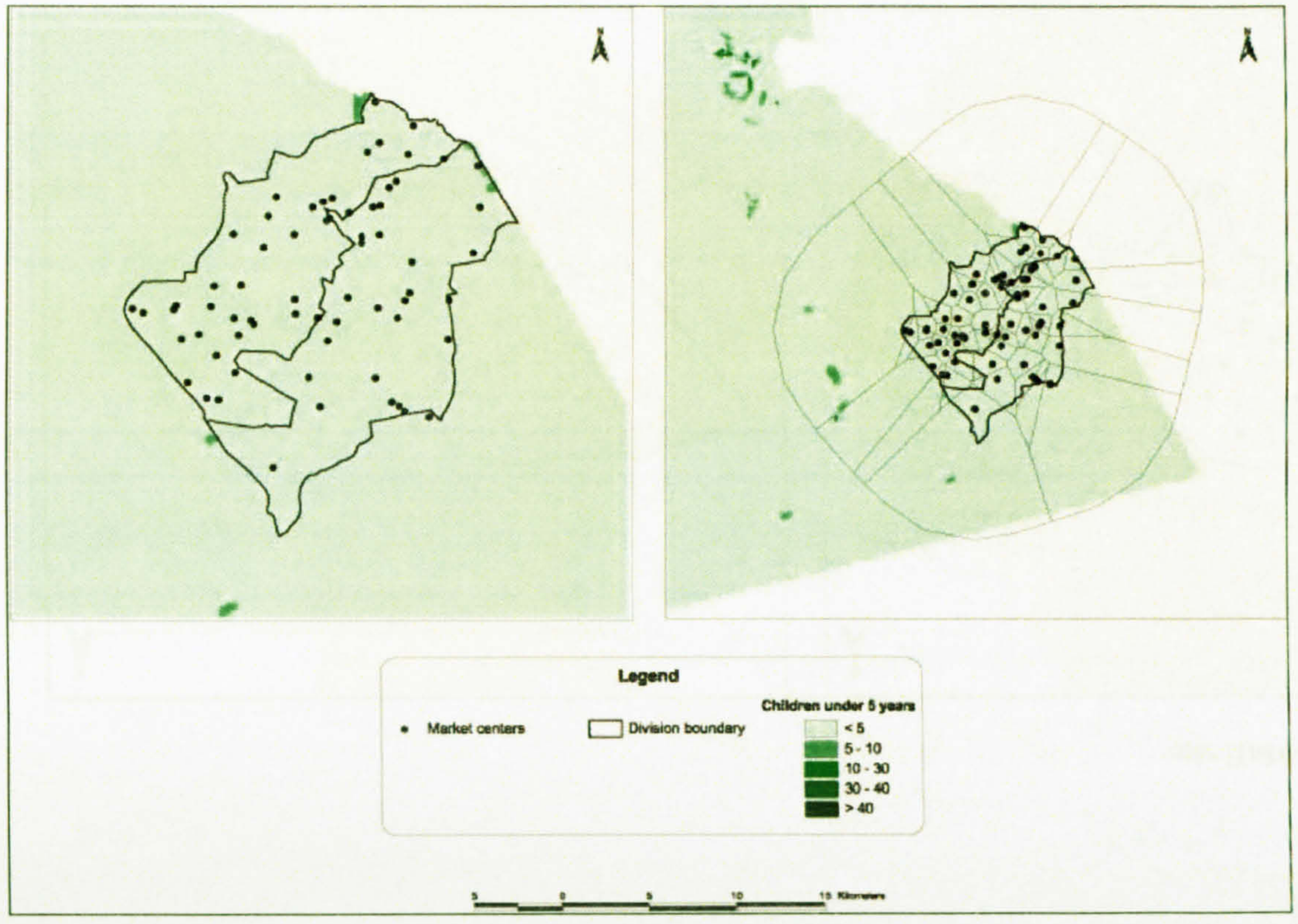


3.2.4 Potential under five users and average distance to access retail outlets

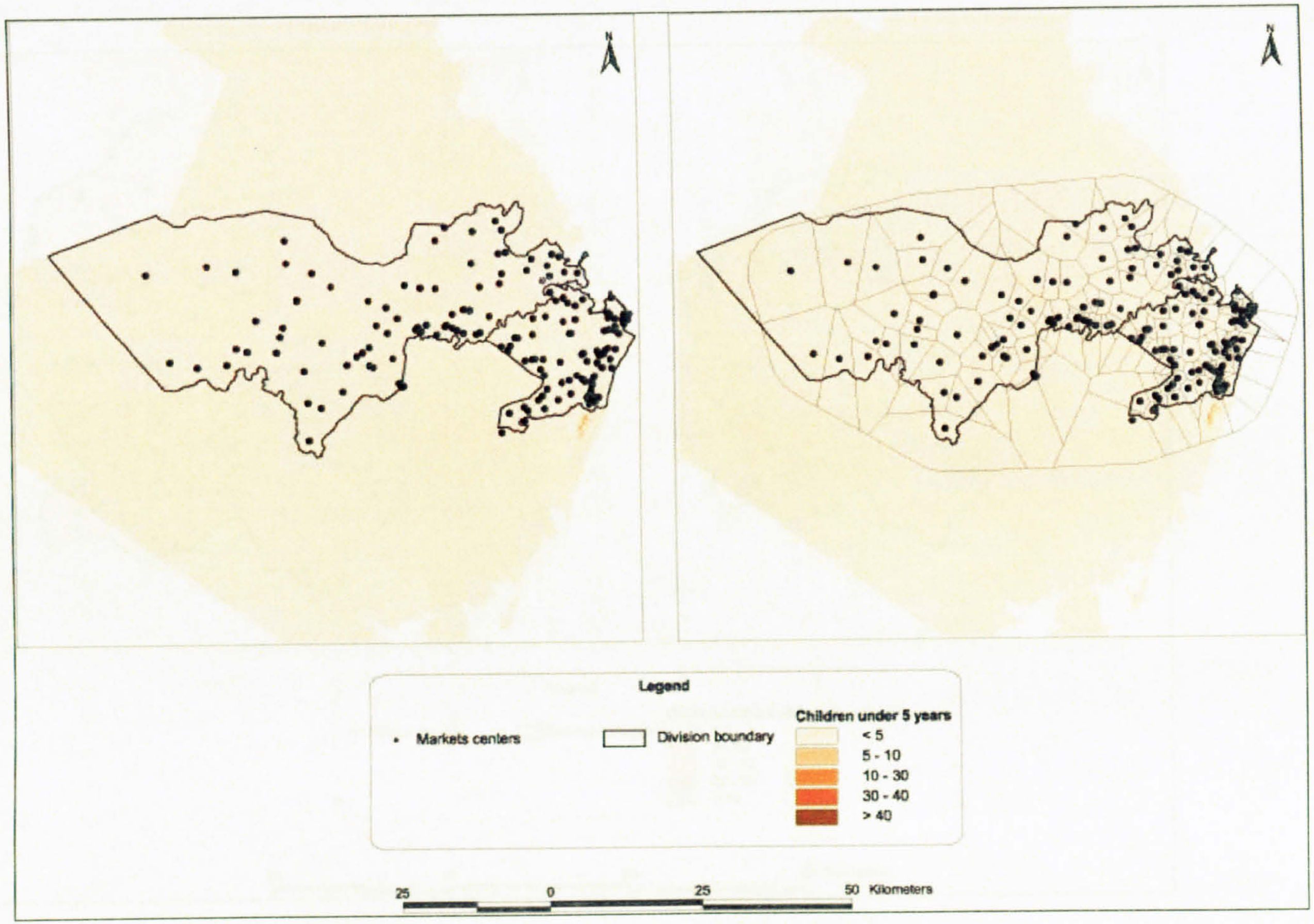
Using the TP technique (chapter two section 2.9.2.3), the under five population was derived in each of the polygons for each market centre. Thereafter mean Euclidean distances (straight line distance to the nearest retail outlet) travelled in Km were computed for each point in the division presented in figure 3.3 a-c.

Figure 3.3 a-c Maps showing surface points as inputs, thiessen polygons and distribution of under five population as outputs

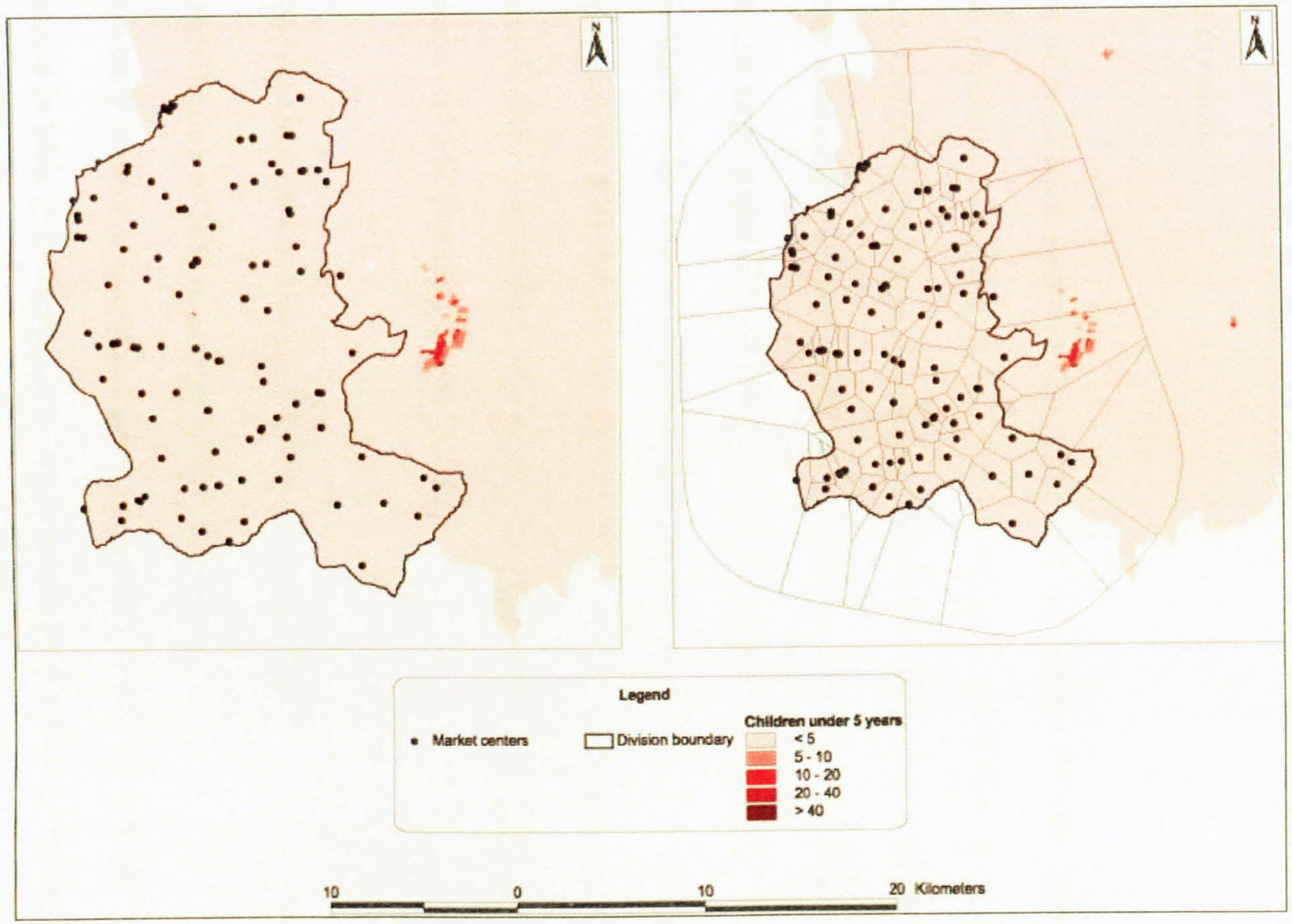
a) Kiamokama division of the Kisii-Merlin site



b) Matuga and Kiamokama divisions of the Kwale-MoH site



c).**Bumula division of the Bungoma-AMREF site**



The site with the lowest average travel distance to a centre with a programme outlet was the Kisii-Merlin site (1.30 km) followed by the Bungoma-AMREF site (1.40 km) and the Kwale-MoH site (1.86 km) (table 3.1). However, the average travel distance to a centre with a trained PMR in each of the divisions of the Kwale-MoH site varied. Matuga division had an average travel distance of 1.05 km compared to 2.66 km in Kinango division.

In terms of population coverage, the under five population for each polygon varied with the population densities. Based on two divisions, the Kwale-MoH site had the highest coverage of the potential target population (47785 children under five years). On further examination of each division, Kinango division had the highest coverage of the potential target population of about 39525 compared to 8260 under fives in Matuga division (table 3.1). The programme with the second highest coverage of target population was the Kisii-Merlin site with 29876 potential under fives and 29475 in the Bungoma-AMREF programme. The subsequent sections present data on the impact of programme on PMR practices and knowledge.

3.3 Description of outlets and PMRs across sites

3.3.1 Distribution of IEC materials in the three sites

Based on early district programme reports, data on the distribution of IEC materials are summarised in table 3.2. They help to illustrate the coverage of reference materials as an indicator of programme performance. The data presented reflect the different intervention designs and implementation processes across sites. IEC materials were to contribute to demand creation and provided essential reference materials for PMRs. As a social marketing programme, the Bungoma-AMREF site relied heavily on the distribution of IEC materials targeting the whole district.

Table 3-2 Distribution of IEC materials

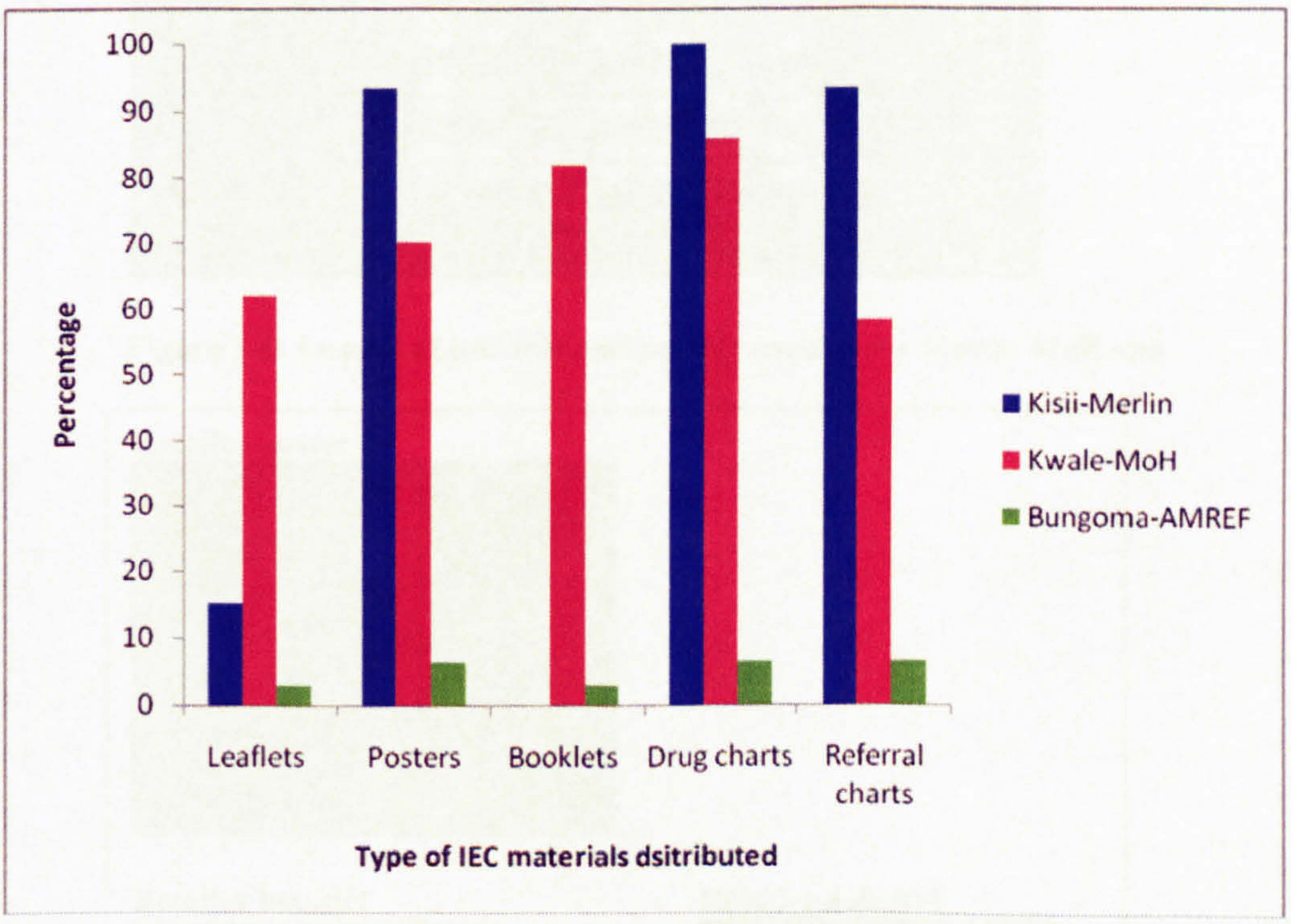
Description	Kisii-Merlin	Kwale-MoH	Bungoma-AMREF
Type of IEC materials*			
A5 size 25 page booklet	94	200	na
A4 size 34 page manager's guide	na	10	na
A2 coloured poster showing intervention outlet	na	200	>450
Wooden sign post	74	na	na
A4 size drug dosage guide[14]	**94**	**60**	**na**
A4 folded colour-picture illustrated leaflet	1048	25000	na
Training flip charts	na	10	na
Flip charts: "*Malaria prevent the spread*"	10	na	na
A4 size one pager: "*What PMRs are expected to do?*"	94	na	na
Calendars with malaria control information	94	na	1000/ calendar year
Brochures: "*Fever could be malaria*"	na	na	20900
Brochures: "*Ushauri wa Nandako*"	na	na	20700
Client job aids–based on SP & AQ medicines	na	na	1420
Shopkeeper job aids- based on AQ and SP medicines	**na**	**na**	**1420**
Government policy on SP & CQ	na	na	67
Receipt booklets	na	na	>400 receipts
T-shirts	na	na	200
Caps	na	na	200
A4 size referral chart	na	60	na
Training manual	na	5	na
Drug cards	na	3 sets of 10	na

**Source: In Kisii-Merlin review of Merlin records for materials distributed in the study area only records. In Kwale -district reports to DoMC and represents outlets in two divisions. These materials were produced centrally and delivered to district. In Bungoma district-based reports on the number reached in the whole district after six months implementation phase 1. Over 40000 brochures were produced but according to reports over 20000 were distributed during the JKJ strategy. Copies of government policy on anti-malarial drug policy were given to mobile vendors drug cards were produced locally and distributed during training workshops. They were made from packages of medicines and used during workshops to help PMR identify different types of medicines.*

[14] ***Materials in bold were important reference materials at shop level***

Availability of the distributed IEC materials in the trained study outlets was recorded during the retail audit. This helped to triangulate information presented in table 3.2. PMRs were asked whether they had booklets, drug or referral charts, leaflets or posters in their outlets at the time of the survey. These materials were to be distributed during training workshops in the case of the Kisii-Merlin and Kwale-MoH sites and during the normal business encounters with mobile vendors or wholesalers in the Bungoma-AMREF site. Figure 3.4 is a graphical illustration of the availability of IEC materials in the trained outlets for each site. The denominator is targeted outlets operational at the time of the survey.

Figure 3.4 Distribution of IEC materials in the intervention areas



There was considerable variation in the availability of IEC materials in the trained outlets across sites. In the Kwale-MoH site, there were a relatively high proportion of study outlets with IEC materials, followed by the Kisii-Merlin and the Bungoma-AMREF site. Availability of reference materials for PMRs such as drug and referral

charts was higher in the Kisii-Merlin compared to the other sites (100% and 93% respectively). There was also a high distribution of durable posters (93%) in Kisii-Merlin, essential to direct clients to trained outlets and enhance demand creation. Examples of IEC materials used in the Kwale-MoH are presented in figure 3.5 and 3.6.

Figure 3.5: Image of drug dosage charts used in the Kwale-MoH site

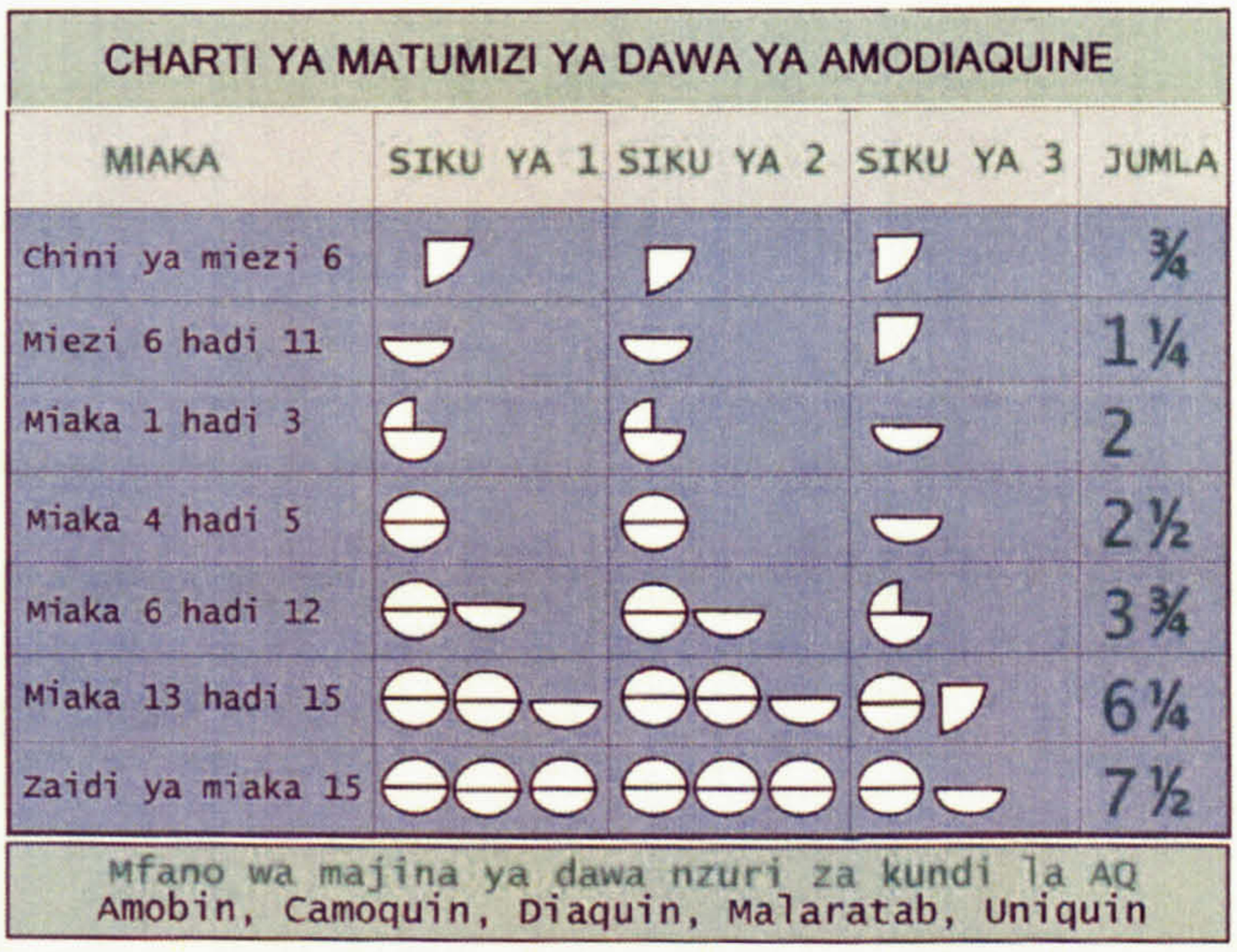
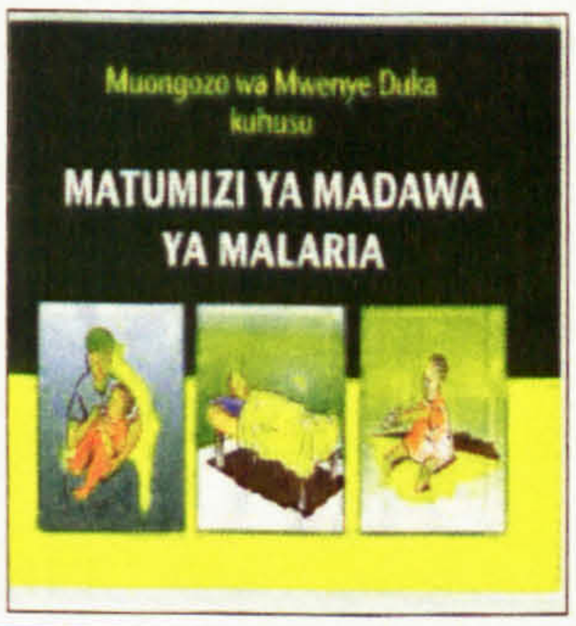


Figure 3.6: Images of job aids and posters used in the Kwale-MoH site

Retailer poster

Retailer booklet



Retailer Job Aid

3.3.2 Number and status of retail outlets visited

The sampling frame for the retail audit and surrogate client surveys aimed to include outlets similar to those in the programme. A key selection criterion for programme outlets was the stocking of anti-malarial medicines. The sampling frame for these surveys therefore aimed to include only outlets stocking anti-malarial medicines (Chapter two section 2.9.1). This was different to the GPS study (chapter two section 2.9.1.5) which sampled from all retail outlets in the intervention sites. The number and status of retail outlets visited during the retail audit and surrogate client surveys are presented in table 3.3. Status refers to whether outlets were open or closed when visited and stocked anti-malarial medicines. Differences in outlet status at the time of visits during the retail audit and surrogate client survey led to differences in the denominators presented in table 3.3.

Amongst the logistical challenges associated with assessing provider behaviour using surrogate clients was the inability to prepare for interviews ahead of visits. Outlets were often visited more than once to secure an observation, particularly intervention outlets in the Kisii-Merlin site (Odds Ratio: (OR); 13.9: 95% Confidence Interval (CI): 4.1, 47.8). A similar phenomenon was observed in the retail audit where temporary or permanent closure was common among trained PMRs in the Kisii-Merlin and Kwale-MoH sites, leading to significant differences between intervention and control outlets in these sites (OR; 5.5: 95% CI: 1.2, 26.1 and OR; 3.2: 95% CI 1.3, 8.2, respectively). Availability of anti-malarial medicines in stock varied in each site. In the Kisii-Merlin site up to two thirds of control and intervention outlets had anti-malarial medicines in stock with no significant differences between the two areas. In the Kwale-MoH and Bungoma-AMREF sites, around half of intervention outlets had anti-malarial medicines in stock (OR; 0.6: 95% CI 0.3, 0.9 and 0.2: 95% CI 0.1, 0.5) respectively.

Table 3-3: Number and status of retail outlets visited

Status	Kisii-Merlin				Kwale-MoH				Bungoma-AMREF			
	I[a] n (%)	C[b] n (%)	P[c]	OR[d] (95% CI)	I[e] n (%)	C[f] n (%)	P[g]	OR[h] (95% CI)	I[i] n (%)	C[j] n (%)	P[k]	OR[l] (95% CI)
Status of outlets during the surrogate client survey												
Outlets visited *	94	97	na†	na	93	109	na	na	66	100	na	na
Outlets visited > once	29/94 (30.9%)	3/97 (3.1%)	<0.001	13.9 (4.1, 47.8)	9/93 (9.7%)	3/109 (2.8%)	0.069	3.8 (0.9, 14.4)	1/66 (1.5%)	11/100 (11.0%)	0.029	0.1 (0.02, 0.9)
Outlets operational	71/94 (75.5%)	91/97 (93.8%)	<0.001	0.2 (0.1, 0.5)	77/93 (82.8%)	99/109 (90.8%)	0.089	0.5 (0.2, 1.1)	64/66 (96.7%)	95/100 (95.0%)	0.704	1.6 (0.3, 8.9)
Status of outlets visited during retail audit												
Outlets visited	91	92	na	na	94	110	na	na	58	95	na	na
Stocked anti-malarial medicines	62/91 (68.1%)	52/92 (56.5%)	0.105	1.6 (0.9, 3.0)	50/94 (53.2%)	74/110 (67.3%)	0.04	0.6 (0.3, 0.9)	32/58 (55.2%)	81/95 (85.3%)	<0.001	0.2 (0.1, 0.5)
No anti-malarial medicines	18/91 (19.8%)	19/92 (20.7%)	0.883	0.9 (0.5, 1.9)	21/94 (22.3%)	28/110 (24.5%)	0.604	0.8 (0.4, 1.8)	22/58 (37.9%)	8/95 (8.4%)	<0.001	6.6 (2.7, 16.3)
No medicines at all	1/91 (1.1%)	19/92 (20.6%)	<0.001	0.04 (0.005, 0.3)	4/94 (4.3%)	0/110 (0%)	0.044	na	4/58 (6.9%)	1/95 (1.0%)	0.069	6.9 (0.8, 63.9)
Closed	10/91 (10.9%)	2/92 (2.2%)	0.018	5.5 (1.2, 26.1)	17/94 (18.1%)	7/110 (6.4%)	0.015	3.2 (1.3, 8.2)	0/58 (0%)	5/95 (5.3%)	0.157	na
refusals	0/91 (0%)	0/92 (0%)	na	na	2/94 (2.1%)	1/110 (0.9%)	0.596	2.3 (2.1, 26.5)	0/58 (0%)	0/95 (0%)	na	na

** In the Kisii-Merlin site, 3/94 outlets in the intervention area were excluded because they were untrained community drug shops, 5/97 outlets in the control area were excluded since they were not general retail shops; In the Kwale-MoH site one additional outlet in the intervention and control areas were visited during the retail audit because they were closed during the surrogate client survey. In the Bungoma-AMREF sites, 8/66 outlets visited during the surrogate client survey in the intervention area were excluded because they were not programme outlets. In the control area, 5/100 outlets were hardware shops and were excluded.* **Throughout this chapter the following labels apply to this table and subsequent tables 3.4, 3.5, 3.8, 3.9, 3.10, 3.11, 3.12, 3.13 and 3.14. a = intervention area (Kiamokama); b = control area (Suneka) of Kisii Central district; c = P value for comparison of intervention and control in Kisii Central district; d = odds ratio of the comparison between control and intervention in Kisii Central district; e= intervention area (Kinango and Matuga); f = control area (Msambweni and Samburu), g = P value for comparison of intervention and control in Kwale; h= odds ratio of the comparison between control and intervention in Kwale; i = intervention area (Bumula); j = control area (Tongaren) in Bungoma district; k=P value of the comparison between intervention and control areas of Bungoma district; l= odds ratio of the comparison between control and intervention in Bungoma district. Odds ratios provided for comparisons in each district were derived from random effect model (using x*tlogit* command).Use of †na -represents cases where that measure was not applicable or could not be derived.**

3.3.3 Characteristics of retail outlets

The basic characteristics of retail outlets and PMRs were derived from the retail audit and are presented in table 3.4. Characteristics of the retail outlets and PMRs are presented to determine comparability of the control and intervention areas, assess the extent of generalisability of the study findings and describe the functioning of the retail sector and its implication for PMR interventions. In the Kisii-Merlin and Kwale-MoH sites, the programmes targeted general retail outlets using the criteria described in chapter two, section 2.5. The denominator is the number of outlets that were open and stocking OTC medicines at the time of visit.

Most outlets were general retail shops, with no significant differences between the intervention and control outlets except in the Bungoma-AMREF site, where specialised drug shops were more common amongst the control group (OR; 0.1: 95% CI: 0.01, 0.6). As an indicator of overall outlet size, a majority of outlets in both areas were manned by one PMR. In terms of gender, education and age, PMRs in the control and intervention areas in all sites were comparable. Across intervention and control sites, most PMRs were relatively young (< 35 years) and had between 8 and 12 years of schooling, although those in Kwale had lower median years of education than the other sites.

Table 3-4 Characteristics of retail outlets and PMRs

Characteristics	Kisii-Merlin				Kwale-MoH				Bungoma-AMREF			
	I[a] n (%)	C[b] n (%)	P[c]	OR[d] (95% CI)	I[e] n (%)	C[f] n (%)	P[g]	OR[h] (95% CI)	I[i] n (%)	C[j] n (%)	P[k]	OR[l] (95% CI)
Type of outlets surveyed *												
General shops	79/80 (98.7%)	70/71 (98.6%)	1.000	1.1 (0.7, 18.3)	71/71 (100%)	102/102 (100%)	na	na	53/54 (98.2%)	73/89 (82.1%)	0.003	11.6 (1.4, 90.3)
Drug shops	1/80 (1.4%)	1/71 (1.3%)	1.000	0.9 (0.05, 14.4)	0/71 (0%)	0/102 (0%)	na	na	1/54 (1.8%)	16/89 (17.9%)	0.03	0.1 (0.01, 0.6)
Average number of sellers†												
One seller	59/78 (75.6%)	58/71 (81.7%)	0.369	0.7 (0.3, 1.5)	60/70 (85.7%)	84/101 (83.7%)	0.653	1.2 (0.3, 4.1)	45/54 (83.3%)	67/82 (81.7%)	1.000	1.1 (0.5, 2.8)
Multiple sellers	19/78 (24.4%)	13/71 (18.3%)	0.369	1.4 (0.6, 3.2)	10/70 (14.3%)	17/102 (16.7%)	0.653	0.8 (0.2, 2.8)	9/54 (16.7%)	15/82 (18.3%)	0.81	0.9 (0.4, 2.2)
Characteristics of main sellers												
Female PMR	44/78 (30.8%)	30/71 (42.3%)	0.145	0.6 (0.3, 1.2)	20/71 (28.2%)	42/101 (40.5%)	0.094	0.6 (0.3, 1.1)	22/54 (40.7%)	37/82 (45.1%)	0.614	0.8 (0.4, 1.7)
Median years for schooling (IQR)	12 (10-12)	8.5 (7-12)	na	na	8 (7-12)	8 (7-12)	na	na	11 (8-12)	12 (8-12)	na	na
Median age in years (IQR)	34 (26-45)	32 (25-42)	na	na	27 (22-32)	30 (24-36)	na	na	29 (25-36)	29 (24-34)	na	na

**Analysis did not include outlets without medicines or closed at the time of survey; † seven outlets of the control areas of Bungoma were dropped because they had programme materials while two outlets in the intervention area of Kisii were also dropped because they were not trained. In the Kwale site there was one control outlet with missing data*

3.3.4: Patterns of medicines stocked in the retail outlets

During the retail audit PMRs were asked questions on medicines in stock at the time of the survey (table 3.5). In interpreting this data, it should be remembered that the outlets sampled were likely to stock anti-malarials, as explained in section 3.3.2. With the exception of the Bungoma-AMREF site, where PMRs in the intervention area less often stocked anti-malarial medicines compared to those in the control areas; (OR; 0.1: 95% CI: 0.1, 0.4), there were no statistical differences between the intervention and control areas on this indicator in the other two sites.

Of importance is the availability of the MoH recommended anti-malarial medicines (AQ). Figure 3.7 shows the proportion of outlets with AQ medicines in stock. In all sites, there were no significant differences between the control and intervention areas in the proportion of outlets with AQ medicines in stock. In the Kisii-Merlin site 96.7% of intervention outlets stocked AQ medicines compared to 86.5% in the control area (OR; 4.6: 95% CI: 0.9, 23.1). In the Kwale-MoH site, the proportion was 92% (intervention) compared to 87.8% in the control areas (OR; 1.6: 95% CI: 0.5, 5.5). In the Bungoma-AMREF site, this was 78.1% (intervention) compared to 71.6% in the control areas (OR; 1.4: 95% CI: 0.5, 3.7).

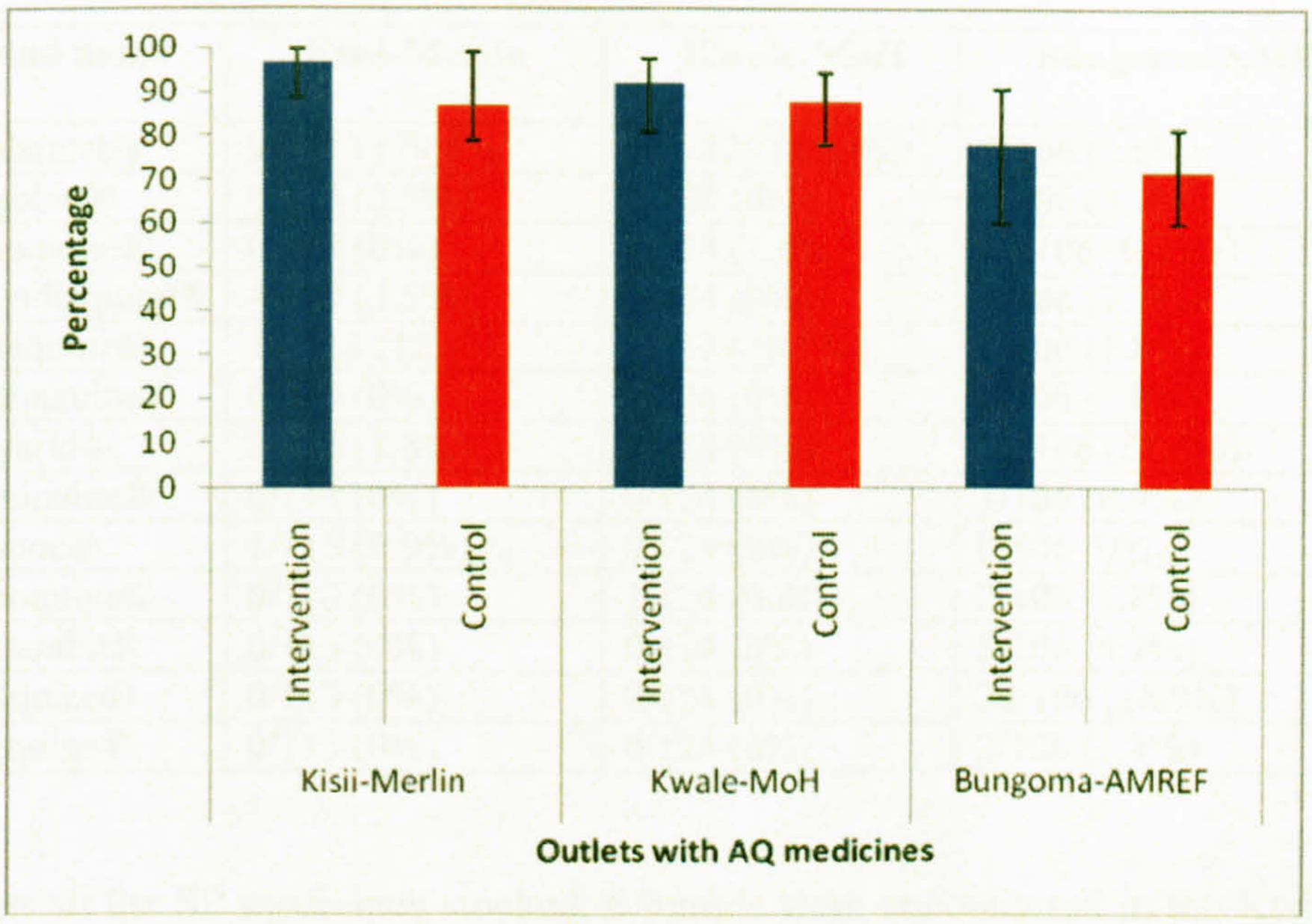
Table 3-5: Stocks of common OTC medicines available

Type of medicines stocked *	Kisii-Merlin				Kwale-MoH				Bungoma-AMREF			
	I[a] n (%)	C[b] n (%)	P[c]	OR[d] (95% CI)	I[e] n (%)	C[f] n (%)	P[g]	OR[h] (95% CI)	I[i] n (%)	C[j] n (%)	P[k]	OR[l] (95% CI)
Anti-malarial medicines	61/78 (78.2%)	52/71 (73.4%)	0.479	1.3 (0.6, 2.8)	50/71 (70.4%)	74/101 (73.3%)	0.682	0.9 (0.4, 1.7)	32/54 (59.3%)	74/82 (90.2%)	<0.001	0.1 (0.1, 0.4)
Antipyretics medicines	76/77 (98.7%)	70/71 (98.5%)	1.000	1.1 (0.1, 17.6)	48/71 (67.6%)	73/102 (71.5%)	0.576	0.8 (0.4, 1.9)	51/54 (94.4%)	78/82 (95.1%)	1.000	0.8 (0.2, 4.1)
Anti-diarrhoea medicines	13/77 (16.7%)	17/71 (23.9%)	0.286	na	49/71 (69.0%)	63/101 (62.4%)	0.369	1.3 (0.7. 2.6)	22/53 (41.5%)	37/82 (45.1%)	0.679	0.8 (0.4, 1.7)
De-worming medicines	19/77 (24.7%)	16/71 (22.5%)	0.760	1.1 (0.5, 2.4)	21/71 (29.8%)	46/100 (46.0%)	0.030	0.5 (0.1, 2.1)	5/54 (9.3%)	26/82 (31.7%)	0.002	0.2 (0.1, 0.6)
Anti-cough medicines	39/77 (50.7%)	36/69 (52.2%)	0.854	0.9 (0.5, 1.8)	54/71 (76.1%)	83/101 (82.3%)	0.326	0.7 (0.3, 1.5)	31/54 (57.4%)	65/82 (79.3%)	0.006	0.3 (0.2, 0.7)
Other medicines†	44/77 (57.1%)	45/66 (68.2%)	0.175	0.6 (0.3, 1.2)	38/70 (54.3%)	68/92 (73.9%)	0.009	0.4 (0.2, 1.1)	31/53 (58.5%)	51/82 (62.2%)	0.667	0.8 (0.4, 1.7)

**the denominator is the number of outlets that were operational at the time of the survey and represent outlets that satisfied the inclusion criteria. The variations in the denominator denote cases where the specific questions on presence of these medicines were not asked or information was not available*

†- Included medicines such as antibiotics and those that clear the flu

Figure 3.7 Proportion of outlets with anti-malarial medicines that stocked AQ



In addition, different brands of anti-malarial medicines were identified in each site. This helped to characterize the retail sector in these districts for comparisons with other settings. Different brands of AQ and SP medicines available at the time of the study are presented in table 3.6 and 3.7. The frequency is expressed as a percentage of all outlets stocking anti-malarial medicines and is aggregated since there were no significant differences between the intervention and control areas. Overall, for AQ and SP medicines (table 3.6 and 3.7), there were variations in the patterns of brand dominance between districts, for example, Betaquine® and Malaratab® were most commonly available in Kisii-Merlin and Kwale-MoH sites, while Malarid® and Uniquine dominated in the Bungoma-AMREF site. In terms of the numbers, 6 brands of AQ medicines were identified in the Kisii-Merlin site, 4 brands in the Kwale-MoH site and 12 in the Bungoma-AMREF site.

Table 3-6 Frequency of AQ brands of medicines

Brand name	Kisii-Merlin	Kwale-MoH	Bungoma-AMREF
Malaratab®	90/113 (79.6%)	107/124 (86.9%)	3/106 (2.8%)
Amobin®	4/113 (3.5%)	0/124 (0%)	4/106 (3.7%)
Emoquine®	0/113 (0%)	2/124 (1.6%)	10/106 (9.4%)
Amodiaquine®	4/113 (3.5%)	0/124 (0%)	4/106 (3.7%)
Betaquine®	14/113 (12.4%)	11/124 (8.9%)	2/106 (1.8%)
Alphaquine®	0/113 (0%)	0/124 (0%)	2/106 (1.8%)
Malarid®	2/113 (1.8%)	0/124 (0%)	55/106 (51.8%)
Falciquine®	0/113 (0%)	0/124 (0%)	1/106 (0.9%)
Kamoc®	1/113 (0.9%)	0/124 (0%)	0/106 (0%)
Laeoquine®	0/113 (0%)	1/124 (0.8%)	2/106 (1.8%)
Malarabit®	0/113 (0%)	0/124 (0%)	5/106 (4.7%)
Uniquine®	0/113 (0%)	0/124 (0%)	20/106 (18.9%)
Diaquine®	0/113 (0%)	0/124 (0%)	2/106 (1.8%)

Amongst all the SP medicines stocked, 6 brands were encountered in the Kisii-Merlin site, with the common brands being Orodar® and Methomine S®. In the Kwale-MoH site 10 brands were identified with Orodar® and Falcidin® being the commonest brand. In the Bungoma-AMREF site 12 brands were encountered with common ones being Malodar® and Malostat® (table 3.7).

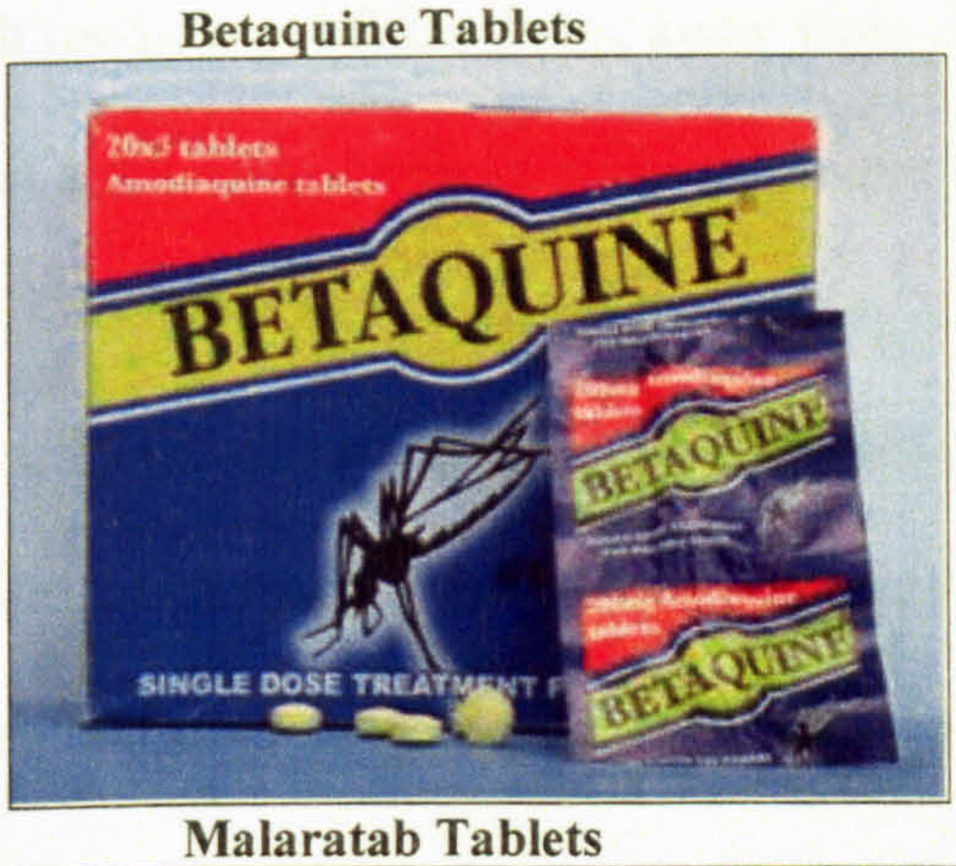
Table 3-7 Frequency of SP brands of medicines.

Brand name	Kisii-Merlin	Kwale-MoH	Bungoma-AMREF
Orodar®	14/113 (12.3%)	16/124 (12.9%)	11/106 (10.3%)
Falcidin®	2/113 (1.8%)	39/124 (31.5%)	3/106 (2.8%)
Fanlar®	1/113 (0.9%)	2/124 (1.6%)	9/106 (8.5%)
Malereich®	0/113 (0%)	1/124 (0.8%)	0/113 (0%)
Fanisdar®	4/113 (3.5%)	3/124 (2.4%)	4/106 (3.7%)
Metakelfin®	1/113 (0.9%)	0/124 (0%)	1/106 (0.9%)
Betakelfin®	0/113 (0%)	0/124 (0%)	1/106 (0.9%)
Methomine S®	9/113 (7.9%)	8/124 (6.5%)	6/106 (5.6%)
Malodar®	0/113 (0%)	0/124 (0%)	13/106 (12.3%)
Malostat®	0/113 (0%)	1/124 (0.8%)	10/106 (37.7%)
Malaramed®	0/113 (0%)	0/124 (0%)	2/106 (1.8%)
Beta SP®	0/113 (0%)	3/124 (2.4%)	1/106 (0.9%)
Malaradose®	0/113 (0%)	0/124 (0%)	1/106 (0.9%)
Zentakelfin®	0/113 (0%)	1/124 (0.8%)	0/106 (0%)
Malarado®	0/113 (0%)	4/124 (3.2%)	0/106 (0%)

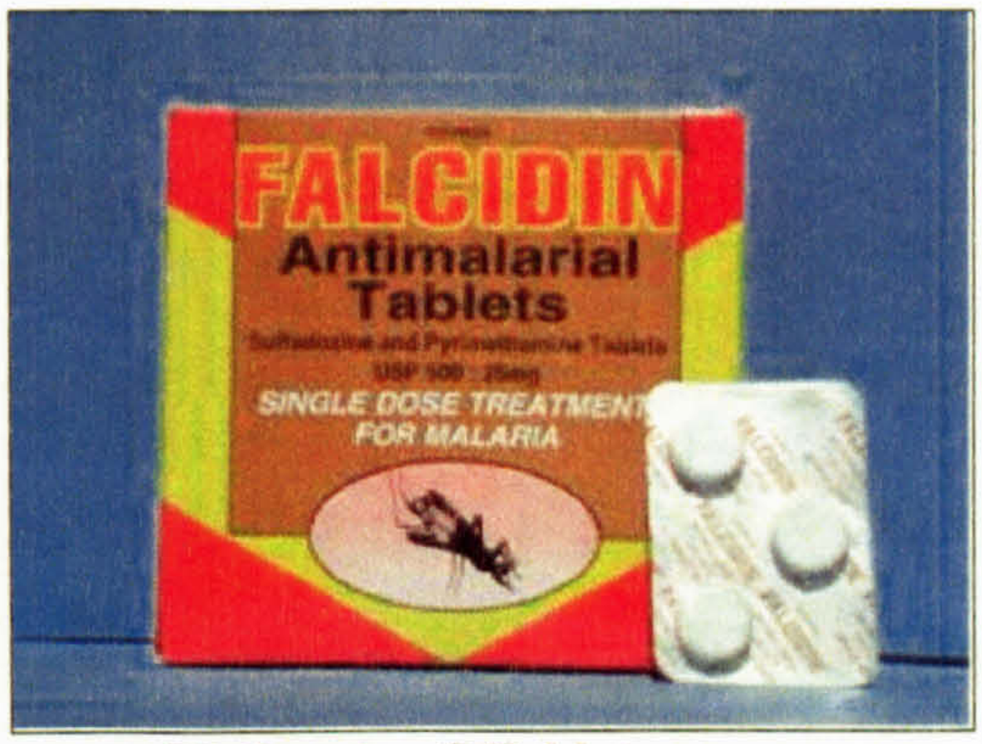
Images of the common types of AQ and SP brands encountered in the study sites are presented in figure 3.8.

Figure 3.8: Images of common brands of AQ and SP medicines encountered

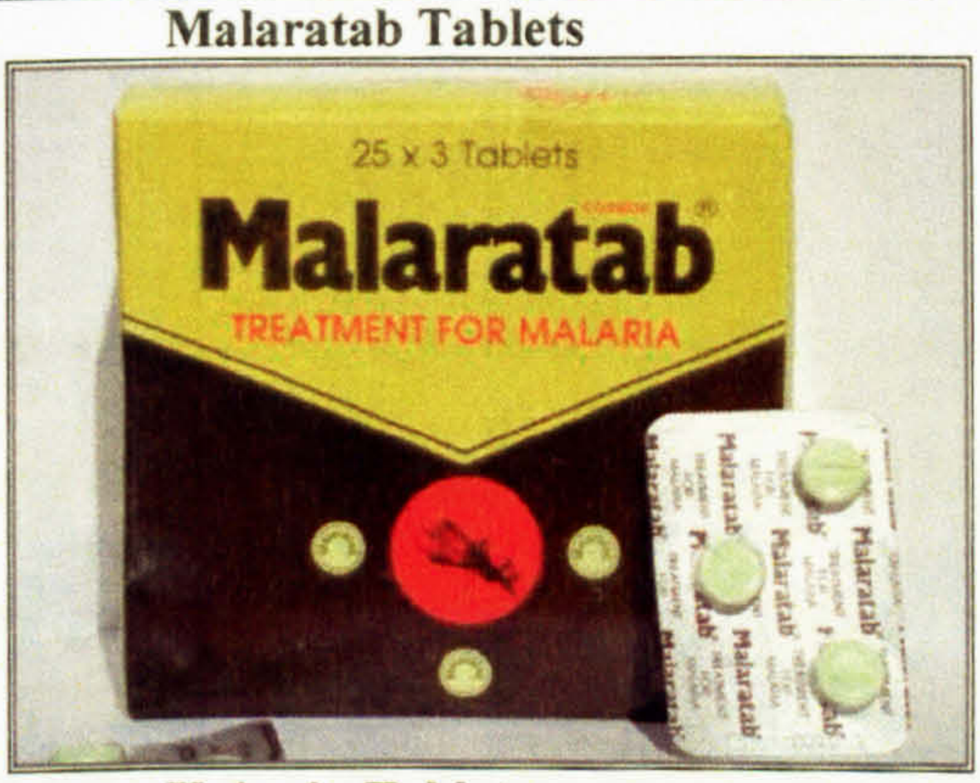
Betaquine Tablets



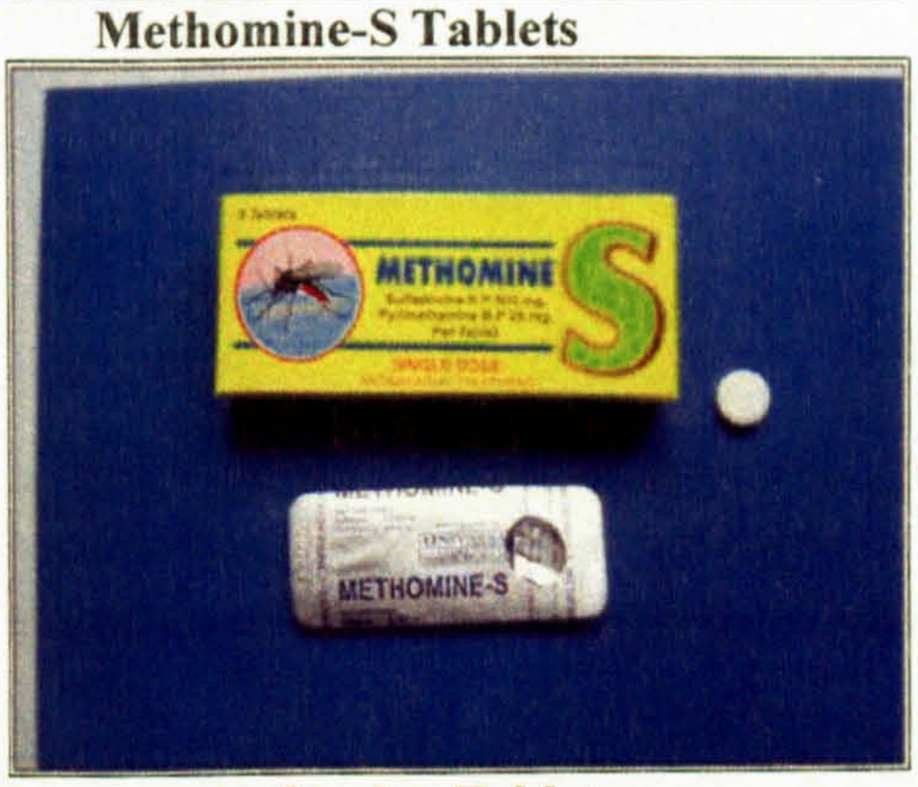
Falcidin Tablets



Malaratab Tablets

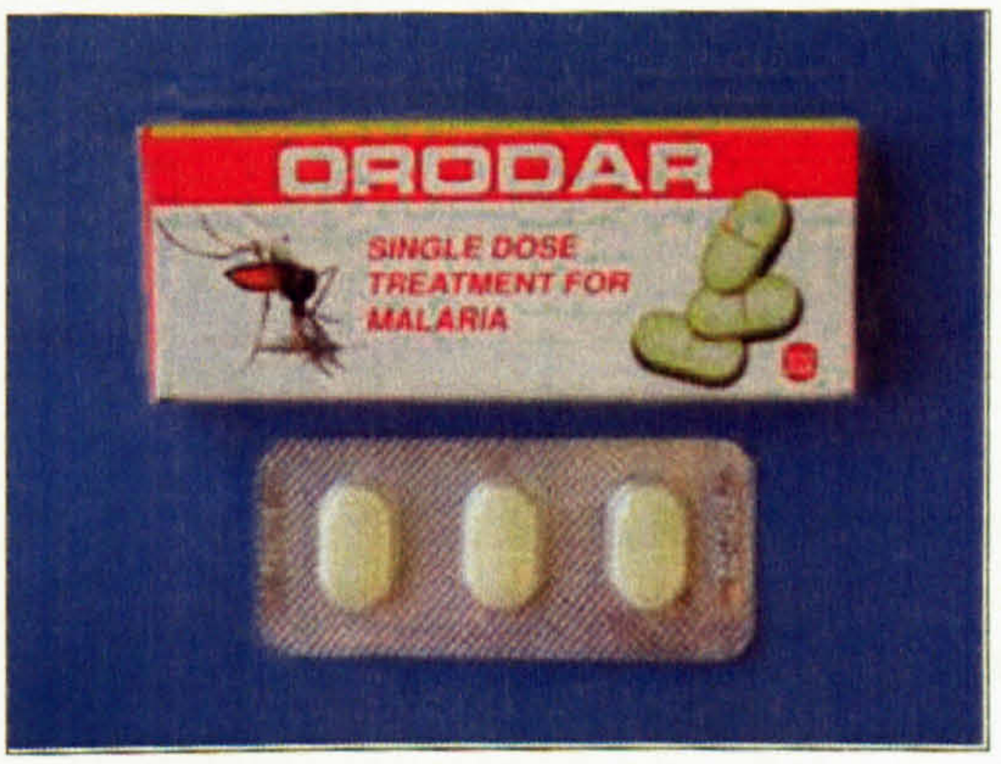


Methomine-S Tablets



Uniquin Tablets:

Orodar Tablets



3.3.5: Storage conditions and expiry dates of anti-malarial medicines

A secondary indicator in this study concerns storage conditions of anti-malarial medicines since all programmes included training on the importance of adequate storage of medicines to maintain their quality. In the Bungoma-AMREF site, PMRs were inducted on general hygiene practices while handling drugs. In the Kisii-Merlin

and Kwale-MoH sites, the training curriculum contained recommendations to store such medicines off the floor, away from direct sunlight and in a dry place. During the retail audit, field workers made an assessment of the extent to which storage conditions satisfied these three criteria by scoring each from 0 to 3, where 3 was a score used when all the criteria were met. To determine whether medicines were within the expiry period, packages of each drug were checked for the manufacturer's printed expiry dates and compared against the date in which data collection was completed for that outlet.

There were no significant differences in storage practices between the intervention and control outlets across all districts and therefore this data was combined. The proportion of outlets which stocked AQ medicines within the expiry period was over 98% in the Kisii-Merlin and the Kwale-MoH sites and 100% in the Bungoma-AMREF site. 83.7% of outlets stored AQ medicines adequately in the Kisii-Merlin site, 90% in the Kwale-MoH and 91.3% in the Bungoma-AMREF sites.

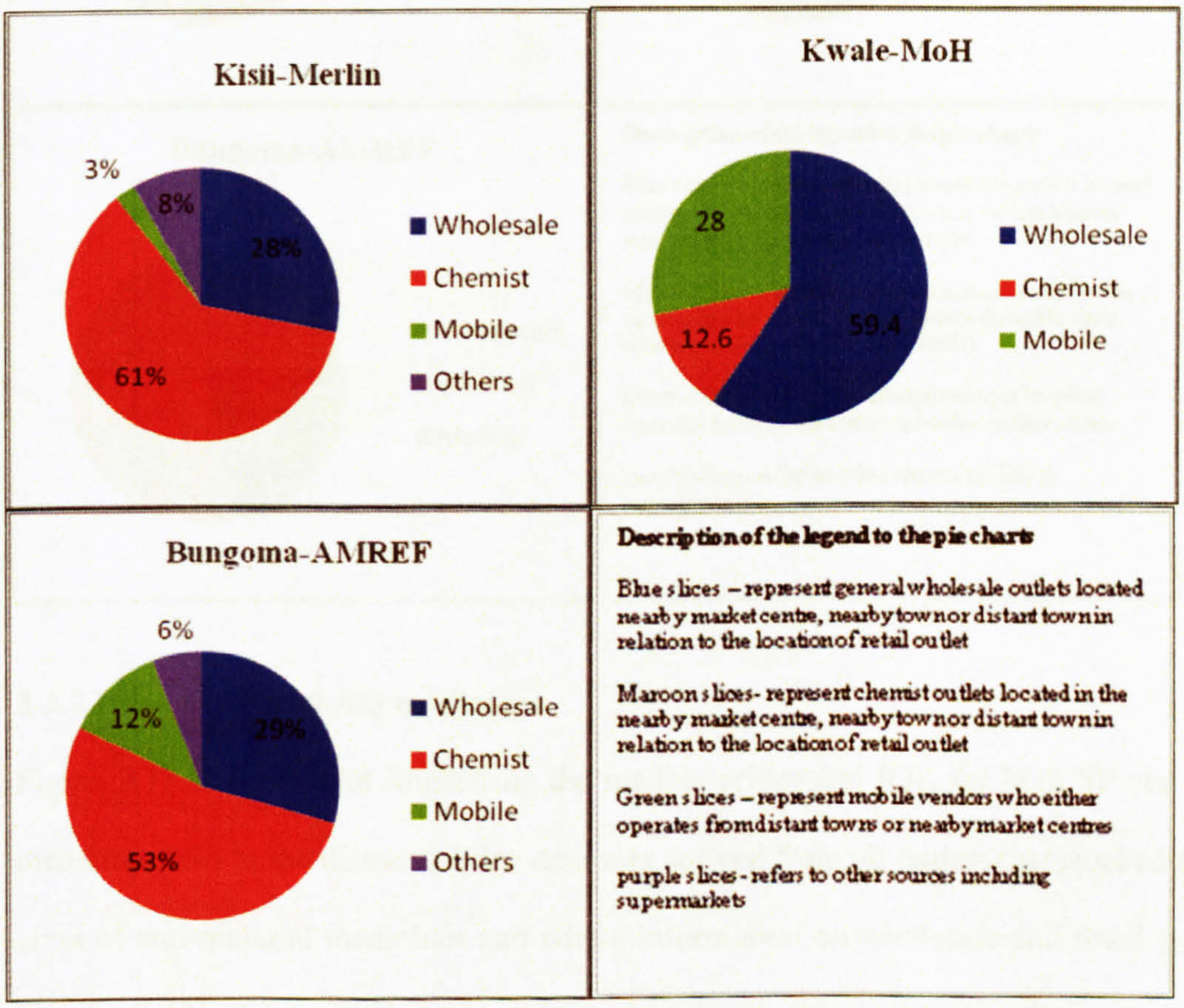
3.3.6 Sources of SP and AQ medicines

Sources and prices of common anti-malarial medicines in stock were useful measures in understanding the functioning of the retail sector, comparability of selected sites and comparisons with other settings. Sources and prices of medicines also have implications for the supply and accessibility of the intervention. Figure 3.9 and 3.10 provide a summary of sources of AQ and SP medicines in the three districts.

Figure 3.9 shows variations in the sources of AQ medicines in each site. Chemist shops and general wholesalers were the main sources of AQ medicines in the Kisii-Merlin site. In Kwale, PMRs sourced AQ medicines from general wholesalers or vendors. Vendors were mainly drug distribution company representatives and others

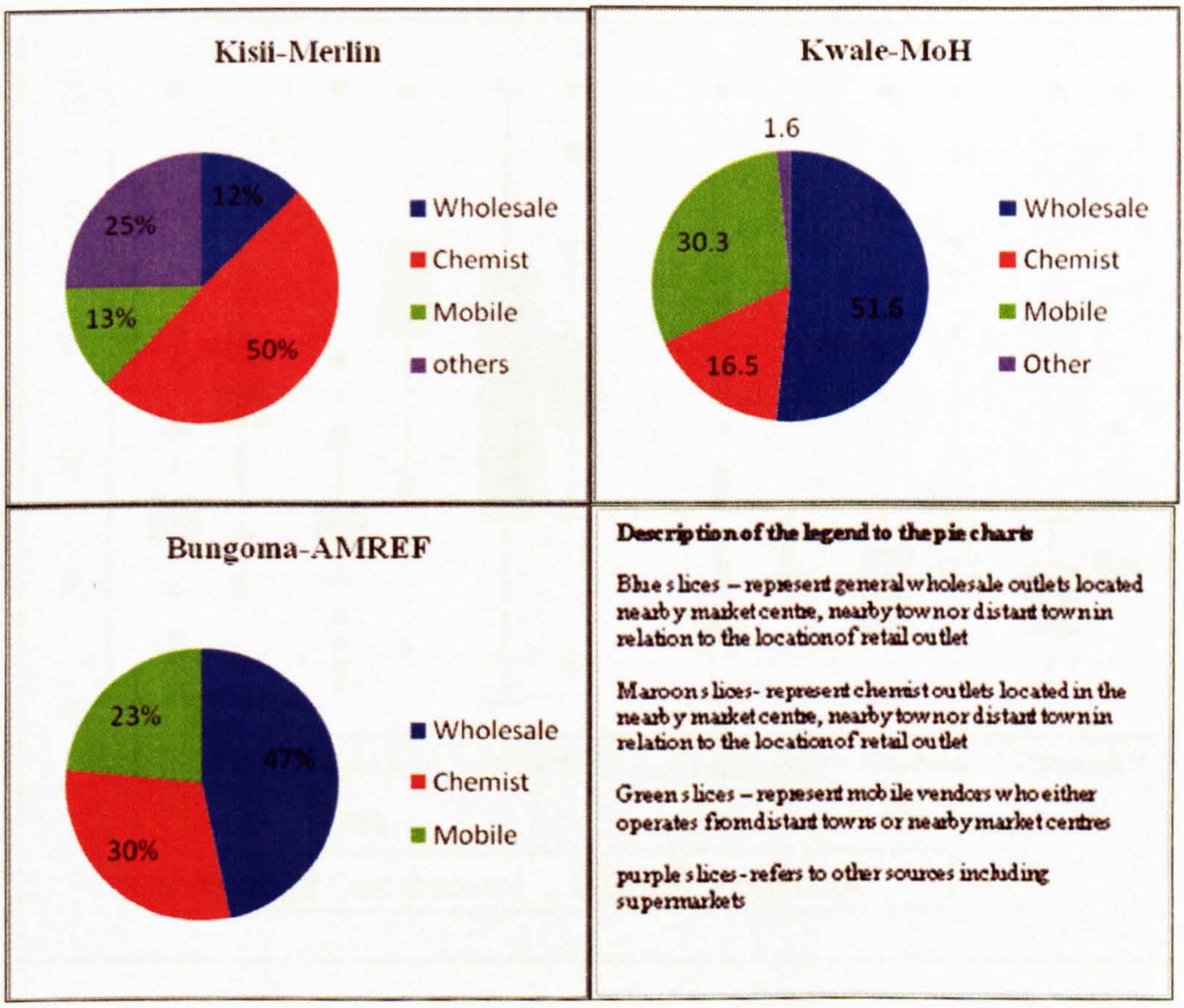
who sold medicines and general wares on motorbikes or vehicles. Although the programme in the Bungoma-AMREF site was anchored on wholesalers and mobile vendors who were already distributing anti-malarial medicines, PMR sourced AQ medicines mainly from chemist shops and wholesalers.

Figure 3.9 Sources of AQ medicines



The common sources of SP class of medicines in the retail outlets of the Kisii-Merlin site were chemist shops and general wholesalers for the Kwale-MoH site. In the Bungoma-AMREF site, PMRs sourced SP medicines from general wholesalers and about a third from chemist shops (figure 3.10).

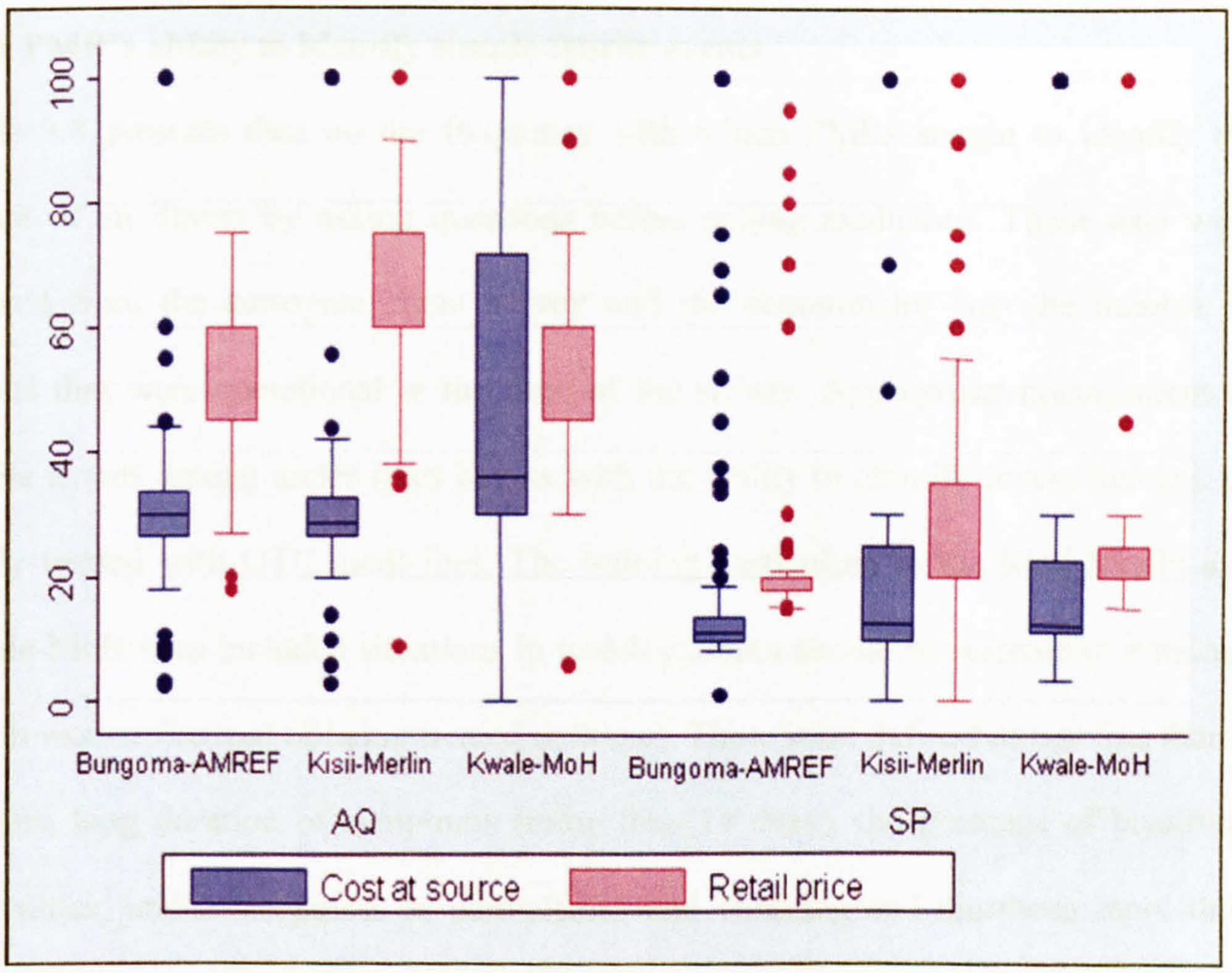
Figure 3.10 Sources of SP medicines



3.3.7 Price of SP and AQ medicines

Figure 3.11 is a box plot illustrating the median prices and IQR for both SP and AQ medicines sold in the districts. Price data was derived from all outlets that stocked each class of anti-malarial medicines and where information on wholesale and retail prices was available. Again there were no variations in the prices between the control and intervention areas in both sites and therefore all data were merged. For each drug class, the PMRs were asked to describe quantities in which they bought and sold the drugs. In almost all cases PMRs sold drugs in tablet form, packed either in blister packs or in some cases in loose tablets from tins. Retail and wholesale prices were derived by multiplying the quantity bought per tablet with the number of tablets required for a full adult course as recommended in the MoH treatment guidelines.

Figure 3.11 Wholesale and the retail prices of SP and AQ classes of medicines



Note: on the y-axis is the cost in KES while the x-axis represents the class of medicines. The dark middle bars in each box represent the median and the blue and red boxes represent the IQR for prices of both AQ and SP boxes respectively. The whiskers represent extreme non-outlier observations while the circles show outliers

In the Kisii-Merlin site, the median wholesale price for a full adult course of AQ medicine was KES 30 (IQR; 26.4, 33.6), and retailed at KES 60 (IQR; 45-60). In the Kwale-MoH site, the median wholesale and retail prices for AQ medicines were KES 36 (IQR; 30-71.5) and KES 60 (IQR; 45-60) respectively. In the Bungoma-AMREF site, these prices were KES 30 (IQR; 26.4-33.6) and KES 45 (IQR; 45-60), respectively. There were no variations on the wholesale and retail prices for full adult courses of SP medicines in the districts. The median wholesale price for SP class of medicines was approximately KES 12 (IQR; 11-22), with retail price of KES 20 (IQR; 20-25). Overall, higher retail prices of each class of medicines represent a retail mark up of about KES 8 for SP medicines and KES 15-30 for AQ medicines based on adult courses.

3.4 Impact of programme on PMR knowledge and practices

3.4.1 PMR's ability to identify simple febrile events

Table 3.8 presents data on the frequency with which PMRs sought to identify the nature of an illness by asking questions before selling medicines. These data were derived from the surrogate client survey and the denominator was the number of outlets that were operational at the time of the survey. Appropriate management of febrile events among under fives begins with the ability to identify fevers that can be safely treated with OTC medicines. The training curriculum in the Kisii-Merlin and Kwale-MoH sites included situations in which children should be referred to a trained health worker (instead of being treated at home). These were defined as age less than 6 months, long duration of symptoms (more than 14 days), the presence of breathing difficulties, undue sleepiness or convulsions and vomiting and diarrhoea more than three times a day. In the Bungoma-AMREF site, danger signs were described as convulsions, breathing difficulties, unconsciousness, pale hands, tongue and inner part of the eyelids, generalized body weakness and dehydration. In this study, this assessment was based on the proportion of PMRs who asked for the presence of at least one danger sign.

Apart from age, PMRs in control and interventions areas, rarely asked questions at the time of selling medicines in all sites. However, in the Kisii-Merlin site, trained PMRs more often asked about the following areas than their colleagues in control outlets: at least one danger sign (OR; 9.9: 95% CI 2.6, 35.4); about the age of user (OR; 4.8: 95% CI 2.3, 10.4); about the presence of fever (OR; 13.8: 95% CI 6.5, 29.7) and about the number of days the user had been unwell (OR; 43.1: 95% CI 5.6, 329.1)

Table 3-8 Frequency for PMR asking questions about users and their symptoms before selling medicines

Questions asked*	Kisii-Merlin				Kwale-MoH				Bungoma-AMREF			
	I[a] n (%)	C[b] n (%)	P[c]	OR[d] (95% CI)	I[e] n (%)	C[f] n (%)	P[g]	OR[h] (95% CI)	I[i] n (%)	C[j] n (%)	P[k]	OR[l] (95% CI)
Age	60/71 (84.5%)	48/91 (52.7%)	<0.001	4.8 (2.3, 10.4)	31/77 (40.3%)	29/99 (29.9%)	0.128	1.6 (0.9, 3.0)	26/64 (40.6%)	59/95 (62.1%)	0.08	0.4 (0.2, 0.8)
Previous treatment	7/71 (9.9%)	4/91 (4.4%)	0.214	2.4 (0.7, 8.4)	2/77 (2.6%)	2/99 (2.0%)	1.000	1.3 (0.2, 9.5)	5/64 (7.8%)	7/95 (7.4%)	1.000	1.1 (0.3, 3.5)
Fever	20//71 (28.2%)	8/91 (8.8%)	0.002	13.8 (6.5, 29.7)	4/77 (5.2%)	4/99 (4.0%)	0.731	1.2 (0.06, 23.5)	8/64 (12.5%)	10/95 (10.5%)	0.700	1.2 (0.5, 3.3)
Days user unwell	23/71 (32.4%)	1/91 (1.1%)	<0.001	43.1 (5.6, 329.1)	2/77 (2.6%)	0/99 (0%)	0.187	na	8/64 (12.5%)	8/95 (8.4%)	0.402	1.6 (0.6, 4.4)
Fits	1/71 (1.4%)	0/91 (0%)	0.438	na	0/77 (0%)	0/99 (0%)	na	na	0/64 (0%)	1/95 (1.1%)	1.00	na
Weakness	7/71 (9.9%)	1/91 (1.1%)	0.022	9.8 (1.2, 81.9)	1/77 (1.3%)	0/99 (0%)	0.438	na	0/64 (0%)	3/95 (3.2%)	0.274	na
Vomiting	10/71 (14.1%)	2/91 (2.2%)	0.005	7.3 (1.5, 34.5)	0/77 (0%)	2/99 (2.0%)	0.505	na	6/64 (9.4%)	1/95 (1.1%)	0.017	9.7 (1.1, 82.9)
Diarrhoea	3/71 (4.2%)	0/91 (0%)	0.082	na	0/77 (0%)	0/99 (0%)	na	na	2/64 (3.1%)	0/95 (0%)	0.160	na
Difficulty in breathing	1/71 (1.1)	0/91 (0%)	0.438	na	0/77 (0%)	0/99 (0%)	na	na	0/64 (0%)	1/95 (1.1%)	1.00	na
At least 1 danger signs†	18/71 (25.4%)	3/91 (3.3%)	<0.001	9.9 (2.6, 35.4)	7/77 (9.1%)	7/99 (7.1%)	0.623	1.3 (0.07, 21.9)	4/64 (6.3%)	4/95 (4.2%)	0.715	1.5 (0.4, 6.3)

**the denominator is the number of outlets operational during the surrogate client survey*
†-Danger sign assessed included fits, vomiting and diarrhoea more than four times a day, weakness and difficulty in breathing

3.4.2 Sale of medicines in the retail outlets

To assess appropriateness of fever management at the retail level, surrogate clients asked for an anti-malarial medicine for a child. If questioned, they provided standardised information on the age and symptoms of the illness (a three-year old febrile child with a simple fever). Table 3.9 presents data on the observations where OTC medicines were sold and reasons for not selling medicines. In the Kwale-MoH and Bungoma-AMREF sites, less than half of PMRs in intervention and control outlets sold medicines for a child of this age, with no significant differences between intervention and control outlets. In Kisii-Merlin, PMRs in intervention outlets were significantly more likely to sell drugs than those in the control group. Reasons for not selling medicines included PMR's perceptions that current medicines in stock were unsuitable for a child of that age. This reason was given significantly more often in control than intervention outlets in both Bungoma-AMREF and Kwale-MoH sites. Lack of anti-malarial medicines was another reason underlying non-sales, and this was more common in intervention than control outlets in the Kisii-Merlin site. In all sites, mothers were often advised to seek advice at a health facility.

One of the primary indicators for this study is to determine the impact of the programme on PMR knowledge and practices. The denominator for this indicator is the number of surrogate client survey observations where a sale took place. The relatively few observations with a sale (table 3.9), presents several limitations. First, sample size calculations were based on the number of anti-malarial sales. This means that the low number of sales potentially limited the power of the study in measuring the true effect of the intervention. Secondly, observations without a sale were not included in the denominator introducing a potential bias probably leading to an overestimate of the measured impacts. Finally, the reasons behind low number of sales identified during the survey included refusal to sell medicines to three year old

children, the absence of drugs in shops, and shop-keepers preferring to refer clients to health facilities. These reasons were given by PMRs spontaneously since surrogate clients were unable to probe due to the covert nature of the study and thus may not represent the real picture. The latter limitation was minimised through the qualitative component of this study which explored reason behind these practices and are discussed in chapter four.

Table 3-9 Sale of OTC medicines and reasons given by PMRs for not selling medicines

	Kisii-Merlin				Kwale-MoH				Bungoma-AMREF			
	I[a] n (%)	C[b] n (%)	P[c]	OR[d] (95% CI)	I[e] n (%)	C[f] n (%)	P[g]	OR[h] (95% CI)	I[i] n (%)	C[j] n (%)	P[k]	OR[l] (95% CI)
Observation with sales	43/71 (60.6%)	36/91 (39.6%)	0.008	2.4 (1.2, 4.4)	32/77 (41.6%)	42/99 (42.4%)	0.908	0.9 (0.5, 1.8)	25/64 (39.1%)	42/95 (44.2%)	0.519	0.8 (0.4, 1.5)
Reasons for not selling medicines												
No OTC medicines in stock	3/28 (10.7%)	9/55 (16.4%)	0.489	0.6 (0.2, 2.4)	11/45 (24.4%)	6/57 (10.5%)	0.061	2.7 (0.7, 9.7)	10/39 (25.6%)	12/53 (22.6%)	0.739	1.1 (0.4, 2.9)
No anti-malarial medicines in stock	10/28 (35.7%)	7/55 (12.7%)	0.014	3.8 (1.2, 11.5)	15/45 (33.3%)	13/57 (22.8%)	0.237	1.7 (0.6, 4.9)	7/39 (17.9%)	9/53 (17.3%)	0.904	1.0 (0.4, 3.1)
3 year old child too young to be treated with OTC anti-malarial medicines	7/28 (25.0%)	9/55 (16.4%)	0.346	1.7 (0.6, 5.2)	16/45 (35.6%)	37/57 (64.9%)	0.003	0.3 (0.1, 1.7)	4/39 (10.3%)	17/53 (32.1%)	0.022	0.2 (0.1, 0.8)
Referred to health facility*	5/28 (17.9%)	28/55 (50.9%)	0.004	0.2 (0.07, 0.6)	3/45 (6.7%)	1/57 (1.7%)	0.318	4.0 (0.4, 39.8)	18/39 (46.2%)	12/53 (22.6%)	0.024	2.7 (1.1, 6.8)
Other reasons†	3/28 (10.7%)	2/55 (3.6%)	0.33	3.2 (0.5, 20.2)	0/45 (0%)	0/57 (0%)	na	na	0/39 (0%)	3/53 (5.7%)	0.259	na‡

** These were exclusively cases where PMR referred clients to health facility without reference to any reasons listed*
†other reasons include options such as does not sell medicine to children.

3.4.3 Type of anti-malarial medicines sold and adequacy of advice given on dosages

Table 3.10 presents data on PMRs' selling practices derived from the surrogate client survey. Against a background where surrogate clients were trained to ask for an anti-malarial medicines, results indicate that more than half of the PMRs visited sold an anti-malarial medicine in the control and intervention areas for all sites. Anti-malarial medicines were more often sold in the intervention compared to the control outlets in the Kisii-Merlin (OR; 4.4: 95% CI 1.1, 17.9) and the Kwale-MoH sites (OR; 4.4: 95% CI 1.4, 13.8). No significant differences were observed in the Bungoma-AMREF site.

The primary indicator for the assessment of PMR practices was the proportion of programme outlets where recommended anti-malarial medicines were sold accompanied by appropriate advice on their use. As described in chapter two, this was based on sales of AQ medicines. Over half of trained PMRs of the Kisii-Merlin and the Kwale-MoH site sold AQ medicine, and this was significantly more frequently experienced in the intervention outlets compared to the controls ((OR; 6.1: 95% CI 1.9, 19.0) and (OR: 6.2: 95% CI 2.2, 17.7), respectively). No significant differences were observed in the Bungoma-AMREF site for this measure. In the Kisii-Merlin site, 60.5% of trained PMRs sold AQ medicines accompanied with adequate advice on use compared to 2.8% of untrained PMRs (OR; 53.5: 95% CI 6.7, 428.3). In the Kwale-MoH site, these percentages were 18.8% in the intervention and 2.3% in the control outlets (OR; 9.4: 95% CI 1.1, 83.1). In the Bungoma-AMREF site there were no significant differences measured between the two areas.

Table 3-10 PMR's practices while selling medicines for a three year old febrile child

Selling practices	Kisii-Merlin				Kwale-MoH				Bungoma-AMREF			
	I[a] (n) %	C[b] (n) %	P[c]	OR[d] (95% CI)	I[e] (n) %	C[f] (n) %	P[g]	OR[h] (95% CI)	I[i] (n) %	C[j] (n) %	P[k]	OR[l] (95% CI)
Sold anti-malarial with or without antipyretic	40/43 (93.0%)	27/36 (75.0%)	0.032	4.4 (1.1, 17.9)	27/32 (84.4%)	23/42 (54.7%)	0.011	4.4 (1.4, 13.8)	23/25 (92.0%)	39/42 (92.8%)	1.00	0.9 (0.1, 5.6)
Sold antipyretic only	3/43 (6.9%)	9/36 (25.0%)	0.026	0.2 (0.1, 0.9)	5/32 (15.6%)	19/42 (45.2%)	0.011	0.2 (0.1, 0.7)	2/25 (8.0%)	2/42 (4.8%)	0.626	1.7 (0.2, 13.2)
Type of anti-malarial sold and adequacy of dosage												
Sold AQ	38/43 (88.4%)	20/36 (55.6%)	0.002	6.1 (1.9, 19.0)	19/32 (59.4%)	8/42 (19.1%)	<0.001	6.2 (2.2, 17.7)	9/25 (36.0%)	15/42 (35.7%)	0.981	1.0 (0.4, 2.8)
Sold AQ with adequate advice	26/43 (60.5%)	1/36 (2.8%)	<0.001	53.5 (6.7, 428.3)	6/32 (18.8%)	1/42 (2.3%)	0.038	9.4 (1.1, 83.1)	1/25 (4.0%)	3/42 (7.1%)	1.00	0.5 (0.1, 5.5)
Sold AQ with adequate advice on dose/all AQ sold	26/38 (68.4%)	1/20 (5.0%)	<0.001	41.2 (4.9, 344.4)	6/19 (31.6%)	1/8 (12.5%)	0.633	3.3 (0.3, 33.9)	1/9 (11.1%)	3/15 (20.0%)	1.000	0.5 (0.04, 5.3)
Sold SP	2/43 (4.7%)	8/36 (22.2%)	0.037	0.2 (0.03, 0.9)	8/32 (25.0%)	15/42 (35.7%)	0.324	0.6 (0.2, 1.7)	14/25 (56.0%)	23/42 (54.8%)	0.921	1.1 (0.4, 2.8)
Sold SP with adequate advice	0/36 (0%)	5/36 (13.8%)	0.017	na*	4/32 (12.5%)	8/42 (19.0%)	0.536	0.6 (0.2, 2.2)	5/25 (20.0%)	10/42 (23.8%)	0.718	0.8 (0.2, 2.6)

Note: the denominator was all medicines sold unless stated otherwise

3.4.4 PMR knowledge on OTC drug types

This section addresses the main secondary indicator, which is the proportion of programme outlets where the main PMR is aware of MoH recommendations on anti-malarial medicines and can identify appropriate dosages for children. The assessment drew on the findings of the retail audit and was based on use of a vignette (Annex II) concerning recommendations for treatment for a five year old febrile child with no other symptoms.

In table 3.11 the proportions are expressed as a percentage of all outlets with anti-malarial medicines in stock. In the Kisii-Merlin 54.1% and 72.9% of the Kwale-MoH trained PMRs recommended an anti-malarial for a febrile event compared to 20.0% and 18.9% of the control PMRs(OR; 4.7: 95% CI 2.0, 11.1) and (OR; 12.0: 95% CI 4.5, 31.9), respectively). No significant differences were observed in the Bungoma-AMREF site. Amongst those who recommended an anti-malarial, 96.8% of trained and 70.0% of control PMRs in the Kisii-Merlin site recommended the use of AQ medicines (OR; 13.3: 95% CI 1.1, 147.5). There were no significant differences observed in the other sites.

Table 3-11 PMR's knowledge on recommendation for febrile illnesses

Recommendation	Kisii-Merlin				Kwale-MoH				Bungoma-AMREF			
	I[a] n (%)	C[b] n (%)	P[c]	OR[d] (95% CI)	I[e] n (%)	C[f] n (%)	P[g]	OR[h] (95% CI)	I[i] n (%)	C[j] n (%)	P[k]	OR[l] (95% CI)
Knowledge on recommendation for febrile children *												
Recommended anti-malarial with or without antipyretic	33/61 (54.1%)	10/50 (20.0%)	<0.001	4.7 (2.0, 11.1)	35/48 (72.9%)	14/74 (18.9%)	<0.001	12.0 (4.5, 31.9)	12/29 (41.4%)	24/76 (31.6%)	0.344	1.5 (0.6, 3.7)
Recommended antipyretics only	22/61 (36.1%)	29/50 (58.0%)	0.021	0.4 (0.2, 0.8)	11/48 (22.9%)	52/74 (79.3%)	<0.001	0.1 (0.05, 0.3)	6/29 (20.7%)	37/76 (48.7%)	0.009	0.3 (0.1, 0.8)
Offered other advice†	6/61 (9.8%)	11/50 (22.0%)	0.077	0.4 (0.2,11.1)	2/48 (4.2%)	8/74 (10.8%)	0.313	0.3 (0.06, 1.9)	11/29 (37.9%)	15/76 (19.7%)	0.053	2.4 (0.9, 6.4)
Knowledge on type of anti-malarial recommended for febrile children												
AQ/all anti-malarial recommended‡	31/32 (96.8%)	7/10 (70.0%)	0.04	13.3 (1.1,147.5)	29/35 (82.9%)	10/14 (71.3%)	0.442	1.9 (0.4, 8.2)	7/12 (58.3%)	15/24 (62.5%)	1.000	0.8 (0.2, 3.4)
SP /all anti-malarial recommended	0/32 (0%)	2/10 (20.0%)	0.05	na	5/35 (14.3%)	2/14 (14.3%)	1.000	1.0 (0.2, 5.8)	5/12 (41.7%)	9/24 (37.9%)	1.000	1.2 (0.3, 4.8)

**The denominator is all cases where information on responses regarding what PMR recommended as a first option for a fever was available. In the Kwale-MoH site there was one case where PMR recommended other medicines other than anti-malarial and is not presented in the table.*

†other advice referred to situations where PMR preferred to send the clients to a health facility for management other than treat the fever with OTC medicines.

‡ in one case the PMR in the intervention area of Kisii-Merlin site recommended a combination of SP and AQ and in the Kwale-MoH site 3 cases recommended the same combination and are not presented here.

3.4.5: PMR's knowledge on dosing anti-malarial medicines

To assess the secondary indicator on PMRs' knowledge of dosing for anti-malarial medicines, PMRs were questioned on the use of any AQ or SP medicines available in the outlets at the time of the survey for a five year old child (table 3.12). 79.3% of trained and 16.7% of control PMRs in the Kisii-Merlin site had correct knowledge on adequate dosing of AQ medicines (OR; 18.6: 95% CI 6.6, 52.2). Trained PMRs also less often recommended AQ in either low or high doses than the control ones. In the Kwale-MoH site, although the measure of effect could not be derived, there were significant differences between the intervention and control areas in the proportion of PMRs who had correct knowledge on dosing of AQ medicines (48.8% versus 0% in the control outlets). No significant differences were observed in this indicator in the Bungoma-AMREF site. A common pattern of incorrect use across all districts was adminstration of AQ for one day. This was often seen in the control sites of the Kisii-Merlin and Kwale-MoH and both control and intervention outlets of the Bungoma-AMREF site.

Across all the districts, there were no statistically significant differences between the control and intervention areas in the proportion of PMRs who had correct knowledge on the dosage of SP medicines. However, there appeared to be a pattern of recommending use of SP for three days in the intervention outlets of the Kisii-Merlin and the Kwale-MoH site. These differences were significant in the Kwale-MoH programme (OR; 8.9: 95% CI 2.1, 37.5).

Table 3-12 PMR's knowledge on dosing SP and AQ medicines

Adequacy on dosages for anti-malarial medicines recommended	Kisii-Merlin				Kwale-MoH				Bungoma-AMREF			
	I[a] n (%)	C[b] n (%)	P[c]	OR[d] (95% CI)	I[e] n (%)	C[f] n (%)	P[g]	OR[h] (95% CI)	I[i] n (%)	C[j] n (%)	P[k]	OR[l] (95% CI)
***Dosing of AQ medicines available**												
Recommended AQ adequately	46/58 (79.3%)	7/42 (16.7%)	<0.001	18.6 (6.6, 52.2)	21/43 (48.8%)	0/58 (0%)	1.000	na	6/20 (30.0%)	23/53 (43.4%)	0.297	0.6 (0.2, 1.7)
Recommended AQ in high dose	3/58 (5.2%)	17/42 (40.5%)	<0.001	0.08 (0.2, 0.3)	12/43 (27.9%)	18/58 (31.0%)	0.734	0.9 (0.3, 2.4)	4/20 (20.0%)	16/53 (30.2%)	0.558	0.6 (0.17, 2.0)
Recommended AQ in low dose	8/58 (13.8%)	17/42 (40.5%)	0.002	0.2 (0.08, 0.6)	10/43 (23.3%)	34/58 (58.6%)	<0.001	0.2 (0.1, 0.5)	10/20 (50.0%)	14/53 (26.4%)	0.056	2.8 (0.9, 8.1)
Recommended AQ for one day	8/58 (13.8%)	19/42 (45.2%)	<0.001	0.2 (0.07, 0.5)	3/43 (6.9%)	34/58 (60.3%)	<0.001	0.03 (0.004, 0.3)	11/20 (55.0%)	14/53 (26.4%)	0.022	3.4 (1.1, 9.9)
***Dosing of SP medicines available**												
Recommended SP adequately	1/5 (20.0%)	8/20 (40.0%)	0.405	0.4 (0.04, 3.9)	11/23 (47.8%)	14/32 (43.7%)	0.765	1.2 (0.4, 3.4)	6/23 (26.1%)	10/73 (13.7%)	0.164	2.2 (0.7, 6.9)
Recommended SP in high dose	4/5 (80.0%)	12/20 (60.0%)	0.621	2.7 (0.3, 28.4)	6/23 (26.1%)	10/32 (31.2%)	0.678	0.8 (0.2, 2.6)	15/23 (65.2%)	62/73 (84.9%)	0.039	0.3 (0.1, 0.9)
Recommended SP in low dose	0/5	0/20	na	na	6/23 (26.1%)	8/32 (25.0%)	0.927	1.1 (0.3, 3.6)	2/23 (8.7%)	1/73 (1.4%)	0.142	6.8 (0.6, 79.3)
Recommended SP for three days	4/5 (80.0%)	6/20 (30.0%)	0.121	9.3 (0.9, 101.2)	11/23 (47.8%)	3/32 (9.4%)	0.002	8.9 (2.1, 37.5)	3/23 (13.0%)	25/73 (34.2%)	0.066	0.3 (0.1, 1.1)

**the denominator is the outlets where either SP or AQ medicines were available at the time of the survey.*

3.5 Discussion

This section discusses two objectives of this thesis; to determine the impact of the programmes on PMR knowledge and practices and to estimate the geographic coverage and utilisation of the PMR programmes. It begins with a summary of the main findings for both objectives. The second part presents study limitations of the methods used. Subsequent sections present a discussion that helps interpret quantitative outcomes on the impact of programme on PMR knowledge and practices. It examines the strength of the evidence for a causal relationship between the intervention and any differences assessed between programme and non programme outlets within each district by assessing factors that may have acted as confounders or produced bias. It also examines the contextual factors that may influence comparisons between sites, and the generalisibility of these findings.

3.5.1 Summary of quantitative outcomes across the three sites

Table 3.13 summarises the main indicators for the two objectives. Quantitative data indicate that the Kisii-Merlin programme had a significant and the greatest impact on PMR knowledge and practices. There was limited impact in these indicators for Kwale-MoH, but the study was unable to show any impact for Bungoma-AMREF, although there are some important limitations to this analysis. Kisii-Merlin also achieved the highest programme coverage, in terms of the proportion of all retail outlets covered by the programme (27.1%). It was the site which accessed most targeted outlets with 69.7% of outlets with anti-malarial medicines reached. Kwale-MoH and Bungoma-AMREF had similar and relatively low coverage with 14.1% and 16.7% outlets reached, respectively. The Bungoma-AMREF site was more successful in covering retail outlets selling anti-malarial medicines than Kwale-MoH (44.5% compared to 25.3%).

In addition, the provider population ratios indicate that the Kisii-Merlin site had the lowest ratio (1: 219) compared to the Kwale-MoH (1:299) and Bungoma-AMREF sites (1:467). However an interesting finding resulted from the utilisation modelling, showing that the highest levels of utilisation were likely to have resulted in one division of the Kwale-MoH site, Kinango, with 39, 575 potential under five users. This was also the division with the lowest number of trained outlets and population density. Potential under five users in the Bungoma-AMREF, Kisii-Merlin and Matuga division of the Kwale-MoH site programme numbered 29,475, 28,876 and 8260, respectively. The PMR services were likely to be accessed within a walking distance of 1.30 km in the Kisii-Merlin site, 1.86 km in Kwale and 1.40 km in Bungoma.

The first objective of this thesis addressed the impact of the intervention on practice (primary indicator) and knowledge (secondary indicator). In relation to the primary indicator, table 3.13 shows that 60.5% of trained PMRs in the Kisii-Merlin site sold AQ medicines with appropriate advice on their use compared to 2.8% of untrained ones (OR; 53.5: 95% CI 6.7, 428.3). This difference was also significant in the Kwale-MoH site, where 18.8% versus 2.3% among the intervention and control PMRs sold AQs medicines with correct advice, respectively (OR; 9.4: 95% CI 1.1, 83.7). No impact was observed in the Bungoma-AMREF site.

Consistency in positive outcomes in the Kisii-Merlin site was further observed in the ability of PMR to identify fevers treatable at the retail level. 25.4% of trained PMRs in the Kisii-Merlin site asked for at least one danger sign compared to 3.3% among control PMRs; (OR; 9.9: 95% CI 2.6. 35.4). In addition, 84.5% of the trained PMRs in the Kisii-Merlin programme asked for the age of user compared to 52.7% among the control PMRs; (OR; 4.8: 95% CI 2.3, 10.4). No significant differences were observed for the two indicators in the other sites.

Table 3-13 Summary of quantitative findings across sites

	Kisii-Merlin				Kwale-MoH				Bungoma-AMREF			
	I [a] n (%)	C [b] n (%)	P [c]	OR [d] (95% CI)	I [e] n (%)	C [f] n (%)	P [g]	OR [h] (95% CI)	I [i] n (%)	C [j] n (%)	P [k]	OR [l] (95% CI)
Indicators of coverage												
% of all outlets trained	27.1%	na			14.1%	na			16.7%	na		
Trained outlets /all outlets with anti-malarial	69.7%	na			25.3%	na			44.5%	na		
Average distance to a centre with a trained PMR (km)	1.30	na			1.86	na			1.40	na		
under five population reached by programme	28 876	na			47 785	na			29 475	na		
Indicators of differences in practice												
% asking at least one danger sign	18/71 (25.4%)	3/91 (3.3%)	<0.001	9.9 (2.6, 35.4)	7/77 (9.1%)	7/99 (7.1%)	0.623	1.3 (0.07, 21.9)	4/64 (6.3%)	4/95 (4.2%)	0.715	1.5 (0.4, 6.3)
% asking about age of user	60/71 (84.5%)	48/91 (52.7%)	<0.001	4.8 (2.3, 10.4)	31/77 (40.3%)	29/99 (29.9%)	0.128	1.6 (0.9, 3.0)	26/64 (40.6%)	59/95 (62.1%)	0.08	0.4 (0.2, 0.8)
% sold anti-malarial medicine for fever	40/43 (93.0%)	27/36 (75.0%)	0.032	4.4 (1.1, 17.9)	27/32 (84.4%)	23/42 (54.7%)	0.011	4.4 (1.4, 13.8)	23/25 (92.0%)	39/42 (92.8%)	1.00	0.9 (0.1, 5.6)
% sold AQ medicine for fever	38/43 (88.4%)	20/36 (55.6%)	0.002	6.1 (1.9, 19.0)	19/32 (59.4%)	8/42 (19.1%)	<0.001	6.2 (2.2, 17.7)	9/25 (36.0%)	15/42 (35.7%)	0.981	1.0 (0.4, 2.8)
% selling AQ in adequate doses*	**26/43 (60.5%)**	**1/36 (2.8%)**	**<0.001**	**53.5 (6.7, 428.3)**	**6/32 (18.8%)**	**1/42 (2.3%)**	**0.038**	**9.4 (1.1, 83.1)**	**1/25 (4.0%)**	**3/42 (7.1%)**	**1.00**	**0.5 (0.1, 5.5)**
Indicators of differences in Knowledge												
% recommended anti-malarial medicine for fever	33/61 (54.1%)	10/50 (20.0%)	<0.001	4.7 (2.0, 11.1)	35/48 (72.9%)	14/74 (18.9%)	<0.001	12.0 (4.5, 31.9)	12/29 (41.4%)	24/76 (31.6%)	0.344	1.5 (0.6, 3.7)
% recommended AQ medicines	31/32 (96.8%)	7/10 (70.0%)	0.04	13.3 (1.1,147.5)	29/35 (82.9%)	10/14 (71.3%)	0.442	1.9 (0.4, 8.2)	7/12 (58.3%)	15/24 (62.5%)	1.000	0.8 (0.2, 3.4)
% recommended AQ medicines adequately†	**46/58 (79.3%)**	**7/42 (16.7%)**	**<0.001**	**18.6 (6.6, 52.2)**	**21/43 (48.8%)**	**0/58 (0%)**	**1.000**	**na**	**6/20 (30.0%)**	**23/53 (43.4%)**	**0.297**	**0.6 (0.2, 1.7)**

** The main primary indicator for assessing practices of PMRs, †The main secondary indicator for assessing knowledge of trained PMRs*

In terms of the main secondary indicator, the intervention appears to have improved PMR knowledge in the Kisii-Merlin and Kwale-MoH site, but no significant differences were detected in the Bungoma-AMREF site. 79.3% of the trained PMRs in the Kisii-Merlin site were aware of appropriate dosages of AQ medicines for children compared to 16.7% among the control PMRs (OR; 18.6: 95% CI 6.6, 52.2). For the same indicator, this was 48.8% in the Kwale-MoH site compared to 0% in the control, but no significant difference was noted in the Bungoma-AMREF site.

3.5.2 Study limitations

3.5.2.1 Limitations of methods used to measure coverage

There are some limitations to the methods used to measure coverage and potential utilization in this study. They include limitations of using provider-population ratios and intrinsic limitations of the methods. The study used provider–population ratios as one estimate of coverage of the intervention. Provider-population ratios ignore overlap in potential border crossing between polygons by patients, which can be substantial in smaller areas, and instead assume homogeneity in utility (Council on Graduate Medical Education, 1998). Secondly they do not incorporate measures of distance dimension (Guagliardo et al., 2004), or provide any information on quality of services provided.

Spatial access to services offered by PMRs was defined using a Euclidean model which has intrinsic limitations. Catchment areas were delineated using the TP techniques based on several assumptions. Firstly, it was assumed that patients would choose the nearest retail outlet regardless of the type and services offered. However, in practice only a certain proportion will use retail sector services and the issue of preferences is not factored in the analysis. Secondly, it assumes that utilization rate is constant throughout a catchment area, and thirdly, the analysis of distance in the TP

assumes that people travel in straight line distances. Another challenge associated with distance-based measures is the determination of actual routes used as well as the mode of transport. Distance-based measures do not provide information on overlapping coverage, size of population served and variability of quality of care (Noor et al., 2003; Rosero-Bixby, 2004; Noor, 2005; Noor et al., 2006a).

3.5.2.2 Limitations in assessing impact on PMR knowledge and practices

This section examines limitations in interpreting the evaluation of PMR knowledge and practices in this study. Two main areas of limitations are those concerning the study design, and limitations that are specific to the methodologies used. On the design limitations and in keeping with Habicht's proposed "plausibility" criteria, an argument is developed from the data on the likelihood of a causative relationship between the programmes implemented and any measured effects. For methodological limitations, the discussion will present ways in which these were addressed in this study.

The evaluation approach for retailer level impacts, as discussed in chapters 1 and 2, was based on a pragmatic design that included multiple methods. Randomised controlled trials are regarded as a gold standard for evaluating the impact of an intervention (Victora et al., 2004), but in practice they may have limitations for the assessment of large scale public health interventions, given the complexity of the latter and the frequent lack of opportunities to undertake such evaluations prospectively (Black, 1996; Habicht et al., 1999; Victora et al., 2004). An alternative approach proposed in the literature is to compare one or more programme and non programme sites, either contemporaneously or historically, and construct an argument for whether the intervention is likely to have led to any differences measured, while addressing possible sources of bias and confounding (Habicht et al., 1999).

Therefore, in all the sites, there is a limitation imposed by the design of basing comparisons on one or two control and intervention clusters and generating data from a single cross sectional survey without baseline data. Lack of randomisation and replication at the point of intervention means that the assessment cannot exclude chance effects or confounding. However, the fact that the main indicator (the proportion of PMRs who sell recommended OTC anti-malarial with appropriate advice) was closely linked to the intervention itself (training of PMRs and communities on use of OTC anti-malarial medicines) may limit the likelihood of such effects.

In the Kisii-Merlin and the Bungoma-AMREF sites, the evaluation employed a retrospective design based on one programme site and one non random contemporaneous control through a single cross sectional survey. Randomisation of several areas as intervention or control areas could not be achieved in these two sites as this was a retrospective evaluation of on-going programmes. On the other hand, the Kwale-MoH programme had been designed as part of the DDP using a prospective cluster randomised design with two intervention and two control areas (annex 1). The prospective design strengthens the evaluation in Kwale, but the analysis is still affected by the low numbers of clusters available. Use of a single survey is a further complication in interpreting the data. Without a historical control, it is not possible to establish whether differences (or similarities) between contemporaneous controls and interventions existed before the intervention, or result from the intervention. As above, plausibility has a major role in assessing the likelihood that important differences between control and intervention areas pre-dated or followed the intervention.

At the outset, in order to limit the effect of potential confounders, the selection of the control areas took into account relevant characteristics of the intervention areas, such

as access to formal health care, malaria burden and geographical location and socio-economic factors. This was done, as explained in chapter two, through discussion with local health and administrative stakeholders.

Some information on the success of this selection process can be obtained by comparing the characteristics of PMRs and outlets in intervention and control areas in each district. There were no significant differences in gender, education or age between intervention and control PMRs within each site. These factors, particularly educational status, were considered important potential sources of bias or confounding for an educational intervention. In addition, a majority of the outlets in the control and intervention areas were classified as general retail shops manned by a single PMR. Specialist drug shops were more common in the control than intervention areas in the Bungoma-AMREF site, pointing to a weakness in the selection of this control area, and potentially influencing the comparison. This effect is discussed later in section 3.5.2.3. Outlets operated by a single PMR points to small outlets with similar economic viability, an indicator that has been previously used to reflect size (Marsh et al., 1999; Amin et al., 2003).

Other characteristics which can be used to illustrate comparability of the outlets in intervention and control areas were the drug stocking patterns, price of medicines and storage conditions. Similarities in all these features suggest that differences in the main outcomes measured were unlikely to have been influenced by characteristics of the retail sector in these settings. Price of medicines at the retail level is also influenced by the normal sources and distribution chains. There were no significant differences in the sources of AQ and SP medicines in intervention and control outlets in all districts. Different sources of these medicines could have influenced retail prices especially if different PMRs sourced medicines from distant suppliers. This would then affect

affordability of medicines by community members. However, in this study, surrogate clients were given money to buy medicine so that the price of medicines was unlikely to have affected the primary indicator, linked to PMR selling practices for anti-malarial medicines. Source and price of medicines would directly influence PMR's stocking pattern which was a secondary indicator for this assessment. However, this characteristic was similar across and within sites.

Another set of limitations concern the methods used, which could potentially introduce bias. The primary indicator was derived through surrogate client surveys, which although frequently used and recommended for evaluating provider performance is open to bias. The surrogate client survey is limited in terms of standardization of information, which potentially undermines the reliability of the results (Madden et al., 1997; Marquez, 2001). A further drawback of the method is inflexibility, including the inability to probe to uncover reasons behind any observed behaviours. For example, data show that surrogate clients who asked for anti-malarial medicines were sometimes sold antipyretic compounds. This could arise from a lack of standardisation of information, for example, the surrogate client might in practice have asked for an antipyretic medicine in error. It could also indicate the PMR's lack of understanding of the difference between anti-malarial and antipyretic medicines or their need to ensure a sale where there were no anti-malarial medicines in stock.

In all sites, data loss was experienced during the surrogate client survey because of relatively high rates of PMRs refusing to sell OTC medicines; (60.6% and 39.6% in the Kisii-Merlin; 41.6% versus 42.4% in Kwale-MoH and 39.1% versus 44.2% in the Bungoma-AMREF sites of the intervention and control area respectively). This is a central challenge for such programmes given that the intervention focussed on strengthening appropriate treatment of OTC medicines to this vulnerable group. The

reasons for these refusals were difficult for surrogate clients to explore without revealing their identity. However, details of the reasons behind such practices were explored qualitatively. Qualitative data pointed to the centrality of confusion from the information presented on the drug packages, which did not recommend use of these medicines for children younger than two years old. The retail audit on the other hand is subject to response bias. Field workers interviewed PMRs on their knowledge of anti-malarial medicines directly. This may have resulted in PMRs reporting practices that they assumed to be "desirable" rather than those they actually undertake, and over reporting of correct practices. In addition, in both the surrogate client survey and retail audit, field workers were not blinded to the control or intervention group which may have influenced information recorded.

Efforts were made to minimise these sources of bias. First, surrogate clients were trained using a skill based approach to support standardisation of information given to PMRs. Secondly, data was collected on simple standardised collection forms and their work was regularly reviewed. However, direct supervision was not possible given the covert nature of the method. Thirdly, to limit the chances that surrogate clients were recognised and "uncovered" in their surrogate role, field workers were recruited locally but visited outlets outside their normal locations. However, inevitably, this meant they were working outside familiar areas and would have to sometimes openly ask local residents about the exact location of the outlets they intended to visit. To avoid this problem, field workers were oriented on the areas they were expected to visit, but getting lost still remained a logistical problem and a potential source of bias. All the above processes drew on experience with this method in other districts (Marsh et al., 2004; Abuya et al., 2007).

A further limitation relates to the number of observations available for use in the analysis, resulting from low numbers of programme outlets, low levels of stocking anti-malarial and high rates of refusal by PMRs to sell anti-malarial medicines. The assessment of the primary indicator was designed to have at least 60 anti-malarial sales in the control or intervention area in order to show a 20% difference between the two areas. It was envisaged that 80 outlets in either the control or intervention area would yield the required numbers. In the Kisii-Merlin site for example, there were 91 trained outlets which appeared adequate at recruitment, but the number of observations with an anti-malarial sale fell below the expected numbers. In practice only 43/71 (60.5%) and 36/91 (39.5%) encounters resulted in sales in the intervention and control areas respectively. In the Kwale-MoH site, out of 94 trained outlets only 32/77 (41.5%) and 42/99 (42.4%) encounters resulted in a sale in the intervention and control areas respectively. The Bungoma-AMREF site had unique challenges in that the IEC materials were distributed within the whole district. It is not possible to know the extent to which the division chosen for this evaluation was representative of those across the district. Only 66 trained outlets were observed in the surrogate client survey making it the site with lowest number of intervention outlets observed. The end result was the problem of low observations with sales ((25/64 (39.1%) and 42/95 (44.2%) in the intervention and control areas, respectively).

3.5.2.3 Specific limitations for the Bungoma-AMREF site

The Bungoma-AMREF site presented difficulties in determining an effective control area due to the design of the intervention (chapter two section 2.5.1.). The different rate of stocking anti-malarial medicines in intervention and control groups in Bungoma (with higher rates seen in control outlets) further suggests that control outlets may not have provided an effective comparison. This is potentially important because specialised drug shops may have been more exposed to information on

pharmaceuticals than general retail shops, leading to better performance in these outlets prior to the intervention. The effect would be negative confounding in the intervention area, with any programme impact being masked by the already higher levels of anti-malarials stocks (and possible associated knowledge) in control outlets. An underlying assumption for this interpretation is that the higher rates of stocking anti-malarials in control outlets is very unlikely to have been a result of the intervention.

In practice, the difficulties in establishing comparable control outlets were linked to the social marketing design of the programme, which meant that programme and non programme outlets would be interspersed, difficult to tell apart and have a high potential for contamination. Several efforts were made to limit this problem. First, use of local knowledge of the DHMT, AMREF personnel and mobile vendors as well as review of programme documents helped in developing a list of programme outlets. Secondly, during the surrogate client survey, field workers were trained to look for specific IEC materials distributed as a potential marker of exposure to the programme. Thirdly, during the retail audit, direct questioning and reporting of the PMR's involvement in the programme facilitated the process of establishing programme outlets and those that were not were excluded from the analysis.

The other set of limitations for the Bungoma-AMREF site concerns the timing of this survey in relation to the programme cycle. This is likely to have negatively impacted on the outcomes of interest, and differed from the other two sites. As mentioned earlier, the period between implementation and evaluation was similar to the other sites. However, the current evaluation was conducted in a phase of implementation that followed withdrawal of the main programme funders. This phenomenon is likely to have impacted on the levels of programme implementation during the evaluation

period, and limits the interpretation of the findings in the Bungoma-AMREF programme as well as the comparison of this programme with Kisii-Merlin and Kwale-MoH (section 3.5.2.4).

To respond to the limitations around the timing of the evaluation in Bungoma, it is worth looking at an earlier evaluation of the programme, conducted by QAP, six months after the first phase of implementation using SP medicines. This early evaluation showed an impact on PMR practices. For example, of all surrogate clients who were sold SP medicines, 38% of intervention PMRs sold SP medicines accompanied with information on correct dose compared to 15% in the comparison group (Tavrov et al., 2002). The study further indicated that although SP medicines were the recommended medicine, AQ medicines was the most commonly stocked anti-malarial (81% versus 39% of SP medicines). Of those that purchased anti-malarial medicines, 35.7% were sold AQ versus 14.7% who were sold SP. The authors also report that of those who purchased AQ medicines, 26% received correct information on how to use it compared to 76% of those who received SP medicines (Tavrow et al., 2003).

The initial evaluation reported above used a retrospective evaluation design comparing control and intervention using a surrogate client survey method (Tavrow et al., 2003), and could be affected by the same limitations that have been discussed in this chapter. In addition, there are several differences that make it difficult to compare data from this earlier evaluation with the current one. First, the previous study used two scenarios that were different to the current evaluation. In addition, the evaluation was based on SP compared to AQ medicines in the current evaluation. Since SP medicines are used in a single dose, it is difficult to extrapolate from knowledge and practice in relation to this drug to the same attributes in relation to a multi-dose medicine, like AQ. In the

earlier study, no information was collected on selling practices for AQ. Despite these limitations, QAP argue for some evidence of an impact of intervention in the initial stage of implementation.

Overall, this section has illustrated that there were more limitations to the evaluation in the Bungoma-AMREF site than the other two sites. These may contribute to the lack of evidence for the impact of intervention on PMR practices and knowledge in the current evaluation.

3.5.2.4 Contextual factors influencing interpretations

The discussion so far has examined the evidence for an effect of the intervention in each of the districts. However, a main aim of the study at the outset was to compare programme impact among districts in order to contribute to an understanding of the relative advantages of different approaches to working with PMRs for malaria control. As part of this latter analysis, this section examines the extent to which different district contexts could influence any comparison of the key outcomes measures between sites. Aspects of this context that will be considered are similar to some of those discussed in section 3.5.2.2 as potential influences for within district comparisons. They include characteristics of the retail sector, including PMRs themselves, poverty and timing of the evaluation. The characteristics of the PMRs, type of outlets, stocking patterns, price of medicines and quality of medicines assessed through storage conditions were similar across sites, although some variations in the type of outlet occurred in Bungoma. These similarities strengthen the validity of comparisons between districts.

Poverty is likely to influence the ability of PMRs to stock anti-malarial medicines and clients' ability to buy medicines, and differences in poverty indices could therefore

contribute to differences in programme impacts between the districts. The influence of poverty on stocking patterns is to an extent excluded in this study since all outlets were selected on the basis of availability of anti-malarial medicines. In addition, all three sites have generally high and similar proportions of community members living below the poverty line (chapter 2). Discussions with PMR and potential clients during the qualitative study highlighted the challenges of stocking anti-malarial medicines among PMR and the ability of clients to afford them, since anti-malarial medicines were perceived to be expensive. The influence of poverty on the implementation process is addressed in chapter four.

A further potential factor is the differences in the timing of the surveys between districts. Although the interval between the last training activities and the evaluation was the same in all three districts, the surveys were conducted in two separate years, with Kwale-MoH programme evaluation being conducted in 2005, and those in Kisii-Merlin and Bungoma in 2006[15]. This allows a possibility that temporal changes may have played a part in the differences in the outcomes measured. Examples of such temporal changes could be rainfall and therefore malaria prevalence, or the introduction of other malaria control activities. However, care was taken to exclude the possibility of contamination by other malaria control programmes in all districts through discussion with the DHMT. An important potential influence linked to the timing of these surveys that cannot be discounted is the introduction of the new national anti-malarial drug policy, which would have been new and unfamiliar in 2005, but may have become more established by 2006. If this had an impact, it may have

[15] In the Kisii-Merlin site training of PMRs were conducted between November 2005 and January 2006. The current evaluation was conducted in July 2006. In the Kwale-MoH site, training of PMRs were conducted between November 2004 and January 2005. The evaluation was conducted in July 2005. In the Bungoma-AMREF site, distribution of IEC materials based on AQ medicines was conducted between December 2005 and February 2006. The current evaluation was conducted in October 2006.

contributed to the relative success of the programme in Kisii in contrast to that seen in Kwale, but no such effect is apparent in Bungoma.

Timing of an evaluation in relation to programme implementation is important in the interpretation of outcomes. Evaluation of interventions conducted once and in relatively short periods of time after implementation may not show whether the impacts observed are on the rise or decaying. Overall, contextual features around the functioning of the retail sector and socio-economic status were unlikely to have had an influence on the comparisons of the primary and secondary outcomes between districts. The next section compares these findings with other studies conducted in other settings to establish generalisibility of the findings.

3.5.2.5 Generalizability of findings

The aim of this section is to show how findings from this study compare with other settings to illustrate generalisability. As has been reviewed in chapter 1, the retail sector is generally characterised by a variety of actors who sell medicines (WHO/RBM, 2005). This study like other evaluations in the sector has focussed on a group of PMRs that appear to represent an optimal opportunity for behaviour change interventions. Characteristics used for involving PMRs included stability in time and place, relative financial security, and diversity of retail activities in contrast, for example, to itinerant hawkers in market places who may be difficult to target for such interventions. First this section endeavours to address the question of how similar the findings on the impact of these PMR interventions are to others. Secondly, it addresses how similar these outlets are to those described elsewhere.

In terms of PMR practices, other studies have shown an improvement in PMR practices after different interventions were implemented. For example in Uganda, the

proportion of drugs stores giving appropriate drugs for uncomplicated malaria increased from 2% to 73% after negotiated sessions while those that recommended correct anti-malarial dose (CQ and SP) increased from 0% to 49% (Tawfik et al., 2006). In Nigeria through training and pre-packing of anti-malarials, the proportion that recommended correct anti-malarial doses improved from 9% to 53% (Greer et al., 2004). In Kenya, 86% of PMRs gave appropriate advice on anti-malarial (CQ) after training compared to 0% on the untrained areas (Marsh et al., 2004).

Regarding the characteristics of the PMRs, data from other sites illustrate variations in type of outlets, education levels and age of PMRs. In terms of education, there are variations across different sites with some PMRs having little or no education or formal training (Goodman et al., 2007a). For example, earlier studies conducted in Bungoma district, indicated that over 25% of PMRs had at least 8 years of schooling (Tavrow et al., 2003). Across four other districts of Kenya, the median number of years in school was 10 years (Amin, 2005) whereas in Uganda most of the PMRs were illiterate (Adome et al., 1996). In terms of the age of the main seller, again this varies from very young sales boys and girls in Nigeria where 89% of PMRs studies were below 21 years (Adikwu, 1996) to relatively middle aged PMR observed in the four districts in Kenya with a median age of 35 years (Amin, 2005).

Although the current evaluation focussed on a selected group of PMRs, the types of outlets surveyed in this evaluation were comparable to those found in other settings. In Tanzania and Kenya for example the majority of outlets were general retail shops selling a range of medicines alongside other household goods such as soap, cooking oil, and grocery (Marsh et al., 1999; Goodman et al., 2004; Amin, 2005). Additional types of PMRs in some areas of East and West Africa include drug shops specialising

in pharmaceuticals (Oshiname and Brieger, 1992; Adikwu, 1996; Adome et al., 1996; Brieger et al., 2004; Dzator and Asafu-Adjaye, 2004; Goodman et al., 2004).

Similarities between PMRs in this study with other settings especially in the East African region can be noted in their drug stocking patterns. Among studies aimed to characterise the availability and range of medicines in the retail sector, nearly all outlets studied stocked medicines under proprietary names. In rural Kenya over 30 brands of SP medicines and 13 brands of AQ medicines were identified. The type of brands were also similar with Falcidin® and Malartab® being the commonest SP and AQ medicines (Amin and Snow, 2005). In Tanzania, of all the general outlets that stocked anti-malarial medicines, nearly all of them had CQ with a wide range of other anti-malarial medicines in stock (Goodman et al., 2004).

Regarding sources of anti-malarial medicines, the current evaluation agrees with the literature on retail sector in other parts of Kenya and Tanzania. In the rural settings of four districts in Kenya, sources of anti-malarial medicines to the district PMRs were classified by type of retailers (either large, small or drugs shops). The study indicated that large retailers obtained their drugs from general wholesalers outside the districts (39.8%), or inside the districts (34.8%). Most small retailers (45.3%) sourced anti-malarial medicines from general wholesalers within the districts (Amin and Snow, 2005). In Tanzania, 92% of sources of anti-malarial medicines mentioned by PMRs were general wholesalers who stocked a variety of other products (Goodman et al., 2004). In summary, the outlets that have been studied are found commonly across Kenya, but many different types of PMRs have also been described across the malaria endemic settings of SSA. If the comparison is then restricted to outlets that are similar to the ones that have been included in this study, the findings on the impact of PMR

interventions in this study are supported by evaluations conducted elsewhere. This strengthens the external validity of the outcomes.

3.6 Summary

In this chapter, quantitative data were presented for two objectives. GIS techniques were used to estimate spatial coverage and physical distance of the three PMR interventions. Two sets of outcomes were presented; measures of spatial access and utilisation. Data on the impact of programme on PMR knowledge and practices were derived from post intervention surveys in programme and non programme outlets. It covered availability of programme materials, descriptive characteristics of PMRs and outlets, impact of programme on PMRs practices on sale of anti-malarial medicines and PMR's knowledge on type and adequacy of anti-malarial medicine recommended. The study design was a mix of cluster randomised trial and a pragmatic non random design tied to the implementation stages in each site. Data was collected through the surrogate client and retail audit surveys.

In terms of coverage and spatial access, the study shows that the Kisii-Merlin site had the highest programme coverage (both in terms of all outlets in the programme area reached as well as targeted outlets) compared to the other sites. However, the programme reached just under 30000 potential under five users, a similar number to the Bungoma-AMREF site but lower than the Kwale-MoH site. The Kwale-MoH site, meanwhile, had the lowest coverage (in terms of all outlets in the programme area reached as well as targeted outlets). All the sites appear to have attained the minimum average travel distance of 2 km range from the household stipulated in the guide for scaling up PMR interventions.

The assessment of the impact of the intervention on PMR knowledge and practices was challenged by a number of limitations. These included the study design of basing comparisons on one or two control and intervention clusters and generating data from a single cross sectional survey without baseline data. Other design limitations were challenges around establishing control areas especially in the Bungoma-AMREF site, low numbers of outlets assessed and timing of the surveys. Methodological limitation was mainly potential information bias from the retail audit and surrogate client surveys.

Despite limitations addressed in this chapter, assessment of the primary and secondary indicators across all sites provides strong evidence of an improvement in PMR knowledge and practices as a result of the programme implemented in Kisii-Merlin. There is also good evidence of significant improvements amongst PMRs who were trained in the Kwale-MoH programme. No impact of the programme was demonstrated in the Bungoma-AMREF site at this stage of the project cycle. Broad comparisons of the impacts measured in the Kisii-Merlin and Kwale-MoH programmes are likely to be valid, but comparisons between these two programmes and the Bungoma-AMREF site are challenged by limitations in the latter's evaluation, and differences in the phase of implementation for the evaluations in these districts. The data further suggest that the levels of programme implementation in the three districts were different. Details of how implementation experiences are likely to be related to the outcomes presented in this chapter are examined in chapter four.

CHAPTER 4:

Qualitative assessment and policy analysis of implementation process

4.1 Introduction

This chapter addresses objective three of the thesis: to examine the factors influencing programme implementation and its performance, with specific concern for the roles and influences of key actors, and for understanding how these experiences help explain programme performance in each site. In addition, this chapter explores reasons for the performance variations between programmes. The key questions that drive this chapter are: what features of programme implementation explain their individual performance and the differences in performance between programmes?

The methods for data collection and analysis for this sub-study have already been outlined in chapter 2 section 2.9.3. After inductive analysis of empirical data a range of interim analyses were prepared to examine experience within and across sites around key issues, including stakeholder positions on the programmes. Review of these analyses then enabled identification of key issues in the experience for each site. This led to a deeper understanding of the inter-play of factors underpinning implementation gaps. In the next step of analysis, two conceptual frameworks (Greenhalgh et al., 2004; Simmons and Shiffman, 2006), were used to support further analysis of experience in the three sites. The study was not set up to allow propositions about factors explaining implementation problems and achievements to be derived from these frameworks and tested. Nonetheless, the use of the frameworks in analysis helped guide systematic consideration, both within and across sites, of factors that wider theory and empirical evidence suggest can facilitate or hamper effective implementation of innovative programmes. This process enabled reflection on explanations for the observed variations across programmes in the primary outcome.

The two conceptual frameworks are based on complementary bodies of theory, innovation diffusion and related policy analysis work around implementation, but draw on different sources of evidence. The Simmons and Shiffman framework is derived from consideration of experiences of public health innovation, and specifically those linked to reproductive health services in low and middle income settings, while that of Greenhalgh et al. is based on a systematic review of evidence from high income country experiences around the introduction of technology, products or health care innovations, and was developed for consideration in the health sector.

These frameworks were used because innovation theory is directly relevant to this chapter's primary questions. All programmes evaluated represented innovative approaches to address an important public health problem: improving access to quality malaria treatment in remote settings. In addition, the programmes involved efforts to scale up PMR training from small-scale pilot activities implemented initially in small areas to district-wide implementation in other areas. Although activities in the Bungoma-AMREF site were not based on pilot activities, initial research within this site did change the scope of activities implemented over time and this is considered one form of scaling up. Overall, this analysis contributes to the scarce literature on innovation and scaling up of public health interventions in low and middle income countries (Gilson and Raphaely, 2008). The next section is a brief account of the two frameworks.

4.2 Overview of the frameworks used

The two frameworks identify five main areas of influence over the successful uptake of an innovation. These are the attributes of: the innovation; the resource team; the user organisation, the scaling up strategy, and the context. Figure 4.1 is a framework for

scaling up innovations in health service delivery. It identifies circumstances that may facilitate or hamper effectiveness and sustainability of an innovation (Simmons and Shiffman, 2006). The current analysis draws heavily on this framework because it provides ways of thinking about how to implement an innovation to achieve success. The additional framework presented in figure 4.2 is a conceptual model that illuminates some additional areas to consider when implementing an innovation (Greenhalgh et al., 2004). The terminologies adopted in this chapter have been derived from the body of knowledge underlying the two frameworks. Innovation implies a new set of ways of working directed to improve quality of care and implemented through coordinated actions. Inherent in this definition is that the innovation should have been tested in pilot settings and proven successful. In addition, diffusion is the passive spread of an innovation whereas dissemination is an active and planned effort to persuade target groups to adopt an innovation.

The first set of influences over successful innovation identified in the frameworks is the attributes of the innovation. Innovations can be conceptualised as having two distinct but interrelated aspects. The first are the actual elements of the innovation itself, referred to as the 'hard core'. The second aspect is the organisational structure and system including management required for implementation, referred to as the 'soft periphery'. For successful adoption the innovation should be perceived by users as compatible with their values, including professional norms; it should be based on sound evidence; and it should be easy to install and implement. In addition, success is likely to be experienced if the potential users see it as relevant in addressing felt problems and have room to modify the innovation to suit their needs.

Figure 4.3 Framework for scaling up innovations in health service delivery (Simmons & Shiffman, 2006)

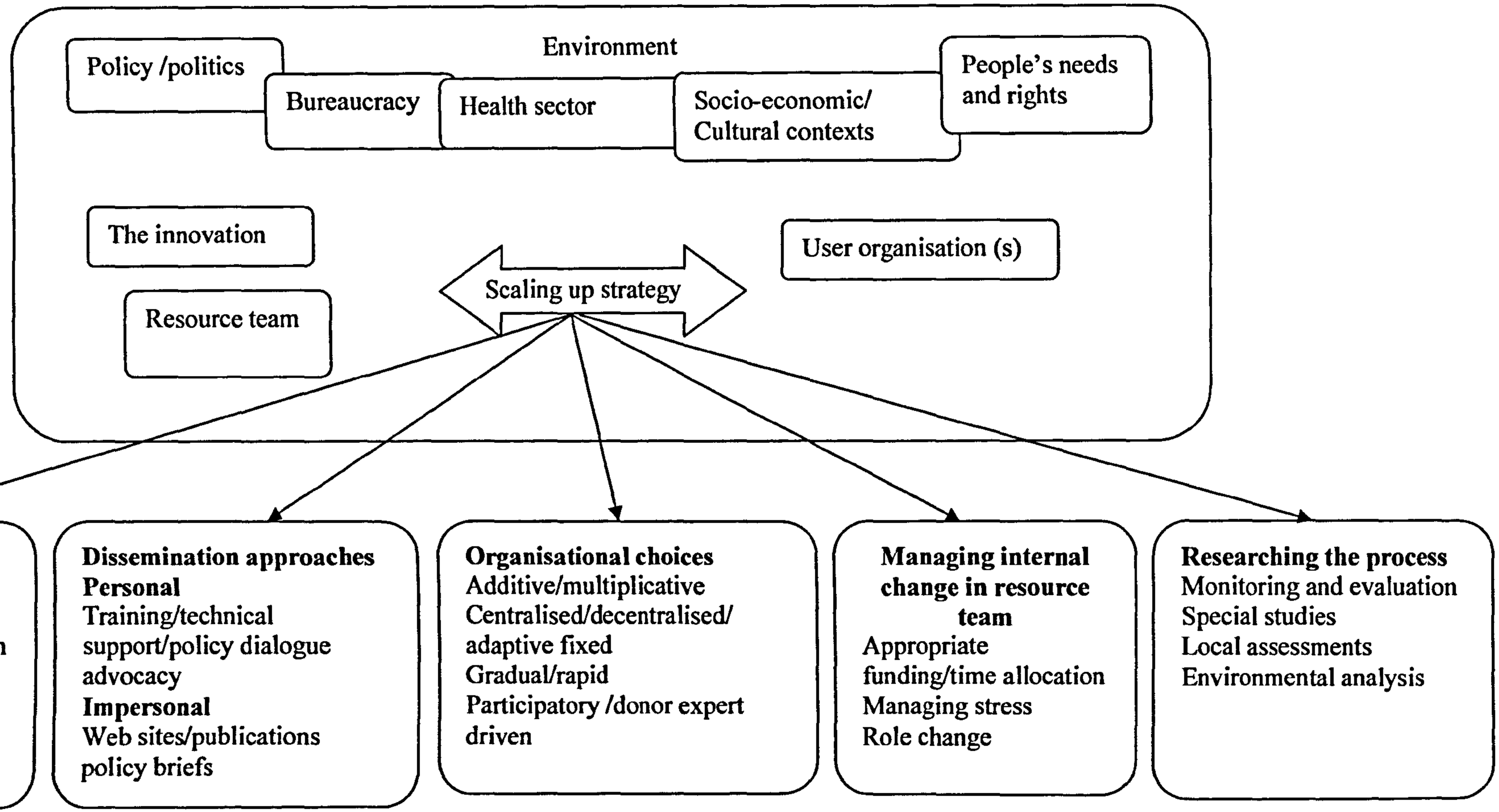
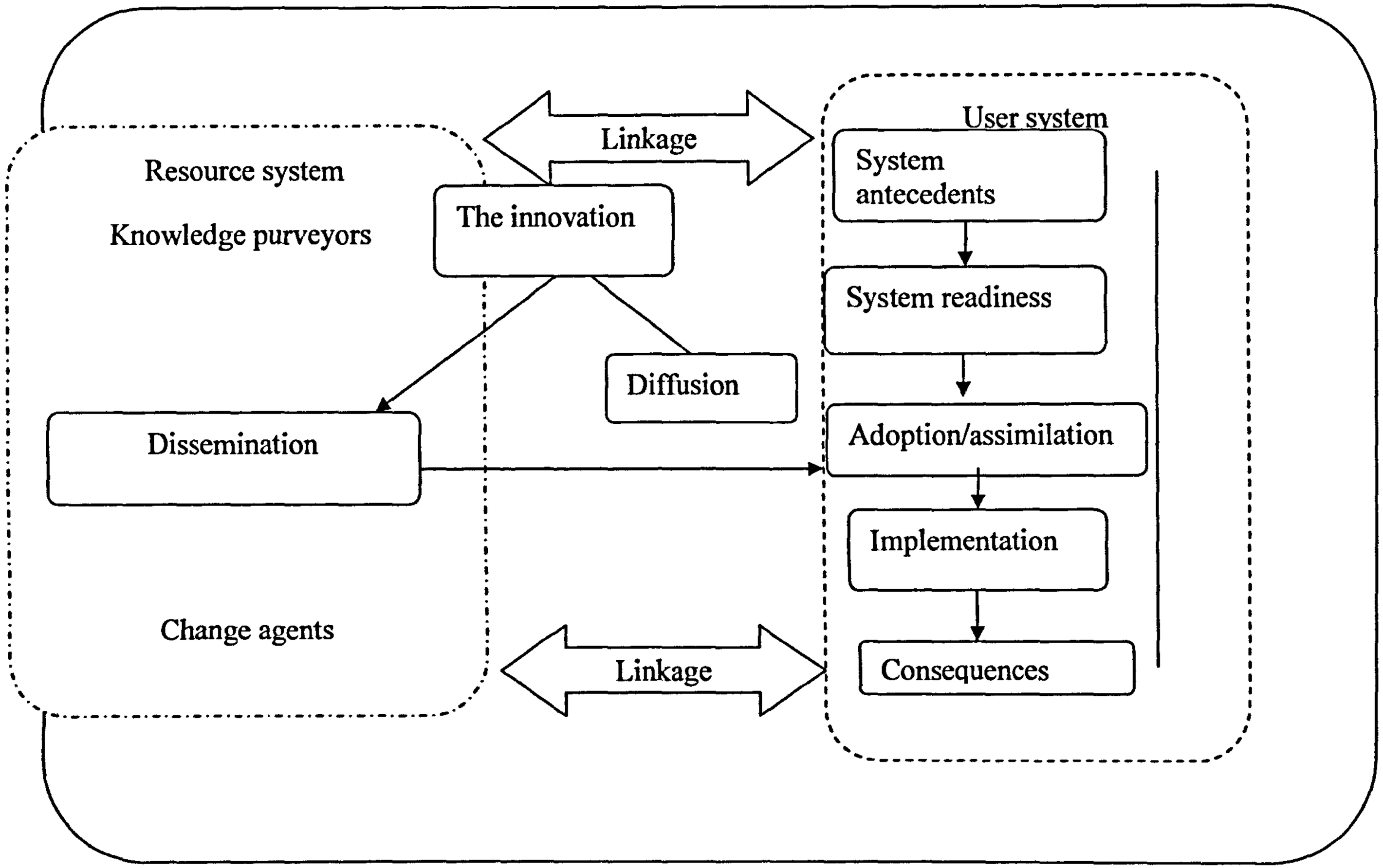


Figure 4.4 Simplified framework for considering determinants of diffusion, dissemination and implementation of innovations (Greenhalgh et al., 2004)



The second set of influences is the resource team and its attributes. The resource team or change agents are individuals or organisations that have been involved in the development and testing of innovations and seek to promote its wider use. Innovations are likely to be adopted if the resource team has effective leaders who command authority, respect and have considerable understanding of the socio-economic environment in which the innovation is being implemented. There is evidence to suggest that their managerial skills, training capacity and ability to generate technical and financial resources are likely to enable adoption.

Thirdly, the attributes of the user organisation are key to successful transfer of an innovation. The term "user organisation" refers to public sector managers working at district level and responsible for provision of health services. The innovation is likely to be successfully transferred if members of the user organisation perceive the need for the innovation and have appropriate capacity to implement it. There is evidence to suggest that successful transfer is likely when the user organisation possesses effective leadership, is in close physical proximity and has similar characteristics to the resource team. Effective leadership and implementation capacity within the user organisation may be affected by hierarchical government systems where managers are faced with multiple priorities and limited resources. Success may be realised if the user system is characterised by individuals who are willing to support the innovation. Members of the user organisation with established linkages both inside and outside the organisation are more likely to influence adoption and ensure innovations become part of the user system (Greenhalgh et al., 2004). Both frameworks recognise that managing internal change (such as roles and adequate funding) associated with implementation of innovations is an important element of success. Determinants such as technical capacity, managerial attitude towards change and resources are positively associated with the ability of the user organisation to adopt an innovation.

The fourth set of factors influencing successful uptake of an innovation is the scaling up strategy. Uptake is more likely if the strategy employed has clear messages on the merits of the innovation, systematically uses evidence on the process and outcomes and employs participatory approaches in implementation. The scaling up framework (Simmons and Shiffman, 2006), suggests that innovations that require large changes in impact would need extensive technical, supervisory and training support, which in turn require well resourced organisations. Greenhalgh and colleagues (Greenhalgh et al., 2004) provide further evidence to suggest that if an innovation is augmented by training it will be more easily assimilated. Personal communication in the form of training, technical assistance through site visits, policy dialogues and advocacy are important dissemination approaches that are likely to increase the chances for adoption since they are interactive. Impersonal communication strategies such as policy briefs, web sites, manuals are essential but insufficient to scale up innovations (Simmons and Shiffman, 2006).

The organizational strategies of managing the innovation adopted may also influence the likelihood of adoption. For example, an innovation is supported when new partners are brought into the promotion of an innovation, referred to as a multiplicative strategy, but this has cost implications and requires alignment of the goals of different partners to avoid tensions associated with lack of consensus. The approach is frustrating especially where capacity building entails training personnel who are subsequently transferred or leave their positions. If the innovation is directed by a central authority like the MoH, it is likely that the innovation will be constrained by a rigid process that may not take into account the local contexts. An innovation is also less likely to be adopted if the resource team is dominated by experts and donors than when there is more participation by the user organisation. The latter is more likely to

provide positive outcomes although capacity constraints in the user organisation may limit sustainability (Simmons and Shiffman, 2006).

The pace at which an innovation is implemented may affect outcome. Gradual expansion through adapting it to local realties is important for successful adoption. There are three paths that can be pursued in the guided expansion of an innovation. One is replication, also referred to as horizontal expansion, where innovations are replicated in different locations or are expanded to cover larger populations or geographic areas. The second type is functional scaling up or diversification where new aspects are added into the existing innovation; and the third type is vertical scaling up, where innovations are implemented through policy or legal action (Simmons and Shiffman, 2006).

The fifth and last set of factors influencing innovation success concerns the wider context and how unexpected circumstances that arise are managed. For example, political directives may include a 'policy push' in the initial stages of implementation and may boost the chances of an innovation succeeding by making financial resources available for implementation (Greenhalgh et al., 2004). Taking advantage of policy windows (opportunities where policy initiatives are supported) may also enhance uptake although long term sustainability may be dependent on resources and sustaining the enthusiasm after the policy window is over (Simmons and Shiffman, 2006). Another important contextual feature is the bureaucratic process of the public sector. Public sector bureaucracies implement policies enacted by political bodies. Many of them are slow characterised by staff with low salaries, infused with political interests and guided by many laws (Simmons and Shiffman, 2006). In terms of authority, bureaucracies vary, with some institutions having considerable authority while others have minimal legitimacy which accomplish little. By understanding such environments

it is important to identify constraints and enabling factors at the onset. This may entail identifying environmental opportunities through analysis of external conditions in the planning phase. If the resource team understands and identifies the kind of bureaucratic environments they are dealing with they will be able to navigate it for successful implementation. Other factors such as socio-economic and cultural forces may also shape the demand and supply of services in question and so either constrain or provide opportunities to scale up the innovation.

The two frameworks illustrate that the five sets of factors do not operate in isolation from each other. Linkages among them may themselves bring about intended or unintended outcomes. For example, effective inter-organisational communication between the user organisation and resource team is likely to enhance implementation of the innovation. In particular, complex innovations require active management of inter-organisational networks and timely feedback on the implementation process for success. Overall, both frameworks highlight factors to consider in examining innovations for successful transfer to the user organisation, either when the focus is to spread nationally or in localised health systems. Both frameworks also recognise that this process is not insulated but is shaped by local and international forces.

4.3 Implementation experiences of evaluated interventions

The second part of this chapter summarises the implementation experiences of the evaluated interventions in Kisii, Kwale and Bungoma districts with a focus on implementation gaps, defined as differences between what was intended and what was implemented in practice, the role of actors and relative power relations. Key elements of the intervention were summarised in table 2.3 in chapter two, section 2.5.1. The table drew out implementation gaps that were considered an important influence over the primary outcome of interest. This section is structured around the intervention

design, the management model of the intervention and the role of actors and relative power relations. The implementation experiences are later analysed to illustrate how they influenced process and outcomes in section 4.4.

4.3.1 Intervention design

This section addresses the "hard" core elements and the "soft periphery" of the innovation and highlights implementation gaps. All the innovations were characterised by a number of common attributes. Across all sites, the innovations aimed at improving home treatment of fevers with first line anti-malarial medicines. They were based on research conducted in malaria endemic areas which showed that training PMRs to provide adequate advice on anti-malarial use improves their performance (Goodman et al., 2007a). The approach of training PMRs differed considerably from the conventional ways of delivering malaria treatment services.

Integrated within the hard core elements of the innovation are two sets of users. The first set comprises the district health managers, who are considered here as the user organisation. The second sets of users are the beneficiaries: PMRs and community members. Both groups are innovation adopters but the role of PMRs in practising the innovation was significant to its success, as it specifically sought to change their practices. In this study the practices of community level actors are considered an integral part of the innovation. Community members and local leaders were key actors involved in creating demand for the services of the innovation. Another set of community level actors were the CORPS involved in the Kwale-MoH site. Their role in recruitment, monitoring, supervision and demand creation aimed to ensure sustainability of the innovation and strengthen local regulation of PMRs' activities.

Across all sites, there were variations in the hard core elements of the innovation that were planned for implementation and were actually implemented. In the Kwale-MoH site, planned refresher training was not implemented. In terms of demand creation, implementation gaps were identified in the Kwale-MoH and Bungoma-AMREF sites. Public information activities planned in the Kwale-MoH site were not implemented while in the Bungoma-AMREF site there was incomplete implementation of the JKJ strategy which was introduced in phase three to strengthen demand. Another element of the innovation was accreditation with the main implementation gap observed in the Kwale-MoH site where trained PMRs were not issued with certificates in recognition of their trained status.

Common strategies to motivate those within the user organisation and PMRs to implement the innovation were present across all sites. For actors from the user organisation and PMRs, allowances for lunches and transport during training were important motivators, with members of the user organisation in the Bungoma-AMREF site receiving higher allowances compared to the other two sites. Additional motivating element for PMRs was profit making, largely through stocking goods with a low profit margin and rapid turn over. A key motivator was the potential to increase profits by selling anti-malarial medicines in adequate doses, since these medicines were generally sold in under-doses prior to the intervention (chapter one). However, costs of purchasing expensive stock of anti-malarial medicines compared to anti-pyretics, lowered this profit and yet trained PMRs were also obliged to incur costs associated with time spent in training and advising their clients, and would not necessarily be able to recoup these due to the inability of customers to afford expensive medicines. They had the additional social costs of the extra responsibility that goes with being an advisor.

In summary, the Kisii-Merlin site implemented practice matched intentions in all important respects at the time of study. In contrast, in the Kwale-MoH site there were four important gaps between implementation intentions and practice: baseline data were not used in the design of the innovation; public information campaigns were not conducted; trained PMRs did not receive certificates to prove qualification, and trained PMRs were not monitored or followed up. Similarly, in the Bungoma-AMREF site, incomplete implementation of the JKJ strategy as well as delays in the production and delivery of IEC materials were key gaps relative to intentions. The ways these experiences shaped programme effectiveness is discussed in section 4.4.

4.3.2 Management model of the innovations.

The management approach of each of the implementing team determined the type of scaling up strategy used in implementing the innovation. In the Kisii-Merlin and Kwale-MoH sites, the implementation process targeted geographical divisions with gradual expansion through replication of activities to other areas with the aim of covering the entire district. The type of scaling up used in the two sites can be termed horizontal scaling up. The Bungoma-AMREF site, a social marketing programme applied more of a functional, diversification or grafting scaling up strategy. The process entailed adding a new element (the JKJ-strategy) to the existing innovation (VTV training) on the basis of research outcomes. Once the experience on the elements of the innovation was gained within the district, then the approach was popularised to other districts interested in the approach.

All the innovations were implemented within a wider context of malaria control activities. For example the innovation in the Kisii-Merlin experience was part of the wider malaria control activities in the district. The Kwale-MoH innovation was part of a national programme for training PMRs within the DoMC. Kwale was one of the

districts chosen for demonstration programmes to inform further scaling up activities. The Bungoma-AMREF innovation was implemented within a larger BDMI project which was built on developing partnerships with several agencies and institutions.

The final characteristic of the management model relates to the decision making processes. In the Kisii-Merlin innovation, implementation was driven by action research reflecting ability to adapt the innovation to the local environment. Decision making was decentralized to local Merlin offices allowing local initiative, mutual learning and problem solving. Decisions about adaptations were made on site after consultations with relevant actors. In contrast, the Kwale-MoH innovation was run by the user organisation with a less flexible decision making process given that it was implemented within a government system. Although extensive research had been conducted on how to adapt the innovation to local realities (Marsh et al., 2004), the planning process for the innovation did not generally take these lessons into consideration during implementation. The Bungoma-AMREF site had a relatively flexible decision making process but changes made utilised research experiences to guide the design and implementation process and established indicators for measuring project success.

4.3.3 Roles of actors

The innovations were implemented by a combination of actors outside and within the district health system. Actors outside the district health team provided technical support to the district health managers and are referred as the resource team. This team worked with the district health managers described earlier as the user organisation. This section provides a description of the identity and role of the resource teams and user organisations and their interests in the programmes, drawing on tables 4.1-4.3 for the Kisii-Merlin, Kwale-MoH and Bungoma-AMREF sites respectively.

In the Kisii-Merlin and Kwale-MoH sites (table 4.1 and 4.2), there were fewer actors involved from the user organisation compared to the Bungoma-AMREF site (table 4.4). Across all sites a core team of individuals acted as a bridge between the resource team and the user organisation. In the Kisii-Merlin site (table 4.1), the resource team selected a core team which comprised a project coordinator, a senior programme officer and two field officers working with two PHOs from the user organisation. In the Kwale-MoH site (table 4.2) the user organisation selected one divisional PHO to be the core person mandated to work with other divisional heads to implement the innovation. The core person was also responsible for collating information about the innovation for both the resource team and user organisation and liased with other divisional level actors to implement the innovation.

Table 4.1 Actor's interests, position and influences on implementation process in the Kisii-Merlin site

Category of actors	Role of actors	Interests in the innovation	How their roles, actions affected process	Level of power and support for innovation
Resource team				
Project coordinator	Core team, overall project coordinator for the Merlin programme, planned, financial management and logistical support	Previous involvement in PMR programmes at research level, participated in several advocacy forums for malaria through Kenya NGOs Alliance Against Malaria (KeNAAM). Keen to see all activities completed as planned	Facilitated development of linkages, networks, accessing funds and had strong personality, experienced facilitating process leading to positive impacts	High influence in all programme activities at all levels. Actor with high power and was supportive of process and approach
Senior programme officer	Core team, in charge of malaria control activities. Team leader, planned and executed all activities. Linked other stakeholders	Represented project leader in national meetings to support malaria control activities. Keen to ensure that innovation was implemented	His role facilitated process, linkages with communities. Supervised core team members and facilitated funding disbursements	High influence in all activities and process at district, national and local level. Had high power and was supportive of process and approach
2 Field offices	Core team, main trainers, logistics, planned workshops. Trained PMRs, support supervision, report writing and mobilisation.	Interests in community development. Keen in ensuring activities were implemented on time. Well inducted, deployed to form the core team. With time they gained more experience on the innovation	Key in executing all activities at district all levels. Ensured completion of activities, influential in changes made in design	High influence of all activities at programme and local levels Had high power and were supportive of process and approach
Project officer (Monitoring/ Evaluation)	Supported development of monitoring tools and internal evaluation	Monitoring & Evaluation activities	Key in ensuring tools and PMR data base was established. Little influence on outcome	Low influence on IEC development at programme level. Actor with low power but was supportive of approach and process
2 IEC officers	Supported development and distribution of IEC materials	As employees of department to support all programmes	Influenced the way public information was conducted	Medium influence in IEC development and distribution at programme and local levels with medium power. Supportive of process and approach

Notes: The distinction between support for process (strategies used for implementation) or approach (underlying principle of the innovation) was triangulated from Interviews reports and field diaries. Middle support indicate actors who were involved in the innovation by facilitating process by virtue of their offices and did not take extra efforts in support of activities

Table 4.1 continued

Category of actors	Role	Interests in the innovation	How their roles, actions affected process or outcome	Level of power and support for the innovation
2 Monitoring & Evaluation officers	Supported monitoring activities		Pre-tested tools and supported data entry and maintenance of data base. Effected changes in IEC materials	Low influence of monitoring and internal evaluation at programme at local levels. Low power but supportive of approach and process
User organisation				
DMOH	Overall management of health service delivery in district. Coordinated activities between Merlin and the DHMT	Keen to see their staff facilitated in terms of mobility to effectively support innovation activities and rewarded adequately in terms of allowances	Supported innovation through linkages and allowing staff to participate. Ensured smooth process of planning, completion of activities through signing memorandum of association (MoU)	High influence of all activities through acceptability at district and local levels. High power and were supportive of approach
DPHO	Heads public health in the district. Provided logistical support and allowed his staff to participate			
2 PHOs from MoH	Core team: Co-trainer, PHOs in implementation areas, trained facilitator, mapped and recruited PMRs, supported monitoring	Interests in community level activities, was influential during epidemic management. Had financial expectations, mobility to oversee other public health activities	Change timing of activities to suit community time table, recruiting and follow up of PMRs. Their financial needs affected their support for continuity of innovation	Medium influence in recruitment, training and follow up at local level and had medium power, were supportive of approach and middle support of process.

Table 4.2 Actor's interests, position and influences on process and outcome in the Kwale-MoH site

Category of actors	Role of actors	Interests in the innovation	How their roles, actions affected process or outcome	Level of power and support for the innovation
Resource team				
DoMC	Provided overall strategic policy direction, funding and overseeing implementation	Interested in scaling up innovation to the whole district and support research to track process to outcome	Role not well understood by local actors. Perceived as KEMRI–CGMRC initiative creating financial expectations. Poor communication with local actors created concerns over government role	High influence during set up phase, training, follow up processing funds, tracking progress and supportive supervision of district actors. Had high power and supportive of approach and process
KEMRI CGMRC	Provided technical support and supported training of trainers and pilot workshops			
Core person				
PHO	Appointed focal person and main trainer. Facilitated programme in the division and district	Well trained facilitator ensuring innovation activities were implemented. Had interest in monetary gains through allowances.	Skills in planning and pre-testing messages facilitated process. His unavailability due to other district activities led to gaps in PMRs selection process	High influence in planning, mobilisation, training and IEC distribution. High power and supportive of process and approach
User organisation				
DPHO	Head of public health activities in the district. Coordinated, provided logistical support, supervision and created awareness within the district	Ensured that materials were pre-tested and trainers inducted during the set up phase and that all activities were implemented in the continuation phase.	Facilitated work plans and budget, authorised participation of divisional level actors in other national campaigns affecting selection process. Relationship with resource team affected by the latter's direct link with divisional level actors. problems with DMOH_3[16] delayed release of money	High influence during set up phase and training. Potential position to influence process in favour of innovation but not fully realised. Was supportive of approach but had middle support of process with high power

[16] There were two DMOH involved in the implementation process. During the tenure of DMOH_2 no implementation activity was going on.

Table 4.2 continued

Category of actors	Role of actors	Interests in the innovation	How their roles, actions affected process or outcome	Level of influence and support for the innovation
DMOH_1	In charge of health activities in the district. Coordinated release of funds	Not identified	Information about funds released was not passed on leading to delays in training after mobilisation	High influence in release of funds and planning meetings. Potential influence of innovation not realised. Not keen on approach but with high power
DMOH_3	Same as above	Not identified	This was the third DMOH and had little information on the innovation. Personal differences with DPHO in some instances delayed process such as training, release of funds and planning	High influence in release of funds, planning, trainings. Actor with high power and middle support of approach and process
DHEO	In charge of health education activities in the district. Supported in the planning stage	Monetary gains from allowances	His office had no grass root officers, sidelined during implementation. His frustration led to sub-optimal involvement	Had little influence during setting up and subsequent activities. Potential influence not realised due to his lack of involvement in later stages. Was supportive of approach but opposed to process and had low power
10 PHO and 13 PHT in charge of programme areas	In charge of different locations in the divisions. Co-trainer, sensitised PMRs, organised workshops and materials, mobilised and facilitated training of PMRs	Financial gains to supplement their salaries, facilitation to reach remote areas through transport allowances and provision of bikes	Financial expectations not met because of little allowances, no motor bikes. Failed to mobilise CORPS for co-trainers workshop and poor communication between divisional and district level actors affected recruitment process.	High influence in planning, mobilising, training, follow up at local levels. Their potential influence on public information not fully realised. Had high power and were opposed to process and approach

Table 4.3: Actor's interests, position and influences on process and outcome in the Bungoma-AMREF site

Category of actors	Role of actors	Interests in the innovation	How their roles, actions affected process or outcome	Level of power and support for the innovation
Resource team				
Project manager-AMREF	In charge of the AMREF office Bungoma. Provided overall technical support	Malaria control activities, represented project at AMREF headquarters and national meetings through KeNAAM. Interests in completion of innovation and financial gains	Personal differences with other actors contributed to incomplete implementation of JKJ. Facilitated linkages	High influence in all activities during set up and continuation with high power was supportive of approach and process
Project Officer with AMREF	Supported project manager in implementing activities and providing leadership in his absence	Not identified	Facilitating activities at project level, built strengthened linkages with partners. Did not make executive decisions about programme without manager's approval	Medium influences during set up and continuation at programme and community level with medium power. Supportive of process and approach
2 QAP members	Contracted to support implementation and enhance quality. Supported in training, logistics, linked with partners such as USAID and CDC	Financial gains, research and testing innovation	Tactful in approach, perceived to be well salaried through their frequent flights creating tension. Intermittent tense relationships with, MoH, AMREF staff heightened expectations affecting training	High influence in planning, formative researches at all levels and through out implementation with high power and were supportive of approach and process
AMREF	Contracted as the lead role in implementing the whole project. Provided technical support to the innovation	Knowledge in research and history in implementing activities favoured them to host programme	Providing technical process and managing funds enabled implementation	High influence in set up phase-funding and through out implementation at all levels. Supportive of approach and process with high power
USAID partners	Funded programme, involved in designing innovation activities	Interested to test novel ideas given their knowledge in working in different settings	Relationships problems with AMREF and other actors generated problems in planning and executing activities such as IEC production, influenced completion of JKJ	High influence of all activities at all levels. Supportive of approach and process with high power

Table 4.3 continued

Category of actors	Role of actors	Interests in the intervention	How their roles, actions affected process or outcome	Level of power and support for the intervention
2 IEC specialists	Contracted to design and develop IEC materials for the innovation	Oversee the process as experts with knowledge of developing materials	Crucial in designing IEC materials influencing content of materials	Medium influence in IEC development at programme level. With medium power and supportive of process
CDC actors	Part of initial team that designed innovation and formative researches. Lead role in IMCI and malaria in pregnancy	Interested in research	Role in design not understood by other actors affecting JKJ activities. Failure to contract local CDC-research team questioned their interest in research affecting process	High influence of planning, funding, formative researches and all activities at all levels with high power. Were supportive of process and approach
Core team				
District Nutritionist	Team leader of the core team. Planning, training, monitoring and evaluation of innovation	Support in malaria in pregnancy	Personality and ability to lead spearheaded completion of activities. Transfer before completion of programme left a gap in leadership	High influence of set up activities and continuation at district and local level with high power. Supportive of process and approach
PHO seconded to the VTV core team	Core team, to provide linkages between DHMT and AMREF. planning, training, monitoring and evaluation	Ensuring activities were implemented on time. Financial gains and training in new areas of malaria control	Executed set up activities Ensured completion of activities and was influential in implementing changes in design	High influence in set up activities and continuation at district, local level with high power. Supportive of approach and process
DHEO	Core team, involved in planning, training, monitoring and evaluation	Health education and use of his skills in innovation	His role on training vendors was instrumental to outcome of knowledge gained	Medium influence in all activities at district level with medium power. Supportive of process and approach
Medical social worker	Core team, supported social welfare of vendors, planning, training, monitoring and evaluation	Support vendors in developing skills to run organised community groups	Support vendors in developing skills and forming self help group, instrumental in the way the programme continued after the active phase ended	Medium influence at set up phase with medium power. High influence in later activities in supporting self help group indicating high power. Supportive of approach and process

Table 4.3 continued

Category of actors	Role of actors	Interests in the intervention	How their roles, actions affected process or outcome	Level of power and support for the intervention
Pharmaceutical technologist	Core team, advised on medicines, supported linkages with manufacturing industry.	Interested in advising on medicines	Key in maintaining a data base of all OTC medicines and facilitating process of training of vendors contributing to outcome	Medium influence in set up phase with medium power. Later high influence, high power, supportive of process, middle support for approach
Medical records officer	Core team, in charge of district health records support and maintain data base, planning, training, monitoring and evaluation	Support and maintain programme data base	Instrumental in providing information to guide programme and track impact	Medium influence during set up phase at district level with high power. Later had medium influence in continuation thus medium power and supportive of process and approach
User organisation				
DPHO	Heads public health in the district. Supported in planning phase and supervision of PHOs	Financial gains from allowances and support in mobility of his extension staff.	Not involved after the set up phase creating tensions with other actors such as DMOH and the core team.	Medium influence at planning stage with medium power, supported process and approach. Not involved in continuation, low power leading to opposition to process and approach
DMOH	Key partner in district health activities, facilitated planning, coordination and collaboration	Financial gains from intervention activities	Supported activities through linkages and allowing staff to participate but interests were not met affecting implementation. Later his involvement was facilitating	High influence in coordination in the set up phase thus high power with middle support to process and approach. Later medium influence during continuation with medium power and middle support to process and approach
PHO/PHT in charge of divisions	Public health officers in charge of programme areas. Coordinated intervention activities	Ensuring public health regulations are adhered to. Financial gains from activities, needed to be recognised as best organisers with winning teams and facilitation to move around district	Role heightened expectations at community level because of poor communication or desire to be the best affecting participation in JKJ, support for continuity at community level	High influence in JKJ phase at local levels. Had high power but were not well mobilised in approach and opposed to process.

The core team in the Bungoma-AMREF site was selected by the user organization on the basis of the actors' roles in the district health system and comprised six members of the user organisation (table 4.3). At the district level the external partners through AMREF requested the user organisation to select a core team to spearhead the innovation. The intent was to cover all the departments perceived relevant to the innovation. Overall, the role of the core team across all sites was intended to be those that of a policy champion, that is, to harness support within the organisation, facilitate implementation and strengthen linkages between the relevant organisations (Greenhalgh et al., 2004).

Across all sites, the primary role of the resource team was to provide technical support to the implementation of the innovation. Composition of this team varied in each site. Tables 4.1-4.3 also indicate that the resource teams had technical skills relevant to designing elements of the innovation. In the Kisii-Merlin site, the resource team within Merlin comprised members of the core team supported by officers from other departments such as IEC, monitoring and evaluation. This group worked closely with PHOs in charge of the implementing division (table 4.1). In the Kwale-MoH site, the resource team comprised officers from the DoMC and actors from the KEMRI-CGMRC (table 4.2). The Bungoma-AMREF site had a large number of actors as a resource team ranging from representatives of the funding agencies-USAID, CDC, AMREF and IEC specialists (table 4.3). In the Kisii-Merlin and Bungoma-AMREF site, the resource team controlled funding for the innovation. In the Kwale-MoH site the resource team were involved in the initial piloting of the innovation outside the district. This was a facilitative team working within government funding structures. Most of the resource team members in the Bungoma AMREF and the Kwale-MoH site were not resident in the sites.

In terms of the management structure, in the Kisii-Merlin experience, the resource team was managed in an organisational environment structured around five departments with clear job descriptions. In the Kwale-MoH site, the overall responsibility for the implementation lay in the district public health office. The resource team utilised the existing government structures. The Bungoma-AMREF site was characterised by an external technical team and donor representatives. They were short term consultants (CDC/QAP) who worked through the government system while partnering with AMREF. At the district level, the user organisation was responsible for planning, implementation, training, supervision and deployment of staff for operational activities.

The user organisations across all sites comprised district health managers and the divisional implementing teams. In the Kwale-MoH site (table 4.2), three district managers were involved, two in the Kisii-Merlin (table 4.1) and four in the Bungoma-AMREF site (table 4.3). They supervised PHOs in charge of the divisions where the innovation was implemented. Their roles in coordination and logistical support for the innovation influenced process and outcome (section 4.3). In the Kisii-Merlin site, the user organisation was characterised by stable leadership unlike the other sites. For example, there were no transfers of personnel who had been inducted on the innovation during the implementation phase unlike the other two sites. In the Bungoma-AMREF and the Kwale-MoH site, the burden of implementing the activities was placed on the core team with support from the resource team. In the Kisii-Merlin site, the resource team took the responsibility of most of the implementation activities.

Finally as part of the "soft periphery" all the innovations were linked to actors beyond the district level and other local actors. Networks and collaborations provide resources that facilitate implementation and contribute to its sustainability (Greenhalgh et al.,

2004). In the Kisii-Merlin experience, actors beyond the district level were involved through linkages developed by the resource team. In the Kwale-MoH site the DoMC formed part of the resource team (table 4.2). In the Bungoma-AMREF experience (table 4.4), the resource team included representatives of donor agencies and technical partners and were instrumental in influencing decisions on the implementation process.

Networks with local actors varied. Networking in the Kisii-Merlin experience were characterised by more formally constituted networks at the district level than the other two sites. The Bungoma-AMREF innovation included networking with existing partners such as governmental, private institutions, the community, NGO's and the donors. In the Kwale-MoH site, partnership was developed with communities through the involvement of CORPS but other local organisations were not drawn into supporting the innovation. These networks, and their importance, are discussed in section 4.4.

4.3.4 Actors' interests and influence over programme implementation

Tables 4.1-4.3 include information on actors' interests, level of power and influence over implementation for the Kisii-Merlin, Kwale-MoH and Bungoma-AMREF sites respectively.

Empirical work illustrates that power matters to implementation and policy outcomes. In a recent article on how to investigate power, authors outline a number of theoretical insights on the practice of power in implementation (Erasmus and Gilson, 2008). They include the top-down theory which emphasises power as the coordination and control by those with authority at upper hierarchies where implementers are tasked with executing the plans to achieve policy objectives. The bottom-up theory has diverse range of explanations with some emphasising power as consensus building to gain

influence whereas others view power as conflict and bargaining. The key issue is around the discretionary power exercised by implementing actors since central decision makers cannot foresee all the circumstances that must be addressed in implementation. Others describe power by looking at how people give meanings to the language of policy. These interpretations influence individuals' responses to policy interventions. Policy language can be constructed not only by politicians or senior government officials but is also constructed by implementers who interpret policy for themselves and their clients (Erasmus and Gilson, 2008). These theoretical positions show that power is multi layered but does not necessarily provide sufficient information on ways in which power is exercised. Authors of this article go further to provide empirical examples of how power was exercised in hospitals and clinics (Erasmus and Gilson, 2008). The methods used to investigate power in this study were largely drawn from the article by Ermin and Gilson (2008).

In this study the term power is used to mean an actor's ability to influence the implementation process either by directly or indirectly resisting or supporting the innovation. Two power issues were examined here. First, the source of power, where, for example, actors may derive their power from the discretionary authority of their offices, their professional roles, their roles in the implementation, their personal characteristics or links established to networks. The second aspect examined was how power was exercised by various actors in the implementation process, identified from any evidence of the actors' actual influence over the process and on the outcomes of interest. This can be shown, for example, when actors adapt policy or interpret it to address their own understanding of local needs (Erasmus and Gilson, 2008).

Information on power was collected in three main ways. First, in-depth interviews on the role of actors in the innovation and the factors that may have hindered or facilitated

their role in the implementation process provided empirical data on power. Secondly, by keeping a field diary of events, informal discussions and observations over the period of data collection a deeper understanding of existing relationships amongst actors was developed. Both methods enabled understanding of actors' interests in the innovation and how these interests influenced the implementation process. Finally, a review of documents allowed an understanding of the role of actors and their potential source of power. This was triangulated with interview and observational data.

A stakeholder analysis was also conducted (Varvasovszky and Brugha, 2000) to examine how the power balances among actors influenced the implementation process. This analysis allowed a deeper understanding of the influence of power dynamics between actors and helped examine the characteristics of the user environment. Using data from the sources described above, information on the power of different actors and its implications for implementation and outcomes is presented in a force field analysis. This is a useful technique for looking at all the forces for and against a decision. It is a way of organising and presenting the outputs of a stakeholder analysis (Varvasovszky and Brugha, 2000). The information used in the force field analysis is drawn from tables 4.1-4.3. Figure 4.3 is a force field map for the Kisii-Merlin site. Two force field maps are presented for the Kwale (Figures 4.4 and 4.5) and Bungoma-AMREF (Figures 4.6 and 4.7) sites since different actors were involved at different times of implementation.

In the Kisii-Merlin site, figure 4.3 shows that there was no opposition from any actor, but some variation in levels of support. Members of the resource team, including the project coordinator and senior programme officer, had relatively high power and were supportive of the innovation. They also had a positive influence (enabling implementation in accordance to plans) of the innovation. For example, they made

resources available on time to implement the hard core elements of the innovation and supported the core team members in terms of skills and materials necessary for implementation. On the other hand, members of the user organisation had middle support for the innovation, which provided a relatively conducive environment for successful implementation of the innovation. This ensured completion of most hard core elements of the innovation on time, contributing to the relative success observed. The PHOs were also actively involved in previous malaria control activities. They wielded medium power and were generally the link between the user organisation and the community in terms of health matters. Their role in the innovation positively influenced implementation and acceptance at community level. Acceptance generated demand which contributed to the relative changes in knowledge and practice observed.

In the other sites there was opposition from different actors at different phases of implementation. In both sites, the resource team wielded relatively high power and were supportive of the approach. In the Kwale-MoH site (figure 4.4 and 4.5), the resource team were actors involved in popularising the innovation and supported the innovation. In the Bungoma-AMREF site (figures 4.6 and 4.7) the resource team involved a number of different organisations with different interests. They all supported the innovation and exhibited relatively high power because of their technical expertise and financial resources which gave them decision making powers. However, in the process of achieving their goals, tensions between actors emerged and hampered successful adoption of the innovation (section 4.4).

Figure 4.3 District level force field analysis of the actor's influence of the innovation in the Kisii-Merlin site

Actor categories	Proponents				Opponents		
	High support	Middle	Low	Non mobilised	Low	Middle	High opposition
District level actors		DMOH/DPHO					
Programme level	PC SPO						
	PO_M & E						
Programme level	Field officers						
	M & E officers						
	IEC Officers						
Divisional level actors		PHO					

Notes and key to levels of power

	High power
	Medium power
	Low power

PC- Project coordinator in charge of Merlin programme, SPO- senior programme officer in charge of malaria department, PO_ M & E- Project officer in charge of monitoring and evaluation, field officers- in charge of retail training programme, M & E officers –Monitoring and evaluation field officers, IEC officers: Information, Education and Communication field officers

Figure 4.4 District level force field analysis of the actor's influence of the innovation during the set up phase in the Kwale-MoH site

Actor categories	Proponents				Opponents		
	High support	Middle	Low	Non mobilised	Low	Middle	High opposition
District level actors		DPHO	DHEO				DMOH_1
Technical partners	DoMC officers						
PHO	PHO-Core person						
Divisional level actors			PHO/PHT				

Key to levels of power and acronyms

	High power
	Medium power
	Low power

DMOH_1- District medical officer of Health heading the district during the set up phase, PHO core person- Public health officer in charge of one division, selected as core person for programme in district.

Figure 4.5 District level force field analysis of the actor's influence of innovation during the continuation phase of the Kwale-MoH site

Actor categories	Proponents						Opponents
	High support	Middle	Low	Non mobilised	Low	Middle	High opposition
District level actors		DPHO	DMOH_3	DHEO			
Technical partners	DoMC officers						
PHO	PHO-Core person						
Divisional level actors			PHO/PHT				

Key to levels of power and acronyms

	High power
	Medium power
	Low power

DMOH_3- District medical officer of Health heading the district during the continuation phase

Figure 4.6: District level force field analysis of the actor's influence on the Bungoma-AMREF innovation during the set up phase

Actor categories	Proponents				Opponents		
	High support	Middle	Low	Non mobilised	Low	Middle	High opposition
District level actors	DPHO	DMOH					
Programme level	PM-AMREF						
	PO-AMREF						
Core team	PHO-seconded /DN/MRO	PT					
	DHEO						
	MSW						
Technical partners	QAP/CDC/USAID		IEC specialists				
AMREF	AMREF officers at head quarters						

Key to levels of power and acronyms

	High power
	Medium power
	Low power

PM-AMREF – Project manager in charge of AMREF in Bungoma , PO-AMREF- Project officer in charge of AMREF in Bungoma, DN- District Nutrionist chairperson of core team MRO- Medical records officer, PT- pharmaceutical technologist, MSW- Medical social worker.

Figure 4.7 District level force field analysis of the actor's influence in the Bungoma-AMREF innovation during the continuation phase

Actor categories	Proponents					Opponents	
	High support	Middle	Low	Non mobilised	Low	Middle	High opposition
District level actors		DMOH				DPHO	
Programme level	PM_AMREF						
	PO_AMREF						
Core Team	PHO-seconded, DN	PT					
	DHEO, MSW, MRO						
Divisional level actors						PHO/PHT	
Technical partners	QAP,CDC,USAID,						
AMREF	AMREF Officers HQ						

Key to levels of power and acronyms

	High power
	Medium power
	Low power

In the Kwale-MoH and Bungoma-AMREF sites, (figure 4.5. 4.6), most core team members were supportive of the innovation because their interests lay in ensuring implementation success. However, the pharmaceutical technologist in the Bungoma-AMREF site (figure 4.6) had slightly less support for the innovation because he had minimal involvement in the implementation process, advising the core team on the legal status of medicines. In the Kwale-MoH site, in contrast, the core person was selected to oversee the implementation because he was a strong facilitator. This position drew more interests thus supportive of the innovation. The position of the divisional level PHOs did not change over time and generally drew low support.

Support for the innovation from the user organization varied across the two sites. Figure 4.4 show variations in the position of different actors in the user organisation in the Kwale-MoH site. The user organisation was characterised by changes in district leadership and tensions between members, which affected implementation of various activities and contributed to lower outcomes compared to the Kisii-Merlin experience. At the district level, DMOH_1 (district health manager in charge of the district during the set up phase) opposed the innovation in the set up phase because of the unclear processes of funding and uncertainty about the value of this innovation in the district health system. His opposition led to delays in setting up the innovation. During the tenure of DMOH_2, there were no implementation activities. His successor (DMOH_3) was partially supportive after being briefed of the activities during the continuation phase, enabling implementation. She attended a few of the PMR training workshops which motivated the divisional level actors. The DPHO had a powerful position but his support for the innovation was in the middle through out the set up and continuation phase influenced largely by his poor relationship with other district heads (figure 4.5). For example, his relationship with the DMOH_3 delayed planning and supervision of the implementation process. The DHEO did not have officers at the

local levels that would have supported implementation of the innovation. He was therefore not involved in most of the implementation activities. As a result of his office he wielded low power and was non-mobilised but his exclusion represents a lost opportunity for supporting implementation.

In the Bungoma-AMREF site (figure 4.7), there were some opposition observed from actors at the divisional level of the user organisation. They were less involved in the initial stages, affecting implementation of public information activities. The DPHO had medium power and was supportive in the set up phase but with time this drifted to opposition because of a lack of involvement. The innovation was run by his department but instead a junior officer was involved during the implementation process (figure 4.7), representing a lost opportunity for the innovation. Similarly the PHO and PHTs had high power and opposed the innovation because they were not involved in the earlier phase of the VTV training. They perceived themselves as having been left out although the programme was driven by their department. Their involvement was only during the JKJ phase influencing support for implementation of the JKJ activities. Although the DMOH's position did not change over time, his relatively high power diminished to medium power because of his minimal involvement at later stages in actual implementation of activities. However, his middle support facilitated implementation by virtue of his office through release of funds and coordinating reporting systems. The next section addresses factors that influenced the implementation process and outcomes across sites. It draws from the implementation experiences described above and other evidence from the analysis, and is framed by the conceptual frameworks already described.

4.4 Explanatory factors influencing implementation process and outcome

This section presents an analysis of explanatory factors underlying the differences in outcomes observed across the three programmes. Table 4.4 summarises the main indicators measured across sites. Data presented in chapter three shows that the Kisii-Merlin programme performed better than the other sites on all dimensions examined. The programme had a significant, and greater, impact on PMR knowledge and practice than elsewhere and achieved higher coverage levels. Planned activities were implemented as expected and the overall performance seems to have been underpinned by good management of the implementation linked to the strengths of the resource team, good relationships with the user organisation and supportive management procedures. The Kwale-MoH programme[17], meanwhile, did impact significantly on PMR knowledge and practice, though not across as many indicators as in Kisii, but coverage was low. Not all planned activities were implemented and the programme was characterised by managerial challenges compounded by a complex implementing context. Finally, in the Bungoma-AMREF site, the study was unable to show an impact on PMR knowledge and practice. As described in chapter 3, this may be attributable to methodological challenges as well as differences in the phases in which it was evaluated. Implementation processes in the Bungoma-AMREF programme makes a particular contribution, therefore, to issues of sustainability. However, at the time of evaluation, the coverage levels were similar to Kwale but lower than Kisii. Although it was well resourced, not all planned activities were implemented. The programme had limited efforts to work with and through local managers to sustain implementation within the local setting.

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[17] Kwale has been taken as a case study for MoH PMR programme in this thesis, its important to note that similar MoH programmes in other districts have been shown to have greater and more consistent impacts on PMR knowledge and practices see annex I

Table 4.4 Summary of key indicators measured across sites

Indicators	Kisii-Merlin	Kwale-MoH	Bungoma-AMREF*
Indicators of differences in practice			
% asking at least one danger sign	√†	×‡	×
% asking about age of user	√	×	×
% sold anti-malarial medicine for fever	√	√	×
% sold AQ medicine for fever	√	√	×
% selling AQ in adequate doses§	√	√	×
Indicators of differences in Knowledge			
% recommended anti-malarial medicine for fever	√	√	×
% recommended AQ medicines	√	×	×
% recommended AQ adequately‖	√	√	×

**The study unable to illustrate impact at this stage of programme evaluation; †√ significant differences between intervention and control areas where trained PMRs performed better than controls; ‡×no significant differences between the intervention and control areas, § The main primary indicator for assessing practices of PMRs,*
‖ the main secondary indicator for assessing knowledge of trained PMRs

This section explores the reasons for this variation in outcomes by examining the five main areas identified from innovation literature that are likely to influence the successful uptake of an innovation. These include the innovation, resource team, user organisation, scaling up strategies, and the wider context. Through out the discussion actors are central and their role and influence on implementation is drawn from the stakeholder analysis. For each of these areas, the factors identified from empirical data of this study as influencing process and outcomes are discussed. This discussion first presents explanations that provide evidence for the relative success of the Kisii-Merlin programme; thereafter a contrast is provided for the factors contributing to the variations in performance of the other two programmes.

4.4.1 Explanatory factors influencing implementation process and outcome in the Kisii-Merlin experience

4.4.1.1 The innovation and its attributes in the Kisii-Merlin site

This section considers how implementation of key hard core and soft periphery elements of the innovation contributed to the relative success of the Kisii-Merlin site.

The explanations also identify the attributes of the innovation that may have contributed to relative success as described in section 4.2.

The strengths of the innovation in the Kisii-Merlin programme included the planning of face to face training by the resource team around a community timetable. This was in response to the socio-economic and cultural activities of the community such as farming that affected the number of PMRs who attended workshops or were available in their shops during follow ups. The proportion of targeted PMRs who were recruited into the programme was higher in the Kisii-Merlin than the other sites. This was attributed to the flexibility in the planning of training sessions (around a community timetable). This also led to follow ups resulting in timely supervision ensuring that knowledge gained was sustained. In contrast, there was less flexibility in the other sites around planning of activities, and a lower proportion of targeted PMRs were recruited. There were however, other factors that contributed to low recruitment, as will be discussed later. Overall, ability to modify the innovation to suit local needs, an attribute identified in section 4.2, may have been a factor that enabled implementation of the innovation to achieve higher impacts compared to the other sites.

Demand creation in Kisii relied on community sensitisation and on a continuous process of producing and distributing a variety of IEC materials for households and community members. These targeted various elements of malaria control such as fever management at home, malaria in pregnancy and use of ITNs. The materials were produced in the local language to ensure easy understanding. In the course of implementation, the resource team also produced durable wooden posters in the local language to help direct customers to trained outlets, and to encourage PMRs to adhere to the knowledge gained. The use of local language was also used in the Bungoma-AMREF but not the Kwale-MoH site. However, use of durable posters was unique to

the Kisii-Merlin site. The comprehensive package of demand creation and continuous information flow to community members may have contributed to relative success of the innovation.

A unique element of the innovation compared to other sites was record keeping using a pre-defined structure and kept by the PMRs. Record keeping allowed PMRs as end users to see the results of the innovation, which is one attribute that contribute to successful adoption of an innovation (Simmons and Shiffman, 2006). For example, record keeping allowed PMRs to monitor trends of cases they treated and enabled them to make informed opinions on the seasons when fevers were on the rise to allow stock build up. As one retailer pointed out: *"It enables you to know a period when you need to stock more drugs from the record that you have kept"*. Record keeping also maintained some level of accountability. For the resource team, the records allowed them to access information for monitoring and facilitated report writing for use by both the funding agency and the user organisation. It also motivated PMRs to continue practising their new skills: "*When I went through my records I realized that in the month of May we had many malaria cases. I sold up to four packets of Malaratab® a month...*"(PMR).

The use of specific selection criteria for programme PMRs was a feature of the Kisii-Merlin programme as well as being used in Kwale. A main criterion was that outlets must have anti-malarial medicines in stock at the time of recruitment. Selecting outlets stocking anti-malarial medicines aimed to maximise programme efficiency by targeting PMRs who were in a position to utilise the knowledge gained in training. This criterion was important because it was well recognised from the local operational research that many PMRs do not regularly stock anti-malarial medicines, but choose

instead to sell cheaper products with a higher turnover, such as antipyretic medicines (Muturi, 2001).

Finally, although the resource team dropped refresher training for logistical reasons, they instead enhanced supportive supervision. This entailed reviewing retailer records with PMRs to understand the extent to which they had practised the innovation. This, in turn, created some level of alertness among PMRs about their practices which facilitated adherence to training messages. This form of support supervision was unique to this site.

4.4.1.2 The resource team and its attributes in Kisii-Merlin site

The section addresses issues around the attributes of the resource team and its power over implementation process and outcome. Merlin had worked in the district since 1999 supporting epidemic management of malaria, and had been involved in the implementation of other programmes with the DHMT before this innovation. The success of the previous programmes generated a positive image among the user organisation enhancing Merlin's credibility and authority a feature necessary for successful adoption of an innovation. As was mentioned in section 4.3.3, members of the resource team were also residents in the district closer to the user organization. Physical proximity enabled frequent contacts with the user organisation where any new information on the innovation was easily shared building capacity and supporting the development of a relationship of trust. It also enabled the resource team to understand the user environment and recognise potential constraints of the user organisation. Further, provision of technical support (involving sharing roles in monitoring and supportive supervision) enabled implementation of the innovation and potential sustainability in the long term.

Members of the resource team had long experience in strategic thinking and operational research around the role of PMRs in malaria control. This means that they had relevant technical skills and ability to impart skills on the innovation. The project coordinator and a field officer were involved in the development of this approach during pilot studies in Kilifi district in 1998 (Marsh et al., 1999). The project coordinator was a member of the DoMC working group that promoted the innovation into a national policy. *"I have been involved in the shopkeeper training programme for a long time and some of the challenges I have already gone through them in other settings. So it was quite easy for me to have a picture of where the programme is going, the challenges you are likely to encounter and how we have dealt with them in other settings."*(Resource team member).

The next set of paragraphs examines the organisational environment of the resource team. Theoretical frameworks described in section 4.2 identify organisational strategies as important influence over successful adoption of an innovation. Organisational strategies reflect on management practices of the resource team which have a bearing on their management skills, a necessary attribute for successful adoption (section 4.2). The resource team was not only well funded but worked within a system that had an efficient process of disbursing funds for implementation (figure 4.8).

Figure 4.8 Funding mechanism of the Kisii-Merlin site

Donor funds were banked in Merlin's headquarters in the UK. During implementation, money was transferred to the Kenya Country office based on the monthly budgets prepared and submitted through the local finance department. A weekly verification of receipts ensured that all expenses were monitored. At the local field site, money for various activities was requested through filling in forms which had to be signed by the senior project officer then submitted to the project coordinator who authorized use of funds. In the field, allowances were paid to participating MoH actors. Payments were guided by an MoU drafted and agreed upon by Merlin and the DHMT. Retailers were paid a flat rate for transport and lunch and not compensated for their time in training.

The funding process described above shows that the resource team had some autonomy in decisions about how to use the available funds and had a relatively flexible funding process. This gave it power in implementation. This was in contrast to the Kwale-MoH site which had a complex funding process tied to the government financial management system. A flexible funding process facilitated changes in the implementation of some of the hard core elements of the innovation. For example, in response to suggestions from PMRs on the need to allow more time to understand the content of training, the resource team prolonged the number of training days from two to three. Modifying the innovation in this way promoted understanding and contributed to improved knowledge and PMRs practices compared to the other sites.

Other aspects of the organisational environment were a flexible local management system. For example, with the introduction of new programmes focussing on HIV/AIDS into the local Merlin site office in Kisii, Merlin re-organised its local staff to set aside a core team which focussed on the PMR innovation only. This improved efficiency in implementing the PMR innovation and allowed the development of expertise in the innovation. Another example of a flexible management system was the establishment of an IEC department to improve efficiency in the production of IEC materials. This was meant to support local malaria control activities. Production was either done at the local site or outsourced where the latter option took advantage of economies of scale or when production required technology unavailable locally. The process of IEC production ensured continuous production of quality materials which took account of local needs and supported demand creation throughout the implementation process. The IEC department supported the development of communication approaches to include targeted dissemination of IEC materials through schools, churches and organised community groups as well as traditional public campaigns through community gatherings. Overall, it is likely that wide availability of

information contributed to the greater changes in PMRs practice seen in the Kisii-Merlin site compared to the other sites.

The local management system was also characterised by an efficient mechanism of managing inter-organisational relationships especially with the user organisation. Ability to manage relationships may have enhanced the resource team's power to support implementation by offsetting potential opposition from actors in the user organisation, as well as enabling a supportive user environment described in section 4.3.3. Relationships between the resource team and user organisation were managed by an MoU introduced in the initial stages of implementation by the resource team. The MoU was negotiated though a common meeting with the DHMT where copies were made available for the user organisation, who communicated the contents to their staff. It spelt out roles of the resource team and the user organisation, how to share resources (human, financial and materials) during the implementation of Merlin's programmes in the district.

The MoU was important in managing financial expectations between the user organisation and the resource team, reducing the barriers for successful adoption of the innovation and increasing its support. Merlin's role was to facilitate implementation, since they did not have staff on the ground to support the innovation and therefore relied on the MoH staff to conduct activities such as monitoring. Clarifying and agreeing on roles for different actors enabled constructive participation in the innovation and resulted in completion of most hard core elements of innovation.

Although the resource team found the process of negotiating the MoU challenging, this agreement facilitated implementation as quoted by a member of the resource team; *"One thing which has been very outstanding is the MoU, I have found it facilitating,*

because when you link with the MoH and you introduce things people will come to the officers in the ground and will complain especially in terms of the field allowance. But the MoU has really made it very easy because that could have been a major problem."

Another organisational feature was the development of networks with agencies at the district level or outside the district mentioned in section 4.3.3. Figure 4.9 summarises the nature and consequences of networking developed by the resource team. The networks represent both ends of a continuum from intermittent collaboration to formalised alliances (Jones, 2007).

Figure 4.9 Networks and its consequences in the Kisii-Merlin site

The Merlin innovation was characterized by a well structured system of networking with partners. At the national level this was through formal alliances with KeNAAM for advocacy in the DoMC. This enabled Merlin to receive funds from GFTAM on top of the funding from the Government of Finland in 2006 to roll out retailer training to other divisions. Informal links with the provincial management committee developed support of implementation of the innovation through reporting and feedback. At the district level, formalised alliances with ICIPE, DHMT and intermittent temporary cooperation with other NGOs in the district enabled resource sharing and access to technical expertise. At the programme level, Merlin developed links with PSI which supplied ITNs for distribution as part of wider malaria control activities. Linkages with World Vision was also a temporary alliance driven by resource sharing (technical and financial) to avoid duplication of activities through curving out areas for different programme implementation. Collaboration with ICIPE represented a formalized alliance through a joint proposal. ICIPE's technical expertise in vector control research allowed Merlin to direct its innovation on the basis of evidence. At the community level Merlin linked with administrators, communities and retailers through sharing of information and establishment of Locational Afya committees for mobilization of communities strengthening grassroots support.

At the national level, collaboration with the DoMC through KeNAAM, allowed the resource team to learn at an early stage about the changes in drug policy that came into effect in 2005 and therefore, to make prompt changes to the IEC materials. Again this enhanced their power to support implementation. However, some collaborative efforts

at the district level were counterproductive. For example, in some instances PSI supplied ITNs to Merlin for distribution through their existing infrastructure. As a result of these activities, some community members perceived Merlin as a well resourced aid agency, leading to increased financial expectations of free drugs amongst PMRs.

Finally, the resource team developed monitoring and evaluation activities as part of the management of the innovation. The continuous and reliable nature of these activities, conducted by a department within the resource team, facilitated evaluation of the implementation progress and emerging problems to be acted upon. Emerging issues were communicated on time to actors both in the user organisation as well as PMRs. This information flow between the user organisation and the resource team helped to build trust and acceptance of the innovation within the user organization.

4.4.1.3 The attributes of the user organisation in the Kisii-Merlin site

The third set of factors that influenced outcomes are the attributes of the user organisation. Firstly, the user organisation was characterised by stable leadership with minimal transfers of actors involved in the innovation from the district compared to Kwale and Bungoma sites (section 4.3.3). Throughout the implementation phase the user organisation was led by one DMOH who supported the innovation (figure 4.4). This created a relatively stable environment in terms of support and expertise necessary for the implementation.

The user organisation offered a supportive environment for the implementation of the innovation. This observation was derived from the stakeholder analyses presented in section 4.3.3. Table 4.1 for example shows that the roles of the DMOH and DPHO were crucial in providing an enabling environment for implementation. As a result of

these roles and their positions, and the stability of their posts, the DPHO and DMOH wielded relatively high power which positively enabled hard core elements to be implemented (figure 4.3). Through their relative power they ensured smooth process of planning and identified effective divisional level actors who participated in the implementation process. For example, the user organisation identified experienced PHOs for the core team who were aware of the community dynamics: *"You know different communities have different attitudes and my longer stay here has prepared me well to understand the type of people I deal with so that when I go there, I know the type of mechanism to put in place so that I can win them. So I think that enabled me to achieve a lot"* (Core team member).

As was mentioned in section 4.2, an innovation is likely to be adopted if the user organisation perceives a need for the innovation and how it works (Simmons and Shiffman, 2006). One of the positive attributes underlying this programme was its relevance in addressing felt problems among the user organisation, PMRs and clients. The user organisation supported the innovation based on their experiences on the need to change PMRs practices given that most community members sought care from the retail sector. This was enhanced by directing the innovation to areas where malaria was pronounced. *"In Kisii Central, this programme took place in Kiamokama and Mosocho. These areas were facing the greatest malaria problems according to the ICIPE research, which was directing Merlin to areas where malaria was a big problem"*. This remark from a member of the user organisation reflects the way that perceptions of the relevance of the innovation generated appreciation and a supportive user environment.

4.4.1.4 Scaling up strategy in the Kisii-Merlin site

This section presents the fourth set of factors that influenced success around the scaling up strategy adopted. In the Kisii-Merlin site, as in Kwale but in contrast to Bungoma, the actors adopted a horizontal scaling up system (Simmons & Shiffman, 2006). This enabled a focussed approach in implementing the innovation geared towards ensuring success at each stage of implementation. This also allowed personal contacts with PMRs enhancing communication and feedback. Personal communication has been identified as an attribute of the scaling up strategy that may support adoption of the innovation (section 4.2). For example, after each workshop, the core team followed up the trained sellers after a week, administered a quiz and resolved any problems encountered with clients while implementing the innovation. They then accredited PMRs through the supply of wooden mounted posters and certificates. This process allowed them to identify and address the loopholes in the retailer's knowledge, and motivated the sellers. The type of scaling up and the pace in which the innovation was implemented enabled adequate technical assistance to PMRs contributing to successful outcomes.

4.4.1.5 Managing wider context in the Kisii-Merlin site

The last set of factors concern the wider context and how its influence over implementation was managed. The contextual features of importance encountered included drug policy changes, socio-economic and cultural factors and the dynamics of the retail environment. In the Kisii-Merlin site, an attempt to work around drug policy changes were effected through management of inter and intra-organisational networks described in figure 4.10.

Figure 4.10: Managing drug policy changes in the Kisii-Merlin site

Information on drug policy changes were relayed through formal government procedures. However due to lack of clarity on the drug of choice for the retail sector Merlin, through its involvement in KeNAAM, actively engaged in seeking official documentation on the role of retailers in malaria control. Merlin was also involved in advocating for cheaper ACT medicines and piloted ways to increase its coverage though the retail sector. Despite these efforts the DoMC did not provide a clear guideline on the status of SP which was being phased out for ACT. The alternative drug for treatment for uncomplicated malaria through the retail sector was AQ. The DoMC finally sent a circular that PMRs could be trained on AQ in the interim with no further guidance. On the basis of this information the resource team made a decision to revise all its materials. Implementation of the changes was easily accomplished because of the internal organisational arrangements such as presence of the IEC department. In spite of this process, actors perceived a lack of adequate strategic action and guidance by the DoMC on the anti-malarial drug policy. In addition the sudden change from SP to AQ and the short time SP had been in the market exacerbated lack of trust in the relationship between clients and retailers.

Figure 4.10, provides an example of how effective communication between different partners and between actors in different departments of the resource team coupled with an enabling organisational environment, contributed to a successful implementation process despite the problematic drug policy context. The effect of drug policy changes for example created challenges at the retailer–client interface. Challenges in selling drugs through the informal sector with minimal regulatory mechanisms, were factors beyond the control of the user organization or the resource team to influence. Efforts made in the Kisii-Merlin experience through linkages to actively access information for timely implementation were a good example of the resource team taking account of the wider context.

Regarding economic issues, poverty was also a feature that undermined buying and selling of medicines across the three sites. Poverty challenged people's ability to afford the medicines, and PMR's difficulty in stocking the recommended medicines among trained PMRs. For example, in Kisii Central district, poverty indices indicate that

about 62% of people live below poverty line (chapter two table 2.4). Data from FGDs with clients and PMRs indicated that both sets of actors felt that that poverty was largely responsible for PMRs stocking anti-pyretic medicines. These medicines are cheap and are so often used for simple fevers. Where recommended anti-malarial were stocked, clients were sometimes not able to afford them, discouraging PMRs from practising the innovation and sometimes leading to demands for free drugs and loans to boost their businesses.

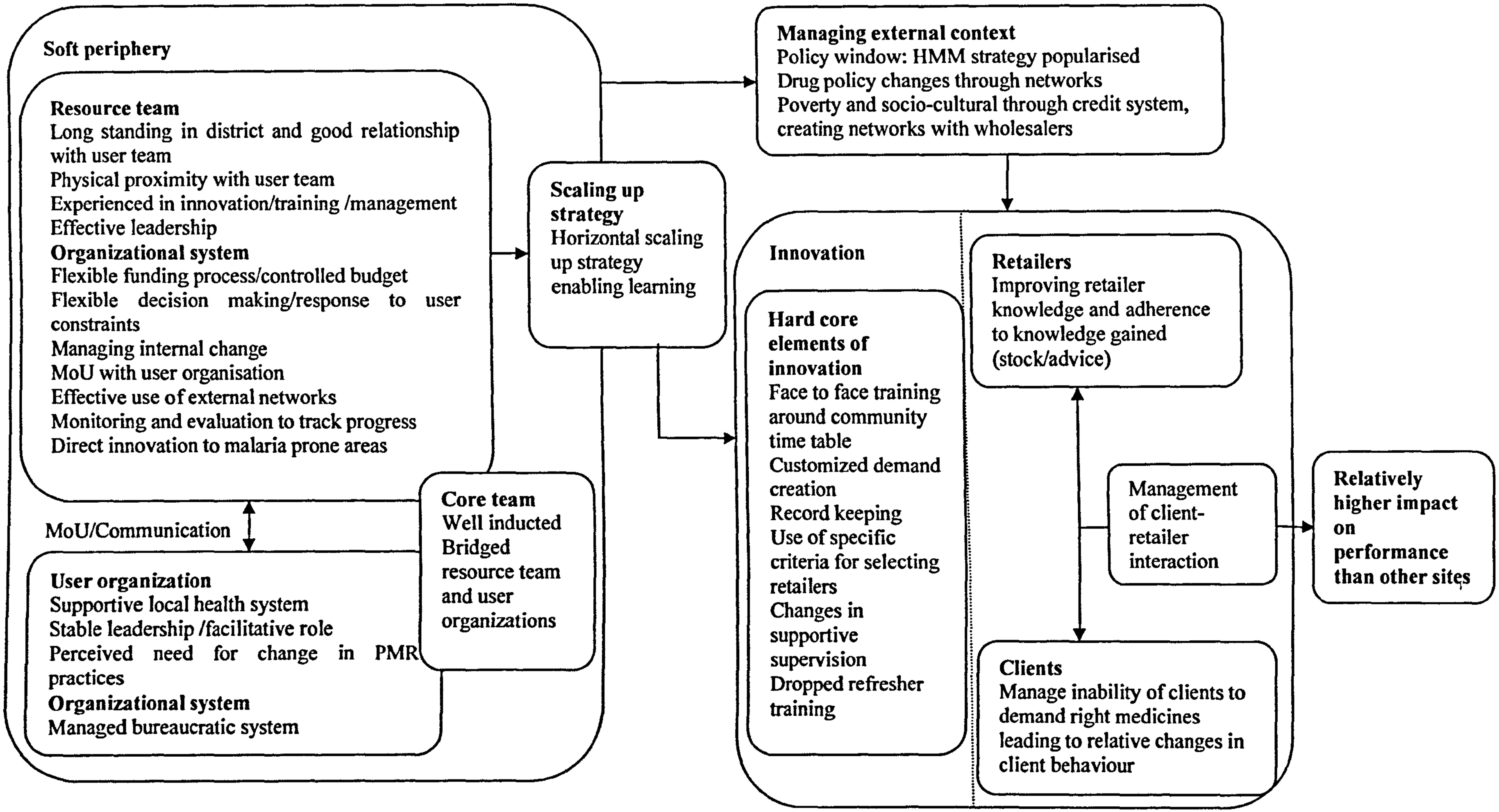
This scenario is complicated by the perceptions of communities members about PMRs who are generally seen as having a commercial orientation and their recommendations would therefore be treated with some suspicion. However in the more rural areas, PMRs who are from the community may be related or well known to many of their clients and feel a sense of social responsibility towards community members. This relationship reportedly accentuated the difficulties that PMRs had in selling to clients who could not afford the recommended anti-malarial as illustrated by a PMR from Kisii: *"We consider that our clients are mostly our kinsmen if you deny them credit and they die they will blame you and when the they will be asking for more money to pay hospital or mortuary bills what you are giving now you may as well have given the drugs to try and help"*. Although on the surface kinship ties may have facilitated access to medicines by communities, this could in the long term undermine the viability of their businesses. PMRs themselves often operate under conditions of financial insecurity, and the level of sales and profit margins are critical for their livelihoods.

Efforts to adapt the programme to socio-economic issues contributed to successful implementation. In the Kisii-Merlin site, knowledge of cultural activities, such as the timing of harvesting or important funeral gatherings, allowed programme activities to

be planned for times when maximum participation was likely. The resource team also attempted to reduce the costs to PMRs by linking trained sellers to particular wholesale chemists in the urban areas to access medicines at discount rates. This was made possible through letters of introduction to the wholesalers by Merlin through its wider malaria control activities which benefited the innovation.

To overcome the problem of high cost of medicines, trained sellers were also encouraged to offer credit to their clients or accepting payments in kind to improve financial access to recommended anti-malarial medicines. Although the credit systems existed before the innovation on a case by case basis, offering of credit was problematic for PMRs, as has already been discussed in relation to the demands of extended families on trained PMRs. One retailer from Kisii indicated: *"Because of poverty, people come for credit, which makes us lose. So it makes us fear to bring more stock. Others also think that we went for training and we are given drugs for free which leads to a conflict..."*. Figure 4.11 summarises the key positive factors emerging from this study that are likely to explain the relative implementation success in the Kisii-Merlin innovation. The next section examines factors that contributed to outcomes measured in the other two programmes.

Figure 4.11 Framework for understanding factors influencing implementation of innovation to influence impacts in the Kisii-Merlin site



4.4.2 Explanatory factors influencing implementation process and outcome in the Kwale-MoH and Bungoma-AMREF sites

This section describes issues that were identified as influencing implementation experiences in the other two sites. These were derived from an inductive analysis of data as well as using relevant theoretical frameworks in the interpretative analysis of how the factors identified played out in each site's experience and influenced implementation. The section combines implementation experiences presented in section 4.3, and key factors that may have influenced process and outcome. By focusing on the key factors an in depth analytical description is provided to contrast with the Kisii-Merlin experience.

4.4.2.1 The innovation in the Kwale-MoH and Bungoma-AMREF sites

This section discusses how implementation of the hard core aspects of the innovation influenced implementation both positively and negatively in these two sites, with consequences for programme achievements. By doing this, the attributes of the innovation identified in section 4.2 as key to success are identified. The issues are: recruitment and selection procedures; the training approach and the need for retraining created by the change in drug policy given; demand creation at community level; monitoring and evaluation; the motivation of key community level actors and the role of formative research.

The decision to select specific PMRs to be trained in the Kwale-MoH and Kisii-Merlin sites was based on recognition that the very large numbers of PMRs operating in Kenya and other similar settings (Marsh et al., 1999; Amin et al., 2003) precluded training all PMRs in any area. However, in practice the selection process undermined aspects of the implementation process in the Kwale-MoH site. The main selection criteria included PMRs working in those outlets for at least six months and who had

stocks of anti-malarial medicines. In Kwale, in practice, however, the criterion of stocking anti-malarial medicines was often not applied. This was reportedly due to the low number of outlets that stocked anti-malarial medicines in one division, and misunderstandings about the criteria themselves among local administrators who were asked to support this process. Due to this problem local leaders included PMRs running seasonal outlets. The core team then decided themselves to select PMRs but also found that few shops met the minimum criteria. As a result, and given low awareness of the programme among local communities, the PMR workshops were poorly attended; generating low levels of programme coverage.

The Kwale-MoH programme trained selected PMRs through a series of skill-based participatory workshops, similar to the Kisii-Merlin experience. This face to face training approach seems likely to have been more effective in generating knowledge gained than that used in Bungoma, where suppliers of medicines to PMRs were trained to provide advice to PMRs, representing an indirect, or cascade, training strategy. Although the Bungoma approach was innovative, it was not based on previous evidence since no previous studies of this approach had been conducted with PMRs. This meant that the implementing team had less prior insight into implementing the innovation compared to the other sites. Adequate experience of an approach was identified as an important attribute for successful implementation of an innovation in section 4.2.

The interaction between implementation of the hard core elements of the innovation and context influenced ability to modify the innovation. For example, the drug policy change from SP to AQ in 2004 led to long delays between the centralised training of trainer's workshops at national level and the eventual initiation of PMR training in the Kwale-MoH site (January 2003 to November 2004 and January 2005). The prolonged

delay rendered IEC materials out of date. This led to reluctance of the user organisation to distribute IEC materials, contributing to gaps in the level of distribution of reference materials. In the Bungoma-AMREF site, meanwhile, vendors had to be re-trained after the AQ policy shift, as their initial training had focussed on SP. However, the re-training came in the period when main funding had come to an end, limiting implementation.

In the Kwale-MoH programme, demand creation was intended to be achieved through public barazas, posters and distribution of fliers. However, in practice limited demand creation was carried out at community level, reportedly due to inadequacies in funding. In addition, there was only limited engagement with the local leaders who were capable of mobilizing community members. Finally, the intended involvement of CORPS in supporting community mobilisation and monitoring brought a number of challenges. First, as the KEMRI-CGMRC partner in the resource team was seen as an NGO (section 4.3.3), CORPS had inappropriate expectations about the level of allowances they would receive, and that there would be opportunities for permanent employment. Failure to meet these expectations de-motivated the local actors, and threatened continuity of these activities.

In the Bungoma-AMREF site, the need for direct demand creation at the community level, later called the JKJ strategy, was identified through an interim survey conducted after six months of implementing the VTV component. However the strategy's introduction seems not to have been preceded by adequate community preparation, leading to poor understanding of it. The JKJ component appears to have created negative misconceptions because of its late "add on" nature, which interviewees interpreted as reflecting low strategic importance. Furthermore, it was implemented at

the time of the funder's decision to begin withdrawal, leading to shortage of resources for implementation.

The amount of formative research conducted in the Bungoma-AMREF site to help design the programme led to suspicion among members of the user organisation about the motivations of some of those linked to the resource team. As one person said, *"...And I think most of the things went into research than the actual programme. So the project design was faulty. Things like JKJ came in very late. They did not start with the project it is like somebody somewhere had realised that it is only two years or one year to end the project what should we do to justify the project and so they decided to bring this JKJ to get more impact".* As a result, there was opposition (figure 4.6-4.7) and sub-optimal participation by members of the user organisation in its management; for example, DPHO did not participate in some planning meetings and PHOs did not conduct follow ups of accessed PMRs as planned.

4.4.2.2. The attributes of the resource team in the Kwale-MoH and Bungoma AMREF sites

The second set of factors that impacted on the implementation process relates to the attributes of the resource team: organisational features and strategic ways of functioning; and its relationships with user organisations and their implications. In contrast to the Kisii-Merlin experience, the Kwale-MoH resource team was a partnership between DoMC and KEMRI-CGMRC that did not have a physical base in the district (section 4.3.3). The Kwale-MoH implementation process strategically placed emphasis on the user organisation's role in managing the programme locally, as a way of strengthening sustainability. In the Bungoma-AMREF site, however, the resource team comprised a partnership between a number of different international agencies, with a national support agency and the user organisation. Its large size sought

to maximise technical support a feature that facilitates adoption of an innovation (section 4.2). However, although some members of the resource team, especially AMREF actors in Bungoma, were resident in district, members of the international team, in particular, were highly mobile. This element generated tensions (see subsequent paragraphs for details) and financial expectations leading to interpersonal conflicts affecting implementation process and acting as a source of opposition (figure 4.7).

In the Kwale-MoH site, some technical visits by the resource team overlooked existing hierarchies within the user organisation, reflecting inadequate recognition by the resource team of the context within which scaling up should take place (section 4.2). For example, following a national centralised trainer's workshop, the resource team visited the programme sites intermittently to resolve problems but these visits were often planned and conducted directly with divisional level actors in the user organisation, overlooking the district actors above them in the bureaucratic hierarchy. A member of the user organisation reported that: *"One thing that happened, our partners sometimes would come directly and go to the division and conduct an activity without us knowing. There was a time we told that we shall let you do things alone. Do not come to us at the last hour. Because they once said they were dealing with the divisional officer, which was fine but we needed to be informed"*. As a result the divisional level actors were not always free to implement the activities since their district bosses were unaware of the activities being implemented. However, the resource team's relationships with divisional level programme implementers did enable some level of programme implementation.

The next set of paragraphs describes features of the organisational environment which had a bearing on managerial skills of the resource team. In the Kwale-MoH site the

resource team was not able to develop a supportive relationship with key members of the user organisation, resulting in conflicts amongst actors, tensions and frequent communication breakdown within the user organisation. This led to opposition among some members of the user organisation (figure 4.4-4.5). Although the resource team had the technical capacity to support the user organisation, working through an inflexible government funding system and a bureaucratic management environment delayed mobilisation activities and led to inadequate demand creation.

The resource team in the Kwale-MoH site were linked with the research organisation (KEMRI-CGMRC) mandated to generate information on programme impact. Baseline surveys were initially conducted but delays in releasing funds for implementation meant that these baseline data could not be used to design the innovation. Inadequate communication by the resource team on reasons for the delay in implementation contributed to the user organisation's perception of low interest from the resource team, and generated tension between these two groups. This tension was further exacerbated by financial expectations (table 4.2) from the user organisation, as one of its members illustrated. "....*if I remember one time, we really argued with them about the package. You know civil servants are hungry (laughs) so if they see a training, they just know today they are going home with something good. But here is a small package; they are not transparent. So people were not really happy with them*".

In contrast, from table 4.3, the resource team in the Bungoma-AMREF site had direct control of the programme funds and this facilitated timely implementation of activities as well as allowing a programmatic response to ground realities such as changes in IEC materials. Nonetheless, expectations around allowances to be paid to actors in the user organisation again generated tensions that affected inter-organisation relationships. In both sites therefore, there were unmet financial expectations within

user organisations and at community level. These expectations contributed to some level of opposition among some actors in the user organisation (figure 4.7).

To illustrate features of organisational environment further, funding arrangements for the Bungoma-AMREF sites (figure 4.12) are described. In contrast, funding arrangements in the Kwale-MoH site are discussed under section 4.4.2.3 since management of funds for that innovation was primarily the user organisation's responsibility.

Figure 4.12: Funding process of the Bungoma-AMREF site

> Money for all activities was disbursed to AMREF through a contractual agreement with USAID. Once the monthly budgets and work plans were presented to AMREF headquarters for approval by the board, the money was sent to the local AMREF office. The project coordinator who was the signatory withdrew money for the intended activity within seven working days. All the returns on expenditures were also sent to the country office for verification. Any expenditure on activities beyond the budgeted amount required justification with supportive documents and once verified this was reimbursed. At the programme level, the DHMT had no role in financial management. Budgeting was done by the core team who decided on payments for field officers on the basis of distance covered and the type of activity. There was minimal active follow up of field officers on activities conducted by the core team except when an officer was noted to be less accountable. If an officer failed to account adequately he or she was relieved of duties in the programme activities. The chairperson of the core team kept all the returns which were submitted to the project coordinator at the end of each month. Lack of involvement by the DHMT led to a perceived lack of transparency on AMREF's part which trickled down to the district development committee and the community. This perception increased the MoH actors' financial expectations because they perceived that the programme was well resourced. This was passively resolved through reference to the government guidelines on payments. Retailers and vendors were given lunch allowances in line with the budgetary allocation.

Features of financial arrangements such as perceived level of funds available led illustrate power dynamics and also led to inter-organisational tensions between the resource team and user organisation. A member of the resource team noted: *"One time, a DHMT member differed with CDC when he needed to be paid money like CDC actors because they have similar qualifications. Again, like the first year's budget,*

people saw that there was a lot of money. Someone even told the district heads that we have sixty million budget every year and they were asking for half million to repair a lorry that had been grounded for the last one year".

In addition, the user organisation was barely involved in financial management, except in accounting for money disbursed in the implementation of the innovation. Limited involvement of the user organisation in the management of funds generated negative perceptions. As a member of the user organisation said: "*One of the biggest challenges was financial resources because people were not transparent. You see if we are partners and if you want us to have active participation then it is also good that people know what the inputs are. I believe in this district nobody knew even when the project ended. People did not know what went into this program for the five years if they knew then they read about it in the final reports. I think people were in the dark. This made people suspicious, and the credibility of the good project was damaged so people always feel they were being cheated'*. These perceptions also contributed to middle support and opposition by some members of the user organisation as illustrated in figure 4.7.

4.4.2.3 The attributes of the user organisation in the Kwale-MoH and Bungoma-AMREF sites

This section describes the attributes of the user organisation and its organisational environment. The factors considered include district level leadership, relationship problems within the user organization drawn from stakeholder analysis and power relations and how this contributed to a lack of supportive environment, especially from key actors, and the influence of communication and bureaucracy within the organisational environment.

In both sites, user organisational leadership was fairly unstable over the period of examination. In the Kwale-MoH experience the transfer of two DMOH during the implementation period led to delays in implementing activities. Each time, the new district head had little information about the innovation and so delayed releasing budgets for planned activities. As a member of the user organisation explained: *"The main problem I experienced was disbursement of funds. The first phase I had a delay in implementing. We had organized, set the dates, mobilized the community but when we went to the district treasury to get these funds we were told, "Now these funds are not ready please re-arrange and organize the dates". When we went again we were told, "No you cannot take this whole amount for the two days pick one for the first day then tomorrow come again to the treasury collect the second lot ". This was causing a lot of delay because you had to queue at the district headquarters to get the first lot then the second day again queue instead of rushing to the field to continue training. So that was a bit of a handicap. But all in all we managed to get through the first phase. So the second phase, there was a discussion and this was resolved with the new DMOH"*

Similar sentiments were expressed in the Bungoma-AMREF site where turnover in district health managers also limited implementation continuity. This was illustrated by a member of the user organisation: "*It is because most of the DHMT members who were there then were transferred apart from one. The new people who came in had no idea about this so adapting to that was a big issue; there was no continuity after the changes"* This experience happened towards the end of the programme contributing to incomplete implementation of the JKJ component. This implies that the timing and circumstances for this component of the innovation may not have been right. In addition, changes in local leadership led to a less supportive user environment, attributes necessary for successful adoption (section 4.2).

In the Kwale-MoH experience, there was also evidence of interpersonal problems amongst members of the user organisation which affected implementation (figure 4.4-4.5). For example one of the conditions of the funding by the GFTAM was that a DHMT meeting be convened before any money was spent. Differences amongst actors delayed the convening of such a meeting. The user organisation in Kwale also felt that the DoMC at national level did not fully support the innovation, given the delays experienced in implementing planned activities and poor communication regarding drug policy changes. As a DHMT member said: "*Personally, I feel within the malaria control programme, there are others, which are given more prominence than some. You know for example, the issue of malaria in pregnancy there is a lot of focus in it and the issue of distribution of ITN*". As a result, DHMT also gave little attention to their tasks in the programme and, for example, provided poor supervision to the PMRs, contributing to low outcomes.

The selection process of the core team generated tension among the user organisation in the Bungoma-AMREF site (section 4.3.3). Failing to include the divisional level actors led to negative consequences as illustrated by a member of the user organisation: "*Actually because it is like they involved people at the DHMT level. But the PHO were brought on board later. And I think that is what they didn't take nicely. We started with VTV we didn't realize that there was something like JKJ coming. I think that's where the main problem was. We didn't do it wisely, the composition varied and you see a player depends on where he plays. It is unfortunate that it is just the DHMT that took over, and we didn't realize that at the end of it we will need other people who are the real stakeholders*"

The consequences of the selection process brought intra-organisational tensions within the user organisation and generated negative perceptions of the programme and

contributed to the opposition by DPHO and PHOs (figure 4.7). Some members of the user organisation believed that vested financial interests such as allowances influenced the choice of the core team. The functioning of the core team also generated problems which polarised relationships in the user organisation. The core team reported to the DHMT and AMREF in matters regarding the implementation process. Frequent meetings were also held with the external partners and at some point junior officers (to the district heads) in the core team were given an opportunity to present findings on the impact of programme in an international meeting. This was perceived to undermine the hierarchical nature of the user organisation, and contributed to tensions between user organisation and resource teams.

"When some people feel that their relationship with another one is not good it affects the project and I think from the time this project started, there were intermittent stages of bad relationships between the officers from the ministry and the BDMI officers. It started immediately when the then DMOH relationship with some members of BDMI were not good and these complaints went up to the ministry's head quarters, the next person was me when I was asked, why are you sabotaging the programme?' you know such things are not good". This comment from a member of the user organisation shows how intra-organisational tensions caused inadequate participation by some members of the user organisation whose support would have facilitated implementation because of their strategic positions in the user organisation as was explained in section 4.3.3.

In the Kwale-MoH site, the complex funding process represents a key feature of the user system that constrained implementation[18] (figure 4.13). The particular

[18] This was particular to Kwale and not necessarily associated with other MoH programmes operating within the same mechanisms

bureaucratic environment in which the resource team in the Kwale-MoH programme worked caused more problems for implementation than in the Kisii-Merlin site. The complex funding procedures within the DoMC led to several delays and negative misconceptions. For example, the DMOH did not inform the divisional level actors of the availability of funds on time (table 4.2), paving the way for rumours that management wanted to divert the money to other activities. Delays in funding often led to activities either not being conducted on time or being inadequately implemented.

The process of accessing funds also took a long time, and harmonisation of divisional level budgets with the district work plans meant that the budgetary needs for the division were not fully met. The inflexibility of budget procedures also prevented changes in the use of funds that might have covered local shortfalls or allowed adaptation to local settings. This led directly to inadequate demand creation and, in some instances, to divisional level actors focussing on some activities and leaving out others. A member of the user organisation indicated: *"Mobilization was not extensively done because according to the plan, there was only a day or so for mobilizing the communities. Now you understand that some of areas are extensive that you can not cover in a day or so many of the areas were not extensively sensitised of the programme."*

Figure 4.13: Funding process of the MoH-Kwale site

The Kwale programme was supported through the GFTAM initiative. At country level the GFTAM activities were monitored by the Country Coordinating Mechanisms (CCM) responsible for coordinating proposals and reporting to the technical review panel of the GFTAM. The CCM appointed a financial consultant Klynveld Peat Marwick and Goerdeler (KPMG) as the principal recipient of money. Within the MoH, all proposals developed from divisional level were incorporated into the district work plans accompanied by a budget and submitted to the DoMC for inclusion in the national malaria business plan. Once the proposals were funded, the DoMC disbursed funds for specific activities to be implemented within each quarter. According to the GFTAM policy, any money advanced to districts required adherence to a number of guidelines: maintaining independent records of expenditures; names and addressees of participants indicating personal identification numbers; the nature of activity held and the period. Training was to be held in government institutions and it was mandatory for the DMOH to convene an executive meeting for the DHMT to discuss implementation plans and evidence of this was required during monitoring of progress. At the district level, initially there were unclear procedures for disbursing funds. Districts were first instructed to establish special accounts to avoid anticipated delays encountered in the normal treasury mechanisms. The first batch of funds from the DoMC was disbursed when the district had not opened a separate account as planned resulting to confusion. This process conflicted with the normal procedures where all money to the districts was channelled through issuance of authority to incur expenditure (AIE) to the DMOH. Later, all subsequent funds were channelled through the normal procedures. The process of accessing funds by the divisional level actors involved placing a formal request through an internal imprest from the district health accounts office. All receipts and financial returns were summarised and surrendered to the district health office through the same process. All payments to the MoH actors involved were based on government guidelines. Retailers were given a token for lunch in accordance with the budget.

Networks and collaborations are important in managing any innovation (section 4.3.3). In the Kwale-MoH experience, the main management activities were undertaken by the user organisation, and the core team were perceived to be less reliant on external networks to create sustainability than in the other two programmes. Figure 4.14, describes the linkages developed in the Kwale-MoH site.

Figure 4.14: Networks and its consequences in the Kwale-MoH site

In Kwale, there were minimal efforts made to develop partnerships with local organizations or institutions to support programme activities and support sustainability. The innovation was supported by an external team (KEMRI-CGMRC) who provided technical support on behalf of the DoMC to the user organisation while the DoMC provided strategic policy direction. The resource team developed direct communication with the divisional level actors leading to a perception that the programme was being popularized by a research firm with donor funding. These generated expectations such as more allowances, disregarding the normal government system, and provision of free drugs to retailers to make more profits at the community level. There were efforts made at community level to involve CORPS to support local monitoring and supervision but these linkages were not sustained due to unmet financial expectations from CORPS

In the Bungoma-AMREF experience, the networks and collaborations initiated included both complex formalised alliances at national level between USAID and AMREF to informal alliances at district and community level (figure 4.15). Due to their position (financial and technical) USAID had high power influencing implementation (see figure 4.6-4.7). Since the innovation involved retail delivery structures, strong linkages with wholesalers and mobile vendors were important. However, minimal involvement of the MoH in the networks created presented a threat to sustainability because the intent was to incorporate the innovation into the user organisation. AMREF also developed informal alliances with pharmaceutical companies to support the vendors partly as a way of managing context and also as a way of ensuring continuity following donor exit. However the timing of this initiative coincided with the withdrawal of funds. AMREF therefore provided initial funds and supported vendors through linkages with social services department to form a community group.

The community group was however dominated by problems of leadership and lack of transparency where its leaders were reported to have squandered money stalling their activities for a year as indicated by one vendor: *"The main problem was when the*

chairman disappeared with the drugs and certificate of registration, AMREF helped us to make follow up together with the social services. They wrote letters to the chairman and the leaders to give us back the certificate. Even now we have just started afresh". AMREF's involvement in the registration process generated a perception among mobile vendors that AMREF recognised their role much more compared to the user organisation affecting continuity and support from the user organisation.

Figure 4.15: Networks and its consequences in the Bungoma-AMREF site

The innovation was characterized by a complex network with many partners to meet their organizational goals. At the national level, USAID developed linkages with AMREF through a contractual agreement, representing a formalized partnership between the organizations. However this partnership brought challenges for example, USAID's changes in the funding strategy led to an unexpected pull out of USAID and incomplete implementation of the JKJ strategy. USAID also contracted QAP and CDC to provide technical expertise, leading to an innovation with many external partners working through the government system. The role of CDC in formative research led to a perception of a hidden agenda by the external partners exacerbating the problem of lack of trust. At the district level, liaison with the DHMT through the core team represented a less formalized structure whose operation led to differences between actors at DHMT level. This was associated with the perceptions of benefits the core team were drawing from the well resourced external partners. Other informal alliances at community level with wholesalers, retailer, vendors, pharmaceutical industries and local administrators were established. Overall the nature of these alliances and the presence of well resourced external partners destabilized relationships, leading to mistrust at the district and community levels.

Another group of actors that represent linkages with the community were those involving local leaders. Their administrative roles were important in demand creation and creating support for the innovation locally. Local leaders had financial expectations of allowances for mobilising community in order to create demand in their area of jurisdiction. In both sites, minimal involvement of local leaders in mobilizing community members undermined direct community engagement, contributing to less demand and threatening sustainability of PMRs' new practices.

4.4.2.4 The scaling up strategy in the Kwale-MoH and Bungoma-AMREF sites

The fourth set of factors influencing implementation is linked to the scaling up strategy employed. In the Kwale-MoH site, the resource team sought to apply the horizontal scaling up approach of conducting implementation in phases (Simmons & Shiffman, 2006), similar to the Kisii-Merlin experience. However, since the bulk of implementation was on the user organisation, other competing district level activities tended to disrupt implementation process. For example, the national measles campaign in 2005, interrupted mobilisation by divisional level actors and led to limited demand creation.

In the Bungoma-AMREF experience, the resource team's scaling up approach involved adding, over time, new intervention elements (JKJ), to the basic programme, to determine whether those intervention elements could be usefully included in similar programmes elsewhere, referred to as functional scaling up strategy (Simmons & Shiffman, 2006), therefore, reflected the different nature of the Bungoma-AMREF programme as compared to the other sites with consequences. The approach to scaling up contradicts sustainability, for example the newly added element meant that the programme inevitably faced the challenge of how to sustain these activities within the local district when its funding came to an end. As one member of the user organisation noted: *"You see unfortunately our attitude as health workers is that when you know that something is being funded you will do the job .....but when it is time to incorporate it in routine, you see resistance".*

Implementing an exit strategy was made difficult by poor communication between AMREF and the funding agency: *"The mistake the USAID did, they said there was a phase two to come but they did not put in writing to say there is no phase two. When we were in the committee we were told they have now started to support the central*

and not the district level. And to me, one of the major challenges is that this was a pilot programme and USAID is partly to blame, they said there would be a phase two but later they did not honour it or even plan the exit" (resource team member).

The withdrawal of funding created a gap in the demand-side activities of the innovation, and so affected outcomes at the retailer level. This resulted to perceived lack of transparency between the resource team, the community members, and the user organisation. This led communities to feel cheated and demoralised, undermining their support of the innovation. At the same time, the unexpected changes brought confusion between agencies working in the district and created tension between them. As a member of resource team said. *"Looking at AMREF's viewpoint we had prepared ourselves on how the exit should be done, but from the donor point of view, poor communication created some misconception that AMREF was supposed to hand over to AMKENI*[19] *because it was USAID funded. I even have a colleague who told me "You are handing over to us, AMREF is getting out and AMKENI is to get in". But I told him "Whether with or without USAID, AMREF will survive".*

Overall, poor communication characterised the relations between the resource team and the user organisation leading to misunderstanding of the scaling up strategy used in the Bungoma-AMREF site. This also contributed to opposition by some members of the user organization (figure 4.7).

4.4.2.5 Managing wider context in the Kwale-MoH and Bungoma-AMREF sites

The last set of factors concern the wider context and how its influence over implementation was managed. The contextual features of importance were similar to those in the Kisii-Merlin site, that is, drug policy changes and socio-economic factors.

[19] AMKENI is an NGO whose name is derived from a Swahili word meaning "awakening "

In addition variation in the types of outlets selling anti-malarial was a relevant factor in the Bungoma-AMREF site, while the low availability of outlets selling anti-malarial medicines was important in Kwale. The drug policy change led to negative impacts on implementation processes in both sites. In the two sites the actors' reaction to these changes and its consequences were similar. Figure 4.16 and 4.17 describe these experiences.

Figure 4.16: Managing drug policy changes in the Kwale-MoH site

In the Kwale-MoH experience, information on changes in drug policy was relayed through formal government procedures. Decision making depended entirely on official communication on the status of the drug of choice for the retail sector from the DoMC. Inadequate communication led to the user's perception of lack of government's seriousness on the involvement of PMRs in malaria control. The slow response from the DoMC also created concerns over the continuity of the innovation, delayed further implementation and created a time gap between capacity building and actual training of PMRs. Materials that had already been produced with SP medicines were never distributed. Revision and production of new ones in bulk could not be done because of budgetary constraints. However, locally produced materials were adapted and produced for use. DoMC communication on training on AQ medicines was unclear. This together with lack of public information attributed to budgetary constraints contributed the user organisation focusing only in workshops. At the retailer-client interface these changes made it difficult for PMRs to convince clients to buy the new medicines in the right dosages. The effect of these changes also eroded trainer's confidence and was reported to be expensive in terms of re-training and production of IEC materials.

Figure 4.17: Managing drug policy changes in the Bungoma-AMREF site

Response to drug policy changes in the Bungoma-AMREF experience was characterised by concern over cost implications of developing new materials and undoing the emphasis made on SP medicines through the JKJ strategy. Although AMREF was a member of KeNAAM, its approach in seeking clarification on the drug of choice for the retail sector was not active as that of Merlin. AMREF relied on official communication from the DoMC regarding the changes which they then used to seek funding for production of new materials. The changes coincided with the time when the funding from USAID was coming to an end and therefore AMREF sought funding from Rotary Club and European Union to produce new materials. Production of these new materials was conducted centrally in line with AMREF procedures although this process was slow given the immediate changes required. The new changes eroded the confidence of trainers especially since the programme emphasised five messages on SP medicines. In addition the process was perceived to be expensive in terms of re-training and production of IEC materials. It challenged the authenticity of information passed to clients affecting delivery of the intervention. Perceived lack of a firm regulatory structure on multiple brands of drugs such as SP and AQ and the marketing strategies of pharmaceutical companies led to the perception that these changes were likely to be spearheaded by drug firms to make profits.

The two experiences indicate that the resource team and the user organisation in both sites employed a fairly passive management style in seeking information on the drug policy changes than in the Kisii-Merlin site. This led to them being more affected by the delays and uncertainties that arose as a result of protracted change. In the Kwale-MoH site, inadequate communication between the national office and the funding process meant that new materials on AQ could not be produced on time. In the Bungoma-AMREF site, despite delays related to communication problems, the resource team was able to mobilise resources from other donors to reprint the materials. Across all sites however, the user organisation and the resource team perceived drug policy changes as expensive because of re–training PMRs and production of new materials.

In addition, changes in drug policy increased the perception of unreliability of PMRs as sources of health care and created a dilemma for trained sellers as indicated by a

remark from a PMR in Bungoma. *"In connection to drugs there have been several drugs in the market, when I go for more drugs I find a new one. They also make us to look for new ways of convincing clients every now and then, because today I may recommend such and such a drug to the client, the next day, I have to change my tactics and recommend another one , this makes the clients doubt us"*. The change in drug policy also created a dilemma for trained PMR as one of them from Kwale said: *"The problem that I have experienced most is on the drugs that are no longer in the market. For those who have been trained on drugs and you took large quantity of drugs, when you come to realize that they are no longer recommended you really get disturbed. Because you are selling knowing well that they are no longer in the market so it really bothers you. If you are not trained then you won't worry much but now since you know selling the drugs to someone becomes a bit problematic it really affects you"*.

The resource team in the Bungoma-AMREF site also argued that the sudden changes in drug policies eroded their confidence *"The sudden change of treatment from SP to AQ was bad, in fact I had withdrawn from doing community education. I told my boss that we should choose other people because you look odd, the other month you were just telling them that SP is the best drug in fact we had taken 3-4 weeks to come up with 5 key SP messages. You see after marketing those then after 3-4 months you are told change that. No sooner had this been put in place than it was stopped, we were now going for ACT, which people cannot afford"*.

It was reported that the occurrence, delays and lack of clarity associated with the drug policy change heightened existing confusions generated by the large number of anti-malarial brands in the market. As one DHMT member in Bungoma pointed. *"People had just gotten the concept of SP and thereafter they were told it is being phased out.*

Manufactures had written on their package that AQ is a single dose treatment. So consumers took it as the truth since it had come from a manufacturer. This message has been ingrained in our communities that this is a single dose treatment. So it has cost us a lot to convince these people to change".

As described earlier, poverty and low affordability of anti-malarial medicines are important challenges to PMR programmes. Poverty indices indicate that Bungoma district had the least proportion of community members living below poverty line (57%) compared to Kwale (63%) (chapter two table 2.4). Overall, levels of poverty may have played a role in sale of recommended medicines. To overcome this, adaptation to socio-economic issues varied in the two sites. In the Bungoma-AMREF site, there was an attempt by the resource team to manage problems of high cost of medicines by establishing links with pharmaceutical industries and setting an agreement to supply vendors with drugs at affordable prices, providing temporary motivation until competition from chemist shops forced many out of business. This may have facilitated continuation of the programme for a while but this was not sustained.

One feature of the context observed only in Bungoma was the number of informal chemist shops. This was largely associated with the weak regulatory framework in the wider health system. Many retired health workers or those working within government facilities opened chemist shops as a source of income. Most of the chemist shops were not registered; people manning them were unqualified as one DHMT members said: "*Like the nurse aides they get a photocopy somewhere and use it. Maybe the owner is unaware. But you will find that when you want to trace these medical personnel whose documents are available at the chemists, you can never get him. I can assure you*".

Presence of drug shops in almost every market centre was reported by general retailers to create competition in the sale of anti-malarial medicines. This is because they sold medicines at relatively cheaper prices compared to general retailers because they buy in bulk and sell loose tablets repackaged in plain envelopes instead of the original package. In addition, although drug shops may not be manned by trained professionals, they were perceived by community members as offering professional services denying trained PMRs opportunities to practice the innovation. Figure 4.18 and 4.19 summarises all the factors that may have influenced implementation and outcomes in the Kwale-MoH and Bungoma-AMREF sites.

Figure 4.18 Framework for understanding factors influencing implementation of innovation to influence impacts in the Kwale-MoH site

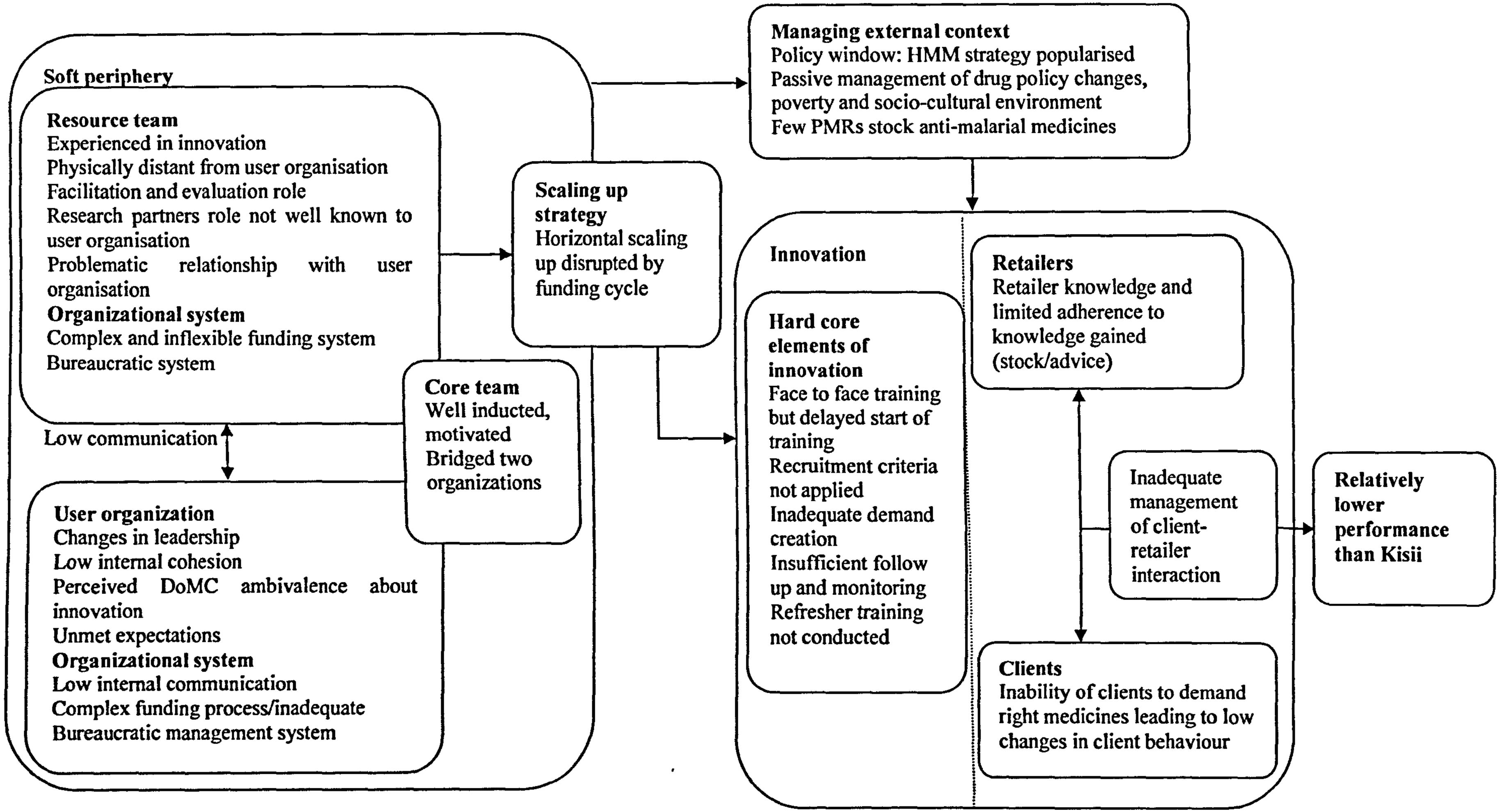
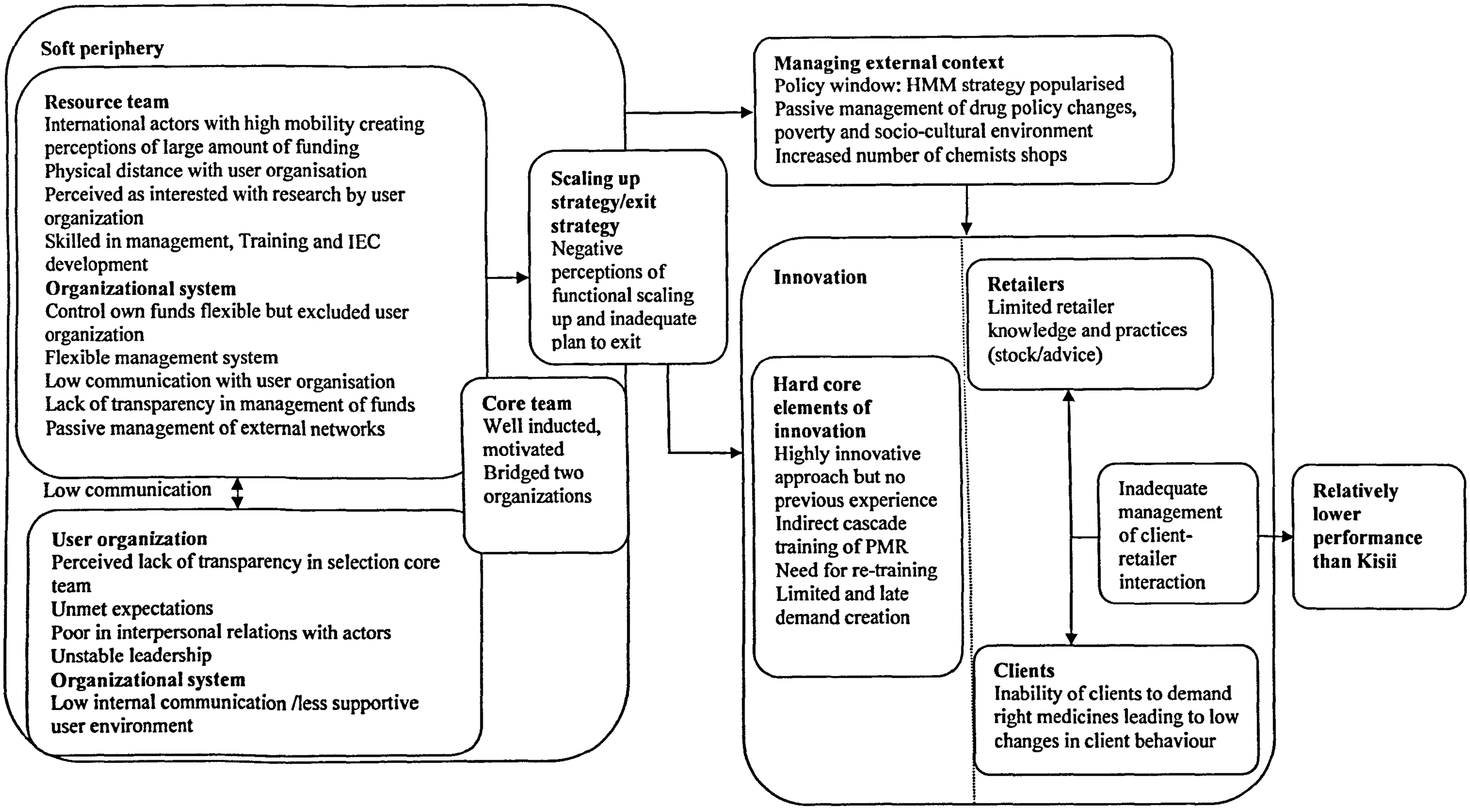


Figure 4.19 Framework for understanding factors underlying implementation of innovation to influence impacts in the Bungoma-AMREF innovation



4.5 Summary

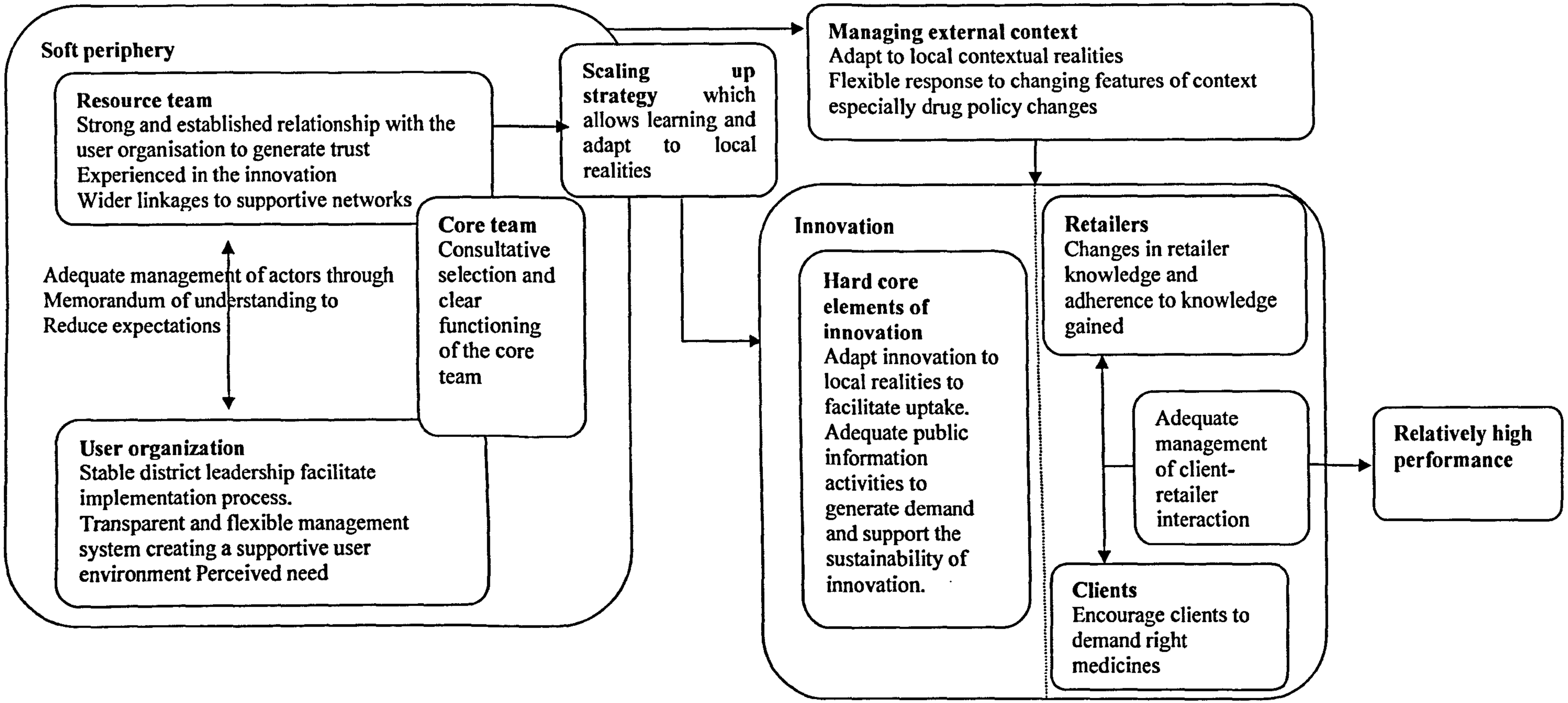
This section presents a summary of key factors which facilitated successful implementation and outcomes as experienced in the Kisii-Merlin site compared to the other sites. It also outlines the limitations of qualitative study and the policy analysis approach used. The main limitation was that the study was not designed to test theoretical propositions derived from the analytical frameworks used, limiting the explanatory power of the analysis presented. Given the range of influencing factors it was, for example, difficult to identify priority influences among those identified. The second limitation is that this analysis did not consider the diffusion of innovation beyond the district level implementers. This means that the study did not focus on how the innovation may have been taken up by PMR or clients. Although this would have been important, it was beyond the scope of this analysis. Yet despite these limitations, the use of an inductive approach to analysis guided by relevant theoretical frameworks helped to clarify how the factors identified played out in each site's experience and influenced implementation. This analysis of implementation processes took account of differences in settings including actors, and the use of stakeholder analysis allowed better understanding of actors involvement in implementation, dynamics in interactions and how that influenced process and outcome. The study therefore provides useful lessons for implementation practice both for specific PMR interventions and generic lessons for general public health implementation practice. Figure 4.20 provides an overview of the key lessons drawn from across all sites about how to manage innovations to enhance programme performance and coverage.

The study identifies several factors specific to managing PMRs interventions that facilitated successful implementation of the innovation. A resource team with a good relationship with the user organisation and a flexible management system allows a

localised decision making process to respond to immediate contextual features and supports effective implementation. In addition, ability to manage relationships between organisations and actors involved, including organisational environments and perceptions of the user organisation about the innovation and implementation process, are critical for successful implementation and outcome. Use of an MoU for example may enhance communication and contain unrealistic actor expectations of financial gains. This may be possible if the resource team possess attributes such as the ability to modify the innovation to suit local needs, credibility, authority, understanding of the user environment and relevant skills. The selection and functioning of the core team also requires adequate consultation for effective implementation. This may help avoid expectations that may polarise relationships within the user organisation. Stability and effective leadership in the user organisation coupled with transparent and flexible management system may also facilitate implementation process.

The scaling up strategies employed should provide an opportunity for learning, allowing actors to gain experience in the intervention which should feedback into the implementation process. Finally, challenges of balancing the relationship at the client–retailer interface require that strategies to manage external context such as socio-economic factors should be taken into consideration to facilitate creation of an enabling environment. However, the interplay of such factors illustrates that there are challenges in the wider context such as poverty and drug policy shifts that are beyond the ability of the implementing team to overcome limiting the success of the innovation. In summary, in these districts these data highlight the difficulties of working with and through the user organisations for service delivery innovations involving the retail sector. They point to the complexity of implementing innovation in a bureaucratic environment constrained by resources as well as many competing interests of other conventionally accepted innovations.

Figure 4.20 Summary of key factors enabling successful implementation of PMR intervention



Chapter 5:

Policy Implications and Conclusions

5.1 Introduction

Prompt and presumptive treatment of fever continues to be one of the main strategies for malaria control. Literature on care seeking studies in SSA shows that the retail sector plays an important role in fever and malaria management. However, treatments obtained from the retail sector are often inappropriate. Due to their popularity and physical accessibility, it is recognised that PMRs can have a role in increasing coverage of appropriate malaria treatment. This recognition led to the WHO advocating for strategies to improve HMM with PMRs interventions as one potential channel to provide prompt and effective treatment of malaria in children under five (chapter one).

This study aimed primarily at understanding the benefits and challenges of different approaches of working with PMRs through a comparison of three programmes implemented in Kenya. At the outset of the study, it had been anticipated that the findings would provide clarification on the effectiveness of particular approaches to working with PMRs, a gap outlined by the Goodman review (Goodman et al., 2007a). Over the duration of the study, the main focus of interest shifted from a comparative evaluation towards an in-depth understanding of the strengths and challenges of each approach evaluated. Findings relating to the relative strengths and weaknesses of programme design and its implementation provide useful lessons on the factors to consider when managing implementation of PMR programmes. Primarily, this shift has been as a result of an emerging understanding that each programme represents a complex set of activities, implemented in different contexts and involving different sets of actors; therefore, implementation and impact inevitably played out differently in each site (both from what was planned and from each other). Secondarily, methodological challenges experienced in evaluating the programmes led to limitations

in interpreting data, discussed in chapter three section 3.5.2 and chapter four section 4.5. Comparability was further made difficult by lack of cost data for potential cost-effectiveness assessment, although this was initially part of the study, lack of quality data made it difficult to estimate the cost of implementing the programmes thus the costing component was dropped.

Regardless of the challenges described, the overall evaluation approach had several strengths. First, the study utilised a pragmatic design in two sites (Kisii and Bungoma districts) and random allocation of intervention and control areas prior to implementation of the intervention (Kwale district). Use of contemporaneous controls made this evaluation relatively stronger than previous PMR assessments (Goodman et al., 2007a). Secondly, indicators used for quantitative assessment for site comparisons were common across all sites, allowing for uniformity in the evaluation. This approach is supported by lessons from IMCI multi-country evaluations where use of a common conceptual framework and uniform indicators and tools ensured a coherent set of studies with outputs for policy implications (Bryce and Victora, 2005). The third strength relates to the use of a series of inter-related studies with mixed methodologies to measure the performance and outcome of different PMR programmes and to understand how implementation experiences may have influenced their performance. This evaluation drew from the public health evaluation and policy analysis literature. Policy analysis is of relevance in this regard, as implementation is one area of inquiry within this broader field of work. Indeed, innovation theory, which draws on concepts from policy analysis and wider organisational management theory, is particularly relevant to this study as it investigated the early stages of implementation and scaling up of a public health innovation. A review of the published literature on the application of health policy analysis in empirical inquiry indicates gaps and weaknesses in this field in LMICs. Instead, the dominant focus of many analyses concentrates on

considering "what happened" rather than investigating "what explains what happened". The review suggests the need for more studies that are carefully designed and use relevant theory to guide systematic investigation of implementation experiences (Gilson and Raphaely, 2008).

Through policy analysis, the study highlights that successfully introducing innovations like these (and indeed other public health innovations) requires that attention be paid not just to the overarching programme design but also to the process of managing the intervention's implementation. In addition, the study also addressed several research gaps identified in chapter 1 from a review of PMR interventions. These gaps include information on the impact of implementation of PMR programmes within the scaling up context, evidence on the impact of PMR programme in different geographic locations, and capturing potential variations in effectiveness across epidemiologic and health system settings and with different types of sellers (Goodman et al., 2007a).

This chapter discusses the policy implications of the outcomes and experiences described in chapters three and four and situating these findings in the wider literature reviewed in chapter one. It is structured around six sections. Section 5.2 summarises key findings and the strengths and weaknesses of the interventions. Section 5.3 addresses the contribution of the study to the existing knowledge on the impact of PMR interventions. Section 5.4 presents insights for the future implementation of PMR programmes and for the introduction, and scaling up, of public health innovations more generally. Section 5.5 outlines implications for future PMR and broader public health evaluation research. The study conclusions are presented in section 5.6.

5.2 Summary of key findings

The main findings are presented in table 5.1. The first set of findings is linked to the impact of programmes on population coverage and utilisation of the interventions. This evaluation indicates that PMR interventions can increase coverage of appropriate treatment. The NGO-led participatory–based training in the Kisii-Merlin programme had the highest coverage and was most effective in reaching the target outlets. Programmes in the other two sites, Kwale-MoH and Bungoma-AMREF, had relatively low coverage, although the Bungoma-AMREF site was more successful in covering target outlets. Of importance to note is the low coverage in the Bungoma–AMREF site given that it was a social marketing programme targeting outlets across the district.

MoH guidelines suggest that trained outlets should be within a walking distance of 2 km to community members (MoH, 2003). The spatial analysis using thiessen polygon technique undertaken in this study indicates that all programmes attained this target. For example, community members were likely to walk an average distance of 1.30Km to access a trained PMR in the Kisii-Merlin site. This was followed by the social marketing approach in the Bungoma-AMREF site (1.40 km) and the Kwale-MoH site (1.86 km).

Despite low coverage of outlets and the highest physical distance to access a trained PMR, the Kwale-MoH site demonstrated a relatively high potential utilisation of target group compared to the other sites (table 5.1), and this was primarily achieved in the most remote and sparsely populated division. It seems likely, therefore, that the long distances to formal health providers, the clustered nature of homes and the wide separation of such clusters from each other could support the existence and use of local retail outlets selling patent medicines alongside general provisions. This is important

since PMR programmes are premised on the need to improve the physical accessibility of fever and malaria treatment in remote rural populations. Reaching large numbers of users indicates the feasibility and potential success of working through PMRs in remote rural areas. However, an important limitation for these PMRs in this type of setting concerns the type of drugs normally stocked (section 5.3.3).

The second set of findings show that PMR programmes implemented in different geographical settings can have an impact on PMR knowledge and practice in selling anti-malarial medicines. There was evidence for a significant impact on PMR knowledge and practice at six months with an NGO-led participatory training approach in the Kisii-Merlin programme. 60.5% of trained PMRs sold AQ medicines with appropriate advice compared to 2.8% among the untrained ones (OR; 53.5: 95% CI 6.7, 428.3). However, the study was unable to consider whether this impact would be sustained over time. There was also some evidence of a limited impact at six months for the MoH-led participatory training approach in the Kwale-MoH programme, where 18.8% of trained PMRs sold AQ medicines with appropriate advice compared to 2.3% of control PMRs (OR; 9.4: 95% CI 1.1, 83.7).This programme was, however, marked by implementation challenges and the study was also unable to consider whether the impact would be sustained. Finally, this study was unable to show evidence of impact from the social marketing approach used in the Bungoma-AMREF programme. No (0%) intervention PMRs sold AQ medicines adequately compared to 7.1% in the control areas (OR; 0.5: 95%CI 0.1-5.5).

As part of the qualitative analysis, the implementation strengths and weaknesses for each programme are outlined in table 5.1. A central theme that cuts across all the three sites is the importance of relationships between actors at various levels and the need for management strategies that support building of good relationships. While

introducing an innovation like this to a district level setting, an underlying issue is the importance of a strong and experienced resource team that is flexible and transparent, which responds to immediate contextual features and enhances good relationship with the user organisation. In addition, a user organisation with stable, effective, transparent and flexible management system may allow adaptation of the innovation to local settings.

Finally, in order to assess overall performance of programmes, putting together data on utilisation and quality of care in the three districts is informative. For coverage to be effective, quality of services is important (Shengelia et al., 2005; Thiede et al., 2007). For example, since 60.5% of trained PMRs in the Kisii-Merlin site sold AQ medicines in adequate doses, this would translate to about 18,074 children who would potentially receive adequate treatment if their care givers sought care from trained PMRs. In comparison, in the Kwale-MoH site with 18.8% of trained PMRs offering adequate treatment, 8994 under fives would receive adequate treatment. Although the impact in the Bungoma-AMREF site was difficult to attribute to the programme, (chapter three section 3.5.2), the quality of services offered at the time of the evaluation means that 1179 under fives would potentially receive adequate treatment. Overall, as discussed in the introduction, this comparative analysis could not establish a single "best approach" for working with PMRs, but it provides important implementation lessons around all three programmes evaluated as summarised in subsequent sections.

Table 5.1 Summary of key findings across sites

	Kisii-Merlin (one division)	Kwale-MoH (two divisions)	Bungoma-AMREF (one division)
Primary indicator for impact on PMR practice			
% selling AQ in adequate doses	60.5% trained versus 2.8% untrained PMRs (OR; 53.5: 95% CI 6.7, 428.3).	18.8% of trained versus 2.3% of control PMRs (OR; 9.4: 95% CI 1.1, 83.7).	4.0% of intervention versus 7.1% in the control areas (OR; 0.5: 95%CI 0.1-5.5)
Main secondary indicator for impact on Knowledge			
% recommending AQ medicines adequately	79.3% trained versus 16.7% untrained PMRs (OR: 18.6: 95% CI 6.6, 52.9)	48.8% of trained versus 0% among trained PMRs	30.0% versus 43.4% among control PMRs (OR: 0.6: 95% CI 0.6, 1.7)
Main indicators for coverage and utilisation			
% of outlets covered	27.1%	14.1%	16.7%
Average distance to a trained PMR (km)	1.30	1.86	1.40
Under five population potentially reached	29876	47785	29475
Under five who would receive adequate treatment with AQ	18074	8983	1179
Implementation strengths			
Intervention design	Face to face training through participatory approaches adapted to local contexts; continuous production and distribution of IEC materials covering all aspects of malaria control; record keeping by PMRs to support monitoring of intervention	Face to face training through participatory approaches	Formative research to inform design of the intervention, continuous process of production and distribution of IEC materials covering all aspects of malaria control
Management of intervention	Adequate communication and good relationships between the resource team and the user organisation enhanced trust; effective management of networks and expectations from different actors through an MoU enhanced relationships; flexible management system - adequate and flexible funding process ensured localised decision process responsive to local realities.	Managed through the government system with potential for institutionalisation of the intervention; horizontal scaling up used allowed opportunity for learning and feedback	Developed linkages with pharmaceutical industries as part of managing socio-economic contexts to enhance sustainability; involvement of many partners at district and national level with potential for supporting intervention technically and financially; flexible management system including funding process ensuring localised decision process responsive to local realities

Table 5.1 continued

	Kisii-Merlin (one division)	Kwale-MoH (two divisions)	Bungoma-AMREF (one division)
	Selection of PMRs for training for efficiency of implementation		
	Selection and induction of a core team to spearhead implementation and liase between the technical team and the district health system		
Implementation weakness			
Intervention design		Limited engagement with community to generate demand	Minimal direct interaction with PMRs reduced chances of enhancing knowledge gained
Management of intervention	Unclear mechanism of institutionalisation to the local district heath system	Inadequate involvement of networks for sustainability including deficiencies of the resource team to build supportive relationship with user organisation; inadequate planning and involvement of community volunteers; inadequate and complex funding process hindering implementation process	Limited efforts to manage expectations of local district health system actors; inadequate communication between partners
Key policy implications for generic public health programmes			
• The importance of managing relationships between actors at various levels and the need for management strategies that support building of good relationships • A strong management team that is flexible, transparent and responds to immediate contextual features • A user organisation with stable, effective, transparent and flexible leadership to allow adaptation of the innovation to local settings. • The need for employing effective public-private partnership for intervention implementation			

5.3 Contribution to knowledge on retail sector interventions

This section outlines the contributions the study has made to existing knowledge on working with PMRs to improve malaria treatment.

5.3.1 Impact of PMR programmes

The study confirms that PMR programmes can impact positively on PMR knowledge and practices. As described in chapter one, previous reports indicate that different PMR interventions have improved rates of appropriate treatment and *PMR knowledge* and practices in small scale studies. However, there is insufficient evidence on the impact of PMR interventions on their knowledge and practice at larger scale (Goodman et al., 2007a). This study supports not only previous evidence that such interventions can improve PMR knowledge and practices but that the impacts are achievable within a moderately large (divisional) scaling up context. This was also the case for all the sites in the MoH DDP programme (PMR interventions were implemented in five initial districts in Kenya as part of scaling up) which included Kwale-MoH site (annex I). The study also provides evidence of the potential to operationalise such programmes through an NGO and the MoH.

5.3.2 Insights on the importance of management processes in implementing innovative PMR programmes

A key finding in this study has been the critical nature of the implementation process in determining the impact of PMR programmes. This section examines specific insights the study has provided on this issue, and relates them to wider evidence. However, as was alluded to in chapter one, there are relatively few studies in LMICs that have examined implementation process using policy analysis that this study can draw from.

By nature an innovation requires a resource team to champion it. Therefore the characteristics and management of the innovation by the resource team is key to its success. In all the three sites, there were many actors involved in implementation, ranging from representatives of the funding agencies to the resource team external to the district health system, the DHMT and the core team. The composition of the resource team (with good credibility, adequate management skills and relevant expertise) had an important influence over the implementation process. This team has a particularly important role to play in managing actors' interests and the power relations among them, as described in chapter four section 4.3.3 and 4.3.4. Management of actors is further compounded by the number of actors involved, their roles and the differences in the organisational arrangements of the different agencies they represent, as was illustrated by the Bungoma-AMREF site with actors drawn from CDC, USAID, QAP, AMREF and the DHMT. The interactions between actors may change the intervention and undermine plans, leading to implementation gaps. This strongly supports the observation that managing relationships between key actors involved is key to successful implementation and the outcome of any policy (Thomas and Gilson, 2004; Simmons and Shiffman, 2006).

The need to develop and maintain a good relationship between the resource team and district health managers is important in generating a supportive user environment (Gladwin et al., 2003). This study provides further evidence to illustrate that such relationships are built over time and require deliberate efforts to manage conflicts. This was illustrated in the Kisii-Merlin site where these relationships were successfully managed. A memorandum of understanding spelt out the roles and responsibilities of all involved and the incentives for implementing PMR activities which acted as reference document within which to manage actors linked to the innovation. This enhanced

transparency, improved communication and minimised conflicts (especially around financial expectations and expectations of the logistical support available from the NGO).

Managing relationships between the resource teams working at district level and their funding agencies is also important. This was clearly an influence in the Bungoma-AMREF site. Although the funding agencies were represented on the ground through actors in the resource team, the contractual agreements between AMREF and USAID was characterised by inadequate communication on the funding cycle, undermining the implementation of activities linked to demand creation and generating the perception of a lack of transparency by the district health system and community members. The overall result was some opposition to the implementation by the user organisation. Although there was no specific contractual agreement between the resource team and the funding agency in the Kwale-MoH site, relationships between district level actors and the DoMC were also characterised by inadequate communication about the release of funds for programme implementation. Again, this resulted in inadequate implementation of the intervention.

The characteristics of the user organisation and the management environment are equally important for successful implementation, including management of inter-personal relationships between actors within the district health system to minimise internal conflicts, and obtain strategic support important for implementation and continuity of intervention activities.

The influence of actors over processes of policy change, including introducing public health innovations and the consequent need to manage them, is supported by a range of empirical work. A study in South Africa indicates that policy reformers have to take active

steps to manage actors to avoid opposition to new policies preventing moves towards implementation (Thomas and Gilson, 2004). In Kenya, the influence of actors in the introduction of Malarone® donation programme showed the political and bargaining influence of national, regional or international actors on the development and implementation of the programme (Shretta et al., 2001). Other studies have shown actors' views and values lead front line providers to implement policies in different ways from what was intended, often undermining effective implementation (Seidel et al., 2000; Kaler and Watkins, 2001; Walker and Gilson, 2004).

A stable district leadership in the user organisation is instrumental for effective implementation of any intervention. This is important regardless of the underlying PMR approach used. In Bungoma, transfer of the actors who had been inducted into the programme led to a leadership gap which slowed implementation of activities during the phase when funding was being withdrawn. In Kwale, frequent transfers of district health managers coupled with ineffective internal communication of district health activities interrupted implementation. Importantly, these problems were not experienced in the Kisii site.

The broad influence over implementation of leadership changes in local health systems has been illustrated elsewhere. In Brazil, staff changes in the implementation sites after every election process stalled implementation activities threatening the sustainability of reproductive services (Díaz et al., 2006). In Zambia, health care reforms led to insecurity amongst providers which saw high turn over of staff during the implementation of new reproductive services. During the pilot phase for example, a third of 20 trained staff were still active at the end of the second year undermining the study's implementation strategy

(Skibiak et al., 2006). Overall, high turn over of health workers to the private sector is observed to drain the public sector of its bloodline for effective implementation of programmes (Berer, 2002).

For both the resource team and the user organisation, there is need for transparent and flexible management systems which allow local managers (from the resource team and the district health system) to adapt interventions to local contexts, and so enhance community acceptability of the intervention. As experience in the Kisii-Merlin site demonstrates, such systems include a budget system that allows local decisions and an efficient communication channel between actors. However, as shown in Kwale, the often centralised bureaucratic procedures of government systems undermine local decision-making flexibility and so present challenges to the implementation of innovations (Simmons and Shiffman, 2006). Across all sites, one strategy adopted by the resource teams to deal with this problem was to ignore or seek to work round the existing hierarchical structures by direct communication to implementing actors at divisional level (within districts). However, this strategy sometimes generated its own opposition from district level actors with negative consequences for implementation and institutionalisation of the intervention.

The process of selecting a core team to spearhead the implementation process as policy champions is also vital (Simmons and Shiffman, 2006). A core working group is recommended as essential in any HMM strategy for effective implementation (WHO, 2007). Based on evidence from the three programmes examined, this study shows the need for a consultative process in selecting the core team to enhance cohesiveness and support implementation. This may involve actors from the user organisation and the

resource team. This process may be facilitated by a good understanding of the management system of both the resource team and the district health system for ease of selection. However, where core team members are drawn from a range of organisations, this study shows that the roles and responsibilities of the core team need to be clearly spelt out.

For successful implementation this study indicates that it will be necessary to adapt the intervention to local realities. The resource teams and district health managers will need to respond flexibly to changing features of context. A good example in this study was the response needed to the changing drug policy as was observed in Kisii where active engagement between the implementing team and national malaria control actors provided information necessary for action reducing the potential knowledge gaps and hindrances to successful implementation process at district level. The transition phase of drug policy changes requires a well instituted communication mechanism between the district level and the national level actors. This may allow effective response to changes of IEC materials and curriculum for PMR training to reduce potential chances of confusion among end users.

The importance of adapting the intervention to local realities is supported by several studies. In Ghana the community based health programme showed an improvement of family planning and safe motherhood indicators after the experimental trial was adapted to the resource constrained district level settings (Awoonor-Williams et al., 2004; Nyonator et al., 2006). Adaptation was also a key element of organisational management of the broad-based initiative for expanding contraceptive choices in the Copper Belt region in Ghana (Skibiak et al., 2006). Similarly in Bangladesh some structural features of the

reproductive project were not scaled up but substantial operational changes were instituted for different settings (Phillips et al., 2006).

This study provided particular insights on the issue of the sustainability and institutionalisation of PMR programmes, as the three programmes were evaluated at different stages of implementation. Evidence of the lack of sustainability is examined at two levels; the organisational level (continuity within the district health system) and the end user level (PMR practising the intervention) (chapter 1).

At the organisational level there was evidence to suggest a lack of sustained effort to maintain the intervention activities within the local district health system. At the time of this evaluation in the Bungoma-AMREF and Kwale-MoH sites, activities such as training, distribution of job aids, on going supportive supervision and public information activities were not being conducted. These programmes had relatively lower impact compared to the Kisii-Merlin site. As discussed in chapter four, in the Bungoma-AMREF experience AMREF and the funders failed to develop an exit strategy that allowed for the hand over of responsibility to the local DHMT. Thus the intervention was not sustained beyond the lifetime of the project and its funding. In the Kwale-MoH site, the strength of the intervention, as outlined in table 5.1, was to ensure that the intervention became part of the routine practice of DHMT operations. To achieve this, the implementation approach tried to minimise the role of the resource team to strengthen sustainability and promote institutionalisation. However, since the intervention was new, it may have required more external support for effective implementation. Thus at the time of study, there were signs of a lack of continuity of intervention activities, in contrast to the Kisii-Merlin site with a very active resource team.

Although not unique to these programmes, the PMR programmes do seem to reflect wider experience of the problems of institutionalising new and innovative programmes in district health systems in SSA (Simmons and Shiffman, 2006). This is the case especially when the new programme being popularised does not seem to match the user's organisational practices. A ten year study in Bangladesh that sought to operationalise a family planning project within a district health system showed that new policies that disrupt long-standing power relationships and organizational culture take considerable effort to implement (Haaga and Maru, 1996). Experience in Zambia, meanwhile, shows how important it is to integrate new interventions within the public health system through a slow transfer of management responsibility to the district team which allows learning (Skibiak et al., 2006). A study in Uganda illustrates the importance of understanding the district level system by the implementing team where power relations led to opposition to a newly introduced information management programme (Gladwin et al., 2003). Future PMR interventions could borrow these lessons to enhance sustainability.

At the end user level, lack of sustainability is illustrated by the Bungoma-AMREF experience. For example, although a community group of PMRs was established to support continuity after exit of donor funding through a revolving fund and supply of drugs, management problems and drop outs led to discontinuation of the programme. A study in Nigeria has shown that retailer associations can support quality care offered through inspection of their services by peers from the organisation (Oshiname and Brieger, 1992). However, lack of adequate management skills in the organised community group in the current study points out that such organisation may require managerial skills in its leadership. For PMR approaches that utilise community level actors for continuity of programme activities, there are likely to be challenges of sustaining programme activities

at end user level due to problems of incentives as was seen where CORPS were involved in Kwale and the Locational Afya Committees in Kisii. Therefore careful consideration need to be given to which actors should be involved to enhance sustainability of PMR interventions to support continuity at this level.

Finally, the type of scaling up strategy used is critical for success. As mentioned in chapter four, functional scaling up may limit sustainability, especially in donor funded programmes with limited timelines as was seen in Bungoma. The scaling up strategies employed in implementing an innovation should, instead, provide an opportunity for learning, allowing actors to gain experience in the intervention which is then fed back into the implementation process (example-Kisii and Kwale).

5.3.3 Importance of context on implementation process

This section examines how this study provides greater understanding of the dynamic influences of context over implementation processes and the effectiveness of PMR programmes. In this way the study has contributed to understanding the effectiveness of PMR interventions in different epidemiologic contexts and health systems and with different types of sellers (Goodman et al., 2007a). Lessons learnt are grouped into three areas: effects of poverty on the delivery of intervention, the challenges of involving different types of PMRs and the influence of malaria epidemiology.

This study expands the knowledge on how the complex dynamics of client-PMR relationship is affected by the wider socio-economic context making it difficult for trained PMRs to balance their commercial role with advising clients to buy the right medicines. As was described in chapter four, the PMR-client relationship is often characterised by

mutual suspicion. For example, there was a general perception that PMRs are commercially oriented, and their recommendations are treated with some suspicion. This observation is supported by wider literature where PMRs are described as popular in part because they often sell anti-pyretics which are cheaper compared to anti-malarials, for treating fevers or malaria, they are physically closer to communities, and often sell medicines according to clients demand (Goodman et al., 2007a). Given their commercial orientation, PMRs' attempts to convince clients to buy expensive anti-malarial medicines are a cause for suspicion to many clients, limiting their ability to promote appropriate practices.

Due to socio-economic challenges, PMRs found it difficult to stock expensive anti-malarial medicines, especially in remote settings. This is informed by their client's inability to afford them, particularly in the right doses as recommended by the intervention. Thus, discussions with implementing actors indicated that most remote outlets in the rural areas were unlikely to stock anti-malarial medicines due to their cost as well as overall low stock turn over. A complication to this description of the PMR-client relationship is that remote settings are also often characterised by strong social relations between clients and PMRs. In these settings, high costs of anti-malarial medicines increased clients' expectations of credit from PMRs, given that clients often knew or were related to their local PMR. This situation tends to destabilize remote outlets where these pre-existing social "obligations" were most likely to occur. They experience additional pressure to provide credit facilities, but may not be able to re-stock anti-malarial medicines. The above challenges illustrate the difficulties trained PMRs experience in convincing clients to buy full courses of anti-malarial medicines, and the need for effective public information and affordable pricing to support such interventions.

Involving different types of PMRs introduces several challenges. For example in Bungoma, involvement of the chemist shops as well as general retail shops into the programme hampered sales of recommended anti-malarial medicines among general retailers. Chemist shops were likely to stock a variety of anti-malarial medicines compared to general retail shops since they buy their drugs in bulk and sell loose tablets often at lower prices than general retail outlets. This generated competition and pushed general retail shops out of business of selling anti-malarial medicines, limiting the coverage of PMR services and undermining the aim of the intervention. Although chemist shops are generally perceived by community members to offer high quality care, there were reports of considerable level of regulatory infringement with some settings having chemist shops being manned by unqualified staff or stocking unregistered anti-malarial medicines (Goodman et al., 2007b).

In terms of effectiveness of PMR programmes in different geographic settings, this study illustrates that different settings did not appear to influence the outcomes measured at PMR level. However, different geographic settings required adaptation of the intervention to these settings for effective delivery as was described in section 5.3.2. In addition, through use of GIS data, it was observed that there are differences between population distribution in relation to the geographic location of PMR services. For example, despite low coverage in the Kwale-MoH site (table 5.1), more under fives were likely to be reached even in remote settings as observed in Kinango division. This is likely to increase prompt and effective treatment of fevers in these settings. However, further work on how GIS can be used to assess the potential to reach different socio-economic groups as well as confirming the current observation is needed.

5.4 Recommendations on strengthening the introduction and implementation of PMR programmes

5.4.1 General recommendations

This section draws out the implications of this study for the future implementation of PMR programmes, building on policy implications from a review of PMR studies, WHO guidelines and experiences of implementing other elements of HMM interventions (WHO, 2004a; Goodman et al., 2007a; WHO, 2007). The main issues discussed in this section focus on recommendations around the need for institutionalisation, conducting a situational analysis, selection procedures of PMRs, using a combination of activities, establishment of partnerships, and understanding the wider context for implementation.

In implementing public health interventions, a recommendation widely recognised is the need to plan for institutionalisation and exit strategies before initiating implementation (Mona et al., 1998; Olsen, 1998; Shediac-Rizkallah and Bone, 1998). This is especially the case where scaling up the intervention is being supported by external agencies such as NGOs. In the context of PMRs, sustainability needs to be built at two levels. One is at the individual level involving PMRs and community members. For example, by maintaining knowledge gained through updates, supportive supervision and public information activities to enhance practices and create demand to sustain the benefits of the intervention. For continuity of programme activities there is a potential for using support groups of PMRs but however, this requires strengthening of their management skills. The second level is at the district, requiring strategies to generate the support of district level actors and ensure that the intervention is part of annual district plans with mechanisms for implementation. There may be some value in outsourcing certain elements of the

intervention to NGOs when the programmes go to scale for continuity until the district health team institutionalises it. This has not been demonstrated in participatory training approaches involving PMRs. However, projects which utilised franchising principles have demonstrated the potential to outsource training and supportive supervision to NGOs or commercial companies (Mensah, 2005; Ombogo, 2005; PSI, 2005).

The importance of a comprehensive situational analysis has been suggested for such programmes. WHO guidelines for scaling up HMM recognise the need to collect information on quality and cost of drugs, distribution and availability of private sector providers, health seeking behaviour patterns and access to anti-malarial treatment (WHO, 2004a). A review of PMR interventions suggested that a comprehensive situational analysis should also cover the legal framework in which PMRs operate, rates of closures and new start ups (Goodman et al., 2007a). Through the application of policy analysis, regardless of the PMR approach to be implemented, this study suggests additional information necessary to include when conducting a situational analysis. Given the innovative nature of these interventions, a comprehensive situational analysis in the set up phase should also include characterisation of the management system to enable an understanding of different organisational systems and actors involved and ways of managing their expectations and interests. This is important especially when implementation is supported by an external technical team to the local district health system. One key result from such analyses is the identification of a mechanism for clarifying responsibilities and sharing resources (financial and human) among the different partners involved. The example of the Kisii-Merlin MoU supported management of expectations and smooth implementation which enabled adaptation of the intervention to local realities.

Selection of PMRs is considered important especially since there are many PMRs in most settings necessitating a selection process to involve PMRs who are potentially able to practice the intervention thus improve programme efficiency. This study provides further insights on how the selection process of PMRs requires a balance between wide coverage to increase access to adequate treatment and ensuring provision of quality of care (for example, through supportive supervision and follow up). One criterion for including retail outlets in the participatory training approaches was existing availability of anti-malarial medicines. Although it was an important criterion for the success of the intervention, using this criterion tended to include many outlets which were located in large market centres and were probably well established financially. Conversely, the most remote outlets were often those least likely to stock anti-malarial medicines. This raises the question of what mechanisms can be instituted to support inclusion of outlets that are less likely to be financially able to stock anti-malarial medicines yet they are in remote settings where such services may be most needed? It is likely that a selection process based on a criterion of existing anti-malarial medicine stock would undermine the aim and the fundamental basis for the intervention.

Previous PMR interventions suggest that a combination of approaches involving both short term training of PMRs and community information are likely to lead to effective outcomes (Goodman et al., 2007a). This study confirms that lack of a combination of approaches may have negatively impacted outcomes. For example, public information activities were not well implemented in the Kwale-MoH and Bungoma-AMREF sites, both of which had limited impact on key outcomes also supported qualitatively. Public information activities have been reported as a strong determinant of outcome for interventions which focus on provider performance especially in cases where drugs are

brought from a commercial-oriented providers such as a PMRs (Marsh et al., 2004). This study confirms that community information to generate appropriate demand for PMR services should be conducted continuously and should take account of the immediate contexts to support the delivery of the intervention at end user level. Community awareness through public information activities have been reported to increase caregiver knowledge (Kaona and Tuba, 2003; CORE Group, 2004), which may translate to sustained benefits of the intervention at community level.

Monitoring and supervision are widely recommended as a way of improving compliance and appropriateness to treatment (WHO, 2004a; Goodman et al., 2007a; WHO, 2007). Experiences from interventions on distribution of pre-packaged anti-malarial suggest that monitoring and supervision offers additional work load for health workers. This means they may be unable to conduct the activities frequently. The alternative is to use community research assistants, but associated increased costs may make this approach less sustainable. Self completed monitoring forms have been recommended (WHO, 2007). One potential way of enhancing monitoring and supervision was illustrated in the Kisii-Merlin site where record keeping was utilised as a source of information for monitoring. This may be adopted for future PMR programme, however, in places where literacy levels among PMRs are low; there may be difficulties in utilising this approach.

This study illustrates the importance of building partnerships as part of innovation management (Simmons and Shiffman, 2006). As part of the set up phase, the WHO guidelines recommend developing an advocacy plan, building partnerships and mobilising resources for the HMM intervention (WHO, 2004a). Experiences from previous PMR interventions recommend the involvement of a range of actors such as public health

officials and community representatives in curriculum development, training and supervision as likely to contribute to acceptability and effectiveness (Goodman et al., 2007a). Experience of other HMM interventions also suggests that to enhance chances of acceptability, the community entry process should involve key figures from social, political, and religious groups and should sustain the interactive nature of consultation and negotiation with stakeholders (WHO, 2007). While the study supports recommendations to involve a wide spectrum of actors in planning and development, it also highlights the challenge that involvement of many actors from different organisations requires careful management and effective communication channels. Through the use of stakeholder analysis, the study demonstrates the influence of power relations among actors within the district health system over the implementation process.

Finally the study highlights the importance of understanding the context-intervention interaction and its influence over the implementation process. The study provides evidence of the way that recognition of a changing context and adapting the intervention to local contexts may strengthen implementation processes. For example in the Bungoma-AMREF programme, the set up phase emphasised use of SP which was mainly sourced from wholesalers. Later changes to AQ saw chemists becoming important suppliers over time, indicating the need for involving them as key channels of delivery as opposed to pervious use of mobile vendors. Another observation was the unwillingness of PMRs to sell anti-malarial medicines for children under five. This was probably associated with the current manufacturers' package instructions which indicate that only children over five years should be treated with OTC anti-malarials, highlighting the need for better coordination between malaria control programmes and pharmaceutical industry over packaging instruction.

Overall the study shows that provision of technical support and adequate resources for successful adoption is vital but not enough. Capacity building should include adequate managerial skills of the user organisation in addition to the content of the intervention. This means that the setting up of such interventions may require time before positive outcomes are realised.

5.4.2 Recommendations on the challenges of new drug policy for PMR interventions

The final sets of recommendations are derived from broader drug policy influences over implementation of PMR interventions. These recommendations also draw from insights on the interplay of factors around PMR-client interactions which may influence the delivery of future PMR interventions.

The transition to ACT medicines as a first line drug for malaria treatment is a critical element but also challenges malaria control activities (Bosman and Mendis, 2007). Some studies have shown that use of ACT is cost effective compared to SP medicines (Coleman et al., 2004; Chanda et al., 2007). However, as was alluded to in chapter one, key challenges around the use of ACT in the public sector are deployment, access, implementing costs and rational use of the drug (Depoortere et al., 2004; Fogg et al., 2004; Malenga et al., 2005; Zurovac et al., 2005; Bosman and Mendis, 2007; Gitonga et al., 2008; Njau et al., 2008; Wasunna et al., 2008; Zurovac et al., 2008).

ACT medicines have been advocated for use in HMM (WHO, 2001), although there are challenges of implementing HMM using ACT medicines. For example, indiscriminate distribution of ACTs is likely to disproportionably increase the cost of HMM interventions because ACT are costly compared to AQ or SP medicines used in the past (D'Alessandro

et al., 2005; Hopkins et al., 2007). Malaria is also a difficult disease to diagnose. It is estimated that clinical diagnosis of malaria by health professional overestimates malaria by about 61% (Amexo et al., 2004). With such high rates of errors by trained professionals, over diagnosis is likely to be greater when mothers or community based drug distributors are involved. In addition, chances of increased parasite resistance, especially under indiscriminate use of ACTs, and potential shortages in supply are likely to be key challenges for using ACTs in the HMM (D'Alessandro, 2005). Other challenges are around the unregulated markets which might provide opportunities for counterfeits and high use of anti-malarial medicines by adults with low risk of malaria increasing the cost of treating malaria (Charlwood, 2004; Abuya et al., 2007).

With such a background, this study offers practical insights drawn from the PMR-client interactions that may have implications for introducing ACT in the retail sector. From the discussion around the influence of context (section 5.3.3), affordability and the relationships of mutual suspicion between PMRs and clients is likely to be an important set back to practising the intervention. The key challenge for costly ACT medicines for the retail sector is around ability of PMRs to stock the medicines as well as their clients' ability to afford them. It is therefore recognised that subsidies will play an important role in achieving high levels of ACT use (Affordable Medicines-Facility Malaria, 2007). However, the amount of subsidy that would be needed to support adequate uptake of OTC ACTs is currently unknown.

Early experiences from pilot programmes of global subsidy in some SSA countries offer promising results. This is largely under the current global ACT subsidy known as the Affordable Medicines Facility-malaria (Institute of Medicine, 2004). The strategy is under

development with consideration by the governing board of the Global Fund and may be launched in a initial set of countries in 2009 (GFTAM, 2008). The pilot project programme in Tanzania is centered on distribution of ACTs to private outlets at highly subsidized prices. The Clinton foundation procures ACTs and sells them to a national pharmaceutical wholesaler at 88% below the manufacturer's price ($0.12 overage compared to $1 normally). The wholesaler then uses existing distribution channels, including sale to regional distributors, to deliver the ACTs to accredited shops in the two intervention districts. The proportion of consumers seeking treatment for children under five in the intervention areas using subsidized ACTs rose from 40%to 62% three months after implementation (Sabot et al., 2008). The main challenge of the subsidy was that the adult course sold more than paediatric courses (Samarasekera, 2008b), similar to an observation also made for other OTC anti-malarials in Kenya (Abuya et al., 2007). In Kenya, efforts to increase access to ACTs, was launched in 2007 through franchised shops referred to as CFW ™. AL is distributed to CFW ™ from the government central medical stores and administered free of charge to patients with uncomplicated malaria after confirmation by a rapid test. Patients pay $0.65 for a consultation and rapid test before receiving AL for confirmed malaria. Evaluation showed that the distribution contributed to less than 10% of the increase in total ACT coverage after 15 months among CFW ™ target clinics (Sabot et al., 2008). Building on such experiences and the ongoing pilot work in Ethiopia and Uganda may help determine effective ways in which PMR interventions could reach the target group.

The main question around ACT subsidy is the level of subsidies to be set for different settings. This study sheds some light on these issues. For example, since a relatively high proportion of PMRs in remote rural areas of Kwale stocked AQ prior to the intervention,

this suggests that these were affordable at their current retail prices (if supply is assumed to reflect demand). Although fewer outlets stocked AQ in Kisii, a less remote area, this different pattern of supply could reflect easier access to free anti-malarials at government health clinics. It could therefore mean that ACTs subsidised to the level of existing OTC anti-malarial prices would be affordable. However, treatment seeking behaviour does not necessarily reflect true affordability, and the costs of these may impose severe, or even catastrophic, costs on families (Chuma et al., 2007).

5.5. Implications for future evaluations

This section addresses the implications of the study for future public health evaluation research. They are grouped into three categories: the importance of prospective studies in evaluating pubic health interventions especially for social marketing programmes, the value of systematic assessment of the implementation process and the use of GIS tools in evaluating coverage and potential utilisation of PMR programmes.

The choice of the evaluation design of any intervention is critical to the interpretation of outcomes (Kirkwood et al., 1997; Habicht et al., 1999; Rosi et al., 1999). Pragmatic designs which are planned prospectively provide an opportunity to maximise the likelihood of constructing comparisons groups similar to the intervention group. Such designs also provide an opportunity to examine previous evaluation in relevant programme area and include variables useful for statistical adjustments (Rosi et al., 1999).

This study has illustrated the difficulty of evaluating social marketing interventions retrospectively. This is because there are challenges of selecting contemporaneous control outlets making the intervention difficult to evaluate compared to the participatory training

approaches. This is linked to both the risk of contamination, since the approaches encompass wide dissemination of information, and to the difficulty in establishing whether exposure has taken place. Given these challenges in selecting comparable controls, the interpretation of outcomes is also difficult. The alternative way is to design a prospective study at the time of implementation to allow a before and after assessment using longitudinal controls (Habicht et al., 1999), to strengthen future evaluation of social marketing programmes.

The study illustrates the value of systematic assessment of the implementation process using policy analysis approaches. These include the application of stakeholder analysis to examine actor's role, behaviour, power balances and its influence on implementation process and outcome. In applying these frameworks, future work could address the current paucity of data on the role of implementation in evaluation work, which has predominantly focussed on epidemiological and descriptive research (Sanders and Haines, 2006).

Although there are other studies that have utilised GPS techniques for assessing coverage of other public health programmes (chapter one), this is the first study to utilise this technique to examining access of PMR programmes. It has provided a provisional benchmark for threshold distances for PMR use, and calls for studies in different settings to establish generalisability. Use of GPS techniques has also illustrated that potential utilisation was higher in remote rural settings than expected which, as explained in section 5.2 may plausibly have been related to population distribution. Therefore programmes utilising PMR as distribution channel for anti-malarial medicines are likely to continue to remain a potential way of improving access.

Finally, in the course of this evaluation, the study supports the need for further research around:

- The need to examine the sustained impact on PMR behaviour and the capacity of the national malaria control programmes to support such innovative initiatives in the long term and at large scale, especially in the context of a rapidly changing drug policies. This should include assessment of impact on health, as well as costs and cost effectiveness (Goodman et al., 2007a).
- The potential for outsourcing certain elements of the participatory based PMR training programmes to local NGOs when they are implemented at scale within government bureaucracies (Goodman et al., 2007a).
- With powerful tools such as GIS, further studies may provide useful insights on the extent in which PMR interventions reach different socio-economic groups (Goodman et al., 2007a).

5.6 Conclusions

This thesis addressed three broad areas: the impact of different programmes on PMR knowledge and practices; the geographic population coverage and utilisation of different PMR programmes; and the role of implementation processes and underlying factors in influencing outcomes observed.

Despite the limitations of the evaluation approach, use of multiple methods has generated lessons for future evaluation and practice of both PMR and wider public health interventions. The study has made several contributions to knowledge specific to PMR interventions and wider public health interventions. The evaluation shows that PMR training interventions operationalised through various institutions in the district level

settings at moderate scale are likely to impact on PMR knowledge and practices and lead to increased coverage of target populations by appropriate treatment. This can occur in diverse geographic and epidemiological settings with varied outcomes, often depending on implementation practice. The changing socio-economic and anti-malarial drug policy landscape and the dynamic retail sector indicate the need for adapting interventions to local realities including flexibility in design, and responsiveness to contextual features.

Overall, deliberate and careful management of the implementation including actors is key to successful uptake and impact at retailer level. This may include a strong and transparent management system for PMR interventions; managing financial resources and relationships between implementing actors; stable district leadership; and a consultative selection process for the core team. These factors are likely to improve coordination and support of implementation process. Finally, the study supports the need to assess implementation processes during the evaluation of public health programmes in addition to impact on behaviour or health. Use of policy analysis techniques may provide useful insights on such evaluations with informative policy implications.

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Appendices

Annex I: Summary of findings of District Demonstration Programme

Key indicators	Kwale			Busia			Makueni			All districts	
	I[a] n (%)	C[b] n (%)	P[c]	I[d] n (%)	C[e] n (%)	P[f]	I[g] n (%)	C[h] n (%)	P[i]	P[j]	OR[k]
Retailer practices											
Asked about age of user	31/77 (40.3%)	29/99 (29.9%)	0.128	46/69 (66.7%)	39/63 (61.9%)	0.568	87/124 (70.2%)	51/126 (40.5%)	<0.001	0.324	2.1 (1.3, 3.4)
Asked about danger signs	7/77 (9.1%)	7/99 (7.1%)	0.780	6/69 (8.7%)	4/63 (6.4%)	0.536	20/124 (16.1%)	0/126 (0%)	<0.001	0.065	5.7 (1.7, 19.4)
Recommended AQ with adequate advice on dose	**6/32 (18.8%)**	**1/42 (2.3%)**	**0.038**	**13/45 (28.9%)**	**6/36 (16.7%)**	**0.197**	**25/66 (37.8%)**	**0/57 (0%)**	**<0.001**	**0.014**	**3.8 (1.2, 11.7)**
Retailer knowledge											
Recommended AQ adequately	**21/43 (48.8%)**	**0/58 (0%)**	**1.000**	**18/47 (38.8%)**	**5/42 (11.9%)**	**0.005**	**68/83 (81.9%)**	**3/26 (11.5%)**	**<0.001**	**0.015**	**32.4 (8.6, 122.3)**
Recommended SP adequately	11/23 (47.8%)	14/32 (43.7%)	0.765	28/48 (58.3%)	18/41 (43.9%)	0.174	7/34 (20.6%)	20/45 (44.4%)	0.027	0.695	0.74 (0.4, 1.5)
Recommended AQ for one day	10/43 (23.3%)	34/58 (55.8%)	<0.001	10/47 (21.3%)	18/42 (42.9%)	0.029	0/83 (0%)	16/26 (61.5%)	<0.001	0.012	0.013 (0.001, 0.1)
Recommended SP for three days	11/23 (47.8%)	3/32 (9.4%)	0.002	8/48 (16.7%)	7/41 (17.1%)	0.959	17/34 (50.0%)	6/45 (13.3%)	<0.001	0.089	4.5 (1.7, 12.1)

Note: The annex summarizes study findings of three DDP sites. Makueni and Busia were part of the DDP districts that were examined alongside Kwale presented in chapter three. Data analyses for all districts were merged and a pooled cluster analysis was conducted using *clhi* commands in STATA using Generalized Linear Latent and Mixed Models (GLLAMM). The summary of key findings reflects both pooled analysis and district level analysis.

a = intervention area (Kinango and Matuga); b = control area (Msambweni and Samburu), c = P value for comparison of intervention and control in Kwale, d = Intervention area (Funyula); e = control area (Budalangi). f= P value for comparison of intervention and control in Busia, g= intervention areas (Kathonzweni and Makindu), h= control areas (Matiliku and Kalawa); i= P value for comparison of intervention and control in Makueni, j= P value for comparison of intervention and control across all the districts adjusted for clustering, k= odd ratios for differences between intervention and control areas for pooled data using Gllamm model

Note: Prints in bold are the key primary and secondary indicators

Annex II: Guide for coding adequateness

Adequate (AD) is defined as within the limits given by standard treatment guidelines for age. Evaluation of adequateness is based on the dosage charts used for the training, adapted from the National Guidelines for diagnosis, treatment and prevention of malaria for health workers, MoH, Kenya, January 1998.

For SP medicines:
High dose: (HD)-If the total amount of drug given is high (higher than recommended amount for age) coded as high dose.
Adequate dose-If the total amount given corresponds with the recommended amount for age then this will be coded as adequate dose. However, we will code SP use as adequate where the recommended amount is given within a 24-hour period. For example, this can mean the total recommended dose was divided within the same day or between an evening dose and a dose the following morning.
Low dose: (LD)-If the total amount of drug given is low, the treatment should be coded as low dose, regardless of how many days it was given over.

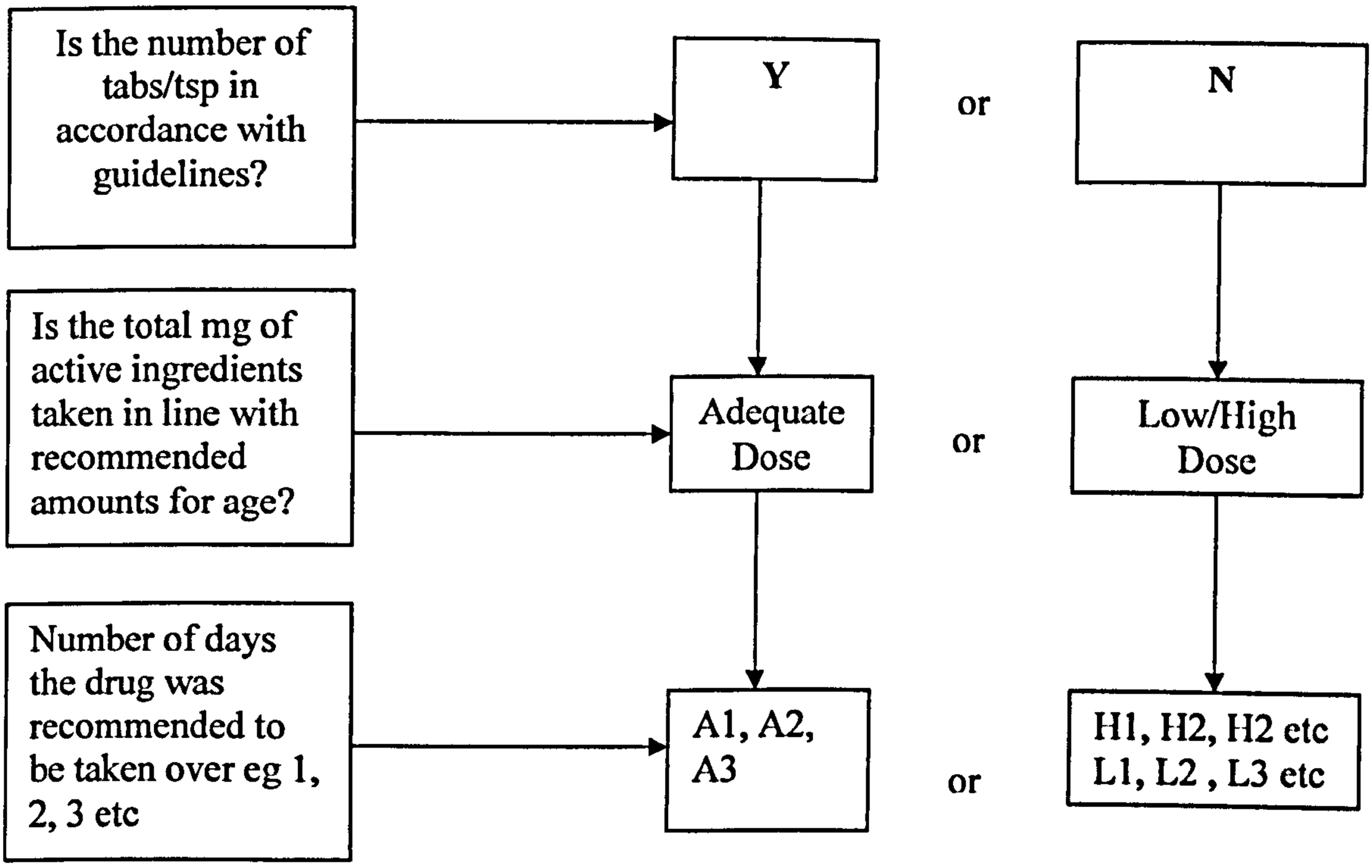
For AQ medicines:
High dose: (HD)-If the amount given overall corresponds to that recommended, but this is given in 1 or 2 days only, the regime should be coded as a high dose since the child will have received **over** the recommended **daily dose** on the days when the drug was administered. Overall, *if the total* amount of drug given is high, the treatment should be coded as a high dose regardless of how many *days it* was given
Adequate dose-If the total amount corresponds to that recommen*ded, and the* course of treatment has lasted 3 days.
Low dose- If the total amount of drug given is low, the treatment should be coded as low dose, regardless of how many days it was given over.
These codes will be followed by subsequent codes as shown in the table below.

Table 1: Additional codes describing the number of days drugs were taken

Codes	Description
A1	Adequate dose taken over 1 day (24 hour period)
A3	Adequate dose taken over 3 days continuously or with a break in between (for multi dose drugs)
H2	High dose taken over 2 days.
H1	High dose taken over 1 day
H3	High dose taken over 3 days continuously or with 1 day break in between
H4	High dose taken over 4 days continuously or with a break in between
L1	Low dose taken over 1 day
L2	Low dose taken over 2 days
L3	Low dose taken over 3 days continuously or with a single day's break in between
L4	Low dose taken over 4 days continuously or with a break in between

Note: this pattern may include drugs taken for several days upto 7 days or a week after, in which specific description will be given.

Figure: Schematic framework for assessing adequateness



Note: A1 and A3- Will be considered the "gold" standard of adequateness for single (SP) and multi dose drugs (AQ) respectively.

AMODIAQUINE TABS AND SYRUP
1 tab=200 mg amodiaquine base
5 ml = 50 mg amodiaqine base

Table 2: Dosage guide for AQ drugs

Age	Days given over	Total no tabs	Total in mg	Total no spoons syrup	
				tsp (5ml)	tbs (10ml)
< 6m	3	¾ - 1	150 – 200	3 – 4 ½	1½ - 2
6 – 11m	3	1¼ - 1¾	250 - 350	5 – 7 ½	2½ - 3½
12 – 47m (3y 11m)	3	2 – 2¼	400 - 450	7 ½ – 9 ½	4 – 5
48 – 71m (5y 11m)	3	2½ - 3½	500 - 700	10 – 14 ½	5 – 7
15 – 15y 11m	3	-	-	-	-
16 +	3	-	-	-	-

SP TABS AND SYRUP
1 tab=500mg sulphadoxine, 25 mg pyrimethamine
5 ml = 250 mg sulphadoxine, 12.5mg pyrimethamine

Table 3: Dosage guide for SP drugs

Age	**Days given over**	**Total no tabs**	**Total in mg***	**Total no spoons syrup**	
				tsp (5ml)	tbs (10ml)
<11m	1	½ - ¾	250 - 375	1 – 1½	½ - ¾
12 – 59 (4y 11m)	1	1 - 1 ¼	500 - 625	2 - 2 ½	1 - 1 ¼
5-8 years	1	1 ½ -1 ¾	750-875		
9-14 years	1	2-2 ¾	1000-1375		
15+	1	3	1500	-	-

*for sulpha component

CQ TABS AND SYRUP
1 tab=150mg base chloroquine, 5 ml=50mg chloroquine

Table 4: Dosage guide for CQ drugs

Age	Days given over	Total no tabs	Total in mg*	Total no spoons syrup tsp (5ml)	tbs (10ml)
< 6m	3	1 ¼ - 1 ¾	187.5-262.5	3 ½ - 4 ½	1 ¾ - 2 ¼
6 – 11m	3	2 – 2 ¼	300 – 337.5	5 – 7	2 ½ - 3 ½
12 – 47m (3y 11m)	3	2 ½ - 3	375 - 450	7 ½ - 9	3 ¾ - 4 ½
48 – 95 (7y 11m)	3	3 ¼ - 6	487.5 - 900	-	-
48 – 71 (5y 11m)	3	-	-	9 - 12	4 ½ - 6
15y – 15 y 11m	3	8 ½ - 9 ½	1275 - 1425	-	-
16 + y	3	10	1500	-	-

*Note that this is the total amount in 24 hrs, and will normally be given in 4 doses in a day e.g. 1 tsp x 4 per day -> total of 4 tsp/day

Annex III
Part I: Quantitative Tools

KEMRI/Wellcome Trust / DoMC Surrogate Client Survey

District: [ ][ ] Division: [___][___] Int/ Cont: [__] Replacement Y/ N [___].
Date of visit 1 (dd/mm) _____/_____/2006 Date of visit 2 __/ _____/ 2006
Decoy name _____ **Decoy code:** |___||___||___|

Shop name _____ **Outlet code** |___||___||___||___||___||___|

Location_____ Village /Market Centre_____

Shop status C / O: visit 1 [___] visit 2 [___] Sex of SK: F/M [__] Trained Y/N [__]

Ask if has malaria drugs. If yes, ask for malaria drugs for a child **(If asked questions, give responses in guide)**

1. Did the SK ask about any of the following? *Enter Y / N / M / R*

   Fever [___] Age [___] No. of days [___] Fits [___] Previous treatment [___]

   Weakness [___] Vomiting [__] Diarrhoea [___] Difficulty in breathing [__]

   NoSigns: [___]

2. Were any drugs sold during this visit?..... .....Y/N [__]

3. If no drugs sold, give SK's reasons:

   1 - no drugs in stock; 2 - no AM drugs in stock; 3 - no suitable drugs in stock; 4 - referred to clinic/chemist 5 - other. I*f not suitable or other, specify*..... [___]

Were AM drugs visible in shop? Y / N. If Y, give brand.....[___]

Note: If no AM drugs are available OR visible, replace outlet.....**code** |___||___||___|
If SK says no suitable AM drugs available, or says no AM drugs but you can see them in stock, do not replace outlet. Discuss with supervisor at review.

(Go to Q6 if no drugs sold) →

Where drugs were sold

Recommended drugs	**Drug 1**	**Drug 2**	**Drug 3**	**Codes**
Brand name				
Type of AM or AP sold				AM1: AM2: AP:
No. tabs/bottles of syrup bought				
Cost per tablet/ bottle of syrup				AM 1: AM 2:
Reason for recommending this type of AM drug				
How to use				AM1: AM2:
Reason for using AM drugs this way				AM1: AM2:

5. Type of drugs recommended and the way used

AM1 dose [__][__][__].[__] mg days [__] AM2 dose [__][__][__].[__]mg days [__] AM dose_days: [__][__]

6. If advised you to go clinic, what advice did the retailer give?

1 - go to clinic if signs persist; 2 - go to clinic now (drugs sold); 3 - go to clinic now (no drugs sold)

4 - other, specify ……[__]

Description of the outlet

Name
outside……
Colour of wall……
Posters on front. ……
Roof material……
Building on right……On left……

Comments (record any difficulties in finding shop, how SK treated you, if you thought s/he was suspicious of you and why, any additional information given or discussion with SK)

……
……

KEMRI/Wellcome Trust / DoMC: Retail Outlet Survey

To be completed for all outlets visited

1. District [B][G]..... 2. Division [_____]

3. Outlet name and ID.....[__][__]-[__|__|__]

4. Today's date (dd/mm).....[__|__]-[__|__] 2006

Type of outlet
1 - chemist owned and run; 2 - chemist owned, run by other; 3 - NGO/mission drug shop;
4 - community drug shop; 5 - general shop; 6 - other, specify.....[__]

6.Location.....[_____]

7. Market centre/ Village .....[_____]

8. Situation:
in large market centre; 2 – small market centre; 3 single outlet, not based in homestead;
4 – single outlet in homestead.....[__]

Outlet status:
1 - open/selling malaria drugs; 2 - open, no malaria drugs; 3 – temporarily closed;
4 - permanently closed; 6-no drugs at all; 7 –refusal; 8- other
specify.....[__]

Interview the main seller

Name of main seller...../...../.....

11.Trained?Y/N
.....[__]

Place and date of training ..... [__][__]/[__]
[__]/[__][__]

Age of main retailer (yrs).....[__][__]

Sex: F/M..... [__]

Education: .....Type [__] 1 – 844; 2 – old system Yrs .....[__][__]

Maximum number of people that ever serve customers in this shop at the same time?..... [__]

17 Types of drugs available for sale **today**: Circle Y/N

Malaria Y / N Fever/headache Y / N Diarrhoea.....Y / N
Cough/cold Y / N Worms Y / N Other Y / N
Specify Other 1 [_____] Other 2 [_____]

To be completed for all outlets selling AM medicines. If there are no AM drugs terminate the interview.

18. Types of malaria drugs currently in shop:

a. Brand name 1: [_____] Tablet/syrup [__].[__] Chemical type: [__][__]

b. Where drug obtained: **G**eneral wholesaler, **C**hemist, **M**obile vendor, **O**ther, specify……..[__]
Nearby market, **T** –nearby town centre, **A** –distant town centre……..……[__]
c. Wholesale price/unit: KS [__][__][__].[__][__] per
[_____]……..[__][__][__].[__][__]
d. Retail price/unit: KS [__][__][__].[__][__] per
[_____]……..[__][__][__].[__][__]
e. Storage conditions: 1-stored away from direct sunlight; 2- dry place 3- clean place……[__]
f. Indicate whether expiry date on packages is within this date……..…Y/N .. [__]

a. Brand name 1: [_____] Tablet/syrup [__].[__] Chemical type: [__][__]
b. Where drug obtained:
General wholesaler, **C**hemist, **M**obile vendor, **O**ther, specify……...[__]
Nearby market, **T** –nearby town centre, **A** –distant town centre……..……[__]
c. Wholesale price/unit: KS [__][__][__].[__][__] per
[_____]……..[__][__][__].[__][__]
d. Retail price/unit: KS [__][__][__].[__][__] per
[_____]……..[__][__][__].[__][__]
e. Storage conditions: 1-stored away from direct sunlight; 2- dry place 3- clean
place……..……..[__]
f. Indicate whether expiry date on packages is within this date……..…Y/N .. [__]

a. Brand name 1: [_____] Tablet/syrup [__].[__] Chemical type: [__][__]
b. Where drug obtained:
General wholesaler, **C**hemist, **M**obile vendor, **O**ther, specify……...[__]
Nearby market, **T** – nearby town centre, **A**–distant town centre……..……[__]
c. Wholesale price/unit: KS [__][__][__].[__][__] per
[_____]……..[__][__][__].[__][__]
d. Retail price/unit: KS [__][__][__].[__][__] per
[_____]……..[__][__][__].[__][__]
e. Storage conditions: 1-stored away from direct sunlight; 2- dry place 3- clean place..[__]
f. Indicate whether expiry date on packages is within this date…… ……..…Y/N .. [__]

19. List the brand names of fever/headache drugs currently in shop

1. [_____] 2. [_____]

3. [_____] 4. [_____]

20.If a customer asked you what medicines to buy for a 5-year-old child with a high fever, but no other symptoms, what would you recommend? *Probe types of drugs or other advice.*

……

Rec_drug: 1 –AMO, 2 –AMP, 3 –AMX, 4 –APO, 5 –APX, 6 – OTH, 7-advice
…….. .[__]

Rec_type: 1 – SP, 2 – AQ, 3 – CQ, 4 – SP/AQ, 5 – OT AM, 6 – AS, 7 – PA, 8 – BO, 9 – BR, 10 –other drug, 11- other advice…… ……..[__]

21. What would you recommend if the child did not get better after 2 days on this treatment, but was not worse? *Probe for types of drugs, or other advice*

……

……

Rec_drug: 1 – AMO, 2 – AMP, 3 – AMX, 4 – APO, 5 – APX, 6 – OTH, 7-advice .....[__]

Rec_type: 1 – SP, 2 – AQ, 3 – CQ, 4 – SP/AQ, 5 – OT AM, 6 – AS, 7 – PA, 8 – BO, 9 – BR, 10 –other drug, 11- other advice .....[__]

22. **Use of currently stocked drugs**: *How would you advise a customer to use malaria drugs that you stock for a 5-year old child?*

Note: if more than one brand of SP or AQ drugs in outlet, ask about brand most commonly sold

For SP drugs stocked: enter brand name .....[_____]

How many days to take? .....[__]

How much each day?	**Day 1**	**Day 2**	**Day 3**
Amount to take at a time (specify tab, tsp or tbs)			
No of times per day			

Total dose [__][__][__].[__] mg Summary dose [__][__] Dose_days [__][__]

For AQ drugs stocked: enter brand name .....[_____]

How many days to take?.....[__]

How much each day?	**Day 1**	**Day 2**	**Day 3**
Amount to take at a time (specify tab, tsp or tbs)			
No of times per day			

Total dose [__][__][__].[__] mg Summary dose [__][__] Dose_days [__][__]

Did seller use any reference charts for drug dosages? Y/N).....[__]

If Y, what type? 1 - Programme chart; 2 - DoMC calendar; 3 - Manufacturer chart;

4 Other specify .....[__]

25. **Referral**: *Are there any situations where you think a child with fever should be taken to a health worker* ***and not treated at home with shop bought drugs?*** Y/ N [__]

26.If Y describe the situation

.....[__]

27.Other shop products for malaria: Indicate if the following are present **today**:

Programme materials: (codes for a-c: 1- easily seen; 2 –not easily seen; 3 – not available)

a.Drug chart .....[__]

b.Referral chart .....[__]

c..Posters.....[__]

d. Leaflets (YN).....[__]

e.Booklets (Y/N).....[__]

f.Bed nets (Y/N) .....[__] Brand name... .....[__]

g.Insecticides for bed nets (Y/N) [__] Brand name.....[__]

h.Aerosol insecticides (Y/N).....[__] i. Coils Y/N..... .....[__]

j. Mosquito repellent body gels/creams (Y/N).....[__]

28. Training programme involved: 1 – VTV Programme with SP; 2 – VTV programme SP+ AQ 3-MOH training programme; 4- MOH and VTV SP; 5 MOH and VTV SP+ AQ 6; None 7; Other specify

.....[__]

Description of the outlet

Name outside.....
Colour of wall.....
Posters on front. .....
Roof material.....
Building on right.....On left.....

Comments (record any difficulties in finding shop, how SK treated you, if you thought s/he was suspicious of you and why, any additional information given or discussion with SK)

.....
.....
...

KEMRI/Wellcome Trust & Division of Malaria Control: Locating retail outlets

1. District [B]G].....2. Division [_____]

3. Location.....[_____]

4. Market Centre/Village.....[_____]

5. Outlet name..... .....

6. Shop owner .....ID..[__][__]-[__|__|__]

7. Date located (dd/mm).....[__|__]-[__|__] 2006

8. Trained ..Y/N...[__]... if Yes Date trained (dd/mm)..... [__|__]-[__|__]-[__|__]

9. Type of outlet

1 – chemist; 2 - NGO/mission drug shop; 3 - community drug shop; 4- Kiosk, 5 - general shop; 6 - other, specify.....[__]

10. Are there any anti malarial drugs in your shop today Y/N.....[__]

11.Maximum number of people that ever serve customers in this shop at the same time. .....[__]

12. Position:

	Reading 1	Reading 2	Reading 3
Latitude	[__]-[__|__]- [__|__|__|__|__]	[__]-[__|__]- [__|__|__|__|__]	[__]-[__|__]- [__|__|__|__|__]
Longitude	[__]-[__|__|__]- __|__|__|__|__]	[__]-[__|__|__]- [__|__|__|__|__]	[__]-[__|__|__] [__|__|__|__|__]

Comments:

.....

Part II: Qualitative Tools

FGDs guide for clients: Demographic data capture sheet

Date of discussion	Moderator
Venue	Note-taker
Time start	No. Participants at start
Time stop	No. Participants at stop

Ice breaker..... tell me about a little your general life experiences within this area

Understanding retailer-client interaction

Since you all come from around .....which is in .....division, may be we should start by discussing how do retailers in this area sell medicines?

(*Seek their views first, and then probe and dig for issues that might be relevant eg:*
Type of drugs retailers sells often why?
Cost of drugs
Process of interaction-how retailers behave while selling medicines
Perceived role of retailers as sources of care
Any problems encountered while buying medicines
Role of religious beliefs in sale of OTC medicines
Role of chemists: quacks, women empowerment, vendors

Perceived impact of programme on retailer practices

Have you noticed any changes in retailer practices recently? (if yes ...*what changes?)*
Do they ask questions
Do they refuse to sell/only certain drugs with information
Attitudes
Perceived impact on death rates
What do you think about these changes- problems/advantages
What do they attribute these changes to-if they say programme and why

If mixed reactions explore reasons why focus on: perceived causes of changes, why they think so if programme is not mentioned ... go on to ask .....

Views regarding programme activities and ownership

Are you aware of any training activities that involve retailers in this area? *If aware ask:*

What activities are they (elements of the programme)
Who is running the activities
Who is involved in these activities and what are their roles
What are their roles
How did they hear/become aware of these activities

Explore *their views/perception and knowledge of programme activities*
Perceived success or failure of these activities
Reasons behind these problems/success
Single out materials and/or public information activities:

Perceived role of materials/public information and appropriateness in local context
Have you come across materials used in this programme?
(Carry samples but show them after they have discussed it)

How did they come across them
What materials?
Are they suitable,
Other communication or channels used,
Views about these materials

Programme goals and appropriateness in local context
What do you think in general about this programme in comparisons with other approaches to treating/controlling malaria eg bed net, hospital care?

Is it a good idea?
Why do you say so?
What makes this such as good programme

If unaware: explain what the programme is all about and ask their opinion on whether it is a good idea.

For both negative and positive responses ask questions on problems and benefits

If negative response

Costs and benefits of programme

Are there specific problems that you haven't mentioned about the programme that makes you say so? What are they and why?
Costs associated with programme
Problems with retailers
Programme managers, others
Potential barriers to success

If positive response

What are the main benefits that are associated with the programme?
Successes as they view it?
Reasons behind success -why they think so, what contributes to it?
What in your view are the main barriers of success of such a programme?
Lack of public information
Costs of drug
Practices of retailers/clients
Others

FGDs guide for PMRs

Ice breaker.. tell me about the general lifestyle in this area: what people do, business activities etc

Understanding client-retailer interaction and coping mechanisms
Can you tell me more about your experiences while selling medicines to clients?
Problems with client's preferences in terms of type of drugs and reasons
Cost of drugs in relation to regime, other, access to drugs through vendors role of policy change in stocking patterns
Role of religious beliefs in OTC sale, drugs shops, free health care

How do you deal with it?
What do you do -*credit, advice, other,*
Reason behind all these mechanisms

Views regarding programme activities and perceived adequateness
What do you think about the training workshop, which you participated?
Who was organising it
How do you feel about it was it adequate?
Were your expectations met, why and how?
What materials were used, how useful?, why?
Other communication channel used in training, how, their view on this channel?

How did you get involved in this programme?
Knowledge,
Recognition
Monetary gain or other reasons
Has your involvement achieved your expectations?

Are you aware of other programme activities? *If aware:*
Specific elements- public information, monitoring and supervision
How did you know of them?
Who was involved?
Their views of whether a success or failure
Why/any problems

If unaware: Ask their views on the supportive environment/activities that will make this programme a success and why

Perceived impact of programme on their practices
Has the training influenced your daily practices?
How?-are main sellers same as trained sellers?
In what way-refuse to sell medicines to young children why?
Why do you say so?

Programme goals and appropriateness in local context
What do you think in general about this programme in comparisons with other approaches to treating/controlling malaria eg bed net, hospital care
Is it a good idea
why do you say so?
What makes this such as good programme?

Costs and benefits of programme

Ask the question on problems and benefits for both negative and positive responses
If negative response
Can you tell me about the problems you have experienced with the programme in general?
(Seek their views first, and then probe and dig for issues that might be relevant)

Barriers to practices –cost of drugs, profit motive
If any of these comes up then ask for more details why they think it is a problem
Their views on this or any other issue that comes up

If positive response.

Are there any benefits that are associated with the programme -successes as they view it?

Why they think so
What contributes to it
To whom does it benefit most)?

Closing debate a summary from above discussions: Overall; do they think this programme is a success or not for and against, reasons

FGD guide for mobile vendors:

Ice breaker.. tell me about the history of drug vending in this area: how it started, how it was before and after the active phase of programme, reason for such a number of vendors etc

Understanding initial programme activities involving vendors
Can you tell us more about the activities that you were involved in the VTV programme?
How were you involved- coerced, Knowledge, Recognition, Monetary gain or other reasons
Who was organising it
Has your involvement achieved your expectations? Why and how?
How were the activities organised: links with drug company, common drug store supporting structures from AMREF, MOH , refresher courses

Views regarding programme activities and perceived adequateness

What do you think about these programme activities which you participated?
How do you feel about it was it adequate?
What materials were used, how useful?, why?
Other communication channel used in training, how, their view on this channel?
Was this programme a success:- any evidence for success or failure?

Are you aware of other programme activities? *If aware:*
Specific elements- public information, monitoring and supervision
How did you know of them?
Who was involved?
Their views of whether a success or failure
Why/any problems

Understanding Vendor -retailer interaction and coping mechanisms

Can you tell me more about your experiences while selling medicines to retailers?
Problems with retailer's *preferences in terms of type of drugs and reasons*
Cost of drugs in relation to regime, other problems?
Role of chemists and the impact of their business
Current activities that vendors are involved in

How do you deal with it?
What do you do -c*redit, advice, other,*
Reason behind all these mechanisms

Perceived impact of programme on retailer practices

Has this programme influenced retailer practices?
How?- refuse to sell medicines to young children, stocking patterns, failure to pass information to retailers
How information can be sustained?

Programme goals and appropriateness in local context
What do you think in general about this programme in comparisons with other approaches to treating/controlling malaria eg bed net, hospital care
Is it a good or a bad idea ?
why do you say so?
What makes this such as good/bad programme?

Costs and benefits of programme
Ask the question on problems and benefits for both negative and positive responses

If negative response

Can you tell me about the problems you have experienced with the programme in general?
(Seek their views first, and then probe and dig for issues that might be relevant)
Barriers to practices –cost of drugs, profit motive
If any of these comes up then ask for more details why they think it is a problem
Their views on this or any other issue that comes up

If positive response.

Are there any benefits that are associated with the programme -successes as they view it?

Why they think so
What contributes to it
To whom does it benefit most)?

Views regarding the CBO formation and it prospects

Can you tell us briefly more about the CBO that you have formed?
How did the idea come about?
Who are the members: criteria for membership, mechanism of operation, why others fell out?
What is the role of the CBO?
What was the process of registration
How about sustainability? How do you perceive that you will maintain goals?
Role of AMREF/MOH in this process
Why have didn't the MOH take up the supportive role and continue with programme activities
How do you perceive the future of this programme?

Closing debate a summary from above discussions: Overall; do they think this programme is a success or not for and against, reasons

In depth guide for trainers and co-trainers

Ice breaker.. tell me about your experiences in this division perhaps in terms of your role in various activities that you been involved in

If main trainer: *tell me about your experiences in this division how long have you worked here, you like it.....why*

Role of actor in implementation of training programme
I understand that you are a co-trainer/trainer in the retailer training in this district. What was/is your role as a co-trainer/trainer?

How do you feel about it?
Have you experienced any problems in fulfilling this role-what and why?
What has helped you fulfil these roles?

How did you got involved in this programme
Why you in particular?
For what reasons-part of your job, recognition, monetary gain, other
Has your involvement achieved your expectations?

Can you tell us about your induction into the programme?
How were you trained –workshops/on the job
Was it relevant to programme?

What other activities have you been involved in, in this programme?
Was it part of your roles or was it additional?, why and how did you get involved,
Have you experienced any constrains in these activities -what and why, ...if not .
What has helped you conduct them successfully?

Who else have been involved with the programme in this district?
What was their role in specific activities?
How did they get involved, why?

Besides the training programme, do you have other roles, which involves interaction with retailers?
What do you think about these roles?
Do they hinder your interaction with them in this programme? How and why?

How do you manage programme activities with other district roles?

Views about programme activities and materials used
Tell me more about mobilisation activities prior to the training of retailer
How was it done?
Who was involved?

What do you think about the training/programme activities that you conducted with retailers
What style of teaching, why,
Own views on effectiveness,
Any problems?
Means of invitation,
Selection process?

Can you share with us your experience with materials which you used in the training/programme?
What do you think about them?
Whose role was it to produce, distribute them
When and how were they distributed?
Were they suitable?
Any problems with materials? Why- show samples: drug chart, referral chart, booklet, poster)

Support and supervisory activities
Have you ever received supervision/guidance in the programme activities? if yes
Who supervised them? when, for what, how, your views about it, was it helpful, how why do you say so?
Were there any problems associated with this supervision? Which ones If not *why, whose role is it?)*

Have you been involved in any supervisory activities/monitoring of retailers? if yes
When, how –did you use any tools, your views about it-any problems associated with it/ any success if not *-why whose role is it?)*

If relevant: if they don't mention any of the following (*retailers and co-trainers induction, public information, monitoring and supervision- ask whether it happened in their context (details-if did not happen- why it didn't happen, whose role was it?)*

Understanding of programme goals

What do you think in general about this programme in comparisons with other approaches to treating malaria –is it a good idea? why do you say so?
What are your views on programme goals and relevance)

Ask the question of problems and benefits for both negative and positive responses

If negative response

Factors affecting implementation process
What sorts of problems did you and others in the district experience in implementing this programme? (Seek their views first, and then probe and dig for issues that might be relevant such as: *Financial-arrangement, returns, incentives/remuneration; Retailers-attitudes and behavior) if* any of these comes up then ask for more details why they think that happened-their views on this or any other issue that comes up and any other problems they have faced)

If positive response

What are the main successes of programme as you see it? What makes this such as good programme (*probe and dig-why they think so, what contributes to it, are there ways this could be improved?)*

Process of implementation

How would you describe how this programme was implemented?
Weakness,
Chronology of activities?
Activities planned and not implemented?

Would you kindly take us through the organizational structure of this programme?
What is your view on the organizational structure for this programme?
Is it a good arrangement? Why?

Tell us about the financial arrangement of this programme?
How does this compare with other programs? why

If you were given a chance again how you implement this programme?
A*sk if different from what they did why was it different and the advantages of this approach*

Does this programme link up with other district programmes/departments/organizations within district? How? any success and failures with such linkages?
What challenges you have experienced in coordinating this programme,

Resources used
Changes required

What is the role of TOTs in the integration of this programme within the MOH?

Linkages and activities of AMREF

What is the future of this programme in he light of the changing drug polices?

Who were the main partners in this BDMI and what were their roles?

What are the current programme activities in the AMREF programme?

Other follow up questions

According to the reports the collaborating agencies had the challenge of implementing the activities and keeping in touch with schedules of activities?

Why is it that MOH/DHMT has not been able to sustain and take up by the approach as key in the district?

What is the role of operational research in the programme?

What are the other organisations that are in Bungoma district and what are their activities?

Interview guide for Managers

Ice breaker ... tell me about a little your experience in the district

I understand that you have overall responsibility in co-ordinating district/AMREF programme activities in Bungoma. What are some of the success and weaknesses of this programme?
Broader achievements of programmes and failures
Any concrete evidence/experiences

What was/is your role in this programme?
Managing-finance, supervision, training, induction, core team member
Have you experienced any problems in fulfilling these roles-what and why?
What are the facilitating factors that have helped achieve these roles -why?)

Tell me about the financial arrangement of this programme? Is it different with other programmes?
How much money was obligated why? Not all
What was the process of releasing the fund?

Who are the main partners in this programme and what was their role?
What were the roles of collaborating agencies: challenges of implementing programme activities, control of programme activities
Role of research activities at baseline? Number and expensive etc
What are the current AMREF programmes

Who else was involved and what was their role in this programme
What activities were they involved in? - Production of materials, retailers and co-trainers induction, training, public information, monitoring and supervision.
Did they experience any problems in carrying out these activities?
Are there any factors that enabled them carry out their roles with ease? why and how,
Any major issues encountered that were brought to you attention?.

If relevant: if they don't mention any of the above activities; ask whether it happened in their context (*if did not happen- why it didn't happen, whose role was it, any future plans regarding these activities?)*

Could you kindly tell me about activities that were planned for the VTV/retailer-training programme?
What was planned?
What activities were implemented and which ones were not? Reasons?

Single out planning training/materials - core elements of programme;
What do you think about these aspects of the programme?
Were you fully involved in planning? If no why how do you feel about it?
Why was there sudden shift of focus to workshop approach

Who was involved in actual training of retailers? Can you tell me more about this activity
What was his role, what materials were used,
What problems were experienced?
Has this training changed retailer's practices-how?

Have you been involved in any supervisory activities of programme activities?
What was your actual role?
How did you find it?
Any problems you experienced, were there any facilitating factors?

In understand you play crucial role in coordination of programme activities either within or outside district?
Within/outside: what was your actual role? How did you find it?

Any problems you experienced, what enabled you coordinate with ease?
Were there any unrealistic expectations from various people in the programme?
Any other people involved in coordination?
What was their role: check for mechanisms of communication with trainers, national office.

Handing over the programme to CBO

I understand the vendors have set up a CBO: When did this start and reasons for this?
What are the mechanism of operation number at handing over and why others fell out
How does this model differ from other experiences?

Why is that the MOH/DHMT has not been able to sustain and take up by the approach as key in the district.

AMREF functioning and its impacts
How does AMREF carry out its functions within local contexts?

Do you think there is something in the functioning of this district management before/during and/or after AMREF withdrawal that helps explain lack of sustainability?

What factors would you cite that may have influenced implementation and sustainability of the programme?

What do you think in general about this programme in comparisons with other approaches to treating/controlling malaria eg bed net, hospital care (*is it a good idea? why do you say so? Do you think it is relevant in this setting?).*

Ask the question of problems and benefits for both negative and positive responses

If negative response

Are there specific problems that you haven't mentioned in implementing this programme that makes you say so? For each of the problems:
How did you became aware of them,
Who was involved, how was it resolved -Seek their views first, if they haven't mentioned them before; probe and dig for issues that might be relevant eg: financial problems- access, adequacy, process, remuneration, other partners ,national office/donors, staff changes, adjustments and expectations
if any of these comes up then ask for more details why they think that happened-their views on this or any other issue that comes up.

If positive response

What are the main successes of programme as you see it? What makes this such as good programme (*probe and dig-why they think so, what contributes to it-check for issues above, who is the greatest beneficiary of this programme -What sort of benefits why? and any other).*

Could you tell us about the organisational structure of the programme? (*Is it good arrangement? Why is it so? Give a chance to implement this how would implement it?)*

In you view do you think this programme has been a success or failure?
Reasons to back responses

What are the potential barriers to the success of such a programme?

Do you think that AMREF/ MERLIN/DHMT plans to continue with this programme?
Why how? Is it a programme that is fit/feasible within the district level activities and among donors and other partners

How would you explain the relationship between the district/AMREF/ MERLIN and national level office?
Have you received support from the national office?
If no why do you think so?
If yes what kind of support?

Does this programme link up with other district programmes/departments/organizations within district?
What is the nature of linkages?
Resources, coordination, technical, other?
For what reasons were these linkages established.
What are the benefits and failures of such linkages?

Could you tell me how you perceive the future of this programme within the AMREF/MERLIN programme?
Nature of integration with the MOH programmes
Sustainability and the relationship with MOH-co-trainers

What are your views regarding the strategic policy direction in the role of retail sector in malaria control I the light of ACT?

Finally, could you describe the chronology of events that have implemented in the retailer-training programme?

PART III: Consent forms: Retail Audit information sheet

Introduction

My name is .....and I work for KEMRI GGMRC in Kilifi. KEMRI is carrying out surveys in shops that sell medicines in several districts in Kenya to collect information about medicines sold over-the-counter. This information is being used to develop programmes to help retailers and their customers get better information on commonly used over-the-counter medicines.

Who is being asked to join in the survey?

A few shopkeepers have been trained in _____, and we are asking the main seller/trained seller from each of these shops to participate in the survey.

What are we requesting from you?

If you agree to participate, i would like to interview you on medicines commonly stocked and sold over the counter. This interview will take approximately 20-30 minutes, however, each time a customer comes, you will attend to him/her first. I will also like to let you know that participation in this survey is voluntary.

Are there any risks or benefits of being involved in the study?

Apart from the time spent now, there are no disadvantages or direct benefits to you from participating in this survey. However, the information we collect will help medicine retailers and people living in Bungoma in developing and strengthening MOH and AMREF programmes on sale of over the counter anti malarial medicines.

Confidentiality

Once we have interviewed you, the information collected in this form will be stored in a locked office until it is entered into a computer in Kilifi. The computer files will only accessible to people working for KEMRI in Kilifi who are involved in this survey. Once the survey is ended, we will compile a report for the MOH in Bungoma and Nairobi. This report will not contain any names or specific locations of people or of shops included, except the divisions involved in the survey. The information will not be used in any way that could threaten your business.

Do you have any questions or concerns regarding the information I have given you?

Do you agree to participate in this survey? Y/N

GPS survey information sheet

Introduction

My name is .....and I am working for KEMRI GGMRC in Kilifi. KEMRI is carrying out a survey in this division, which will attempt to locate all shops and collect information about their geographical position. This information is being used to estimate coverage of a ministry of health programme that involves training of retailers in this division.

Who is being asked to join in the survey?

We are visiting all outlets in this division whether trained or not and we are requesting all retailers who sell in these shops to participate in the survey.

What are we requesting from you?

If you agree to participate, i would like to ask you a few questions regarding ownership of the shop, whether you have attended any training on anti malarial medicines and whether you have any anti malarial drugs in stock. This interview will take approximately 10 minutes, however, each time a customer comes, you will attend to him/her first. I will also take readings of the position of this outlet using this hand held machine. Finally I would like you to know that participation in this survey is voluntary.

Are there any risks or benefits of being involved in the study?

Apart from the time spent now, there are no disadvantages or direct benefits to you from participating in this survey. However, the information we collect will help the ministry of health strengthen the programme and estimate coverage.

Confidentiality

Once we have interviewed you, the information collected in this form will be stored in a locked office until it is entered into a computer in Kilifi. The computer files will only accessible to people working for KEMRI in Kilifi who are involved in this survey. Once the survey is ended, we will compile a report for the MOH in this district and Nairobi. The information will not be used in any way to harm your business.

Do you have any questions or concerns regarding the information I have given you?

Do you agree to participate in this survey? Y/N

Community member's information sheet and consent form for FGDs

Introduction
Welcome, my name is _____ and I work for KEMRI CGMRC in Kilifi. KEMRI is holding interviews and discussions with community members in several districts in Kenya on medicines sold over-the-counter. This information is being used to develop programmes to help retailers and their customers get better information on commonly used over-the-counter medicines.

Who is being asked to join in the discussions?
We have decided to hold discussions with different members of the community based on gender, level of education and age.

What are we requesting from you?
If you agree to participate, the discussion will take one to one and a half hours. During the discussion, one of us will ask questions as the other takes notes. We will also record the discussion so that we do not miss out on anything we have talked about today. At the end of the discussion, we will record your age and years of education. It is upon you to choose whether you want to participate in the discussion or not. You should also feel free to withdraw from the discussion at any point. Everyone's participation is very important and I would like you all to feel comfortable to give your opinions throughout the discussion. Please remember, there are no right or wrong answers.

Are there any risks or benefits of being involved in the study?
Apart from the time spent now, there are no disadvantages to you for participating in the discussion. However, the information we collect will help medicine retailers and people living in Makueni generally in future through MOH programmes to get better information to retailers and their customers on shop-bought drugs.

Confidentiality
We will not record participant's names during note taking and will instead assign numbers to individuals that will be matched against their responses. Notes from the discussion will be stored in a locked office and later entered into a computer. The computer files will only be accessible to people working for KEMRI in Kilifi who are involved in this study. At the end of the discussions, we will compile a report for the MOH in Makueni and Nairobi. This report will not contain any names or specific locations of people but only the divisions in which the discussions were conducted.

Group consent
Are you willing to participate in this discussion as a group? Y/N /___/
If you agree to participate, you are requested on behalf of the group, to sign in the space below as a sign of having understood the purpose and content of the discussion.
I _____have signed on behalf of the group to confirm that sufficient information regarding the discussion has been given and that we have willingly accepted to take part in this discussion.

Signature Date: Name of witness Signature

Date:

PMRs FGDs consent form

Introduction
My name is and I work for KEMRI GGMRC in Kilifi. KEMRI is carrying out interviews in several districts in Kenya in shops that sell medicines and were involved in the shopkeeper training. We intend to collect information about medicines sold over-the-counter, and your views on the training and the shopkeepers' programme as a whole.

Who is being asked to join in the interviews?
We have chosen the names of 9 shops from a list of all those selling medicines in Makueni district. The main sellers in these shops have been chosen based on gender, age and level of education and requested to participate in the interviews.

What are we requesting from you?
If you agree to participate, the interview will take approximately one hour. It is your choice to participate or not to.

Are there any risks or benefits of being involved in the study?
Apart from the time spent now, there are no disadvantages or direct benefits to you for participating in this interview. However, the information we collect will help medicine retailers and people living in Makueni generally in the future through MOH programmes to get better information to retailers and their customers on shop-bought drugs.

Confidentiality
Notes from the interview will be stored in a locked office and later entered into a computer. The computer files will only be accessible to people working for KEMRI in Kilifi who are involved in this study. At the end of the interview, we will compile a report for the MOH in Makueni and Nairobi. This report will not contain any names or specific locations of people or shops involved in the interview, but only the divisions in which the shops involved are located. The information will not be used in any way that could endanger your business.

Group consent
Are you willing to participate in this discussion? **Y/N /___/**

If you agree to participate, you are requested on behalf of the group, to sign in the space below as a sign of having understood the purpose and content of the discussion.

I _____have signed on behalf of the group to confirm that sufficient information regarding the discussion has been given and that we have willingly accepted to take part in this discussion.

Signature Date:

Name of witness Signature

Date:

Trainers' /Managers interview information sheet

Introduction
My name is and I work for KEMRI GGMRC in Kilifi. KEMRI is carrying out interviews in several districts in Kenya in shops that sell medicines and were involved in the shopkeeper training. We intend to collect information about medicines sold over-the-counter, and your views on the training and the shopkeepers' programme as a whole.

Who is being asked to join in the interviews?
We are holding discussions with community members, trained retailers, trainers like you and programme managers to find out their perceptions about the retailer training and other aspects of the programme.

What are we requesting from you?
If you agree to participate, the interview will take approximately one hour. It is your choice to participate or not to.

Are there any risks or benefits of being involved in the study?
Apart from the time spent now, there are no disadvantages or direct benefits to you for participating in this interview. However, the information we collect will help medicine retailers and people living in his area generally in the future through MOH programmes to get better information to retailers and their customers on shop-bought drugs.

Confidentiality
Notes from the interview will be stored in a locked office and later entered into a computer. The computer files will only be accessible to people working for KEMRI in Kilifi who are involved in this study. At the end of the interview, we will compile a report for the MOH in the districts and Nairobi. This report will not contain any names or specific locations of people or shops involved in the interview, but only the divisions in which the shops involved are located. The information will not be used in any way that could endanger your business.

Individual consent
Are you willing to participate in this discussion? **Y/N /___/**

If you agree to participate, you are requested to sign in the space below as a sign of having understood the purpose and content of the discussion.

I _____ have hereby signed to confirm that sufficient information regarding the discussion has been given and that I have willingly accepted to take part in this interview.

Signature Date: