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**An Economic Analysis of the Retail Market for
Fever and Malaria Treatment in Rural Tanzania**

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ABSTRACT

In low income countries the majority of health care is sought in the private sector, often through drug retailers, but little information is available on retail competition and regulation. This thesis addresses this gap, in the context of the market for fever and malaria treatment in rural Tanzania, investigating how market structure, provider conduct, regulation and consumer demand influence treatment outcomes.

Data were collected in three districts, where the main treatment providers were public and private health facilities, drug stores and general shops. Following a census of retailers, data on supply were collected from facilities and shops through in-depth interviews, a structured survey, and retail audits. Data on demand were collected through a household survey. Analysis focused on retailers, supplemented by data on facility services and consumer demand, where this was central to an understanding of retailer behaviour.

Retailers were an important source of fever/malaria treatment, with the majority of retail antimalarial sales occurring through drug stores. Retail providers increased the accessibility, range and reliability of drug stocks, but several market failures were evident. Market concentration was high, price competition was weak, information on treatment quality was poor, and negative externalities arose from inappropriate drug use. These failures contributed to low antimalarial coverage, use of ineffective antimalarials, under-dosing, and inequitable access to quality care. Government failures were also evident, in the form of poor quality public sector treatment, and inadequately implemented regulation.

To optimise the planned introduction of antimalarial combination therapy, public facility care must be improved. However, facility-only provision will not improve treatment for the majority of fever/malaria visits, which are likely to remain to shops. Implications for widening combination therapy provision to the retail sector are outlined, including the selection of appropriate retailers, maintenance of affordable prices, effective communication with consumers and providers, and a constructive role for regulation.

TABLE OF CONTENTS

Abstract	1
Table of Contents	2
List of Boxes, Tables and Figures	8
Abbreviations	12
Acknowledgments	14
Part I : Background to the Thesis	
Chapter 1 : Introduction	15
1.1 The Role of the Private Sector	15
1.2 The Malaria Disease Burden	16
1.3 Thesis Outline	17
Chapter 2 : Review of the Literature on Fever and Malaria Treatment and the Retail Sector in Sub-Saharan Africa	19
2.1 Introduction	19
2.2 The Demand for Fever and Malaria Treatment	19
2.2.1 Methods for Studying Household Demand	19
2.2.2 Choosing Providers	20
2.2.3 Drugs Obtained	23
2.2.4 The Determinants of Consumer Demand	24
2.3 Retail Supply	30
2.3.1 The Range of Providers	30
2.3.2 Methods for Studying Retail Providers	30
2.3.3 Provider Characteristics	31
2.3.4 The Determinants of Provider Behaviour	33
2.3.5 Retail Regulation	34
2.4 Retail Sector Interventions	35
2.5 Summary and Limitations of the Literature	36

Chapter 3 : A Review of the Economic Literature on Markets and Competition	39
3.1 Introduction	39
3.2 The Structure-Conduct-Performance (SCP) Paradigm and Standard	39
Models of Competition	
3.3 Defining the Market	43
3.3.1 Defining the Product	44
3.3.2 Defining the Geographical Area	44
3.4 Economic Theory and Market Structure	46
3.4.1 Market Concentration	47
3.4.2 Information Characteristics of Products	48
3.4.3 Barriers to Entry and Exit	50
3.4.4 Regulation	51
3.5 Economic Theory and Provider Conduct	52
3.5.1 Price Setting	52
3.5.2 Product Differentiation	53
3.5.3 Imperfect Agency and Demand Inducement	55
3.5.4 Strategies to Increase Market Concentration	55
3.5.5 Provider Collusion and Restrictive Practices	56
3.5.6 Influencing the Design and Implementation of Regulation	57
3.6 Evidence on Competition in Health Care, Pharmaceutical and Retail Markets	57
3.6.1 Competition in Health Care Markets	57
3.6.2 Competition in Pharmaceutical Markets	59
3.6.3 Competition in African Retail Markets	61
3.7 Conclusion	64
Chapter 4 : Tanzania and its Policies on Malaria and Pharmaceutical Regulation	65
4.1 The Tanzanian Economy	65
4.2 Malaria and its Treatment	66
4.3 Pharmaceutical Regulation	67
PART II : Methodology	
Chapter 5 : Study Design and Methods	69
5.1 Introduction	69
5.2 Study Design	69
5.2.1 Aims and Objectives	69

5.2.2 Conceptual Framework	70
5.2.3 Defining the Scope of the Study	72
5.3 Study Sites	73
5.3.1 Study Site Selection	73
5.3.2 Characteristics of the Study Districts	74
5.3.3 Areas under Demographic Surveillance	76
5.4 Methods for Data Collection and Analysis	77
5.4.1 Overview of Data Collection	77
5.4.2 Ethical Clearance and Informed Consent	79
5.4.3 Household Survey	80
5.4.4 Outlet Censuses	84
5.4.5 Semi-Structured Qualitative Provider Interviews	85
5.4.6 Outlet Survey	88
5.4.7 Antimalarial Retail Audits	91
5.4.8 Quantitative Data Entry and Analysis	94
5.4.9 Timing of Data Collection Activities	96
5.5 Summary and Plan of Analysis	97

Part III : Results

Chapter 6 : Fever/Malaria Treatment Obtained	98
6.1 Introduction	98
6.2 Characteristics of Households and the Prevalence of Fever/Malaria	99
6.3 Providers Stocking Drugs	100
6.4 Choice of Fever/Malaria Treatment Provider	102
6.5 Antimalarial Drug Volumes and Values	105
6.6 Appropriateness of Care Obtained	107
6.6.1 Speed of Treatment Seeking	107
6.6.2 Drugs and Doses Obtained	108
6.6.3 Antimalarial Tablet Packaging and Labelling	116
6.6.4 Antimalarial Drug Quality	118
6.6.5 Assessing the Appropriateness of Total Antimalarial Drug Volumes	118
6.7 Comparison of DSS areas	120
6.8 Summary and Conclusions	120

Chapter 7 : Market Structure	122
7.1 Introduction	122
7.2 Market Definition	124
7.2.1 Product Definition	124
7.2.2 Geographical Definition	125
7.3 Market Concentration	128
7.3.1 Concentration by Provider	128
7.3.2 Concentration by Product	130
7.4 Barriers to Entry and Exit	131
7.4.1 Providers' Perceptions of Entry and Exit Barriers	132
7.4.2 Turnover of retail outlets	133
7.5 Market Structure among Wholesale Suppliers	135
7.6 Summary and Conclusions	138
Chapter 8 : Product Differentiation and Non-price Competition	139
8.1 Introduction	139
8.2 Product Range and Reliability	140
8.2.1 Drug Product Range	140
8.2.2 Stock Reliability	144
8.2.3 Perceived Drug Quality	146
8.2.4 Availability of Injections and Confirmed Diagnosis	147
8.3 Staff Expertise	148
8.4 Convenience	152
8.5 Strategies to Increase Affordability	154
8.6 Consumer Relations	155
8.7 Summarising Non-Price Characteristics by Outlet Type	155
Chapter 9 : Pricing and Price Competition	158
9.1 Introduction	158
9.2 Reporting Price Data	159
9.3 Average Prices by Provider Type	160
9.4 Price Setting in the Retail Sector	163
9.5 Price Markups in the Retail Sector	164
9.6 Retail Price Variation	168
9.7 Regression Analysis of Retail Prices	170
9.8 Summary and Conclusions	173

Chapter 10 : Retail Regulation	174
10.1 Introduction	174
10.2 Business Licences	175
10.3 Health-Related Regulation	176
10.4 Explaining Infringements of Pharmaceutical Regulation	179
10.5 Summary and Conclusions	183
Part IV: Discussion, Policy Implications and Conclusions	
Chapter 11 : Methodological Strengths and Limitations	185
11.1 Introduction	185
11.2 Insights from the Conceptual Framework	185
11.3 Data Collection Strengths	186
11.4 Reliability and Validity Concerns	187
11.5 Data Gaps	191
11.6 Key Methodological Challenges	191
11.6.1 Market Definitions	192
11.6.2 Homogeneity of Study Areas	192
11.6.3 Analysing a Changing Market	192
11.7 Conclusions	195
Chapter 12 : Discussion	196
12.1 Introduction	196
12.2 The Relative Roles of Retailers and Facilities	196
12.3 Comparison with the Literature on Fever/Malaria Treatment	197
12.4 The Nature of Competition	200
12.4.1 How Competitive is the Market for Fever/Malaria Treatment?	200
12.4.2 The Relevance of Models of Monopolistic and Oligopolistic Competition	202
12.4.3 Competition and Treatment Accessibility	205
12.4.4 Competition and Treatment Quality	205
12.4.5 Competition and Affordability	208
12.5 The Nature of Regulation	209
12.6 Summary and Conclusions	212

Chapter 13: Policy Implications	214
13.1 Introduction	214
13.2 Applicability of Analysis to the Tanzanian Policy Context	214
13.3 ACT Delivery Models	217
13.4 Implications for Facility-only ACT Provision	219
13.4.1 Government Facility Quality and Utilisation	219
13.4.2 Non-ACT Treatment in the Retail Sector	221
13.5 Implications for Retail Sector ACT Distribution	224
13.5.1 Choice of Retailers for ACT Distribution	225
13.5.2 Retail Pricing	227
13.5.3 Training and Communications	228
13.5.4 Retail Regulation	231
13.6 Summary and Conclusions	232
Chapter 14 : Conclusions	234
14.1 Policy Context	234
14.2 New Knowledge	234
14.3 Policy Implications	236
14.4 Research Priorities	237
14.4.1 Analysing Markets in Other Settings	237
14.4.2 Further Investigation of Drug Prices, Drug Quality and the Distribution Chain	237
14.4.3 Documenting the Impact of ACT Introduction	238
14.4.4 Evaluation of Retail Sector Interventions	239
14.5 Final Conclusions	240
References	241
Annex 1 : Appendix of Tables and Figures	262
Annex 2 : Framework for Potential Determinants of Household Demand and Retail Provider Supply	280
Annex 3 : The IMPACT-TZ Evaluation	283
Annex 4 : Data Collection Instruments	285
Annex 5 : Construction of an Index of Household Socio-Economic Status	345
Annex 6 : Calculation of Antimalarial Sales Volumes and Values	349

List of Boxes, Tables and Figures

Boxes

Box 3.1 Models of Oligopoly	41
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Tables

Table 5.1 Summary of data collection activities	79
Table 5.2 Household survey interviews completed	82
Table 5.3 Semi-structured qualitative provider interviews: Characteristics of interviewees and their outlets	87
Table 5.4 Outlet survey sample size and outlets interviewed	90
Table 5.5 Characteristics of outlet survey interviewees and outlets	90
Table 5.6 Antimalarial to retail audit sample size and outlets interviewed	93
Table 5.7 Timing of data collection activities	96
Table 6.1 Sources of treatment for individuals reporting fever/malaria episode	102
Table 6.2 Variation in choice of provider by household and patient characteristics	104
Table 6.3 Speed of treatment seeking: all visits and first visits to outlets taking place within 24 hours of symptom onset	107
Table 6.4 Drugs obtained by patients for fever/malaria treatment	109
Table 6.5 Drugs obtained during provider visits	110
Table 6.6 Appropriateness of treatment obtained per episode: variation by household and patient characteristics	114
Table 6.7 Definition of variables for logit models of the probability of patient with fever/malaria obtaining an antimalarial and a minimum dose of an antimalarial	115
Table 6.8 Logit regression of probability of obtaining an antimalarial	115
Table 6.9 Logit regression of probability of obtaining at least a minimum dose of an antimalarial	116
Table 6.10 Percentage of antimalarial tablet sales volumes and values packaged	117
Table 6.11 Number of SP samples containing an insufficient quantity of active ingredient	119
Table 7.1 Proportion of provider visits taking place outside the careseeker's own village, ward, sub-market and DSS area by outlet type	126
Table 7.2 Provider visits outside caretaker's own sub-market (by sub-market)	127
Table 7.3 Concentration measures by sub-market	129

Table 7.4 Number of antimalarial products identified across all DSS areas	131
Table 7.5 Turnover of commercial drug shops and general retailers stocking drugs between mid-2000 and mid-2001	133
Table 7.6 Type and location of retailers' wholesale sources for drug supplies	136
Table 8.1 Number of antimalarial products stocked per outlet	141
Table 8.2 Characteristics of general shops stocking antimalarials	143
Table 8.3 Reported reasons why chloroquine and SP were not stocked by general retailers	144
Table 8.4 Outlets reporting stockouts of tablet products in the previous month	145
Table 8.5 Proportion of drugs stocked having characteristics argued to be associated with high quality	146
Table 8.6 Reasons for lack of microscopy in public and private facilities	148
Table 8.7 Qualifications of staff who regularly served customers	151
Table 8.8 Knowledge of antimalarial doses for a two-year-old by interviewees in shops stocking chloroquine and/or SP tablets	152
Table 8.9 Travel time to nearest outlet of each type reported by household heads	152
Table 8.10 Time spent at outlet to obtain treatment during provider visits for fever/malaria (excluding travel time)	153
Table 8.11 Opening hours of providers	154
Table 9.1 Antimalarial and painkiller prices by outlet type (Tsh)	161
Table 9.2 Fee charging policies reported by facility staff	162
Table 9.3 Facility fees paid by patients reporting fever/malaria	163
Table 9.4 Average total markups in shops (median shop retail price over median IRP)	165
Table 9.5 Average retail markups over wholesale drug costs in shops	167
Table 9.6 Price dispersion for antimalarial tablets in drug shops	169
Table 9.7 Definition of variables for model of the price of antimalarial and painkiller tablets in shops	171
Table 9.8 OLS log-lin regression of antimalarial and painkiller tablet prices for shops	172
Table 10.1 Infringement of health-related regulation	176
Table 10.2 Shelflife of antimalarial products (all formulations)	178
Table 10.3 Shop interviewee knowledge of whether they were allowed to stock chloroquine and SP	180
Table 10.4 Regulatory inspection: visits by Environmental Health and Drug Inspectors recalled by interviewees	181

Figures	
Figure 5.1 Conceptual framework	71
Figure 5.2 Location of IMPACT study districts and demographic surveillance system (DSS) areas.	73
Figure 5.3 Examples of outlets providing manufactured drugs in DSS areas	78
Figure 6.1 Breakdown of provider visits for fever/malaria by provider type	103
Figure 6.2 Antimalarial volumes dispensed by source (% of equivalent doses)	106
Figure 6.3 Manufactured medicines obtained for fever/malaria treatment reported during the household survey	108
Figure 7.1 Socio-economic status and concentration in private sector antimalarial sales by sub-market	130
Figure 7.2 Turnover of retail outlets stocking drugs between mid-2000 and mid-2001	135
Figure 7.3 General retailers with drugs in stock mentioning at least one of the top 3 and top 5 wholesale sources	137
Figure 8.1 Antimalarial stocking patterns in private outlets between mid-2000 and mid-2002 (all formulations)	142
Figure 8.2 Ranking by outlet type on key dimensions of non-price competition	156
Figure 9.1 Average ratio of retail prices to IRPs for antimalarials in commercial drug shops	166
Figure 13.1 ACT delivery models	217
Figure 13.2 Actors influencing retailer behaviour	230

Tables and Figures included in the Annexes

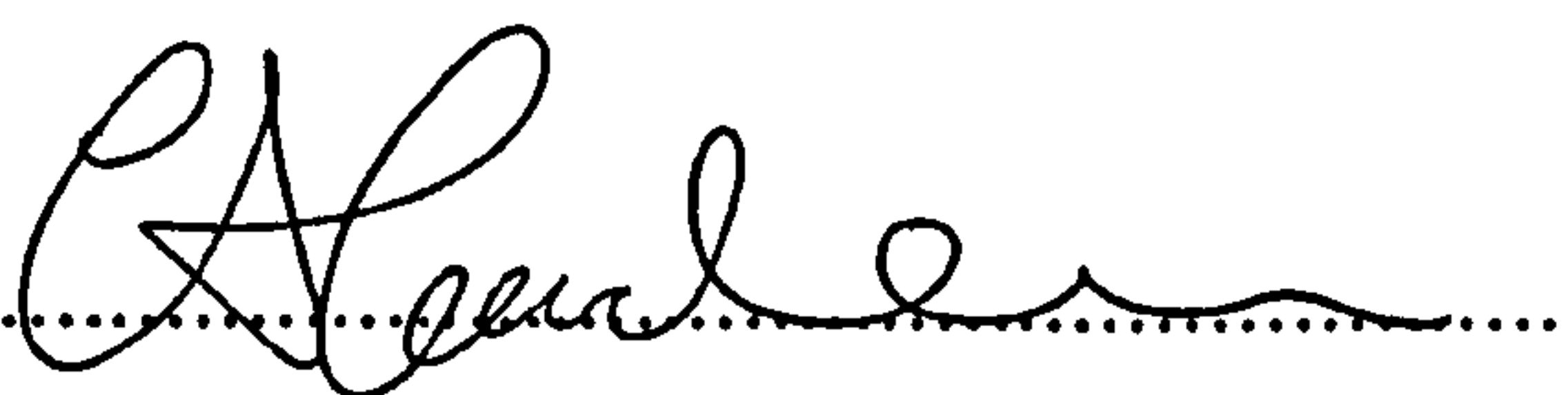
Annex 1: Appendix of Tables and Figures

Table A1.1 Structure, conduct and performance under standard competition models	263
Table A1.2 Background information on study districts	264
Table A1.3 Adequacy of household survey sample size for analysis of treatment seeking behaviour	264
Table A1.4 Minimum antimalarial doses used to calculate adequacy of treatment reported in household survey	265

Table A1.5 Outlet survey sample size calculations	266
Table A1.6 Antimalarial purchase required for standard doses for a two-year-old child and an adult	266
Table A1.7 Characteristics of household survey respondents	267
Table A1.8 Prevalence of reported fever/malaria episodes and <i>P. falciparum</i> parasitaemia	268
Table A1.9 Number of outlets with drugs in stock	269
Table A1.10 Fever/malaria drugs stocked	270
Table A1.11 Number of providers visited per individual reporting fever/malaria	271
Table A1.12 Estimated antimalarials dispensed per annum in volume and value terms	271
Table A1.13 Breakdown of sales volumes by antimalarial for each outlet type	272
Table A1.14 Estimated mean antimalarial sales per outlet p.a. in volumes and values	272
Table A1.15 Proportion of antimalarials for fever/malaria dispensed as under-doses	273
Table A1.16 Variation in antimalarial tablet prices in shops by outlet and product characteristic	274
Table A1.17 Variation in painkiller tablet prices in shops by outlet and product characteristic	276
Figure A1.1 Coding scheme for analysis of qualitative provider interviews	278
Figure A1.2 Antimalarial values dispensed by source	279
 Annex 5	
Table A5.1 Results of principal components analysis of household survey variables to construct an index of SES	346
Figure A5.1 Histogram showing distribution of PCA scores used in calculation of asset index	347
 Annex 6	
Table A6.1 Estimated 14 day antimalarial drug volumes in equivalent adult doses for retail audits 1 and 2	351

Statement of Authorship:

I confirm that this thesis is all my own work



ABBREVIATIONS

ACT	Artemisinin-Based Combination Therapy
ADDO	Accredited Drug Dispensing Outlet
AL	Artemether-Lumefantrine
AM	Antimalarial
AMMP	Adult Morbidity and Mortality Project
CHW	Community Health Worker
CDC	US Centres for Disease Control and Prevention
CIF	Cost, Insurance, Freight
DHMT	District Health Management Team
DHS	Demographic Health Survey
DRG	Diagnostic Related Group
DSS	Demographic Surveillance System
FOB	Free on Board
GDP	Gross Domestic Product
Hb	Haemoglobin
HHI	Hirschman-Hirfandahl Index
HMO	Health Maintenance Organisation
IEC	Information, Education and Communication
IHRDC	Ifakara Health Research and Development Centre
ILO	International Labour Organisation
IMCI	Integrated Management of Childhood Illness
IMF	International Monetary Fund
IMPACT	Interdisciplinary Monitoring Project for Antimalarial Combination Therapy
INN	International Non-Proprietary Name
IPTp	Intermittent Preventive Treatment for Pregnant Women
IRP	International Reference Price
IQR	Interquartile Range
ITN	Insecticide Treated Net
KINET	Kilombero Social Marketing Project for Insecticide Treated Nets
MOH	Ministry of Health
MSD	Medical Stores Department
NGO	Non-Governmental Organisation
NMCP	National Malaria Control Programme
OLS	Ordinary Least Squares
ORS	Oral Rehydration Solution
OTC	Over-the-Counter

PCA	Principal Components Analysis
PCL	Paracetamol
RCT	Randomised Controlled Trial
RDT	Rapid Diagnostic Test
RPM	Resale Price Maintenance
RRP	Recommended Retail Price
SCP	Structure-Conduct-Performance Paradigm
SEAM	Strategies for Enhancing Access to Medicines
SES	Socio-Economic Status
SID	Supplier Induced Demand
SMP	Sulphamethoxypyrazine Pyrimethamine
SP	Sulphadoxine Pyrimethamine
TEHIP	Tanzania Essential Health Interventions Project
TFDA	Tanzania Food and Drugs Agency
Tsh	Tanzanian Shilling
UNDP	United Nations Development Programme
USP	United States Pharmacopoeia
WHO	World Health Organisation

Exchange rate on 1/1/2002:

US\$1=Tsh950.14

(Onanda currency website <http://www.oanda.com/>)

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PART I

BACKGROUND TO THE THESIS

**Part I introduces the thesis, reviews relevant literature,
and provides background information on Tanzania**

CHAPTER 1

INTRODUCTION

1.1 The Role of the Private Sector

In low income countries the private sector is a very common source for many health products and services (Mills et al. 2002; Waters, Hatt and Peters 2003). Within the private sector, the retail sector accounts for a high proportion of care for common health problems, such as malaria, acute respiratory infection, sexually transmitted infections and tuberculosis (Berman 2000; Brugha and Zwi 1999; McCombie 2002; Uplekar et al. 1998). For other health interventions, such as contraception, the private sector is less widely used, but represents a potential resource for rapid expansion of coverage (Hanson, Kumaranayake and Thomas 2001). For both sets of services the retail sector may hold the key to the substantial expansion in coverage required for the achievement of the Millennium Development Goals. However, there is widespread concern that retail sector care is of low quality, particularly among those providers most accessible to the poor.

Health care policy in Africa has traditionally been made by and for the public health system, at most including commercial and not-for-profit facilities. Despite its importance, the retail sector has been largely ignored, with initiatives generally limited to haphazard and poorly implemented regulation. It is increasingly recognised that to improve the majority of treatment for many common health problems, the government has to look beyond the public sector and facilities, acknowledge the reality of widespread retail sector use, and address the ways in which government policy intentionally and unintentionally influences private sector behaviour (WHO 1998). The policy focus is therefore starting to shift towards partnerships with private providers at all levels, from drug importers and manufacturers to retail sellers such as pharmacies and other shop owners (Brugha, Chandramohan and Zwi 1999). A range of strategies have been proposed to improve the general quality of retail sector treatment, such as training of providers,

consumer education, social marketing, pre-packaging of drugs, franchising, subsidies and strengthening regulation. If policy makers are to design effective strategies, they need to understand the determinants of current household and provider behaviour in the retail sector, but existing knowledge is highly inadequate (Bloland and Ettlign 1999; Brugha, Chandramohan and Zwi 1999; Goel et al. 1996; Le Grand, Hogerzeil and Haaijer-Ruskamp 1999). Moreover, no studies have used an economic framework to analyse the retail market for health care in Africa, although such a framework is likely to be well-suited to improving our understanding of these commercial providers. This study addresses this knowledge gap, in the context of the market for fever and malaria treatment in Tanzania.

1.2 The Malaria Disease Burden

Malaria is a routine part of the daily life of millions of rural Africans, and a leading cause of the burden of disease, frequently accounting for over a third of all outpatient visits and inpatient admissions (Chima, Goodman and Mills 2003). In endemic areas, young children and pregnant women have the lowest immunity and are at most risk (WHO & UNICEF 2003). The symptoms of mild or uncomplicated malaria include fever, chills, headache and nausea, and patients are generally treated on an ambulatory basis. The coverage of blood tests for diagnosing malarial parasitaemia is low across sub-Saharan Africa. The vast majority of cases are treated presumptively, on the basis of fever alone, although many febrile patients are not parasitaemic (Bloland, Kachur and Williams 2003). The recommended treatment consists of a course of antimalarials, supplemented by antipyretics to help reduce fever and pain. In many settings more than half the patients buy drugs from shops, often obtaining treatment contrary to national guidelines. Prompt access to appropriate treatment is essential because *P. falciparum* malaria can rapidly progress to severe disease (Greenwood et al. 1987), with symptoms such as convulsions, coma and severe acidosis, and a high case fatality rate. Around a million deaths in Africa each year are believed to be the direct result of severe malaria (Snow et al. 1999). Access to effective treatment in Africa is currently very poor. At a meeting in Abuja in 2000, African Heads of State set a target that 60% of children with fever should obtain appropriate treatment within 24 hours by 2005. However, in 2004 the Roll Back Malaria partnership reported that only 42% of febrile children received an antimalarial, and that many of these treatments were delayed or contained an inadequate dose (WHO & UNICEF 2003).

The urgency of this issue has been increased by the crisis posed by antimalarial drug resistance. For several decades, chloroquine has been the most widely used antimalarial in Africa, but resistance to chloroquine is now common, with clinical failure rates documented in the 1990s of, for example, 31-48% in Zambia, 50% in Kenya, and 28-72% in Tanzania (Bloland et al. 1998; Ministry of Health 1999). As a result, some countries have adopted other relatively cheap

antimalarials as their first line drug, such as sulfadoxine-pyrimethamine (SP) and amodiaquine. However the growth of resistance to these alternatives has already begun, and is expected to accelerate with wider use (Greenwood 2004). The development of resistance has undoubtedly harmed the quality of facility and retail sector treatment (Trape 2001; Zucker et al. 1996). In addition poor quality retail treatment in the form of unnecessary drug use, under-dosing and sub-standard products is argued to have contributed to the growth of resistance itself (Basco 2004; Bloland et al. 1993; ten Ham 1992; White 1999).

In response, the introduction of artemisinin-based combination therapy (ACT) as first line therapy has been proposed to improve treatment efficacy. Moreover, it is argued that the use of ACT will slow the development of resistance to both component drugs, and so prolong their useful lives (White et al. 1999). Over the last five years the political will behind these proposals has grown. By March 2004, 15 African countries had decided to adopt ACT as their first line therapy, and 6 had begun deployment, mainly using funds from the Global Fund for AIDS, TB and Malaria (WHO RMB 2004).

1.3 Thesis Outline

To improve the quality of malaria treatment, and maximise the benefits from ACT implementation, an understanding of the retail market for fever and malaria treatment is essential. This thesis uses insights from economic theories of competition and industrial organisation to investigate how the interplay of market structure, provider conduct, regulation and consumer demand influences treatment outcomes. The study is set in three districts in rural Tanzania: Kilombero, Ulanga and Rufiji. It forms part of the Interdisciplinary Monitoring Project for Antimalarial Combination Therapy in Tanzania (IMPACT-TZ), and uses a variety of data collection methods to gather information from households, health-care workers and retail staff.

Part I of the thesis continues with a review of the empirical literature on fever and malaria treatment and the retail sector (Chapter 2), and the economic literature on markets and competition (Chapter 3). Background information is provided on Tanzania and its policy on malaria and the retail sector (Chapter 4). In Part II, the study design and methods for data collection and analysis are described (Chapter 5). Part III comprises five results chapters on treatment obtained, market structure, product differentiation and non-price competition, pricing and price competition, and retail regulation (Chapters 6-10). Part IV explores the implications of the results. Chapter 11 examines the methodological strengths and limitations, and in Chapter 12 the findings are analysed and discussed in the light of the existing literature. Chapter 13 addresses the policy implications of the results and analysis. As Tanzania and many other

countries plan to introduce ACT in the near future, the policy implications are considered mainly in the context of an ACT-based strategy. Finally, Chapter 14 concludes the thesis with an assessment of new knowledge gained and research priorities for the future.

CHAPTER 2

REVIEW OF THE LITERATURE ON FEVER AND MALARIA TREATMENT AND THE RETAIL SECTOR IN SUB-SAHARAN AFRICA

2.1 Introduction

This chapter reviews the literature on fever and malaria treatment and the role of the retail sector in sub-Saharan Africa. Fever and malaria are considered together because most malaria diagnoses are based on febrile symptoms alone. The review begins with an assessment of the demand for treatment, exploring methods for data collection, patterns of provider utilisation, drugs obtained, and influences on demand. Section 2.3 reviews the methods and findings of studies of retail supply, and considers likely determinants of provider behaviour, including government regulation. In Section 2.4, evidence on interventions to improve retail care is assessed. Finally, Section 2.5 summarises the current state of the literature, and highlights its limitations.

2.2 The Demand for Fever and Malaria Treatment

2.2.1 Methods for Studying Household Demand

The literature on treatment seeking behaviour for fever and malaria is extensive (McCombie 1996; McCombie 2002; Williams and Jones 2004). It consists mainly of evidence from cross-sectional household surveys and qualitative interviews/discussions. The latter encompass individual interviews, illness narratives, ranking or categorising activities, and focus group discussions, which generally cover local understanding of disease aetiology, associated symptoms, and factors influencing treatment choice. In addition, there is a limited amount of longer-term ethnographic research, investigating the context and complexities of treatment seeking in more depth (Hausmann Muela, Muela Ribera and Tanner 1998; Oberlander and Elverdan 2000). Large-scale cross-sectional household surveys are generally used to describe treatment-seeking patterns, and sometimes drugs obtained, and to perform quantitative analysis of relationships between behaviour and individual, household and community-level characteristics. Such standardised surveys permit some degree of generalisation from a representative sample of households to the larger population. After reviewing the literature, McCombie argues that most weight should be placed on surveys of reported behaviour, as opposed to those of likely actions in a hypothetical situation, as the latter are of limited utility in estimating actual treatment rates (McCombie 1996). Behaviours are generally reported for treatment sought for fever episodes in the previous two or four weeks, and most consider

children under 5 or 10 years only. While the majority of studies focus on bivariate analysis, a minority have used econometric techniques to perform multivariate analysis on the relative importance of influences on provider choice, and the magnitude of their marginal impact.

A first step in such studies is to investigate the local terms used for malaria. This is complex as they may be broader than the biomedical concept of malaria, encompassing other common illnesses, or narrower, focusing on specific malaria symptoms (McCombie 2002). The symptoms of uncomplicated malaria are usually associated with local terms for common febrile illness and malaria, although these may capture many other causes of fever as well. In Uganda, local terms for fever had a "broad spectrum definition", including any condition of feeling cold/shivering, feeling hot, joint pain, headache, dizziness and lack of appetite (Adome, Whyte and Hardon 1996). Symptoms of severe malaria are often associated with different local terms. For example, in Kenya and Tanzania there were specific local terms for splenomegaly (enlarged spleen) (Minja et al. 2001; Nyamongo 2002). Convulsions may be perceived as unrelated to malaria and mild fevers, resulting from supernatural intervention via spirit possession, magic spells or bad luck (Ahorlu 1997; Hausmann Muela and Muela Ribera 2000; Mwenesi, Harpham and Snow 1995; Oberlander and Elverdan 2000; Winch et al. 1996), although no such supernatural causes were cited in Burkina Faso (Muller et al. 2003). Household surveys are generally not large enough to capture a representative sample of severe cases, so most surveys focus on fever as the best indicator of uncomplicated malaria.

2.2.2 Choosing Providers

The evidence shows that most reported febrile illnesses are treated. Several studies found overall treatment rates of 90% or more (Deming et al. 1989; Mwabu 1986; Molyneux et al. 1999; Mwenesi, Harpham and Snow 1995), with most others finding rates of over 70% (McCombie 2002). Rather than being passive recipients of care and advice, consumers take an active role in the choice of outlets, and in some cases choice of treatment, often based on their own self-diagnosis (Leonard 2000; Williams and Jones 2004). Women are generally the primary care-givers, but often consult senior male household members before selecting providers and remedies (Molyneux et al. 2002; Mwenesi, Harpham and Snow 1995; Oberlander and Elverdan 2000; Tanner and Vlassoff 1998). Treatment seeking takes place within a pluralistic health system, encompassing health facilities in the public, non-governmental organisation (NGO) and commercial private sectors, community health workers, traditional healers and retailers (Williams and Jones 2004). Drug retailers may include pharmacies and drug shops, general stores, market vendors and itinerant sellers. While some patients use just one treatment source, recourse to multiple providers is common, and patients may combine modern and traditional remedies during one episode (Agyepong and Manderson 1994; Ahorlu 1997; Alilio and

Tembele 1994; Baume, Helitzer and Kachur 2000; Hausmann Muela and Muela Ribera 2000; Oberlander and Elverdan 2000). Several studies describe a trial and error approach to treatment choice, where perceived failure of one strategy may lead to a re-evaluation of the diagnosis and appropriate response (Williams and Jones 2004).

McCombie notes that there are almost as many ways of categorising treatments as there are studies, and comparability is certainly hampered by variation in the way providers are grouped in survey reports (McCombie 2002). In particular, a category of home or self-treatment is often used, although its definition varies between studies, potentially including tepid sponging, local herbs, drugs kept at home or obtained from neighbours, and drugs purchased from general shops or pharmacies, even though the latter may involve consultation with retail staff. In their review of behavioural issues in malaria treatment, Williams and Jones conclude that some sort of home/self-treatment is generally the first response to illness, and that it is widely used, even in areas with good access to health facilities and traditional practitioners (Williams and Jones 2004). Many studies found that people tended to begin with home treatment, proceeding to the official sector when home treatment strategies were perceived to have failed (Nyamongo 2002), although home treatment remained an important option at all stages of illness. However, the prominence of home treatment is not universal across Africa. McCombie defines the official sector as health facilities, private practitioners and village health workers (McCombie 1996). Her review found that it was used by between 19% and 87% of patients, with considerable variation both between and within African countries. In some areas the share of initial actions involving health facilities and home treatment was relatively similar (Amin et al. 2003), but in other areas home treatment was rare. For example, in The Gambia home treatment was used in less than 10% of cases (Clarke et al. 2003; Menon et al. 1988; von Seidlein et al. 2002), and low rates were also found in Zambia and Zimbabwe (Baume, Helitzer and Kachur 2000; Tsuyuoka, Wagatsuma and Makunike 2001).

Shop visits can be distinguished in a sub-set of household surveys, which show that buying drugs from retailers is generally very common. The median percentage using shops during recent childhood illness is roughly 50%, although experience is varied, ranging from 15% to 82% across studies (Brieger et al. 2004b). For example, on the Kenyan coast, shop-bought medicines were used first, or only, in 69% of childhood fevers treated (Molyneux et al. 1999). In Togo, only 20% of children under 5 years with fever were seen at a health centre during their illness, while 83% were treated at home with an antimalarial, mainly chloroquine obtained from a street or market vendor (Deming et al. 1989). Very few studies categorised retailers by type of shop. An important exception was a Ugandan study which estimated that of all medicines obtained, 15% were from drug shops, 37% from ordinary shops, and 6% from markets (Adome,

Whyte and Hardon 1996). The percentages were very similar if only antimalarials were considered.

In some settings it is common to maintain drug stocks in the home. For example, in cities in Nigeria and Congo, over half of households kept antimalarials (McCombie 2002). The drugs may be left over from previous episodes, or purchased deliberately as reserves from shops. In Western Kenya, 28% of fever episodes were treated with drugs already in the home (Ruebush et al. 1995). However, in other settings, only a small minority of households keep substantial drug stocks (Adome, Whyte and Hardon 1996).

Generally speaking, reported use of traditional healers and traditional medicines for uncomplicated malaria is low (Amin et al. 2003; Deming et al. 1989; Hamel et al. 2001; Lindblade et al. 2000; Muller et al. 2003; Thera et al. 2000), though there are exceptions. For example, in Somalia 53% of respondents said they would use traditional medicine to treat malaria (McCombie 1996). The use of traditional treatment may be understated in surveys because of perceived disapproval, but the weight of evidence indicates that in most settings it is rarely used for fever and uncomplicated malaria.

Initial treatment-seeking actions are generally taken between a few hours and two days after symptom onset (Williams and Jones 2004), although prompt *appropriate* treatment is rare. WHO defines appropriate treatment of childhood fevers as receipt of an antimalarial within 24 hours of symptom onset (WHO & UNICEF 2003), but in Kenya this was achieved for only 5% of cases (Amin et al. 2003). There is some evidence that home treatment reduces the time to obtaining care (Hamel et al. 2001). For example, a study in Kenya found that most mothers purchased drugs from retail outlets within one day of noticing the symptoms of childhood malaria, but the average time lag before a health facility visit was 3 days (Mwenesi, Harpham and Snow 1995).

McCombie notes that relatively little is known about variation in treatment by age, gender, endemicity, and personal experience with malaria (McCombie 2002). She finds some of the most striking variation in studies comparing rural and urban areas, with rural residents in some studies more likely to use traditional remedies and home treatment, and less likely to use facilities. However, in coastal Kenya mothers in rural and urban areas had similar treatment-seeking patterns, with the initial response in both groups being to buy drugs from shops (Molyneux et al. 1999). In an outlet-based study in Eastern Uganda splenomegaly was significantly more common in children visiting health facilities, than those visiting drug shops (Nshakira et al. 2002). A number of studies report greater use of the official sector for "severe" illness (Glik et al. 1989; Lindblade et al. 2000; Snow et al. 1992), but interpretation of these

data is hampered by the lack of standardised methods for categorising household reports of degrees of severity (McCombie 1996). As noted above, symptoms of severe malaria are often linked with supernatural causes, so traditional remedies may be viewed as complementary, or more appropriate than modern drugs for these cases (Baume, Helitzer and Kachur 2000; Hausmann Muela and Muela Ribera 2000; Mwenesi, Harpham and Snow 1995). Little difference in treatment seeking was generally found by gender (Armstrong Schellenberg et al. 2003; Krause and Sauerborn 2000) although there were exceptions: for example in Western Kenya schoolboys were more likely to self-treat than schoolgirls (Geissler et al. 2000). Analysis of variation across age groups is hampered by the limited number of studies including patients over five years (Agyepong and Manderson 1994; Guyatt and Snow 2004; Krause and Sauerborn 2000; Lindblade et al. 2000). Some studies found that young children were more likely to be taken to health facilities (Agyepong and Manderson 1994; Geissler et al. 2000; Krause and Sauerborn 2000). For example, in Western Kenya, school-age children were far less frequent among patients at the local health centre than infants and toddlers (Geissler et al. 2000). However, in epidemic-prone areas of Kenya and Uganda differences across age groups were not significant (Guyatt and Snow 2004; Lindblade et al. 2000).

2.2.3 Drugs Obtained

Data on therapies obtained or used are reported in a sub-set of studies. They indicate that the use of modern medicines is high, but first-line treatment often includes antipyretics/painkillers only (Williams and Jones 2004). McCombie estimates that overall only a third to a half of illnesses are treated with antimalarials (McCombie 2002). Particular concerns have been expressed about the quality of retail sector treatment, in view of the high prevalence of inappropriate prescription and dosage. In Kenya, 54% of care-seekers at government facilities received an antimalarial, compared with 33% of retail outlets (Amin et al. 2003). McCombie found that under-dosing during self-treatment ranged from 33% to 83% across studies, and over-dosing from 14% to 39% (McCombie 2002). In a baseline survey in Kenya, only 4% of children given store-bought chloroquine received an appropriate dose and only 2% received this dose over the recommended 3-day period. Aspirin was widely used, although it is not recommended for children, with 22% receiving potentially toxic doses (Marsh et al. 1999). While individual treatments are frequently inadequate, multiple treatment seeking over the course of an illness episode may result in cumulative over-dosing. Other problems believed to be widespread are polypharmacy, where providers prescribe additional unnecessary drugs, although evidence is limited. For example, rates of antibiotic use during fever episodes are very variable, with unclear justification. Among school-age children in Kenya, there was no use of antibiotics for fever-related complaints at shops or facilities, and in Burkina Faso, only 4% of drugs provided for childhood treatment were antibiotics, divided roughly equally between home and facility treatment (Geissler et al.

2000; Muller et al. 2003). However, in Uganda, 48% of febrile children were given antibiotics at drug shops, and 67% at government health facilities, although physical examination revealed that antibiotics were indicated for only 18% of febrile cases (Nshakira et al. 2002).

Poor quality antimalarials on the private market have been documented in Cameroon, Nigeria, Tanzania, Kenya and Uganda (Amin et al. 2004; Minzi et al. 2003; Ogwal Okeng, Okello and Odyek 1998; Risha et al. 2002; Shakoor, Taylor and Behrens 1997; Taylor et al. 2001). For example, of samples collected from illegitimate outlets in urban and rural areas of Cameroon, 12% of anti-folates (including SP), 38% of chloroquine and 74% of quinine samples had either no active ingredient, an insufficient active ingredient, the wrong ingredient, or an unknown ingredient (Basco 2004). A number of tablets sold as quinine contained chloroquine instead, and drugs sold loose were more likely to be of poor quality or counterfeit than packaged products.

Many of these quality problems are also found during visits to official outlets, such as government health facilities. For example, in Uganda chloroquine doses prescribed for children were inaccurate in 77% of drug shop visits, and 61% of health facility visits (Nshakira et al. 2002). Moreover, the evidence does not suggest that visiting health facilities inevitably leads to good outcomes. In Tanzania, of children under five believed to have died of malaria, 59% had visited a government or mission health facility as their first choice of care (de Savigny et al. 2004).

2.2.4 The Determinants of Consumer Demand

Consumer demand is expected to depend on a number of factors, including their knowledge and beliefs, prices and incomes, their preferences for product characteristics, and their preferences for provider characteristics, such as accessibility, waiting times, drug availability and courtesy.

Information on disease causation and treatment efficacy is widely believed to be crucial in explaining treatment demand. One might expect accurate knowledge to be correlated with general education levels, and higher educational attainment has been associated with higher use of health facilities (Slutsker et al. 1994; Tarimo, Urassa and Msamanga 1998). Among those self-treating in Malawi, those with higher levels of education were more likely to obtain an antimalarial (Slutsker et al. 1994). Inaccurate dosing may partly reflect the desire of poor consumers to conserve medicines for future episodes, but is also likely to stem from poor knowledge. McCombie found the proportion of consumers stating a correct antimalarial dose ranged from 3% to 58% across studies (McCombie 2002). For instance, only 20% of shoppers at drug stores in Dar es Salaam knew the correct dose of chloroquine for adults (Massele et al. 1993). In Kenya, knowledge of correct doses was associated with reading ability (Nyamongo

1999). In addition, there may be confusion over the difference between antimalarials and antipyretics, and between brand name and generic products (McCombie 2002). Consumers may perceive two brands of chloroquine to be different drugs (Foster 1991), or switch from chloroquine tablets to chloroquine injections without realising that they are different formulations of the same drug (Williams et al. 1999).

Very little is known about households' understanding of drug resistance. In north-eastern Tanzania in the late 1990s the presence of drug resistant malaria parasites was largely unrecognised by local people, and the concept did not exist in their explanatory models of disease (Oberlander and Elverdan 2000). However, in central Tanzania in 2000, when chloroquine treatment failure was over 50%, half of care-takers at health facilities were aware that chloroquine could fail, although some consumers perceived more effective antimalarials as "too strong" for young children (Tarimo, Minjas and Bygbjerg 2001). Higher education levels were associated with greater knowledge about antimalarials, the causes of treatment failure and appropriate responses. In Zambia, some caretakers perceived drug resistance as an individual property rather than a characteristic of a specific episode, saying that "chloroquine no longer works at all for me", or "my child became resistant to chloroquine tablets" (Kachur et al. unpub. report). It has been observed that medicines that have been widely available and valued for generations may still be preferred by community members, even after their efficacy diminishes (Van der Geest, Hardon and Whyte 1990). This was borne out in Malawi; four years after chloroquine had to be abandoned as official first line drug due to resistance, SP was ranked as superior on average, but chloroquine was still preferred by many consumers, widely available in shops and produced by local manufacturers (Kachur et al. unpub. report).

In addition to perceived efficacy, other product characteristics are important to consumers, such as shorter or simpler dosage regimens, antipyretic action, fewer minor side-effects, a more pleasant taste, and even colour (Adome, Whyte and Hardon 1996). However, some apparently unpleasant characteristics may be linked with greater perceived efficacy (Williams et al. 1999). For example, while syrup formulations of chloroquine are generally preferred for young children, as they are easier to administer than bitter-tasting tablets (Tarimo, Minjas and Bygbjerg 2001), some communities associate the bitter taste of antimalarials with strength (Kachur et al. unpub. report). In Kenya some patients regarded chloroquine-induced itching as a signal that the drug was working (Nyamongo 1999). It is widely believed that injectable formulations are more powerful than tablets (Adome, Whyte and Hardon 1996; Agyepong and Manderson 1994; Hamel et al. 2001; Ruebush et al. 1995), but in some settings injecting a child who has a high fever is believed to precipitate convulsions or cause death (Ahorlu 1997; Makemba et al. 1996; Mwenesi, Harpham and Snow 1995; Oberlander and Elverdan 2000; Tarimo et al. 2000). There may also be a tendency to believe that more expensive therapies are

more effective (Nunley 1996). The emphasis to be placed on such factors needs to be investigated empirically. For example, there had been much concern that replacing chloroquine by SP as first line drug would adversely affect consumer confidence and treatment seeking behaviour because SP was less well-known, has less of an antipyretic effect, is not bitter tasting, and is not available in an injectable formulation (Williams et al. 1999). However, when the perceptions of caretakers were compared during a drug efficacy study in Zambia, parents whose children were treated with SP readily accepted the new drug and reported higher perceived efficacy than those whose children were treated with chloroquine (Williams et al. 1999).

Patients' preferences for the characteristics of the providers from whom they obtain their drugs are very important in shaping their demand. Essential drugs are officially provided free or are heavily subsidised in most African public health systems but, as noted above, patients often choose to pay for drugs at private outlets. A key explanatory factor is accessibility; shops and vendors selling drugs are often a much more convenient source of drugs than public clinics (Adome, Whyte and Hardon 1996; Snow et al. 1992; Van der Geest 1987). In coastal Kenya, 87% of rural households live within 1km of a shop, but only 32% within 2km of a government dispensary or private clinic (Molyneux et al. 1999). The accessibility of facilities may be particularly limited during the rainy season, when roads are impassable (Nyamongo 1999). Even where government facilities are easily accessible, the phenomenon of bypassing is frequently observed, where patients chose to visit a private provider even if it involves the same or even greater journey time (Akin and Hutchinson 1999). This can be explained by studies of patients' views, which document a range of problems with the perceived quality of public services (Adome, Whyte and Hardon 1996; Gilson, Alilio and Heggenhougen 1994; Ruebush et al. 1995; Snow et al. 1992), leading Leonard to argue that government facilities represent the low-quality, last resort part of the African medical market, with mission/NGO or private-for-profit facilities frequently preferred even though the cost is higher (Leonard 2000). Rude and insensitive staff, limited opening hours and long waiting times are common complaints, and lack of drugs is frequently identified as a major shortcoming (Williams and Jones 2004). A study of health services in Tanzania found that the most common reason for not using government services was that they had a poor drug supply (Abel-Smith and Rawal 1992). Second and third line drugs were generally not available at peripheral facilities, even where treatment failure with the first line remedy was high (Ruebush et al. 1995). Illicit activities have been reported at public facilities, including illegal charging for drugs during consultation, and leakage in the form of the sale of drugs by health workers in their private clinics or selling to informal drug sellers or shops (McPake et al. 1999). One might expect observable elements of quality, such as accessibility, drug availability and courtesy, to have a greater impact on choice of provider than less observable elements, such as accurate diagnosis and prescription. However, consumers can select practitioners subject to observable institutional arrangements,

such as mission affiliation, which have a reputation for high technical quality, because of the incentives and objectives of staff (Leonard 2000). Despite the many problems with government facilities, high levels of confidence in public sector providers persist in many areas, linked to their reputation and the belief that they have undergone appropriate training (Baume, Helitzer and Kachur 2000).

Consumers choose between different private providers using similar criteria, such as accessibility, the availability of drugs, waiting times, the provision of examination, and the courtesy of staff. The provision of complementary services, such as diagnostics and examination, may be seen as an advantage by some consumers, especially for the treatment of certain patient groups, such as young children or the severely ill (Slutsker et al. 1994). Others prefer outlets without these facilities, if they are more accessible, service is much faster and other family members can be sent to collect the drugs (Adome, Whyte and Hardon 1996; Kachur et al. unpub. report; Snow et al. 1992). Patients may prefer shops if they find their staff friendly, and willing to negotiate charges and give credit (Williams and Jones 2004). Another reason for the frequent use of shops is that they are more likely than formal private clinics and pharmacies to sell an incomplete dose of antimalarial drugs. This may be appreciated by the patient when cash is not available to buy a full course of treatment (Adome, Whyte and Hardon 1996; Van der Geest 1987).

While patients are often more satisfied with drug availability and the interpersonal quality of care in private outlets, they frequently identify other problems with service delivery. Patients may perceive private providers to rely excessively on diagnostic tests and to charge very high prices, or they may be sceptical about the motivation of private providers, believing them to be primarily interested in generating income for themselves rather than in the welfare of their patients (Kamat 2001; Smithson, Asamoah-Baah and Mills 1997). In Uganda, consumers complained that in profit-oriented outlets, lab tests were always positive, in order to increase drug sales (Adome, Whyte and Hardon 1996). Drug vendors in Malawi and Zambia were seen as a valuable community resource because “they bring medicines close to the people”, but were seldom consulted for advice, because they were not considered knowledgeable and because their motivation was usually suspect, since their primary motivation was perceived to be to sell medicines (Kachur et al. unpub. report).

Last but not least, price and income levels are key factors affecting demand, influencing the choice of provider, the choice of drug, and the dose purchased. Cost is frequently mentioned as a reason for not using health facilities (Williams and Jones 2004). For example, in Kenya interviewees generally began with self-treatment as a cost-saving strategy, even though they perceived official sector care to be more effective (Nyamongo 2002). A separate Kenyan study

found median drug costs to patients in Kenyan shillings (Ksh) to range from Ksh 17 at retail outlets to Ksh 58 government clinics, Ksh 100 at government hospitals, Ksh 150 at private clinics and Ksh 215 at private hospitals (Amin et al. 2003). In Lagos, Nigeria, prices paid for drugs followed a similar pattern (Brieger et al. 2001). Total patient costs are generally cheaper at shops because there are no consultation or lab fees, or under-the-table charges, and small quantities of drugs can be purchased (Adome, Whyte and Hardon 1996). In addition to the cost of drugs and services, ability to pay may also be influenced by credit availability, the acceptability of payment-in-kind, and the availability of loans or gifts, for example through savings schemes or from the extended family (Hausmann Muela, Mushi and Muela Ribera 2000; Mariam 2000). Even where there are no facility fees, the time and travel costs of visiting facilities may be much higher than for retailers (McCombie 1996).

As one would expect, these factors lead to variations in demand by household wealth. In his analysis of sub-Saharan African Demographic Health Survey (DHS) data, Filmer found that higher socio-economic status (SES) measured using an asset index was associated with greater use of government hospitals, and private facilities (Filmer 2002). There was no clear pattern in the use of lower-level government facilities or shops across SES groups. In Tanzania, there was a positive association between SES and use of the official sector for fever (62% in the least poor quintile compared with 31% in the poorest) (Armstrong Schellenberg et al. 2003). Children in the poorest quintile were half as likely to have been given antimalarials as those in the wealthiest. It is possible that such disparities in treatment lead to serious inequalities in health outcomes. In the same region of Tanzania, mortality in children following acute fever was 39% higher among the poorest compared with the least poor (Mwageni E. unpublished data, quoted in Barat et al. (Barat et al. 2004)). Barat et al. hypothesise that this might reflect both financial barriers to prevention and curative services, and non-financial barriers, such as education, distance from health services, and the opportunity cost of time lost at work.

The last two decades have seen a substantial rise in the number of econometric analyses of health care demand¹. Studies of the decision to seek care and/or choice of provider for general curative care in sub-Saharan Africa were identified from Benin, Burkina Faso, Cameroun, Côte d'Ivoire, Ethiopia, Ghana, Kenya, Mali, Niger, Nigeria and Tanzania (Akin, Guilkey and Denton 1995; Appleton 1998; Bolduc, Lacroix and Muller 1996; Chawla and Ellis 2000; Dor and van der Gaag 1993; Gertler and van der Gaag 1990; Lavy and Quigley 1993; Leonard and Leonard 1999; Mariam 2000; Mariko 2003; Mwabu 1989; Mwabu and Mwangi 1986; Ndeso-Atanga 2000; Sauerborn, Nougara and Latimer 1994; Vogel 1994). Most analysts base their empirical models on the theoretical foundations of the random utility model (RUM) developed

¹ Econometrics is the branch of economics that uses the methods of statistics to measure and estimate quantitative economic relationships.

by (McFadden 1981), using discrete choice logit or probit models. Despite the recent proliferation of such studies, a number of theoretical and practical methodological issues remain open to debate, including approaches that allow the in-built assumption of the independence of irrelevant alternatives to be relaxed², the potential endogeneity of illness reporting when certain groups are more likely to report episodes, and the appropriate measurement of price and quality for the treatment alternatives (Akin, Guilkey and Denton 1995; Akin et al. 1998; Appleton 1998; Chawla and Ellis 2000; Gertler and van der Gaag 1990; Lavy and Quigley 1993).

In general, such studies have found that price elasticities of demand³ are very low, although some studies showed that poorer groups and children tend to have more elastic demand than the general population (Ching 1995; Dor and van der Gaag 1993; Gertler, Locay and Sanderson 1987; Gertler and van der Gaag 1990). Several studies have also found quality measures to be important. For example, in Nigeria demand for outpatient health care was influenced by per capita facility expenditure, drug availability and the condition of the physical infrastructure (Akin, Guilkey and Denton 1995). In Tanzania, clinician knowledge, consultation performance, attentiveness and appropriateness of prescription all had a positive impact on demand (Leonard 2000). In many studies travel time is found to be an important and significant determinant, and other variables found to be significant in some, though not all, studies include age, education of household head, gender, household size, severity, area of residence, assistance of relatives, or participation in savings mechanisms (Ching 1995; Gertler and van der Gaag 1990; Mariam 2000; Nanda 1999).

Econometric studies specifically focusing on treatment seeking for malaria/febrile illness are much more rare, and only three African studies were identified, two from Ghana and one from Benin (Asenso-Okyere, Dzator and Osei-Akoto 1997; Dzator and Asafu Adjaye 2004; Mensah 2000). The studies all found that the choice of provider for fever/malaria was significantly influenced by treatment cost, but differed in their other findings. For example, in Benin, Mensah found gender, occupation, total household expenditure and credit scheme membership to be significant variables, but Dzator and Asafu-Adjaye found in Ghana that travel time, education, and household size were significant. They also showed choice of provider to be inelastic with respect to treatment costs and time costs, with demand more inelastic in drug shops than in facilities. All econometric studies of fever/malaria treatment have focused on the choice of provider; no such analysis was found of the choice of drug.

² the restriction that the relative probability of choosing 2 existing alternatives is unaffected by (independent of) the presence of additional alternatives.

³ price elasticity of demand measures the responsiveness of demand to a change in price.

2.3 Retail Supply

2.3.1 The Range of Providers

Retail suppliers of fever/malaria drugs can include pharmacies, licensed and unlicensed drug shops, general shops, kiosks, market stalls and itinerant drug hawkers. The non-pharmacy retailers are known variously as drugs sellers, chemical sellers, patent medicine vendors or informal private providers. They operate on a commercial retail basis, selling drugs over-the-counter. No professional consultation is required for purchase, and staff are not required to be fully qualified pharmacists, but they are allowed to stock only non-prescription medicines. This section focuses on these non-pharmacy outlets, although it is recognised that there are many similarities with the operation of some formal pharmacies, which are not always staffed by appropriate personnel (Goel et al. 1996). There may also be other drug sources for consumers, such as clinics that sell drugs without consultation, facility staff who illegally sell drugs intended for facility patients, or householders who buy in bulk and sell to fellow-villagers (Adome, Whyte and Hardon 1996; Geissler et al. 2000; Van der Geest 1987). However, this review focuses on commercial retailers, such as shops, stalls and hawkers.

2.3.2 Methods for Studying Retail Providers

Methods for studying retail supply of public health commodities have been reviewed by Conteh and Hanson (Conteh and Hanson 2003). They document ten possible data collection techniques: structured questionnaires, unstructured interviews, direct observation, unobtrusive observation (under-cover care-seekers⁴), record review, retail audits (sales level surveys), group discussions, point of purchase surveys (exit interviews), and diaries. They highlight a number of key issues. Firstly, it is often necessary to develop some kind of sampling frame of outlets where no official lists are available, and this is essential if representative data are required. Secondly, there are important trade-offs in the choice of method between the potential to capture representative quantitative data (e.g. structured questionnaires) and the potential to capture detailed qualitative information, and to develop a discussion and rapport (e.g. unstructured interviews, direct observation, group discussions). A mixture of data collection methods is generally appropriate, allowing information from different sources to be triangulated, and sources of discrepancy to be investigated. This is particularly important if providers are likely to put on their 'best behaviour' before an open observer, or present a 'wishful self-image' under questioning.

⁴ under-cover care-seekers are research assistants with fictitious case scenarios, who visit providers and request their assistance, without informing the providers that they are involved in research, in order to collect data on typical provision.

A range of studies have looked specifically at the retail supply of antimalarials in sub-Saharan Africa (Alilio et al. 1997; Djimde et al. 1998; Faye et al. 1996; Jimmy, Achelonu and Orji 2000; Julvez 1999; Marsh et al. 1999; Massele et al. 1993; Molyneux et al. 1999; Nsimba et al. 1999; Ongore and Nyabola 1996; Tavrow, Shabahang and Makama 2003) and others have looked more broadly at retail sector drug supply (Adikwu 1996; Adome, Whyte and Hardon 1996; Brieger et al. 2004a; Cocks and Dold 2000; Fassin 1988; Geissler et al. 2000; Maiga et al. 2003; Mujinja, Mpembeni and Lake 2003; Murray et al. 1998; Oshiname and Brieger 1992; Reynolds Whyte and Birungi 2000; Van der Geest 1987).

The studies are roughly equally divided between rural and urban/peri-urban areas, with several covering both settings. Most use structured questionnaires administered to sales staff, supplemented in some cases by in-depth interviews, undercover care-seekers, direct observation, outlet mapping, exit interviews and household surveys. For example, in Mali, structured questionnaires were conducted with health workers, pharmacists and drug sellers, supplemented by an undercover care-seeker assessment (Djimde et al. 1998). In coastal Kenya, all shops and pharmacies were mapped, an audit taken of antimalarials stocked, and semi-structured interviews held with a range of health care providers (Molyneux et al. 1999). Analysis of quantitative data has been limited to relatively simple descriptive work; only one study of pharmacy transactions in Mali used multivariate analytical techniques (Maiga et al. 2003). Many studies report difficulties in collecting data from retail providers. Refusal rates were over 20% in some settings (Faye et al. 1996; Jimmy, Achelonu and Orji 2000; Mujinja, Mpembeni and Lake 2003), and others found evidence of a divergence between reported and actual provider behaviour (Alilio et al. 1997).

2.3.3 Provider Characteristics

There is considerable variation in retailer type across settings. In Senegal, Mali, Nigeria and Cameroon drugs are sold in static shops, but itinerant vendors are also important retail suppliers (Djimde et al. 1998; Faye et al. 1996; Oshiname and Brieger 1992; Van der Geest 1987). In Nigeria, medicine pedlars on motorcycles were found to provide the bulk of Western health care to remote hamlets (Oshiname and Brieger 1992). Itinerant sellers are less common in East and Southern Africa, where retailers are generally all static. In some areas of East and West Africa, drugs are sold by small drug shops specialising in pharmaceuticals, as well as general stores (Adikwu 1996; Adome, Whyte and Hardon 1996; Brieger et al. 2004a; Dzator and Asafu Adjaye 2004; Nsimba et al. 1999). However, in rural areas of western and coastal Kenya, there are no such drug stores, and all retail drug purchases are made from general retailers, sometimes

called ordinary provision stores, which also sell food and a range of household goods (Marsh et al. 1999; Molyneux et al. 1999; Tavrow, Shabahang and Makama 2003).

Some similarities across drug retailers can be noted, particularly in stocking patterns. Nearly all stock modern manufactured medicines only, an exception being the *Amayeza* stores in South Africa's Eastern Cape province, which also stock a wide range of traditional remedies (Cocks and Dold 2000). Retailers tend to stock a wide variety of painkillers/antipyretics and the first line antimalarial, which at the time of most studies was chloroquine. Chloroquine was generally available under its generic (non-proprietary) name and under a variety of brand names (Adome, Whyte and Hardon 1996; Molyneux et al. 1999; Nsimba et al. 1999). In Kenya, 13 different chloroquine brands were identified (Ongore and Nyabola 1996). Other products found include antihelminthics, antihistamines, antiprotozoals, and cough and stomach ache remedies. Most drug stores stock prescription-only medicines illegally, such as antibiotics and tranquillisers, which are often kept under the counter (Adikwu 1996; Adome, Whyte and Hardon 1996; Fassin 1988; Geissler et al. 2000; Murray et al. 1998; Oshiname and Brieger 1992; Van der Geest 1987). In coastal Kenya, 7% of rural and 40% of urban general stores stocking drugs had prescription-only medicines (Molyneux et al. 1999). Drugs are often stored and handled in an inappropriate way, for example being kept in conditions of excessive heat, light and moisture, and stored in re-used, wrongly labelled containers (Geissler et al. 2000; Van der Geest 1987).

The use of prescriptions from health professionals is very unusual, and in most cases sellers simply sell the drugs requested by customers (Adome, Whyte and Hardon 1996; Brieger et al. 2004a; Fassin 1988; Geissler et al. 2000; Ongore and Nyabola 1996; Oshiname and Brieger 1992). Customers may request products by their scientific name or by commonly recognised descriptions, such as "white capsules for diarrhoea" (Adome, Whyte and Hardon 1996). It is very rare for sellers to refuse to sell a drug. However, some sellers give a considerable amount of advice on drugs and doses (Brieger et al. 2004a). In Uganda, many customers asked for such advice, and drug shop staff often made instant diagnoses and drug recommendations, operating as storefront clinics (Adome, Whyte and Hardon 1996). Staff appeared to be influenced by practices in government outlets; 77% of drugs used in self-medication were on the essential drug list, and the advice given was often similar to government protocols.

Education levels vary across providers, but most have little or no formal training in medicine or pharmacy. Drug shop staff may be untrained, or qualified as, for example, medical assistants or nurses, perhaps with some experience in the formal health sector (Adome, Whyte and Hardon 1996; Nsimba et al. 1999; Oshiname and Brieger 1992). In some cases current government staff also work in drug stores (Adome, Whyte and Hardon 1996). In Nigeria it was the convention that patent medicine vendors had completed primary school, but this was not a legal

requirement and no other qualifications were required (Oshiname and Brieger 1992). Even where the official owner or licensee has health-related qualifications, outlets are often staffed by other less qualified assistants (Brieger et al. 2004a; Kumaranayake et al. 2003; Oshiname and Brieger 1992). Staff in general shops very rarely have any training or relevant experience, and in Uganda many were illiterate (Adome, Whyte and Hardon 1996).

Relatively little is known about the distribution chain to drug retailers, beyond their immediate sources. Retailers usually obtain their drugs from general wholesalers, or large retail or wholesale pharmacies, although mobile distributors operate in some settings (Marsh et al. 2004). In Western Kenya all pharmacies bought from large wholesale pharmacies, but 60% of shops/kiosks used wholesale general shops, and mobile vendors also frequently supplied rural shop/kiosks (Tavrow, Shabahang and Makama 2003). In Nigeria, sales representatives from pharmacies and pharmaceutical companies were the main source of drugs for patent medicine vendors in a peri-urban area (Adikwu 1996). Several studies report the presence of significant quantities of smuggled drugs in shops (Faye et al. 1996; Van der Geest 1987).

Common information sources for shopkeepers are the radio, their wholesalers, and the instructions provided by manufacturers (Alilio et al. 1997; Ongore and Nyabola 1996). In most settings retailers are not members of professional associations, but there are exceptions. In a town in western Nigeria, the majority of drug sellers were members of the local branch of The Nigerian Association of Patent and Propriety Medicine Dealers, founded in 1951 (Oshiname and Brieger 1992).

2.3.4 The Determinants of Provider Behaviour

The determinants of provider behaviour are much less studied than those of consumer behaviour, but a couple of authors have tried to provide a framework for doing so. Tawfiq suggests that the behaviour of informal providers is influenced by four main factors: their knowledge and clinical skills, client expectations, profit margins, and pharmaceutical company promotions (Tawfik 2001). For retail pharmacies, Goel et al. propose a framework based on pharmacy staffing and organisational patterns, client expectations, physician practice and local regulatory factors (Goel et al. 1996).

Most studies focus on provider knowledge, although it is recognised that knowledge is not a good predictor of behaviour (Williams and Jones 2004). The studies show that provider knowledge of drugs and doses is often very poor. For example, amongst retailers in rural Tanzania, knowledge of signs and symptoms of malaria was adequate, but 90% did not know precise chloroquine doses for children (Alilio et al. 1997). In Nigeria only one out of 49 patent

medicine vendor owners knew the correct dose of chloroquine for a three -year-old (Oshiname and Brieger 1992).

Another important determinant of provider behaviour is their beliefs about patients' attitudes and preferences, which will in turn depend on the characteristics of their clients, such as education, socio-economic status, age and gender (Goel et al. 1996). For example, even if they are aware that an oral therapy would be appropriate, they may sell injectable formulations if they know that patients believe injections to be more effective. Careful interpretation of claims of such consumer pressure is required, as providers may choose to blame consumers for their own profit-maximising strategies. For example, private practitioners in Bombay reported strong pressure to respond to demand for IV saline in order to retain patients (Kamat 2001). However, during observation in their clinics such patient demands were rarely heard, although several practitioners were observed persuading their patients to accept an IV drip!

One would also expect retailer behaviour to be influenced by their cost structure, profit margins and competition from other providers, but there is very little evidence about such financial incentives. There are also a range of incentives that may feature in the objective function of staff which are not immediately financial (although some could be seen to some degree as long-term competitive strategies). For example, provider objectives may include promotion, serving the community, and being seen as a respectable, trustworthy citizen, or being seen as professionally competent by one's peers (Goel et al. 1996). The impact of these factors on provision will depend on the role of the different staff, and the degree of autonomy each member has.

2.3.5 Retail Regulation

The scope of retail outlet regulation concerns the availability, labelling, dispensing, and marketing of drugs, the qualifications of staff, the location and nature of the premises, and in some circumstances the prices charged. In Africa the main regulatory role is taken by government, as regulation by professional or consumer associations is very limited (Leonard 2000). The legal status of retailers varies. Some operate entirely within the law, others are legal entities but perform some illegal activities, and others are completely illegal outlets. The legal boundaries for drug retailing vary across countries, so a legal activity in one country may be considered illicit elsewhere.

Regulation is notoriously ineffective. Some retailers are required to be licensed by government at a national or local level, but many do not comply. For example, in Kano State, Nigeria, only 15% of drug sellers were registered with the Federal Government (Tawfik 2001). In a study of drug stores and pharmacies in Dar es Salaam, 85% of undercover care-seekers obtained

prescription-only drugs without a prescription, and 24% of drug shop staff freely admitted operating outside the regulations (Kumaranayake et al. 2003; Mujinja, Mpembeni and Lake 2003). In Uganda, 60% of chloroquine purchases reported in a household survey came from sources not authorised to provide antimalarials (Adome, Whyte and Hardon 1996). In Nigeria, all patent medicine vendors were aware that certain drugs were prescription-only, but only 13% believed the law was being obeyed (Adikwu 1996).

Strengthening regulatory control has posed great challenges due to the lack of enforcement capability (Kumaranayake 1997; Tawfik 2001). In Dar es Salaam over half of pharmacy owners rated the government's effectiveness in regulating the pharmaceutical sector as low or very low (Mujinja, Lake and Mpembeni 1999), for example citing the failure to penalise shops flouting regulations, and the lack of regular inspections. This was argued to reflect inadequate staffing and transport. In a peri-urban area of Nigeria, only 33% of patent medicine vendors reported an inspection visit during the previous two years (Adikwu 1996). Implementation is likely to be even less adequate among the more informal outlets, especially in rural areas (Foster 1991; Tawfik 2001).

2.4 Retail Sector Interventions

There has been increasing interest from national and international policymakers in interventions to improve retail sector outcomes. For example, WHO now advocates strategies to improve home-based management for malaria, with retailer interventions seen as one possible channel for these strategies (WHO 2004). However, this enthusiasm is not universally shared. In many countries calls for a more active role for retailers have met with resistance from at least some government health personnel, who favour stricter enforcement of pharmaceutical laws or outright banning of drug retailers (Brieger 2002; Reynolds Whyte and Birungi 2000).

Interventions to improve child health and malaria-related activities of African retailers have been reviewed by Brieger et al. (Brieger et al. 2004b). The review identified only 15 interventions, all but two of which had taken place in the last five years, demonstrating that the widespread interest in this area is a relatively recent phenomenon. The interventions were geographically concentrated, with five in Kenya, four in Nigeria, and none outside Anglophone Africa (although this may reflect an anglophone bias in the search strategy employed).

Brieger et al. categorise the activities used in these interventions into four areas. Firstly, training/capacity building strategies were implemented by all 15 programmes, including workshops, in-shop education and job aids. Secondly, eleven programmes addressed the enabling environment, for example, through changes in drug policy and regulations, or

improvements to product quality. Ten programmes included demand generation, through mass media or community volunteers to encourage appropriate use of retailers and medicine by consumers. Finally, six addressed quality assurance through franchising and accreditation, retailer associations, or monitoring and supervision.

In Nigeria, for example, training was provided to patent medicine vendors on recognition and treatment of a range of common health problems (Oshiname and Brieger 1992). In Western Kenya, wholesalers who supplied drug retailers were given training, and supplied with information, education and communication (IEC) materials for distribution to their customers (Tavrow, Shabahang and Makama 2003). In Tanzania, drug stores were given the opportunity to join an accredited network, once they had fulfilled certain criteria, and their staff had attended a three-month training course (Sigonda-Ndomondo 2004). They benefited from the branding and marketing of this network, and were permitted to stock a wider range of products than other drug stores.

Brieger et al. found the evidence base on retailer interventions to be weak; only 11 interventions had been evaluated, and in most cases evaluation outcome measures were limited. The only study which attempted to estimate the impact on care received took place in Kilifi, rural Kenya, where training workshops were held for general shopkeepers, accompanied by community mobilisation and monitoring/supervision activities. The proportion of shop-treated childhood fevers receiving an adequate amount of a recommended antimalarial rose from 2% to 15%, at an economic cost of US\$4.00 per additional appropriately treated case (year 2000 prices). It was estimated that a modified district-scale programme could reduce this cost to \$0.84 (varying between \$0.37 and \$1.36 in a sensitivity analysis) (Goodman et al. submitted; Marsh et al. 2004). Brieger et al. concluded that retail sector interventions can increase the frequency of appropriate treatment, but the evidence for sustained impact is limited, and it is not possible to judge the relative merits of different strategies.

2.5 Summary and Limitations of the Literature

An extensive literature exists describing consumer perceptions of malaria, treatment-seeking patterns, and their determinants. It provides rich background information, drawing out common themes and patterns across different settings. Most studies focus on children under five, as the group most biologically vulnerable to malaria. While there is cross-country variation, in many settings self/home-treatment is a major source of care for fever/malaria, often using drugs purchased through shops. Treatment both from shops and facilities is often inadequate, characterised by inappropriate drugs, incorrect dosing, and poor quality drugs. Key determinants of treatment choice include consumer knowledge, SES, and preferences for the

characteristics of drugs and providers, including accessibility, speed of service, stock reliability, expertise, courtesy, and of course cost.

The range of non-pharmacy retailers supplying drugs includes drug shops, general stores, kiosks, market stalls, and itinerant drug hawkers, with their relative importance varying across settings. They stock painkillers/antipyretics, and often have common antimalarials, as well as illegally stocked prescription-only medicines. Staff education levels and advice given to patients are highly variable. Little is known about the determinants of provider behaviour, but they are likely to include provider knowledge, patient expectations, financial incentives, and the maintenance of a good reputation. Retail regulations are poorly implemented, reflecting weak enforcement capacity. A number of interventions for improving retail care have been piloted, but the evidence base on their effectiveness remains limited.

This review highlights a number of key gaps and unanswered questions concerning both the demand and supply of treatment of fever/malaria. On the demand side, a considerable quantity of qualitative or quantitative data has been collected on treatment seeking for fever/malaria among young children, but there is relatively little information about the practices for adults and older children. Although the under-five group experiences the highest mortality risks, antimalarial drug use is common across all age groups. Knowledge of treatment patterns in older age groups is important for understanding their health outcomes and overall drug pressure, and for quantifying drug needs for the future (Guyatt and Snow 2004). Secondly, there is a need for more investigation of factors affecting demand for non-facility outlets such as drug shops and general stores. In existing consumer-focused research these outlets are often grouped in the "self/home-treatment" or even "no treatment" category. Even where shop visits are categorised separately, few studies distinguish between shop types.

Literature on retail supply of fever/malaria treatment is not nearly as extensive as that on demand. Conteh and Hanson conclude that methods for studying the behaviour of retail providers remain relatively under-developed, and particularly lack adaptation for informal outlets (Conteh and Hanson 2003). Although a number of studies have described informal outlets such as shops and kiosks, in view of their importance in treatment seeking, much more work is needed in this area. In addition, only a few studies incorporate the full range of providers from hospitals to informal kiosks, and allow an analysis of the substitutability and complementarity between these different provider types.

There is a complete lack of accurate quantitative data on the actual size of the market in terms of sales volumes and values, and no established methods for estimating this. Nearly all reviews continue to quote the back-of-the-envelope estimates of the share of antimalarials distributed

through the private sector made by Foster over a decade ago (Foster 1991). In addition there are few representative studies of drug quality in Africa, especially in retail outlets, despite frequent perception that this is a serious problem. Although regulatory non-compliance is well-documented, there is little analysis of its underlying causes.

Finally, most studies have had a medical focus, emphasising training and knowledge of providers, and whether their behaviour conforms to recommended treatment guidelines (Brieger 2002). There is a lack of analysis of retailers as economic agents facing a wide range of financial and non-financial incentives, and almost no discussion of the influence of market structure or the nature of retail competition on these commercial providers (Conteh and Hanson 2003; Goel et al. 1996).

The research described in this thesis contributes towards addressing these gaps in several ways. Firstly, data are reported on demand for fever/malaria treatment for all age groups, providing descriptive information on behaviour amongst older children and adults, which is currently lacking. The demand analysis also distinguishes between drug and general stores. On the supply side, the focus of the thesis is on retailers, such as drug shops, general shops and kiosks. However, the full spectrum of formal and informal providers of drugs for fever/malaria treatment is included in data collection, to allow comparison across provider type. Market size and concentration are estimated in the study areas, and retail drug quality assessed. Finally, an economic framework is used to explore the operation of retailers, and the influences on their behaviour. The next chapter reviews the economics literature to draw out key concepts, theories and methods that may form part of this framework of analysis.

CHAPTER 3

A REVIEW OF THE ECONOMIC LITERATURE ON MARKETS AND COMPETITION

3.1 Introduction

This chapter reviews economic theories of markets and competition which may provide insights for the analysis of the retail market for fever/malaria treatment. It begins in Section 3.2 with a review of the structure-conduct-performance paradigm and standard models of competition. Section 3.3 reviews methods for defining the market under consideration. The light that economic theory can shed on the determinants of market structure is considered in Section 3.4, and on provider conduct in Section 3.5. Finally, Section 3.6 summarises the evidence on the key features of competition in markets for health care and pharmaceuticals, and the African retail sector.

3.2 The Structure-Conduct-Performance (SCP) Paradigm and Standard Models of Competition

The original SCP model associated with Joe Bain and Edward Mason was based on a deterministic relationship: structure (the number of sellers, degree of product differentiation, barriers to entry and vertical integration) determined firm conduct (business goals, strategies and competitive practices), and so yielded predictions about market performance in terms of efficiency, profitability, technical progress and growth (Clarke 1985). Broadly speaking, a more highly concentrated market structure¹ was associated with less price competition, higher prices and higher profits, termed the “market concentration doctrine” (Demsetz 1973). Different levels of market concentration were associated with particular models of competition, ranging from the least concentrated (perfect competition) to the most concentrated (monopoly). Although uncommon, these extreme forms of competition demonstrate the range of potential outcomes. In between these two extremes lies a continuum of imperfect competition, encompassing monopolistic competition (relatively low concentration) and oligopoly/duopoly (high concentration). The structure, conduct and performance associated with each of these four models are summarised in Table A1.1 in Annex 1.

A key difference between the models lies in the degree of control individual firms have over the price they are paid. In a perfectly competitive market, theory predicts that the market price will equal the marginal cost of production. All firms will be “price-takers”; they have no discretion

¹ in a highly concentrated market a few large firms account for the majority of production or sales

concerning the price they charge because if they sell at less than the market equilibrium price they will make a loss, and if they choose a higher price, they will have no customers. By contrast, under imperfect competition, firms have some degree of market power. This may arise, for example, from product differentiation combined with heterogeneous consumer preferences, so that switching to another provider will reduce a patient's utility. Alternatively consumers may have imperfect information on product characteristics, but will not search the whole market due to search-related costs. As a result, individual firms face downward sloping demand curves and can raise price without losing all their customers.

The main features distinguishing monopolistic and oligopolistic competition are that under monopolistic competition, entry and exit are possible, and there are a sufficient number of providers that each one in selecting its own action takes the actions of the competing providers as given (Chamberlin 1933). Although in reality the behaviour of any firm is likely to influence at least its close neighbours in geographical or product space, this assumption provides a useful abstraction from such strategic behaviour (Tirole 1988). In the short-run firms may charge a price greater than average cost, but in the long-run new firms will enter, to the point where each firm makes zero economic profits. However, price will generally remain above marginal cost as each firm operates at less than minimum efficient scale². The societal costs of this inefficiency compared with perfect competition should be weighed against the societal benefits of product variety (Varian 1999).

Under oligopolistic competition the number of firms is small enough that each firm factors into their decisions the knowledge that the quantity they sell depends on the pricing and capacity decisions of other producers, as well as their own price (Parkin, Powell and Matthews 1997). Scherer states "in general it is considered that when the leading four firms control 40% or more of the total market, it is fair to assume that oligopoly is beginning to rear its head" (Scherer 1970). There is no one model of oligopoly that applies in all settings; in fact Tirole notes that "the proliferation of theories is mirrored by an equally rich array of behavioural patterns actually observed under oligopoly" (Tirole 1988). The different models vary in their assumptions about the choice of decision parameters and the sequence of decisions. In some models firms select the quantity to produce, and let the market determine the price through the interaction of demand and supply; in others they set price, and let the market determine the quantity sold. Some key oligopoly models are described in Box 3.1, illustrating the range of possible implications for price and quantity produced.

² the minimum efficient scale is the level of output that minimises average cost.

Box 3.1 Models of Oligopoly

Three classes of models describing price and quantity setting under oligopoly are described below, based on simultaneous decisions by firms, leader-follower scenarios and collusion. In addition, the Kinked Demand model provides insights into the causes of price rigidity. The simpler case of duopoly is often used as an illustration, as it has the virtue of simplicity while still capturing the main elements of oligopolistic competition.

The Cournot and Bertrand models are based on the assumption of simultaneous decision-making by firms, over the quantity produced for Cournot, and over the price charged for Bertrand (Varian 1999). Firms choose their quantity or price to maximise profits, given their expectations about the decisions of other firms. For Cournot, firms will gradually approach equilibrium where their expectations about each other's behaviour are confirmed. At this point each firm is producing the output which maximises profits, given the output of the other firm. The output and price set lie between those in perfect competition and monopoly. As the number of firms increases, each firm's influence on market price decreases, market output rises, market price falls, and when the number of firms becomes large enough, the market approaches the perfectly competitive equilibrium. For Bertrand, with homogenous goods, firms will see it to their advantage to cut their price in each period, if they assume the other firm's price is fixed. This will continue until the perfect competition equilibrium is reached, a surprising conclusion in an oligopolistic structure. A weakness of these models is the assumption of zero conjectural variations; they assume each firm will take the other firm's choices as given from one period to the next, when in fact both continue to revise their choices until equilibrium is reached. In addition, the Bertrand conclusion is sensitive to the assumption of homogeneity of goods.

A second class of models is based on a leader-follower scenario, argued to apply in situations where one firm clearly dominates the market (Varian 1999). In the Stackleberg model, the follower sets their quantity produced, given the output of the leader, and the leader chooses their quantity to maximise profits, given the reaction function of the follower. In Price Leadership models (also called Dominant Firm theories) the leader sets price, given the supply function of the follower. In the case of homogenous goods, in equilibrium the follower must then set their price equal to this market rate, and will produce up to the point where this price equals their marginal cost.

The third class of models focuses on the potential for collusion between oligopolists. Firms in a cartel are hypothesised to co-operate to choose price or quantity supplied to maximise total industry profits, and therefore act collectively as a monopolist. The strategic interdependence and the high level of concentration under oligopoly increases the probability of price collusion,

although this will not necessarily be initiated nor sustained. In the short-run it is to the advantage of each individual firm to cheat on a collusive agreement by lowering price or increasing quantity in order to gain market share. The insights of game theory have been used to explore the incentives for cheating, and the characteristics of competitive interaction which may discourage this (Tirole 1988). Cheating is argued to be less likely where the number of firms is small, interaction is repeated, secret price cutting is not possible, the market is stable, firms sell homogenous products and face homogenous demand and cost conditions, and have multi-market contact (the same firms compete on several different products). Cheating may also be discouraged if firms adopt credible retaliation strategies to punish cheaters.

Finally, the Kinked Demand model shows how prices may be rigid if firms believe that any price cuts they make will be matched by other firms, but that any price increases will not. As a result, for differentiated products the demand curve facing each firm will be more elastic for price increases than for price cuts, and for homogenous products the demand curve will be infinitely elastic for price increases (i.e. their sales will fall to zero). The resulting discontinuity in the marginal revenue function implies that firms may not change their price in the face of quite large changes in costs or demand.

The implications for equilibrium price vary considerably across the different models (Varian 1999). At one extreme, the Bertrand model predicts that price will fall to its perfectly competitive level; at the other extreme, under successful collusion the monopoly price will prevail. The Cournot, Stackleberg and Price Leadership models imply a price somewhere in between. The Kinked Demand model makes no specific prediction about how prices are set initially, but explains how existing prices may be sticky downwards. Ultimately the choice of an appropriate model cannot be made on a purely theoretical basis, but must reflect empirical evidence on how firms make their decisions in practice.

The nature of the relationship between market structure and provider conduct has been a source of considerable debate in the industrial organisation literature over the last three decades. As a result, emphasis on the deterministic relationship between structure and conduct has diminished, with increasing recognition that the direction of causation between structure and conduct is two-way (Scherer 1970; Waterson 1984). For example, a firm's conduct can be targeted strategically at changing the structure of the industry through advertising or predatory pricing policies. Secondly, it is recognised that the nature of competition is shaped by potential competition rather than just current levels of market concentration (Baumol, Panzar and Willig 1988). In a perfectly contestable market, potential entrants and incumbents operate under identical cost or product quality conditions and the new entrant is able to enter and leave the industry at no net

cost. Where a market has high levels of contestability, firms may have very little market power, even if there are currently few firms in the market.

In addition, all providers are not solely motivated by the objective of profit maximisation that underlies all four basic competition models. Firstly, in many firms there is a separation of ownership and control between managers and owners, and managers will aim to maximise their own utility, which may include their salary, job security, promotion, power and reputation, as well as company profits. Secondly, many health care providers have not-for-profit status, and therefore neither owners nor managers would be expected to pursue profit maximisation, but are likely to include the quality of patient health outcomes and the welfare of the community explicitly among their objectives. Even where firms have an official for-profit status, such objectives may be important to practitioners, who are concerned with patient welfare and/or influenced by strong codes of professional ethics. Finally, the model of staff as maximisers may be inappropriate; in reality they may exhibit “satisficing” behaviour, aimed at achieving satisfactory target levels rather than maximum levels of the variables in the objective function. Under any of these scenarios one would expect the relationship between structure and conduct to differ from the pure profit maximisation case. In particular, an organisation may not use its market power, for example to raise prices or induce demand, even where this potential exists.

Incorporating these elements, the analysis of structure and conduct continues to provide a useful starting point for exploring the nature of competition in markets. The framework can be used to investigate what providers compete over, what strategies they use to enhance their competitive position and the intensity of this competition. Before discussing the key features of structure and conduct below, the difficult question of market definition is considered.

3.3 Defining the Market

The first step in any analysis of competition is to identify the competitors which make up the market. A variety of definitions of the term “market” are available, beginning with the simplest – any set of arrangements by which buyers and sellers are in contact to exchange goods and services. Economic theory is based on a rather more precise concept, with a well-defined market consisting of the set of suppliers and demanders whose trading establishes the price, quantity and quality of a good or service (Dranove and White 1998), or the group of sellers and buyers of a set of products who are in sufficiently close contact for their transactions to affect the terms on which the others buy or sell (Tirole 1988).

The delineation of markets is generally considered along two dimensions – the product and the geographical area. Although much attention has been focused on the issue of health care market

definition for the purpose of antitrust cases in the US hospital market, there remain many methodological and empirical problems in identifying the providers to include.

3.3.1 Defining the Product

The range of products in a market can be considered from the perspective of substitutability in demand or supply (Zwanziger, Melnick and Eyre 1994). Products are substitutable in demand if, following an increase in price, the consumer could easily switch from one to the other (high cross price elasticity of demand), meaning that the products are good substitutes from the consumer's perspective. They are substitutable in supply if it is almost costless for a supplier to convert their production process from one product to another, meaning that the market definition should include providers which either produce the same product or could easily do so (reflecting the insights of contestability theory).

In many health care markets identifying the product of interest is not straightforward. A central issue is the degree of aggregation to use. For example, in the analysis of hospital competition, product definition could be based on a single procedure, a single diagnostic related group (DRG), a major diagnostic category, a speciality, or even a group of specialities (Ashton and Press 1997). Such a “cluster market” approach has often been used, for example based on “general acute hospital services” (Gaynor and Vogt 2000), although it may not be clear that the whole cluster is substitutable in demand or supply. The choice of product definition will have an important impact on the analysis as, for example, the more aggregate the measure, the lower the expected concentration.

3.3.2 Defining the Geographical Area

Once the product/product group has been specified, the next step is to define the geographical area within which providers of this product operate in one market. In health care this will be highly dependent on the local context, and in particular how far people are prepared to travel to seek care. This is likely to vary with the urgency and severity of the condition and the ease of travel, with patients likely to be willing to travel a greater distance for more specialized services.

There are several possible methods of market area definition:

- **Political boundary approaches**, where an arbitrary geographical or political area is used, such as a district or metropolitan area (Joskow 1980)
- **Fixed radius approaches**, where a provider's market is defined as the area surrounding it of a given radius (Robinson and Luft 1987)

- **Shipment methods**, which use utilisation data by patient origin to define the market area by minimising the proportion of customers who travel outside the area to purchase the product, and maximizing the proportion who remain within the area. In other words, the geographic market is expanded until “imports” and “exports” are a small proportion of total sales (Gaynor and Vogt 2000)
- **Price based approaches**, where the geographic market is defined as the area within which a price movement at any one location causes related price changes everywhere else.

Zwanziger et al. note that “Three basic approaches have been proposed or used to define geographic markets: ones based on political boundaries, price, and shipments. None of them adequately reflects the characteristics of hospital markets” (Zwanziger, Melnick and Eyre 1994). While price based approaches could be considered as conceptually sound, being the most directly related to the economic definition of a market, they suffer from serious operational problems. It is difficult to look at “price” for a highly differentiated product, and difficult to isolate price change as a response to a competitor’s price change from changes due to any other non-competitive factors (Zwanziger, Melnick and Eyre 1994). Moreover, a price based approach is of little use in markets where consumers and providers do not respond to price signals, which may be the case where health care insurance coverage is high.

An advantage of shipment methods is that utilisation data by patient origin are generally relatively easily available. A disadvantage is that the cut-offs for imports and exports are essentially arbitrary. Also such data pertain only to the current mix of competitors serving a geographical area, ignoring contestability. For example, two areas may be defined as separate markets because no product currently flows between them, although such flows would take place if the provider in one area increased their price. Conversely producers in two different markets may sell highly differentiated products, so that there are considerable flows between the markets, but the producers are not in the same market.

Approaches based on political boundaries are very simple to use, but Zwanziger et al. argue that they are “usually misleading proxies for hospital market areas” (Zwanziger, Melnick and Eyre 1994). They do not account for local market conditions and provider characteristics, or the potential for different services to have different sized catchment areas. Zwanziger et al. argue that they tend to overstate competition, as all hospitals in the area are considered as competing with all others, although in reality they often compete with only a few close neighbours. Alternatively a competing hospital may be ignored because it is located just on the other side of a political boundary, although people regularly cross such borders to seek care. Fixed radius approaches suffer from many of the same critiques. In addition they take no account of

geographic boundaries, ease of travel, and the nature of population centres (Luft and Maerki 1984).

A general problem with all the non-price based methods is that they are designed to describe the range of competitors for one given provider. By contrast, defining a closed group of providers that comprise a defined market is much more difficult, because the spatial character of health care competition means that there are often overlapping sets of competitors. Moreover, some providers may serve customers in a local area only, but compete with others that serve customers from a wider region.

In addition, with both product and geographic market definitions, the difference between distinct markets and market segmentation is difficult to define. Segmentation may occur where consumers differ in their preferences, leading firms to offer different quality products (Sutton 1991). For product definitions it is difficult to draw the line between products in the same market and products that are considered to operate in different markets but to be substitutes to some degree. For geographic definitions it may be unclear whether two areas should be defined as distinct and separate markets or as different segments of the same market.

These grey areas lead Tirole to argue that the notion of a market in economics is an “idealization or a limit case” (Tirole 1988). Due to the complexities and subjectivities involved, it may be appropriate to use a combination of methods to define markets, incorporating both quantitative shipment data and qualitative data on provider perceptions of the substitutability of different products and providers.

3.4 Economic Theory and Market Structure

In this section the main elements of market structure are considered, and in the following section, the main elements of provider conduct. As noted above, the links between the two are numerous, because structure influences conduct, and some provider conduct is aimed at changing elements of market structure. Structure can be considered to comprise not just the level of market concentration, but also the nature of the product, barriers to entry and exit, and the regulatory system.³

³ The structure of many health care markets is distinctive in the large role played by insurance providers or health maintenance organisations. A vast health economics literature exists documenting their behaviour and impact, and in developed countries and many developing countries, an analysis of their operation would be central to an understanding of the operation of the health care market. However, the focus of this thesis is a market in which the role of insurance or prepayment is very limited or non-existent, with most care delivered on a fee-for-service basis, through out-of-pocket payments. As a result, the impact of such institutions has not been covered in this review.

3.4.1 Market Concentration

A market has higher horizontal concentration the fewer the number of firms in production or the more unequal the distribution of market shares (Clarke 1985). While there is no guarantee that competitive markets will have low levels of concentration and vice versa, it is expected that markets with low concentration are potentially more competitive. Moreover concentration is more amenable to measurement than many other aspects of competition. Most attention in the literature has focused on horizontal concentration, which is discussed first below. However, as vertical integration can also be an important source of market power, some consideration is also given to its nature and importance.

As with market definitions, measures of horizontal concentration are subject to a number of methodological and empirical weaknesses. The simplest measure of concentration is the number of providers within the market area, but this gives no idea of their relative size. In order to incorporate firm size, the mainstream economics literature has employed measures of market share based on employment, net output or sales. For hospital markets a range of measures are used, including total revenues, inpatient revenues, bed numbers, admissions or patient days.

It is then possible to examine the distribution of market shares among providers, or to plot the concentration curve – the cumulative percentage of output plotted against the cumulative number of firms ranked from largest to smallest (Clarke 1985). Market A is more concentrated if its curve lies everywhere above that of market B. When concentration curves cross, it is not possible to rank them unambiguously, and for empirical analysis, some summary measure of concentration is generally required which embodies the distribution of market shares across firms.

Two types of summary measure can be distinguished: absolute measures which relate to both firm numbers and relative market shares, and inequality measures which consider only the dispersion of market shares. Inequality measures include the Gini coefficient, the co-efficient of variation (ratio of standard deviation of firm size to mean firm size), and variance of logarithms of firm size (Clarke 1985). However, absolute measures are more widely used, with the most common being the concentration ratio and the Hirschman-Herfindahl index (HHI).

The concentration ratio measures the proportion of output accounted for by the r largest firms, with r often set at 3, 5 or 10, for example. Formally:

$$CR_r = \sum_{i=1}^r S_i$$

where S_i is the share of the i^{th} firm in the market. Concentration ratios are widely used in descriptive empirical work, as they are easy to calculate and understand. Their disadvantages are that they consider only the r largest firms in the industry, and the choice of r is arbitrary. Only a single point on the concentration curve is considered, and where the concentration curves of two markets intersect, the concentration ratio will give a different assessment of their relative concentration for different r .

The HHI is the sum of squared firm market shares of all firms in the industry, taking account of all points on the concentration curve, and depending on both market share inequality and on firm numbers.

$$HHI = \sum_{i=1}^N S_i^2$$

where N is the total number of firms in the industry. The HHI ranges from 0 (large number of competitors with small market shares) to 1 (single monopoly supplier). US antitrust guidelines state that an HHI below 0.1 is considered unconcentrated, 0.1-0.18 moderately concentrated, and greater than 0.18 highly concentrated (Gaynor and Vogt 2000). Although these cut-offs are essentially arbitrary, the HHI can be a useful yardstick, especially when a combination of measures are used.

Vertical integration refers to the extent to which a single business unit carries out successive stages in the processing and distribution of a product. Integration may be backward/upstream where a firm moves into production of raw materials and inputs, or forward/downstream where a firm moves into final production and distribution. Different degrees of integration can also be distinguished; even where full integration has not taken place there may be considerable on-going vertical coordination, involving cooperation, long-term contracts or vertical restraints on operation. For example, manufacturers may fix the retail price of drugs, delineate the area of operation of their distributors, or tie the distribution of two or more of their products together.

Standardised measures of vertical integration akin to those for horizontal integration do not exist, although some attempts have been made to measure vertical concentration empirically. For example, integration in an industry may be measured as the average ratio of employment in auxiliary activities to total employment across firms (Clarke 1985).

3.4.2 Information Characteristics of Products

The nature of the product has a crucial impact on competition, a key issue being its information characteristics, which reflect the ability of consumers to observe product characteristics. These characteristics could be considered as either part of market structure, or a feature of consumer

demand. Products can be characterised as search, experience, reputation or credence goods, although many goods have a mix of attributes. Search goods can be evaluated by inspection prior to purchase, examples being clothing or furniture. If goods must be purchased before quality can be assessed, for example, food or cars, they are termed experience goods (Nelson 1970). If consumers tend to rely on word of mouth information about the quality of a product, it is termed a reputation good. For some products, termed credence goods, consumers never discover their true need for the product or its quality, and sellers frequently act as experts, determining the customers' requirements (Darby and Karni 1973). Examples of credence goods include many medical, legal and financial services. These information characteristics affect the nature of competition in several ways. For example, with experience and credence goods, where it is not possible to observe quality before purchase, consumers are likely to be less sensitive to quality differences. Where sellers not only provide the product but also advise on customer requirements, as with many credence goods, there is potential for imperfect agency, where the provider influences the consumer's choice in line with the provider's self-interest (see Section 3.5.3).

The problems in observing quality differences can lead to the emergence of a "market for lemons" (Akerlof 1970). Consumers unable to observe quality at the time of purchase will be unwilling to pay any price higher than that corresponding to a good of average quality. All goods therefore change hands at a price associated with average quality, leading higher quality sellers to exit, reducing average quality and price, which could lead to eventual market disintegration. This informational problem could be attenuated if the seller can provide guarantees or indirectly signal high quality (see Section 3.5.2), or if government regulation enforces quality controls, minimum quality standards, occupational licensing and certification.

In addition, repeat purchases potentially enable the customer to learn from experience about product attributes. Repeat purchases need not be narrowly defined as restricted only to purchases made by the same consumer of the same good. The effect may be obtained through word-of-mouth from other consumers, and brand names or chains can support the development of a reputation influencing the choice of similar goods. The impact will be more powerful where consumers learn quickly about the quality of the good, repurchase frequently, and the quality of the good remains constant over time (e.g. wine of given vintage and vineyard). If the producer can change product attributes (e.g. restaurant meals), repeat purchases will not be so informative about future quality.

Consumers typically have highly imperfect information about health care. Even for products or services with search good characteristics, the scientific or technical aspects of the health problem may be poorly understood, and there may be little time to collect information because

the patient is in a crisis situation. Pauly and Satterthwaite have argued that physician care could be considered a reputation good, as demand depends on the doctor's reputation for technical ability and interpersonal relations (Pauly and Satterthwaite 1981). In their "Increasing Monopoly" model they hypothesise that an increase in the number of providers can decrease the consumer experience and information available about each provider, making consumers less price sensitive, and so providing providers with greater market power. This model is most likely to be relevant for types of care which are frequently used, and which are not particularly sophisticated, so that patients feel they are able to judge the quality of the service provided. However, for many health care goods and services, the ability of consumers to learn from experience is limited either by the infrequency of purchases (e.g. acute hospital care), technological change, or because quality or need cannot be judged even after use (Thomson 1994).

3.4.3 Barriers to Entry and Exit

Bain provides one of the broadest definitions of barriers to entry, encompassing anything which allows incumbent firms to earn excess profits in the long-run without inducing potential entrants to enter (Bain 1956).

Bain considers 3 basic sources of barriers:

- **Absolute cost advantages**, which reflect the ability of incumbents to produce a given output level at lower unit cost than the potential entrant, for example due to access to cheaper input sources, or greater ease in raising capital
- **Significant economies of scale relative to market size**, which imply that if the entrant enters at minimum efficient scale, there is likely to be a significant fall in price, but if they enter on a smaller scale, they will suffer a significant cost disadvantage
- **Product differentiation advantages**, where established firms have advantage over entrants because of consumer preferences for their products. This differentiation may reflect the consumer goodwill connected to the reputation of established brand names and the cumulative effect of past advertising. However, such advantages may be of limited duration if new entrants are able to establish rival products after an initial "break-in" period.

Other barriers to entry arise from entry regulation, for example through permits, licenses, patents or the granting of import licences (Djankov et al. 2000). The impact of entry regulation on competition is not clear-cut. On the one hand it may foster cartelising behaviour by providers, hindering competition. Moreover, it may cause further barriers to entry because of delay and corruption in the licensing process (de Soto 1990). However, regulations can also act

as a signal of minimum quality standards, which will enhance competition where information is imperfect.

Less attention is generally paid to the ease of exit from a given market. Heavy investment in plant and machinery may act as a barrier to exit because exiting firms are likely to incur substantial costs if their assets cannot be resold. Exit potential will also be affected by the risk of revocation of licenses by government authorities, and the potential for an organisation to go bankrupt. For example, some not-for-profit entities will be able to continue to function even if they do not break even, by relying on additional contributions from donor agencies.

3.4.4 Regulation

The remit of regulation is broader than the entry controls described above, potentially also including other targets, such as product quality, input quantities, price, location, and non-competitive behaviour, such as price collusion and restrictive practices (Kumaranayake et al. 2000). These variables need not always be targeted through formal legal controls. Other potential instruments include informal codes of conduct, financial incentives, such as taxes and subsidies, or non-financial incentives, such as the opportunity to join an accreditation mechanism⁴.

In health care, regulation has focused on responding to imperfect information, and the lack of incentives to minimise cost in markets served by health insurance, generally through legal instruments (Folland, Goodman and Stano 1993). For example, in Tanzania, Kumaranayake et al. found that all but one of the regulations were legally based (Kumaranayake et al. 2000). The majority focused on entry requirements for health care personnel (licensing) and for facilities (registration), with relatively little regulation to promote competitive practices or protect the consumer.

The actual impact of regulation on the desired targets will depend on the market structure, cost conditions, objectives of the firms and availability of information. In particular, the outcome will be highly dependent on the enforcement capacity of the regulatory agency, and the way in which providers respond, discussed below under provider conduct.

⁴ accreditation occurs when an independent agency defines and monitors the standards of facilities who voluntarily participate in the scheme.

3.5 Economic Theory and Provider Conduct

Provider conduct may be a reaction to market structure or an attempt to shape it. The key conduct variables are discussed below, encompassing the choice of price and non-price attributes of products, the provider's agency role, strategies to increase market concentration, provider collusion and other restrictive practices, and attempts to influence the regulatory environment.

3.5.1 Price Setting

As noted in Section 3.2, market structure is argued to influence price setting behaviour. Under perfect competition, firms cannot raise price above marginal cost without losing all customers. Under monopolistic or oligopolistic competition we may expect price to exceed marginal cost, because each provider has some market power, due for instance to product differentiation, imperfect information, barriers to entry, or local pockets of high concentration.

Strategies that providers can use both to maintain price above marginal cost, and to expand demand for their own products, are discussed below. In many cases suppliers may not explicitly calculate the impact of such strategies on the elasticity of demand, setting prices by “rules of thumb”, such as using a standard percentage mark-up over costs, or following the prices of market leaders. However, overall the market can be modelled as if they make such calculations.

Providers may not charge just one price for a given product. A seller with market power may engage in price discrimination, where different buyers are charged different prices for the same good. Price discrimination could not be maintained if those offered lower prices could resell to those offered higher prices. The potential for such arbitrage will depend on the nature of the good, and the transaction costs involved in resale. Three types of price discrimination can be distinguished. Under first degree or “perfect price discrimination” prices may vary for different units of output and from person to person. Under second degree discrimination, prices vary for different units of output but not from person to person (e.g. bulk discounts); and under third degree discrimination prices vary from person to person but not for different units of output, examples being discounts for senior citizens or students, who have a higher price elasticity of demand than other groups. Even where the characteristics of groups with varying price elasticities are not easily observable, providers may be able to segment the market by charging higher prices for more luxurious services, encouraging groups with a higher willingness to pay to self-select to purchase those products.

There is widespread historical evidence of third degree discrimination in health care, with physicians using sliding scales of fees to charge richer patients more than the poorer ones (Jacobs 1997). Through cross-subsidisation, such a strategy increases the access of poor patients to care, as well as being profit maximising for the provider. It is possible to maintain such discrimination because, for much health care, the potential for arbitrage is limited because the output is embodied in the patients treated.

3.5.2 Product Differentiation

Product differentiation exists when “due to difference in physical attributes, ancillary service, geographic location and/or subjective image, one firm’s products are clearly preferred by at least some buyers over rival products at a given price” (Scherer 1970). As described above, it is a key feature of monopolistic competition which, combined with heterogeneous consumer preferences, facilitates market segmentation and provides firms with a degree of market power. Some elements of product differentiation are inherent in the nature of the goods concerned, and could be considered as part of market structure. Many others are deliberately engineered by the provider to enhance their competitive position, and therefore fall under provider conduct.

Product differentiation can be either horizontal or vertical. Under horizontal differentiation the differences are rooted in differences in consumers’ tastes and do not imply any inherent superiority of one product over another (e.g. sweetness of desert, colour of car, location of shop). In a vertically differentiated product space, all consumers agree over the preference ordering of product characteristics, but some goods have more desirable characteristics than others (e.g. audio equipment ranging from basic tape players to deluxe music systems; public and private rooms in an government hospital). In reality, a range of characteristics are likely to be relevant in both horizontal and vertical differentiation (Lancaster 1966). In health care this range of characteristics might include clinical curative aspects, information provision and reassurance, caring and comfort (Bennett 1996).

Horizontal differentiation on the basis of one key characteristic can be analysed by analogy to spatial competition, following the work of Hotelling (Hotelling 1929). Products and consumers are modelled as located along a linear or circular product space, their proximity indicating the degree of match between consumer tastes and product characteristics. According to the principle of differentiation, firms generally do not want to locate at the same place in the product space, as product differentiation gives each provider some market power over the consumers in its own market niche, softening price competition. In the simplest version of the Hotelling model, buyers’ preferences are uniformly distributed around a circle and as a result, the alternative brands locate evenly round the circle, sharing the market out between them.

However, the Hotelling model may also lead to minimal differentiation under certain market characteristics. Agglomeration may occur because consumers are distributed unevenly in geographical or product space, so many firms have an incentive to locate where the demand is, even though this will increase price competition. Firms may even deliberately try to imitate the product of a current market leader by locating as close as possible to an existing successful brand. They may also benefit from gathering in areas where costs are lowest, such as close to a source of raw materials. The existence of positive externalities between firms may also encourage them to locate in close proximity, for example to reduce the search costs of consumers. Alternatively, where price competition is heavily restricted through regulation or resale-price maintenance, there may be little incentive to differentiate.

The relative importance of price and non-price competition through product differentiation will depend on the relative responsiveness of consumers to price and quality (Dranove and Satterthwaite 1992). If product quality is very difficult to observe or “noisy”, purchasers may be relatively price sensitive, but quality insensitive. Providers will have little incentive to provide high quality services, and the equilibrium level of quality may be too low (at the extreme leading to the “market for lemons” scenario described above). To some degree providers can resist such tendencies by signalling their overall quality to potential purchasers (Spence 1973). In health care such signals might include gaining qualifications, and use of procedures associated with higher levels of expertise, such as surgery.

Where consumers are price insensitive (for example due to the existence of third party payers), but quality sensitive, a quality competition model may emerge. The equilibrium level of quality may be excessive, and an increase in competition may result in a rise in price due to the costs of higher quality, rather than the fall in price anticipated from traditional economic theory. If certain elements of quality, such as patient amenities and technologically advanced equipment, are more easily perceived than others, providers may over-invest in such aspects of care, while neglecting less observable elements of technical quality.

Providers may also aim to increase product differentiation through advertising and promotion. Some elements of advertising act as a source of information, which decreases market power by reducing product differentiation associated with imperfect information (Nelson 1970). However, in practice, much advertising conveys little “hard” information (e.g. existence of product, price, distributors and appearance), but plenty of “soft” information (e.g. product image), and may therefore increase product differentiation.

3.5.3 Imperfect Agency and Demand Inducement

In situations where consumer information is imperfect and asymmetry of information exists between consumers and better informed providers, a principal-agent relationship may arise where the consumer relies on the provider as their agent for advice on appropriate demand. A health care provider acting as a perfect agent would choose as the patient would choose if the patient possessed the information that the provider does (Folland, Goodman and Stano 1993). There is potential for imperfect agency, where the provider influences demand for their own self-interest, termed supplier induced demand (SID). For example, it is argued that, faced with an increase in provider supply, providers will respond by using their influence to increase demand, in order to maintain a certain target income level (Rice and Labelle 1989). However, even where the potential for such action exists, SID may be constrained by mechanisms to control imperfect agency, including licensing, threats of legal action, ethical constraints, and the presence of a sufficient number of informed consumers. Asymmetry of information is recognised as a common situation in the provision of some (but not all) health care services, but the extent of SID is very difficult to establish, due to problems with its empirical measurement (Folland, Goodman and Stano 1993).

3.5.4 Strategies to Increase Market Concentration

The most obvious way for a firm to increase market concentration is through a merger or acquisition of another firm. Horizontal mergers involve two or more firms producing competing products, and may be used to reap economies of scale and/or increase market power. Vertical mergers involve two firms at different stages of the production process, and can be profit maximising wherever the behaviour of firms at one stage in the distribution chain affects the profits of firms at another stage. It may also be motivated by a desire to reduce the transaction costs, for example of discovering market prices and negotiating market contracts (Coase 1937). Other potential motivations include avoiding sales tax, guaranteeing input supplies or output markets, or erecting barriers to entry by controlling the terms on which non-integrated entrants gain access to inputs or distribution networks.

Incumbent firms can also influence concentration by using actual or threatened strategic behaviour to deter entry deliberately. Examples include limit pricing, where incumbents eschew short-term profit maximisation by maintaining low prices, in order to make the market look less attractive to newcomers. Alternatively, they may threaten or build a reputation for predatory pricing tactics if entry takes place, to drive a new entrant out of business. Other deterrent strategies include significant investment in spare capacity (Spence 1977), and product proliferation, where incumbents “pack” the market with many products or brands, so that

insufficient room exists for a new firm's product to compete profitably (e.g. as in the case of breakfast cereals (Schmalensee 1978)).

3.5.5 Provider Collusion and Restrictive Practices

Collusion involves an explicit agreement or implicit understanding among competitors to limit price competition by agreeing on the quantity produced and/or fixing the market price. Firms may also collude on the setting of terms and conditions, market shares, customers, or suppliers. Explicit agreements to restrict price competition are illegal, but cautious pricing behaviour directed at avoiding conflicts in price policies is not.

As noted in Box 3.1, when concentration increases and providers are fewer in number, the probability of price collusion generally increases because with few suppliers, the cost of detecting cheating is relatively low, and the impact of one supplier's price cuts is less dispersed. However, collusive behaviour may also be found in less concentrated markets, if the providers are well organised. For example the market for physicians is often not concentrated, but organised medical associations are able to control members and prevent them from engaging in competitive practices such as price cutting or advertising (Jacobs 1997).

Restrictive practices are not limited to agreements between firms, but may encompass a wide range of single firm practices aimed at restricting or distorting competition: Clarke observes that "The scope for single-firm anti-competitive practices is limited only by human ingenuity" (Clarke 1985). Firms use a variety of vertical restraints, including resale-price maintenance (RPM), where the price at which a retailer may resell a good is fixed, and exclusive dealing, where the downstream firm is prevented from selling brands that compete directly with the products of the upstream firm.

The set of vertical restraints that can be used in practice will depend on the ability of the seller to observe the behaviour of the downstream firm, and to enforce their agreement. The willingness of downstream firms to agree to such restraints will also depend on the level of uncertainty and their attitude to risk. For example, a downstream firm will not agree to RPM if they fear a change in other retail costs. Finally all such restrictive or collusive arrangements will only be effective as long as new entrants are prevented from entering the market and undermining the current arrangements.

3.5.6 Influencing the Design and Implementation of Regulation

One can distinguish two broad standpoints for the analysis of the design and implementation of regulation: the public interest and self-interest approaches. Within the public interest approach, regulation is viewed as being imposed independently on providers by outside agencies in order to further the public interest. However, based on the insights of the public choice literature, regulation may also be seen as an inherently political process with a range of groups and individuals with vested self-interests attempting to influence the design of the regulatory mechanism and its implementation (Peltzmann 1976; Stigler 1971). It has been argued that in some settings, regulation operates systematically in the interest of the suppliers, rather than consumers or the public in general. For example, qualified physicians may try to influence the regulator to tighten entry requirements such as licensing for their own profession and their potential competitors in order to reinforce their market power (Folland, Goodman and Stano 1993). Attempts to influence the design or implementation of regulation take the form of political lobbying, advertising campaigns, legal action, or more informal interaction. Firms can also influence the potential for regulatory enforcement by deliberately concealing information.

Over time, continued contact between regulator and regulatee may lead to the formation of a symbiotic relationship, where the regulator effectively promotes the interest of the industry under question at the expense of its consumers, termed “regulatory capture”. This is particularly likely where the regulator is heavily reliant on the firms in question for information.

3.6 Evidence on Competition in Health Care, Pharmaceutical and Retail Markets

No studies were identified applying these economic models and concepts to the retail market for drugs in the developing world. However, there may be insights from analyses in related areas, so a brief review is provided of studies of competition in health care and pharmaceutical markets, and in the African retail sector.

3.6.1 Competition in Health Care Markets

The majority of analysis of the nature of competition in health care markets concerns the US hospital market and its particular institutional arrangements, such as insurance, health maintenance organisations (HMOs), and physician networks (Dranove and Satterthwaite 2000). There is also a smaller literature relating to institutional arrangements in other developed countries, such as the UK and New Zealand (Ashton and Press 1997; Propper and Soderlund 1998; Roberts 1993). In the developing world, there is a small set of studies on hospital markets from Thailand, India, Bangladesh, the Philippines and Zambia (Amin 2002; Bennett 1996;

Ginson-Bautista 1995; Muraleedharan 1999; Nakamba, Hanson and McPake 2002). The non-hospital sector is far less studied in both the developed and developing world.

The available evidence indicates that the market for health care generally consists of many separate geographic markets that are further segmented by type of provider (Dranove and Satterthwaite 2000). Within these segments the vast majority of health care and pharmaceutical markets are neither perfectly competitive nor completely monopolistic (Dranove and Satterthwaite 2000; Jacobs 1997; Scherer 2000). Dranove and Satterthwaite argue that monopolistic competition describes the market for most health services “tolerably well” because providers compete with a substantial number of other firms whose services are good but not perfect substitutes for their own. They argue that markets are not generally oligopolistic, as for a specific provider no one or two competitors are central enough that it is worthwhile thinking how they will react to a change in price or service attributes. However, Gaynor and Vogt argue that while the US physician market is monopolistically competitive because most physicians are located in close proximity in urban markets, most hospital markets are characterized by a relatively small number of hospitals interacting over a long period, implying a differentiated product oligopoly (Gaynor and Vogt 2000). Silvia and Leibenluft note that even in the historically monopolistically competitive US physician markets, the growth of large group practices and networks may be increasing concentration and market power (Silvia and Leibenluft 1998). Hospital markets in Bangkok and Bangladesh were found to be relatively concentrated (Amin 2002; Bennett 1996), and strong market segmentation between high quality/high price and low quality/low price hospitals was found in both Bangladesh and Zambia (Amin 2002; Nakamba, Hanson and McPake 2002).

The following features have been identified as central in maintaining some degree of market power for health care providers: product differentiation with heterogeneous preferences; asymmetric information (potentially leading to imperfect agency); barriers to entry as a result of both economies of scale and regulatory intervention; and institutional structures such as insurance, which reduce the sensitivity of consumers to price. This market power can be seen as both a primary cause of market failure⁵ (e.g. consumer insensitivity to technical quality), and the result of policy interventions designed to correct these failures (e.g. barriers to entry resulting from licensing of practitioners).

Consumers in the US hospital market are believed to be insensitive to price, due to institutional structures which involve third party payers, low co-payments, and retrospective fee-for-service reimbursement of providers. It has been argued that a quality competition model therefore

⁵ Market failure refers to the failure of an unregulated market to achieve an efficient allocation of resources.

prevails, with greatest emphasis placed on the most easily observable elements of quality, which may lead to the development of a “Medical Arms Race” (Robinson 1988). In support of this hypothesis, many econometric studies have found a significant inverse relationship between the degree of concentration and costs or quality measures (Chirikos 1992; Robinson and Luft 1987; Robinson et al. 1988; Wilson and Jadow 1982). In Thailand, Bennett found evidence of a negative correlation between profits and concentration in the Bangkok market for hospital services, combined with some association between lower concentration and higher quality (Bennett 1996). However, a number of measurement problems remain in the literature, such as the definition of the relevant market, the accuracy of the quality proxies used, and the failure to allow for simultaneous price and quality competition (Dranove and Satterthwaite 2000; Dranove, Shanley and Simon 1992; Noether 1988).

Other key market failures in health care are unrelated to market power, such as externalities and the public good characteristics of certain services⁶. In conjunction with equity concerns, these failures have led to the conclusion that markets for health care are very different to markets for most other goods. Moreover, health care markets also diverge from the competitive model because profit maximisation is frequently an inaccurate approximation of provider objectives. For example, Newhouse argues that a not-for-profit hospital can be viewed as aiming to maximise a utility function which reflects a combination of the quantity and quality of care provided (Newhouse 1970). Palmer and Mills found that the behaviour of private GPs in South Africa was strongly influenced by the desire to maintain a good professional reputation, and to serve the local community, as well as financial considerations (Palmer and Mills 2003).

3.6.2 Competition in Pharmaceutical Markets

There is an extensive literature on pharmaceutical markets, mainly focusing on competition between drug manufacturers, and their interactions with institutions responsible for health care provision in the developed world. Many analyses address whether and how drugs should be reimbursed by private and social insurance systems, the role of patent protection, the impact of generic entry, and pharmaceutical regulation (Ferrandiz 1999; Garattini and Tediosi 2000; Maynard and Bloor 2003; Mossialos, Walley and Mrazek 2004; Scherer 2000; Scott-Morton 2000). There is a more limited literature on competition and regulation in the retail pharmacy market, focusing on remuneration and regulation, although this sector has been described as “heavily under-researched” (Huttin 1996; OFT 2003). Literature related to the developing world predominantly addresses concerns about the lack of effective drugs and their high cost, through

⁶ Public goods are non-rival in consumption (one person's consumption does not reduce the quantity available for another) and non-excludable (it is impossible to exclude those who do not pay). Externalities represent benefits or costs of consumption or production that are not fully valued by the consumer/producer.

discussion of the role of essential drugs policies, patent law, and incentives for research and development for neglected diseases (Mrazek 2002; Mrazek and Mossialos 2003; Ratanawijitrasin, Soumerai and Weerasuriya 2001).

Pharmaceutical markets are distinguished by a number of key features (Scherer 2000). First, drugs are divided into prescription-only and over-the-counter products, with many restrictions on the availability of the former. Secondly, demand for pharmaceuticals is generally inelastic, reflecting the predominance of third party payers, and a high willingness to pay for medicines. Thirdly, research and development costs are relatively high and, fourthly, patent protection plays a very important role in profitability. Finally, there is considerable use of government regulation, mainly to ensure the safety and efficacy of medicines, and the affordability of drugs through widespread price regulation (Maynard and Bloor 2003; Mossialos, Walley and Mrazek 2004; Ratanawijitrasin, Soumerai and Weerasuriya 2001).

In terms of structure, pharmaceutical markets generally consist of a high number of firms with very unequal market shares (Lobo 1979). As a broad generalisation, there are a small number of multinational "pioneer" firms that undertake research and development to discover new drugs and bring them to the market, and a large number of smaller generic or "imitator" firms, distributed more widely around the globe (Scott-Morton 2000). The market structure for retail pharmacies depends on entry regulation, with some markets dominated by chain stores, while in others independent pharmacies continue to predominate (OFT 2003).

There are many sources of market power for pharmaceutical manufacturers, including patent protection, the need for regulatory approval of drugs, poor consumer information on alternative medicines, product differentiation and barriers to entry. Scherer notes that, as a result, well-established pharmaceuticals in the US generally have substantial price-cost margins (Scherer 2000). These factors, combined with third party payment by insurance firms and the agency role of physicians in prescription, have led the market to be described as "unique with regard to the extent and depth of its failure to meet the criteria for a perfect market" (Mossialos, Walley and Mrazek 2004). Product differentiation is often enhanced by intensive marketing, through detailing visits to physicians, and direct-to-consumer advertising where permitted. While it is argued that there are few technical economies of scale in drug production, economies of scale in pharmaceutical advertising may present a significant barrier to entry, even in the absence of patent protection (Lobo 1979).

While still under patent, the market is likely to be characterised as a differentiated oligopoly, as the drugs compete only with different chemical entities for the same health problem, which are imperfect substitutes. Following patent expiration, considerable entry generally takes place, by

manufacturers of both branded and unbranded generics. Monopolistic competition is likely to prevail, with all firms retaining some market power (Scherer 2000). A frequently observed phenomenon is the "generic competition paradox" that occurs when, following the expiry of a patent, generic alternatives enter the market, but the originally patented brand continues to be sold at a higher price (Scherer 2000). This gap is often maintained or even gets wider over time. There are essentially two markets or market segments: one of price insensitive consumers willing to pay high prices for the original brand, and another consisting of price sensitive consumers willing to shift to generics (Suh et al. 2000). Price insensitivity in the first group may arise because established products have built up accumulated goodwill and reputation during the patent period. Higher prices may also be maintained because consumers lack information about generics, because they are concerned about the quality of newer products, or because prescribers and patients are not directly affected by the financial consequences of their drug choice (Ferrandiz 1999). Several authors have argued that such first mover advantages also exist in the market for generics (which are often clearly differentiated by brand, even though the drugs are off-patent). Grabowski & Verno (1992) found that for virtually all products they studied, the market leader was an early entrant (Grabowski and Vernon 1992).

3.6.3 Competition in African Retail Markets

Markets play an extremely important role in product and service distribution in sub-Saharan Africa. Over the last three decades states have gradually abandoned post-colonial attempts at Soviet-inspired command economy models, which involved price regulation, and the prohibition of some private trading activities. It has been argued that the region is now more market-oriented than many advanced countries, as in the latter much resource allocation takes place within large firms and public entities (Fafchamps 1997). Sub-Saharan Africa has been characterised as having a dual industrial structure, with a small number of large enterprises, but a very large number of very small firms or micro-enterprises, with few medium-sized enterprises (Fafchamps 1994). The proportion of the workforce that is self-employed in their own business is much higher than in developed countries, with many entrepreneurs running several small businesses simultaneously (Fafchamps 1997). Micro-enterprises are argued to thrive for a number of reasons. Firstly they are able to find market niches where they do not face competition from large firms. Secondly, they can take advantage of better worker supervision, entrepreneurial motivation, and access to small venture capital. Finally, many laws and regulations, which increase costs for medium-sized firms, either explicitly exclude micro-enterprises, or are easy for them to evade (Fafchamps 1994).

Micro-enterprises are often referred to as the informal sector, although there is no consensus on the definition of this term (Broom and Joyce-Clarke 1990). A 1972 International Labour

Organisation (ILO) report defined it to apply to markets which exhibit ease of entry, reliance on indigenous resources, family ownership of firms, small-scale operation, labour-intensive and adapted technology, skills acquisition outside formal education, and a lack of regulation (Broom and Joyce-Clarke 1990). There is some overlap with other terms frequently used, such as parallel markets, which arise to evade price and quantity controls, and black markets, which refer to illegal trade (Jones, Lindauer and Roemer 1991). However, many informal sector activities are legitimate, if unrecorded business.

There are frequent complaints about the paucity of information on African markets, particularly as official statistics for micro-enterprises are poor or non-existent (Fafchamps 1997; Porter 1990). Findlay and Paddison highlight the acute shortage of reliable data on retailing environments in all developing countries (Findlay and Paddison 1990). In a recent review of the characteristics and behaviour of product markets in Africa, Jerome and Ogunkola state that “Almost nothing is known about the nature of existing markets, the magnitude of commodity trade, facilities used and the cost of performing the relevant functions, the operating margin of assemblers, wholesalers and the processes of price determination” (Jerome and Ogunkola 2000). This appears somewhat extreme, as much has been written on the informal sector from a development economics perspective. The literature focuses on why the sector exists, its role in development, and how it can be assisted to grow, but mainly considers manufacturing and agriculture, rather than retailing (Paddison, Findlay and Dawson 1990).

The retail sector has been more studied by geographers, marketing specialists, and occasionally anthropologists. Retailers are argued to have a central role in society in developing countries (Findlay and Paddison 1990). Two key characteristics of the sector are its diversity and dynamism. Retail outlets range from modern shopping centres and supermarkets to direct producer-consumer relationships, such as the hawking of home-made food. They are subject to considerable change, in response to population growth, urbanisation, general macroeconomic fluctuations, and improved accessibility through the development of transport networks (Jerome and Ogunkola 2000; Porter 1990). Reflecting the spread of globalisation, the goods marketed are increasingly produced by large, multinational companies, with examples being imported staples and soft drinks (Findlay and Paddison 1990). However, the market structure has not been replaced by Western retail models. Instead traditional practices have evolved to produce a hybrid market structure, which still exhibits continuity with some 19th century practices (Findlay and Paddison 1990; Porter 1990). Western retail is generally based on fixed shop units, and increasingly dominated by large distribution firms with multiple retail outlets (Paddison, Findlay and Dawson 1990). By contrast, in developing countries the sector remains dominated by the small-scale retailer, and there are many ambulatory sellers, and periodic markets. Specialist shops are relatively rare, exceptions being electrical and drug stores, where it is

argued that a certain level of expertise in sales and service is required (Porter 1990). The prevalence of small-scale, informal, non-permanent retailers does not mean that the sector is chaotic. In fact even casual street trading is usually highly structured (Paddison, Findlay and Dawson 1990). For example, periodic markets, held on one or more specified days per week, provide a well-organised supply of basic commodities to local people, and act as collection points for rural surplus (Hollier 1990; Jerome and Ogunkola 2000). It is argued that micro-enterprises make good business sense in the retail sector, because geographical dispersion generates information asymmetries, making it very costly for retail chains to monitor employee performance (Fafchamps 1994).

In developing countries, retailing is more focused on basic needs such as food and clothing than in the Western world (Paddison, Findlay and Dawson 1990). Due to the low incomes of consumers, they are argued to be more sensitive to price than to quality, service or promotion. Marketing is not generally an important influence on distribution, although there are exceptions where consumers spend considerable sums on goods with prestige value (Paddison, Findlay and Dawson 1990). Barriers to entry are relatively low, as trading provides an opportunity for self-employment with minimal capital requirements and technical constraints. One might therefore expect the sector to be quite close to the perfectly competitive model. However, the literature on micro-enterprises raises a number of reasons why this may not be the case, despite the large numbers of buyers and sellers, and low entry barriers. The marketing infrastructure of transport, communications, credit and storage facilities in Africa is the poorest in the world, inhibiting the smooth functioning of the market (Jerome and Ogunkola 2000). Prohibitive transport costs and poor communication channels lead to fragmented markets, and incomplete credit markets limit entry and expansion (Jones, Lindauer and Roemer 1991). In these heavily segmented markets, competition is reduced, and the price of products fluctuates more than one would expect from differences in transport costs alone.

In addition, there may be strong non-market-based links between providers, in the form of ethnic and family networks for information sharing, saving schemes and employment opportunities, and long-term relationships with wholesalers for advancing goods (Fafchamps 1994). For example, Speece describes the “ethnodomination” of much retailing and wholesaling by Asian merchants in East Africa in the mid-20th century (Speece 1990). Such links allow trust to develop over time, helping to reduce opportunistic behaviour, but may also reduce competition. Tripp notes that many of the poorest microenterprises do not appear to profit maximise, and instead prioritise norms of reciprocity, mutuality and fairness. They are “as likely to co-operate as to compete”, for example by sharing information, assisting similar local businesses, or engaging in collective income generating activities (Tripp 2003).

In sum, retail markets are a vibrant distribution channel in Africa, generally dominated by small-scale outlets. While relatively little is known about retail market structure and provider conduct, there are indications that poor marketing infrastructure may lead to substantial divergence from the perfectly competitive model.

3.7 Conclusion

This methodological review shows the value of the industrial organisation literature in characterising competition in many markets, and developing hypotheses on their performance. It has been widely used to analyse markets for hospital services, mainly in developed countries, but little used in the retail sector in developing countries, with no studies identified on the retail pharmaceutical sector in sub-Saharan Africa. The review highlights many concepts of potential use in the analysis of the market for fever and malaria treatment in Tanzania, including product and geographical market definition, market concentration, models of oligopoly and monopolistic competition, information characteristics of products, barriers to entry and exit, price discrimination, product differentiation, imperfect agency, collusion and restrictive practices, and responses to regulation.

The way these concepts are brought together into a conceptual framework for analysis is described in Chapter 5. However, before turning to the details of the study, some background on Tanzania and its policies on malaria and pharmaceutical regulation is provided in Chapter 4.

CHAPTER 4

TANZANIA AND ITS POLICIES ON MALARIA AND PHARMACEUTICAL REGULATION

4.1 The Tanzanian Economy

Tanzania has a population of 34.8 million¹. The country is divided into 21 regions and 121 councils (rural Districts or municipalities). About 76% of the population live in rural communities, and agriculture dominates the economy, accounting for over 50% of GDP, and 82% of the employed labour force (Government of Tanzania 2004a; IMF 2004). The second largest sector is trade, which accounts for 12% of GDP, and 7% of the employed labour force, of which 69% are workers in services or shops.

The growth of the private sector is a relatively new phenomenon in Tanzania. From the Arusha Declaration in 1967 until the mid-1980s Tanzania followed a socialist economic model, with the restriction of private sector activities, and central government controls in all key areas, including price controls (Naschold and Fozzard 2002). This even included strong discouragement of private retailing. In 1976, "Operation *Maduka*" (shops) led to the closure of many private shops in favour of co-operative/village outlets, which in 1980 the Government announced should be publicly run in the manner of government schools and health facilities (Rutashobya 1998). By the early 1980s, the country was experiencing deep economic crisis. Since then, a programme of liberalisation has been gradually implemented. As a result markets operate more freely, and the private sector has expanded exponentially.

However, Tanzania remains one of the world's poorest countries. Gross national income per capita is \$290, 36% of the population are below the basic needs poverty line, and 20% live on less than \$1 per day (National Bureau of Statistics Tanzania 2002; UNDP 2004; World Bank 2004). In 2001, 29% of children under five were malnourished, under five mortality was 165/1000, maternal mortality 1100/100,000, and life expectancy at birth 43.5 years (UNDP 2004; World Bank 2004). HIV prevalence was estimated to be 9% of the population aged 15-45 years in 2003 (UNDP 2004). The government is aiming to tackle these huge health problems with a Ministry of Health (MOH) budget of only \$6.3 per person per year (2003) (Government of Tanzania 2004b).

¹ World Population Prospects Population Database, 2002 Revision: <http://esa.un.org/unpp/>

4.2 Malaria and its Treatment

The whole population of Tanzania is at risk of malaria: 75% are subject to stable perennial or stable seasonal malaria transmission, 8% to unstable highly seasonal transmission, and 17% are at risk of periodic malaria epidemics (de Savigny et al. 2004). Over 90% of malaria infections are caused by *Plasmodium falciparum*, the most virulent strain of the *Plasmodium* species (National Malaria Control Programme 2003). Malaria is a primary cause of disease burden. It is the leading cause of outpatient and inpatient health service attendance at all ages, although the most vulnerable groups in areas of stable transmission are children under five years and pregnant women, whose immunity is low. The number of clinical malaria cases per year is estimated to be between 14 and 18 million, and the number of deaths per year at 100,000 to 125,000, of which 80,000 are in children under the age of five years (National Malaria Control Programme 2003).

The strategic plan of the National Malaria Control Programme (NMCP) is built around four pillars: 1) improved malaria case management; 2) national scale utilisation of insecticide treated nets (ITNs); 3) prevention of malaria in pregnancy; and 4) malaria epidemic prevention and control. Progress is being made on the two main preventive strategies. A nationwide social marketing programme to expand the commercial market for ITNs is in place, and intermittent preventive treatment for pregnant women (IPTp) is being expanded through antenatal care. However, coverage remains low: in 2002 only 29% of pregnant women received two doses of IPTp, and only 15% of the population were covered with ITNs (Malaria Consortium 2004).

The government has set itself the target of raising the use of appropriate treatment for fever episodes in children under five within 24 hours from 19% to 60% by the 2007, in line with the target set by Heads of State in Abuja in 2000. A Roll Back Malaria consultative mission recently concluded that Tanzania was likely to achieve the Abuja targets for ITNs and IPTp by the end of 2005, but not the target for appropriate treatment (Malaria Consortium 2004).

Tanzania changed its antimalarial drug policy in mid-2001. High levels of resistance led chloroquine to be abandoned as first line treatment in favour of SP², prescribed with paracetamol. Amodiaquine was selected as second line, and quinine as third line and first choice in severe malaria. The policy took several months to be rolled out in all government facilities. SP initially received some negative media attention about adverse side-effects and drug quality,

² unless otherwise stated, the abbreviation SP is used in this thesis to cover drugs from both the sulphadoxine pyrimethamine and sulphamethoxypyrazine pyrimethamine (SMP) groups, which have the same indication and dosing requirements (Ministry of Health, 2000).

although it has been increasingly accepted over time (Williams et al. 2003).

The useful life of SP as first line is not expected to be long. There is already some SP resistance in Tanzania, and experience elsewhere has shown it to grow rapidly (EANMAT 2003; Greenwood 2004). The government plans to introduce artemisinin-based combination therapy (ACT) in 2006, and has already submitted a successful application for funds for this policy change to the Global Fund for AIDS, TB and Malaria.

Facility-based antimalarial treatment is provided through a network of dispensaries, health centres and hospitals. Health centres are generally larger than dispensaries, with a wider range of staff and, in some cases, a small inpatient ward. Of a total of 4844 health facilities, 59% are government, 6% parastatal, 18% mission/NGO and 17% private commercial (National Malaria Control Programme 2003). Dispensaries and health centres should provide treatment of uncomplicated cases, and pre-referral treatment of severe cases and treatment failures (Ministry of Health 2000). They should also deliver patient education, and identify anaemia cases. Diagnosis may be by blood smear, but is generally by clinical history and physical examination alone. While clinical diagnosis relies mainly on the presence of fever, health workers are also instructed to check for the following additional malaria symptoms: headache, joint pains, malaise, body weakness, vomiting, diarrhoea, chest pains and poor appetite.

4.3 Pharmaceutical Regulation

The regulation of pharmaceuticals is now covered by the 2003 Food, Drugs and Cosmetics Act, and overseen by the Tanzania Food and Drugs Agency (TFDA). However, at the time of data collection, pharmaceutical regulation was the responsibility of the Pharmacy Board, through the 1978 Pharmaceuticals and Poisons Act and the 1990 Pharmaceuticals and Poisons Regulations. These covered the qualification and registration of pharmacists, and regulation of manufacture, importation, labelling, identification, storage and sale of pharmaceuticals.

Although, fever/malaria drugs are frequently obtained from retailers in Tanzania, formal health care coverage is relatively good by sub-Saharan African standards, with over 90% of the population living within 10km of a facility (National Malaria Control Programme 2003). There are three types of retail outlets for drugs in Tanzania: Part I and Part II pharmacies, and general stores. Part I pharmacies must be run by registered pharmacist, and are allowed to sell both Part I (prescription-only) and Part II (over-the-counter) medicines. In 2003 there were 344 Part I pharmacies, 60% of which were in Dar es Salaam, with the rest distributed unevenly throughout the regions, always in urban areas (Battersby et al. 2003).

Drugs are widely available in both urban and rural areas from Part II drug shops and general retailers. In 2003, the Pharmacy Board had records of 5666 Part II stores, although the total number may be considerably higher because some are unregistered (Battersby et al. 2003). Under the 1978 Act, Part II pharmacies, or drug stores, could be run by anyone with basic medical training (e.g. nurse, pharmacy assistant). Established to address the lack of access to drugs for much of the rural and peri-urban population, they were supposed to be located only in areas currently "underserved". They were allowed to stock Part II medicines only, known as "*baridi*" drugs. These included common painkillers and a few oral antimalarials (before the 2001 policy change these comprised chloroquine and amodiaquine tablets and syrup; after the policy change the chloroquine formulations were replaced with SP tablets). They were not permitted to sell any oral antibiotics, nor injectables of any kind.

General retailers range from large shops to small roadside stalls, typically stocking a mixture of food products and household goods. The legal position on drugs in general stores was unclear at the time of the study because they were not covered under the 1978 Act. It seemed that general stores were not strictly allowed to stock any drugs, but in practice were permitted to sell some over-the-counter medicines, such as common painkillers, and chloroquine before the policy change.

Drug registration came into force in 1999, and in theory all drugs should have been registered before they were made available for consumption. However, this was applied strictly only to imported drugs; locally manufactured products could receive temporary approval for distribution, while improvements to manufacturing standards were put in place. At the time of data collection, no locally manufactured antimalarials were registered. Regulations were enforced by the Pharmacy Board, with Regional Pharmacists and Regional Medical Officers designated as inspectors outside Dar es Salaam, who in turn passed this responsibility on to District Medical Officers in some regions. General stores were inspected by Health Assistants only, who are Ward-level environmental health staff.

Tanzania is striving to improve both pharmaceutical regulation and community-based malaria treatment. The newly established TFDA is aiming to improve the quality of drugs throughout the distribution chain through collaboration with domestic manufacturers, and more frequent quality testing of imports. Specific goals and strategies have been defined for community-based malaria treatment, including increasing the proportion of households receiving educational interventions, improving the quality of first line antimalarials in shops, ensuring correct dosing, and increasing the knowledge of shopkeepers (National Malaria Control Programme 2003). It is hoped that this thesis may contribute to strengthening these reforms and new initiatives in malaria treatment and the pharmaceutical sector.

PART II

METHODOLOGY

CHAPTER 5

STUDY DESIGN AND METHODS

5.1 Introduction

This chapter covers the study design, study sites and methods for data collection and analysis. Section 5.2 on study design specifies the aims and objectives of the thesis; the conceptual framework is described, and the scope of the study defined. Section 5.3 covers the selection of study sites, and their characteristics. In Section 5.4, methods for data collection and analysis are described, including ethical issues, and details of each data collection activity, their analysis and timing.

5.2 Study Design

5.2.1 Aims and Objectives

The aim of this thesis is to analyse the market for fever and malaria treatment in three rural Tanzanian districts, with a particular focus on retail outlets, and to draw implications for the improvement of malaria treatment.

Specific objectives are to:

1. Describe treatment seeking and drug purchase for fever and malaria, and assess the appropriateness of care obtained
2. Analyse the nature of competition in the fever and malaria treatment market, through an assessment of market structure, price and non-price competition
3. Assess the impact of government regulation on the operation of retailers
4. Analyse the implications of competition and regulation for the accessibility, quality and affordability of care obtained
5. Identify policy implications for improving malaria treatment, and in particular for the delivery of artemisinin-based combination therapy (ACT).

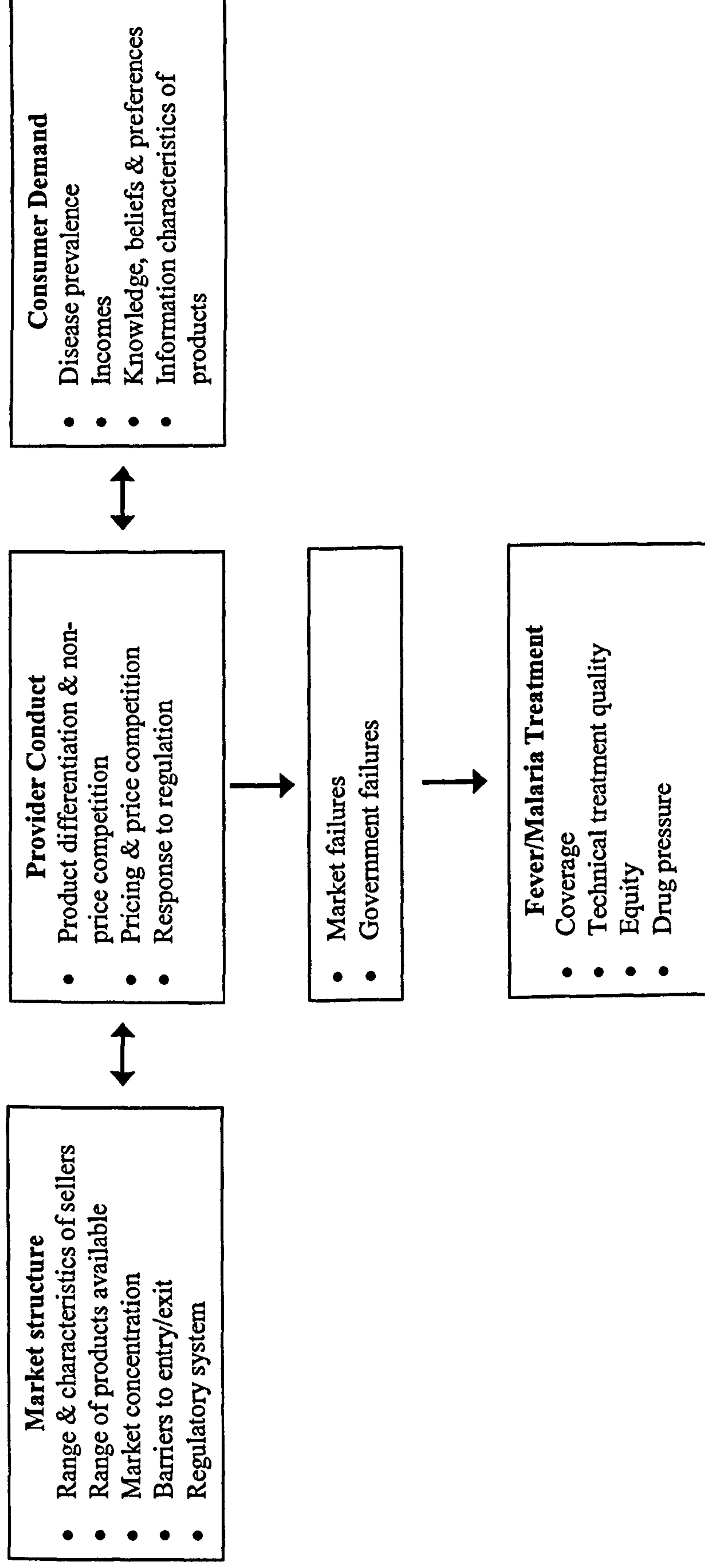
5.2.2 Conceptual Framework

To meet the above objectives a framework was required which could provide analytical concepts and tools for the study of competition and its implications. The industrial organisation literature on markets reviewed in Chapter 3 was identified as having the potential to provide important insights in this area, and to have been usefully employed in the analysis of health care markets in other settings. This led to the identification of the conceptual framework shown in Figure 5.1. It draws on the industrial organisation paradigm, which emphasises the links between market structure and provider conduct in determining market performance, acknowledging that the direction of causation between these elements can be two-way (Tirole 1988). Following Conteh and Hanson (2003), the framework was adapted to include demand-side influences on provider conduct explicitly, and to recast the measures of performance in terms of goals related to public health. Within the context of government provision and regulation, the interplay of market structure, provider conduct and consumer demand is hypothesised to determine the nature of competition in the market for fever and malaria treatment, and to influence the nature of both market and government failure¹. In order to adapt this framework to the specific market under study, potential incentives shaping provider and consumer behaviour were identified, drawn from both the industrial organisation literature reviewed in Chapter 3, and evidence from the behavioural, sociological and anthropological literature on treatment seeking and provider behaviour reviewed in Chapter 2 (Annex 2).

Performance is defined primarily by the coverage of fever/malaria treatment, and its technical quality. In addition, the equity of treatment obtained is considered. Issues of horizontal equity may arise through unequal treatment by socio-economic group, gender, religion, or area of residence. Vertical equity issues are also relevant, in the greater importance of appropriate treatment for the most biologically vulnerable groups. Finally, drug pressure is a key market outcome because of its influence on the development of drug resistance, and therefore, the future effectiveness and cost of malaria treatment. The thesis assesses these outcomes, and then aims to understand them through an analysis of the nature of competition and regulation in the fever/malaria treatment market.

¹ Government failure occurs when government policy fails to address a market failure, or creates an even more inefficient allocation of resources.

Figure 5.1 Conceptual framework



5.2.3 Defining the Scope of the Study

The analysis addresses the market for fever and malaria treatment. The main focus is on the behaviour of drug retailers, but as retailers are potential substitutes and complements for other providers, such as public and private health care facilities, a comprehensive market analysis must consider all important fever and malaria treatment providers. The thesis aims to assess competition between providers directly interacting with customers, rather than between pharmaceutical manufacturers, although the pharmaceutical products stocked are considered.

The term "private facilities" is used to refer to all non-governmental health facilities owned by missions, non-governmental organisations (NGOs) or private individuals. The "retail sector" is defined as all drug shops and general stores or stalls selling drugs; the "private sector" encompasses the retail sector and private facilities. The generic terms "outlet" and "provider" are used for any source of fever/malaria treatment.

Treatment is assessed for the broadly defined health problem of fever and/or malaria. In Tanzania the biomedical concept of uncomplicated malaria overlaps with the local illness concepts of *homa* (usually translated as fever, although it can include other symptoms), and *malaria* or *homa ya malaria* (Minja et al. 2001; Winch et al. 1996). As uncomplicated malaria is generally treated on the basis of clinical symptoms alone, the market for malaria treatment cannot be distinguished from the more general market for the treatment of febrile illness, so the study is based on *homa* and *malaria*. A history of fever is a very sensitive indicator of uncomplicated malaria, but lacks specificity, meaning that a high proportion of fevers will have non-malarial causes. Some community members use other terms for the manifestations of severe disease, such as *degedege* for convulsions, and *bandama* for splenomegaly, which may not be captured under the *homa* and *malaria* umbrella (Minja et al. 2001). This was not a major concern, as the main focus of the research was uncomplicated malaria. Fever/malaria drugs were defined to include the two main categories of drugs used, antimalarials and painkillers. The latter may be used for pain relief and/or their antipyretic action. Key complementary services included diagnosis and medical advice.

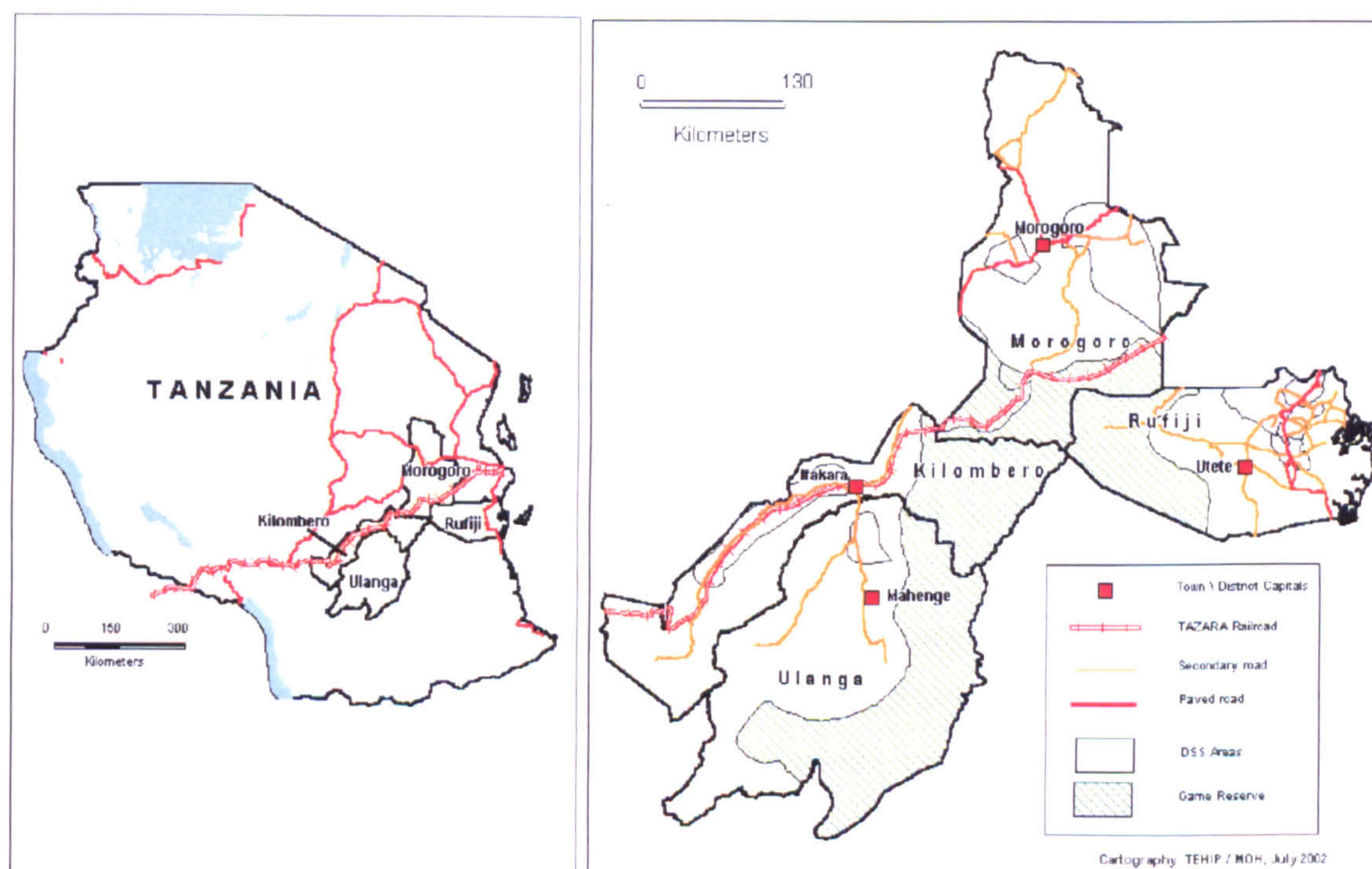
More detailed product and geographical market definitions are considered empirically in Chapter 7 on Market Structure.

5.3 Study Sites

5.3.1 Study Site Selection

The study sites were selected for the Interdisciplinary Monitoring Project for Antimalarial Combination Therapy in Tanzania (IMPACT-TZ), of which this study forms one component. IMPACT collaborators, objectives and data collection activities are summarised in Annex 3. The main aim of IMPACT is to evaluate the effectiveness of ACT in inhibiting antimalarial drug resistance. In addition, the wide range of complementary data collected by the project will help improve many aspects of malaria control. Between 2000 and 2002 the IMPACT project collected baseline data, under a first-line regimen of chloroquine until August 2001 and SP thereafter. In early 2003 ACT (SP+3-day-Artesunate) was introduced as first line drug in facilities in Rufiji District. The IMPACT evaluation is comparing ACT in Rufiji with SP monotherapy in the 3 districts of Morogoro-Rural, Kilombero and Ulanga, over a 5 year period (Figure 5.2).

Figure 5.2 Location of IMPACT study districts and demographic surveillance system (DSS) areas.



These four districts were selected for the IMPACT evaluation for a number of reasons. Malaria endemicity is similar in all districts, and malaria is a leading cause of morbidity and mortality. Although the districts share borders, population mixing between Rufiji and the other districts is

very limited, due to the presence of the Selous Game Reserve along their common borders. The work of the Ifakara Health Research and Development Centre (IHRDC), the Tanzanian Essential Health Interventions Project (TEHIP), and the Adult Morbidity and Mortality Project (AMMP) has led to good knowledge of the epidemiological and health system characteristics of the districts, and the development of an excellent research infrastructure. In particular, each district has a large proportion of their population under continuous demographic surveillance, providing a reliable sampling frame for community-based research, and the potential for relatively objective quantification of disease burden. The majority of IMPACT data collection is taking place in these demographic surveillance system (DSS) areas.

The data for this thesis were collected between mid-2000 and mid-2002, during the baseline phase of the IMPACT project. Data collection took place in the DSS areas of three of the IMPACT study districts: Kilombero, Ulanga and Rufiji. The fourth IMPACT district, Morogoro-Rural, was excluded for two reasons. Firstly it surrounds a large town (Morogoro-Urban), a separate administrative area, which forms the economic hub for the surrounding villages. To understand the market in Morogoro-Rural, detailed analysis of Morogoro-Urban would also be required which was felt to be beyond the scope of this protocol. Secondly, due to the relatively limited DSS infrastructure in Morogoro, the IMPACT household survey from which much of the data on treatment seeking were captured was not undertaken in this district in 2001.

5.3.2 Characteristics of the Study Districts

Kilombero and Ulanga Districts lie in Morogoro Region in southeastern Tanzania, 350-400km from Dar-es-Salaam. Rufiji District is to the south of Dar-es-Salaam in Coast Region. The districts have two main rainy seasons, the short rains in October-December and the long rains in March-May, although there is variation from year-to-year. There are very few paved roads, and some villages are difficult to reach during the long rains. Although buses run on main roads, most transport is by minibus-taxi, lorry or bicycle. The Tazara railway runs through Kilombero, carrying freight and passengers, with stations in many settlements. Most houses have mud walls and thatched or corrugated iron roofs. The main economic activity is subsistence farming, supplemented by limited cash-cropping. Major crops include rice, maize, cassava, millet, sesame, coconut and cashew nuts, and fishing is also common. Many families have a second house known as a *shamba* (farm) house in low-lying farmland areas where they stay during the rice planting and harvesting seasons. In Kilombero and Ulanga, median monthly household expenditure was under US\$100 in 1997, of which about 75% was for food (INDEPTH Network 2002). In addition to local languages, KiSwahili is widely spoken, but English is not commonly

used. Literacy rates for men were 88% in Kilombero/Ulanga, and 66% in Rufiji, and for women, 69% and 30% respectively (INDEPTH Network 2002).

The districts were relatively well matched in terms of population density, general health status, and predicted intensity and duration of malaria transmission (Table A1.2 in Annex 1). Health services were also broadly comparable across the districts. However, three differences between the districts should be highlighted. Government facilities were officially free in Rufiji, but in Kilombero and Ulanga user fees had been introduced in dispensaries (but not in health centres). Fees were retained at facility level and could be used for minor expenditures, such as drug purchase during stockouts or facility repairs. They were not designed to provide financial incentives to government staff. Secondly, the WHO/UNICEF initiative for the Integrated Management of Childhood Illness (IMCI) was implemented in formal facilities in Rufiji (and Morogoro-Rural) from 1997, while standard case management remained in place in Kilombero and Ulanga Districts until 2002. Facility-level IMCI includes the development of clear guidelines for healthcare workers, 11-day training courses for staff treating children, and system support through improved supervision and commodity supplies (Armstrong Schellenberg et al. 2004). Thirdly, there were differences in bednet coverage. Although all three districts were covered by social marketing programmes for treated mosquito nets, the Kilombero programme (KINET) had been in place for longer. As a result, around one-third of children under five slept under a bednet in Ulanga and Rufiji Districts, compared with two-thirds in Kilombero. However there were fairly uniform (and low) rates of use of insecticide-treated bednets.

According to health service data and the perceptions of local people, malaria was the foremost health problem for both adults and children in the study districts (INDEPTH Network 2002; Tanner et al. 1991). *Anopheles gambiae* and *Anopheles funestus* were the main malaria vectors, with an estimated 200-300 infective bites per person per year occurring in rural areas close to Ifakara Town, the District headquarters for Kilombero (INDEPTH Network 2002). *P. falciparum* malaria transmission was intense and perennial, although mosquito densities peaked between November and May. Uncomplicated malaria was the leading diagnosis for outpatient visits in all districts. The vast majority were diagnosed on the basis of clinical symptoms alone, most commonly just the presence of fever, leading to substantial over-diagnosis. IMPACT facility surveys have shown that 51% of outpatients diagnosed with malaria were parasite positive at dispensaries, 39% at health centres, and 38% at hospitals (Causer et al. 2003). Mortality data from Rufiji DSS showed that acute febrile illness (including malaria) was one of the major causes of mortality, in addition to acute lower-respiratory infections, tuberculosis, AIDS and perinatal illnesses (INDEPTH Network 2002).

Chloroquine resistance, measured by total treatment failure² in under fives, was found to be 72% in Kilombero in 1999 (compared with an average of 52% across all Tanzanian sentinel sites) (Ministry of Health 1999). Chloroquine has not been tested since for ethical reasons. The IMPACT project has collected *in vivo* data for SP in Ulanga and Rufiji Districts on an annual basis. Total treatment failure with SP increased in Rufiji from zero in 2000, to 1% in 2001, and 8% in 2002. In Ulanga the pattern was less clear, with a failure rate of 2% in 2000, 5% in 2001, and zero in 2002 (MacArthur et al., unpublished data, IMPACT collaboration).

5.3.3 Areas under Demographic Surveillance

All three study districts contain an area covered by DSS. In Rufiji the DSS was co-managed by TEHIP and AMMP. The areas in Kilombero and Ulanga are managed by IHRDC under one DSS system. The Kilombero and Ulanga DSS areas are separated by the Kilombero River, which runs along the border between the two districts (Figure 5.2). Throughout the thesis the term DSS systems is therefore used to refer to the two systems of Kilombero/Ulanga and Rufiji, and the term DSS areas, to the 3 areas of Kilombero, Ulanga and Rufiji. The DSS covered an area of 60km x 30km in Rufiji, 80km x 18km in Kilombero and 40km x 25km in Ulanga. In mid-2001 the DSS populations were 73,839 in Rufiji, 37,064 in Kilombero and 29,439 in Ulanga. Three rounds of DSS interviews are conducted per year in all areas, meaning that each household is visited every four months, to collect information on pregnancies, births, deaths and migrations. Between household visits, village-based key informants report births and deaths as they occur. Each household has a unique household number, which is marked discreetly on their buildings.

In terms of administrative structure, rural areas in Tanzania are divided into sub-villages (*vitongoji*), villages (*vijiji*) and wards (*tawi*) (2 to 8 villages). The Kilombero/Ulanga DSS system contained 25 villages, and Rufiji, 31. There are no towns in DSS areas, although Ifakara Town is located a few kilometres from the start of Ulanga and Kilombero DSS areas. Important rural market centres are officially designated as "minor settlements"; there are two such market centres in Rufiji DSS (Ikwiriri and Kibiti), one in Kilombero DSS (Mchombe), and one in Ulanga DSS (Lupiro).

The DSS areas are served by a mixture of government and mission health centres and dispensaries. The Government District hospitals in Ulanga and Rufiji are rarely used by DSS residents because of travel distance, being located in the District headquarters of Mahenge and Utete respectively (Figure 5.2). Instead both Ulanga and Kilombero DSS residents tend to use St Francis, the mission-owned Designated-District hospital in Ifakara town. Rufiji DSS

² Total treatment failure refers to clinical failure and parasitaemia by day 14 following treatment.

residents use Mchukwi Mission Hospital, located within the DSS. Manufactured drugs are also widely available from Part II drug stores and general stores in DSS areas. Typical examples of each type of drug provider are shown in Figure 5.3.

5.4 Methods for Data Collection and Analysis

5.4.1 Overview of Data Collection

Data were collected from households and drug outlets within the 3 DSS areas, through the data collection activities summarised in Table 5.1. Demand-side data were collected through a cross-sectional household survey, drawing on the DSS household sampling frame, and previous qualitative and quantitative studies in the area for the questionnaire design. Due to the relatively limited amount of previous work on the supply-side, and on retail outlets in particular, a wider range of data collection tools were employed. A sampling frame for all private drug outlets was constructed through outlet censuses, and qualitative interviews were conducted in shops and private facilities. These activities were then followed by a larger scale quantitative outlet survey, and retail audits of antimalarial sales³.

Data collection instruments were drafted in English, translated into KiSwahili by native speakers, and piloted in the study districts outside the DSS areas. All interviews were conducted in KiSwahili. English versions of all data collection instruments are contained in Annex 4.

All data collection at drug outlets was designed and managed by the author. The household survey was conducted in collaboration with other members of the IMPACT study team (Patrick Kachur, Salim Abdulla, Rashid Khatibu, Ernest Smith and John MacArthur), as the data were collected for use in several separate analyses. Other team members were responsible for all laboratory investigations. However, all household survey analysis presented in this thesis was the responsibility of the author. Samples for drug quality testing were collected by the author, but analysis was conducted by IMPACT team members from the US Centers for Disease Control and Prevention (CDC), Atlanta (Michael Green and Ernest Smith).

³ data on the distribution chain to the retail outlets in the study sites were collected in a separate survey, but are not reported in the thesis

Figure 5.3 Examples of typical outlet types: a) government dispensary, b) private dispensary, c) Part II drug shop, d) and e) general shops



Table 5.1 Summary of data collection activities

Activity	Sample
Demand-side	
Household Survey, May-Sep 2001 Quantitative data on parasitaemia, fever and reported household demand for treatment for households under DSS surveillance in Kilombero, Ulanga & Rufiji	Total sample size of 2500 randomly selected households, stratified by DSS system, of which 2191 were interviewed. Sample of 1250 households allocated to detailed survey (Group A) for which data were collected on 1101 households, 3853 individuals and 577 provider visits
Supply-side	
Outlet Censuses, May-Sep 2000 & 2001 Census of all private drug outlets in DSS areas and drugs stocked at each outlet, updated in 2001	588 outlets interviewed in 2000, 682 in 2001 (private facilities, drugs stores & general stores)
Provider Qualitative Interviews, Aug-Sep 2001 In-depth semi-structured interviews with providers in shops and private facilities in DSS areas on their behaviour and its determinants	Purposively selected sample of 18 private providers, stratified by DSS system, outlet type, location and antimalarial stocking (private facilities, drug stores & general stores)
Outlet Survey, Nov-Dec 2001 <ul style="list-style-type: none"> • Quantitative data on retail provider behaviour and its determinants through structured interviews with providers in shops and public and private facilities in DSS areas • Antimalarial quality testing of quantity of active ingredient of SP tablets stocked 	All facilities and drug shops in DSS areas, and a random sample of general stores stocking drugs stratified by DSS system. Total sample of 331 outlets, of which 294 were interviewed.
Antimalarial Retail Audits, Feb/Apr & June/July 2002 Measurement of antimalarial sales during two 2-week periods	All facilities and drug shops in DSS areas, and random sample of general stores previously reported to be selling antimalarials, stratified by DSS system. In Retail Audit 1 sample size of 122 and data collection completed for 112 outlets. In Retail Audit 2 sample size of 123 and data collection completed for 119

5.4.2 Ethical Clearance and Informed Consent

The study received ethical approval from the institutional review boards of IHRDC, the London School of Hygiene and Tropical Medicine, and the Tanzanian Medical Research Coordinating Committee. The household survey component was also approved by the US CDC.

Local DSS staff visited the households and drug outlets sampled for each data collection activity to inform them about the study, deliver a letter of invitation and make an appointment for the survey team. Sub-village leaders and staff of the District Health Management Team (DHMT) were also informed.

Before the start of all interviews, the interviewee was read an information sheet explaining the purpose of the research, the institutions involved, and the nature of their requested participation, and given the opportunity to ask questions. It was emphasised that the information collected would be confidential, and in drug outlets that no individual details would be passed on to regulatory authorities. Written consent was obtained from household survey interviewees, or from parents or guardians on behalf of children. In drug outlets, verbal consent was obtained, as experience with private sector actors suggested that some providers are threatened and discouraged by a written consent procedure, which may limit participation or bias the information collected. Consent was also sought specifically for the use of tape recorders during qualitative interviews. Care was taken in the presentation of results to avoid identification of any specific outlets or individuals.

5.4.3 Household Survey

The IMPACT 2001 household survey was based on a total sample of 2500 randomly selected households, drawn from the DSS databases. The sample was stratified by DSS system, comprising 1250 households from Rufiji DSS area and 1250 from Kilombero and Ulanga DSS areas combined. The DSS systems define households as "a set of people who eat from the same pot and recognise one person as their head". The DSS systems produce a dynamic set of data sets; the samples were drawn from the data files dated 1 May 2001 in Kilombero/Ulanga and from the data files dated 29 May 2001 in Rufiji.

The sample size was determined on the basis of the needs of the main IMPACT evaluation, to estimate the prevalence of SP-resistance markers, although its adequacy for analysing treatment seeking behaviour was considered (Table A1.3 in Annex 1). Kilombero and Ulanga DSS areas are considered as one area for the purpose of the main IMPACT evaluation of resistance markers, due to their proximity. However, as the fever/malaria treatment markets in Kilombero and Ulanga DSS areas proved to be geographically distinct (see Chapter 7 on Market Structure), they are analysed as two separate areas within this thesis where appropriate.

At the time of selection for the household survey, each household was randomly assigned to either Group A or Group X, with Group A completing a more detailed survey. Data reported in this thesis are drawn from Group A households (sample of 625 in Rufiji and 625 in Kilombero/Ulanga DSS systems), with the exception that the measures of relative socio-economic status described below are calculated across Group A and Group X households.

Data collection was undertaken by DSS staff between May and September 2001. Participants were asked to take part in an interview and provide a blood sample. Households where one or

more members were not present were revisited once. Households that had closed, declined participation, or where individuals were not present on a second visit were not replaced. The interview was based on a structured questionnaire. The design and wording were informed by previous quantitative and qualitative work on treatment seeking behaviour undertaken in the study sites, such as the IMCI 1999 household survey, the IMPACT 2000 household survey, TEHIP Health Behaviours Research, anthropological work by Hausmann and others (Hausmann Muela and Muela Ribera 2000; Hausmann Muela, Muela Ribera and Tanner 1998), and previous DSS surveys in Kilombero and Ulanga (Armstrong Schellenberg et al. 2003).

The questionnaire for Group A was divided into three parts. Module A was directed to the head of household, and covered socio-economic status variables including household construction and assets; education level, religion and ethnic group of head of household; proximity of nearest providers of each type; malaria-related knowledge and preference for chloroquine or SP. Module B was directed to each resident present at the time of the interview or their caretaker for a child. Individuals who reported fever in the previous 2 weeks⁴ were asked about its perceived severity, associated symptoms and treatment providers visited. Individuals not reporting fever/malaria were also asked about any medications they had taken during the recall period. One Module C was completed for each health care provider from whom participants had sought treatment for fever/malaria episodes, covering detailed information on the provider used, treatment obtained and costs incurred. The definition of provider was broad, including health facilities, shops, traditional healers and any other sources used. Households in Group X completed only a household questionnaire and shorter individual questionnaire.

If a respondent reported more than one fever episode during the previous fortnight, information was obtained about all treatment seeking for fever during that period, and no attempt was made to collect data separately for each episode, because of the difficulty in distinguishing between new episodes and recrudescence.

To test for malaria parasitemia, finger prick blood samples were obtained from each consenting household member for thick and thin blood films, which were read at laboratories in Kilombero and Rufiji.

Of the total sample of 2500 households surveyed, data were obtained for 2191 households, giving an overall completion rate of 92% in Kilombero/Ulanga, and 83% in Rufiji (Table 5.2). Within these households, data were obtained on 7,630 individuals. The refusal rate was 1.5% (0.6% for individuals in Kilombero/Ulanga DSS system and 2.4% in Rufiji), and 7.2% of

⁴ including episodes which began more than two weeks ago that continued into the recall period.

individuals could not be located⁵. In Group A, interviews were completed at 1101 households and for 3851 individuals. Of these individuals, 628 (16.3%) reported a fever episode in the previous two weeks, and 468 of these (74.5%) had visited at least one provider, generating data on 577 provider visits. Basic data on household and individual characteristics of respondents are reported in Chapter 6.

Table 5.2 Household survey interviews completed

Modules Completed	Group A (detailed survey)			Group X (abbreviated survey)			Grand Total
	Kilombero /Ulanga DSS	Rufiji DSS	Total	Kilombero /Ulanga DSS	Rufiji DSS	Total	
Household	585	516	1101	569	521	1090	2191
Individual	1887	1964	3851	1880	1899	3779	7630
Provider visited	266	311	577				577

Measuring socio-economic status

A relative index of household socio-economic status (SES) was derived based on 19 dichotomous variables using principal component analysis (PCA). This method was chosen due to the time requirements for collecting household income or expenditure data, and associated problems of recall bias and mis-measurement, for example of home-produced consumption. PCA indices have proved a reasonable measure of household wealth in Indonesia, Pakistan, Nepal, India, Argentina and Mexico (Filmer and Pritchett 2001; McKenzie 2003). The index was based primarily on the variables already collected by the Rufiji DSS for assessment of SES, as these had been selected on the basis of earlier qualitative work by the DSS team. This allowed us to avoid duplication of data collection in Rufiji, as information on these assets was accessible through the DSS database. The variables were a combination of household construction (walls, roof and floor), utilities (sources of water and cooking fuel, use of toilet), and ownership of assets (livestock, bed, clock/watch, mattress, iron, mosquito net, radio, clothing cupboard, bicycle, sofa, motorbike and car/tractor). In addition, we added light source, as this had proved an important indicator of SES in other Tanzania-based work (Hanson and Jones 2000).

The index was calculated across both Group X and Group A households. Data were incomplete for 1 household in Ulanga and 87 households in Rufiji, which were therefore not assigned PCA scores (of which 46 households in Rufiji were in Group A)⁶. The first principal component explained 21% of the variability in the SES variables, a similar proportion to that explained in other such analyses (Armstrong Schellenberg et al. 2003; Filmer and Pritchett 2001; McKenzie

⁵ cover sheets containing the reason for non-participation were misplaced for roughly one-third of Rufiji households, so rates of refusal and failure to locate have been estimated from the remaining data.

⁶ the high frequency of missing data in Rufiji reflected problems in linking some households to their SES records in the Rufiji DSS database.

2003). The assets which made the greatest change to PCA score were ownership of a sofa or clothing cupboard, floor construction and cooking fuel. Households were classified on the basis of their PCA scores into SES thirds of poorest, middle or better off. Full details of the methods and results of the PCA are provided in Annex 5.

Assessment of the appropriateness of care obtained

The household data were used to assess whether individuals reporting fever/malaria episodes had obtained appropriate treatment. As the vast majority of cases were not subject to diagnostic tests, the assessment of drugs obtained was based on their suitability for the reported symptoms. For several reasons it was not possible to judge treatment quality definitively from the drug data collected:

- data were collected on drugs obtained, which may exceed the number of drugs and doses actually consumed
- data on drugs obtained were subject to potential reporting error, as respondents may not have remembered or correctly identified all their medicines, and recall of quantities obtained may be particularly poor
- data were collected on individuals reporting an episode of *homa* or *malaria*. Although *homa*, is the KiSwahili term most widely used for fever, it can be used to refer to illnesses of other types, such as stomach problems, which might not warrant malarial treatment (Tarimo et al. 2000; Winch et al. 1996)
- while some episodes were completed, others were ongoing, and these individuals may have obtained additional treatment after the interview
- while children under five with a fever should definitely be treated with an antimalarial according to WHO guidelines, this may not be appropriate for all mild fevers in older children and adults, as their higher levels of immunity increase the likelihood that the fever has another cause
- without a clinician's assessment, it was difficult to judge whether any antibiotics and injectable antimalarials provided were required.

However, given these provisos, it was possible to get an indication of the appropriateness of drugs by examining the proportion of individuals reporting fever/malaria who obtained an antimalarial, and the proportion who obtained at least the minimum dose. This is reported both for all antimalarials and for “effective antimalarials” only (which excluded chloroquine due to the higher levels of resistance to this drug). Minimum antimalarial doses were defined on the basis of the age-specific dosing schedules shown in Table A1.4 in Annex 1. Adequate dosing was assessed per provider visit, or per individual (including drugs from all providers and home/neighbours). Where individuals had obtained more than one antimalarial of the same generic type (e.g. two sets of chloroquine tablets, or quinine tablets and quinine injections), the

doses were summed to assess whether an adequate quantity had been consumed. No attempt was made to assess the frequency of over-dosing, or the timing of doses, as data were collected on drugs obtained from providers, rather than those consumed.

Analysis of the appropriateness of medication also encompassed unnecessary or inappropriate drugs obtained. Firstly, the proportion of individuals obtaining an antimalarial who did not report fever/malaria was investigated. Secondly, particularly high rates of antibiotic or injectable antimalarial use would be of concern, and some indication of their unnecessary use was assessed from the following reported symptoms. Injectable antimalarials might be required for patients with symptoms of severe febrile illness (vomiting, unable to eat, convulsions, or loss of consciousness). Antibiotics might be necessary for patients reporting cough, fast breathing, diarrhoea or the symptoms of very severe febrile illness (Ministry of Health, WHO and UNICEF 2002). Finally, aspirin is not recommended for children under five because of its association with the liver disorder, Reye's Syndrome. The percentage of under fives reporting fever/malaria receiving aspirin was therefore also described. No attempt was made to evaluate dosing for other drugs such as antibiotics.

5.4.4 Outlet Censuses

The first supply-side data collection activity was a census of all private sources of manufactured drugs in the DSS areas, which took place from May to September 2000, repeated in the same months in 2001. This was an essential first step of supply-side investigation, as no complete list of private providers previously existed. Private sources were found to comprise facilities, drug stores and general shops⁷.

DSS field staff drew up a list of all outlets that might sell drugs, categorised by outlet type. The 30 field staff in the Kilombero/Ulangua DSS system, and 39 in Rufiji, knew the areas very well since they worked in teams that covered a small geographical area, lived in the communities where they worked, and visited each household every four months. Any queries on the sampling frame were checked during their regular fieldwork, and lists were updated if any additional outlets were identified during data collection. The local knowledge of data collection staff facilitated the identification of outlets, but it is possible that a few were missed. To assess this we compared the results for the 2000 census with treatment sources recorded in the IMPACT household survey conducted over the same period. Less than 7% of shops specified by householders could not be matched with those listed in the census, and in some cases this may

⁷ One traditional healer was found to stock an antibiotic in the 2001 outlet census in Rufiji, but as this was purely for use after circumcision ceremonies, he was not included in the analysis. No other traditional healers were identified stocking manufactured drugs.

have reflected the use of different names for a given shop. We concluded that we had identified nearly all retail pharmaceutical outlets used by the population at the time of the study.

DSS staff visited each outlet and administered a structured questionnaire covering products stocked in three therapeutic classes (painkillers, antimalarials and antibiotics); and wholesale drug sources. Some features of the outlet census were common to all supply-side data collection. Firstly, the team aimed to interview the person most involved with the outlet's day-to-day management and supervision, which in some outlets was the owner, in others the manager, and in some the main seller. If this person was not available, any person staffing the outlet was interviewed. Secondly, interviews in shops were generally conducted in the outlet, with breaks each time a customer arrived. Facility interviews were generally conducted in staff offices. Thirdly, when collecting data on fever/malaria drugs stocked, a check list of common brand names was used to ensure that all relevant products were reported. The checklist was read out to the interviewee, who was also asked whether they had any other drugs in these categories. The interviewer checked visually that each drug reported was in stock.

During the first outlet census we initially identified 612 private outlets, and 588 interviews were completed. Of those not interviewed, 13 had closed permanently, 5 were temporarily closed, and 2 were omitted in error. Only 4 outlets refused to participate (0.7% of functioning outlets).

When the census was repeated from May to September 2001, the questionnaire was revised to update the drug checklist, and add questions on seasonal operation of shops. During the second census 816 outlets were initially identified, and 682 interviews completed. Of those not interviewed, 125 had closed permanently, 5 were temporarily closed, 3 were omitted in error, and 1 refused.

The 2001 outlet census was used as a sampling frame for the other supply-side data collection activities. The census data on the identity of each outlet by village, sub-village, name of shop, name of owner, type of outlet, and location (DSS house number or number of nearest house) was used to identify the sampled outlets.

5.4.5 Semi-Structured Qualitative Provider Interviews

A number of studies have demonstrated the potential utility of qualitative data in understanding private provider behaviour (Adome, Whyte and Hardon 1996; Cocks and Dold 2000; Kamat 2001; Kamat and Nichter 1997; Kamat and Nichter 1998; Van der Geest 1987), and qualitative methods are argued to have the potential to make an important contribution to health economics theory and analysis (Coast, McDonald and Baker 2004). A limited number of semi-structured

interviews were therefore conducted, with two broad aims. Firstly they informed the design of the outlet survey and retail audits, by generating hypotheses for quantitative investigation, providing background information for the audit methodology, and identifying the most appropriate and comprehensible wording to use. Secondly, they facilitated collection of data on subjective perceptions and opinions of outlet staff, and the exploration of sensitive commercial and regulatory issues, which are not readily addressed using quantitative methods (Conteh and Hanson 2003).

The ontological approach taken in these interviews could be described as one of “subtle realism”⁸ (Mays and Pope 2000). We aimed to uncover insights into the underlying nature of competition between outlets, but recognised that these phenomena would be seen through the subjective perceptions of the interviewees, and reflect the dynamic of the interview setting and characteristics of the interviewers. The approach was primarily deductive, starting from ideas and hypotheses drawn from economic theory and evidence within the industrial organisation literature, as outlined in the conceptual framework in Figure 5.1. This framework guided the choice of research questions, sample selection, the design of interview guides, and the construction of the preliminary coding scheme. However, this was not followed rigidly; there was also a conscious attempt to be open to issues and theoretical ideas arising from the data during their collection, and interim and final analyses. Semi-structured interviews provided a flexible format for these discussions, while ensuring that comparable issues were raised during each interview (Russell Bernard 1995). Interview guides covered a range of issues related to the operation of the outlet, the customers, competition with other providers, and government regulation, with a focus on the provision of fever/malaria treatment. The information sought on each topic was a mixture of facts and perceptions/opinions. There were slight differences in the guides for shops and facilities, both in the language used in the questions (e.g. “patients” v. “customers”; “providing services” v. “running a business”), and in some of the topics covered (e.g. user fees and exemptions were relevant only to facilities; retail inspectors were relevant only to shops).

A sample of 18 private outlets was selected purposively, stratified by DSS system, outlet type, location inside or outside a market centre and, for general shops, whether antimalarials were stocked during the outlet census. Other criteria for selection were that outlets stocked drugs at the time of the interview, were located in a range of different villages, and accessible by

⁸ a position of “subtle realism” acknowledges that all research involves subjective perceptions, but argues that there is an underlying reality which can be studied. This contrasts with an antirealist or constructivist ontological paradigm, often used in qualitative research, which denies the concept of a single unequivocal social reality or truth which is entirely independent of the researcher and the research process (Mays and Pope 2000).

vehicle⁹. Though not statistically representative, the resulting sample was theoretically informed and relevant to the research questions, and possible bias from selecting a sample on the basis of convenience was reduced.

Of the outlets initially selected, two had closed down, one no longer stocked drugs, and staff at two outlets declined to participate¹⁰. These five outlets were replaced with others of the same type, and in the same village where possible. The final sample included 10 general shops, 5 drug stores, and 3 dispensaries (2 mission-owned and one commercial). Background characteristics of the interviewees and outlets are presented in Table 5.3.

Table 5.3 Semi-structured qualitative provider interviews: Characteristics of interviewees and their outlets

Characteristics	General shops	Drug stores	Private facilities
Interviewees			
n¹	11	5	5
Sex:			
Male	9	1	4
Female	2	4	1
Age:			
<25	3	2	0
25-50	8	2	5
>50	0	1	0
Role in outlet:			
Owner	7	1	0
Employee	4	4	5
Outlets			
n	10	5	3
Number of staff:			
1	0	1	0
2	7	4	0
3	2	0	1
>3	1	0	2
Antimalarials in stock:			
Yes	3	5	3
No	7	0	0
Location:			
In market centre	5	4	2
Outside market centre	5	1	1
DSS area:			
Kilombero	2	1	1
Ulanga	2	1	1
Rufiji	6	3	1

¹ The number of interviewees is greater than the number of outlets as in two dispensaries and one general shop two staff participated in the interview, where different people were most knowledgeable about certain questions.

⁹ By excluding outlets not accessible by vehicle the sample was biased away from a few very remote general shops. Excluding outlets with no drugs at the time of the interview may have biased the sample away from general shopkeepers who were intermittent stockers.

¹⁰ In one case they said they were too busy, and in the second the owner had recently died.

Each outlet was visited by the author and two research assistants in August-September 2001. The research assistants were Tanzanian university graduates with fluent KiSwahili, and were trained on the general principles of interviewing for qualitative research, and the meaning and purpose of the interview questions. In some cases, more than one respondent participated where, for example, different people were most knowledgeable about retail sales and wholesale supplies. The interviews took between 1.5 and 3.5 hours. Following each interview, the research team held a debrief session to discuss the issues raised, impressions about the interviewee's attitude and behaviour, and any responses needing clarification, which in some cases necessitated repeat visits. Between interviews some minor changes were made to the interview guide to make the questions clearer, and incorporate new areas of discussion or remove unfruitful ones. Informal analysis of the interview data began through the drafting of memos to summarise important findings, and emerging themes, research questions and hypotheses.

The interviews were tape-recorded, fully transcribed in KiSwahili, translated into English, and the translations checked against the original KiSwahili manuscript. They were supplemented by notes on observations during the interviews. The general approach to data analysis followed a path of familiarisation with the data, construction of a preliminary coding scheme, followed by manual qualitative content analysis and interpretation. After initial open coding, each code was examined in great detail, the coding scheme was refined, and finally codes were grouped under key themes (Figure A1.1 in Annex 1).

5.4.6 Outlet Survey

The outlet survey aimed to collect representative quantitative data on the characteristics of outlets, their staff and the products they stocked, using a structured questionnaire. It was conducted at all government and private health facilities and drug stores and a sample of general shops stocking drugs in the DSS areas.

The sample was stratified by DSS system (Kilombero/Ulanga and Rufiji) and by outlet type (government facility, private facility, drug store and general store)¹¹. As in the household survey, Kilombero and Ulanga were considered as one area for the purpose of sample stratification, but are analysed as separate areas where appropriate, as their markets proved to be geographically distinct. As there were relatively small numbers of facilities and drug stores,

¹¹ As the category of general shops was highly heterogeneous, we considered stratifying by type (e.g. larger general shops versus smaller, less formal kiosks/stalls). However, during the outlet censuses we found such classifications to be unreliable as they varied between the research staff, with the perception of consumers during an earlier IMPACT household survey in 2000, and with official classifications for licence purposes.

they were over-sampled, by selecting all outlets in these groups¹². The sampling frame for general shops included all those which during the 2001 outlet census had drugs when visited or reported stocking them in the previous 2 months¹³. The sample size calculations determined that roughly 100 general shops would be required in each DSS system to detect certain key differences between two groups of roughly equal size (e.g. DSS systems, inside and outside market centres), with 5% significance and 80% power (Table A1.5 in Annex 1). We randomly selected 135 general stores in each DSS system (roughly 50% of the sampling frame), with the aim of obtaining data on at least 100 after wastage. We did not attempt to weight the sample by utilisation using probability proportion to clientele size because the primary purpose was to describe the average characteristics of each outlet type, rather than to describe the average characteristics experienced by customers across all outlets.

Data collection was undertaken by a team of interviewers, moving sequentially through the DSS areas over a 6-week period in November and December 2001. Interviews at drug stores and facilities were done by pairs of interviewers because of the high number of drug products stocked. If an outlet had shut down completely, or the staff refused, the outlet was not replaced. If the outlet was temporarily closed, or the interviewee requested an alternative time, a second visit was made where logistically possible. If the outlet had changed ownership since the outlet census 2001, it was included under the new owner's name.

We visited 331 outlets, and completed 294 interviews (Table 5.4). Of those not interviewed, 26 had closed permanently, 7 were temporarily closed, and in one case no reason was recorded. Only 3 general stores refused to participate (1% of functioning outlets). Interviews were completed at 18 government facilities (4 health centres and 14 dispensaries), 8 private facilities (6 mission dispensaries, 1 mission hospital, and 1 commercial dispensary), 30 commercial Part II drug stores, 2 not-for-profit village-run drug stores, and 236 general stores (shops, kiosks & stalls).

¹² a first aid post run by a construction company in Rufiji was excluded, because it provided services to the company's workers only

¹³ two general shops were excluded from the sampling frame: one shop in Rufiji because their participation in a qualitative interview had been cut short when a neighbour became suspicious about the purpose of the interview; and one in Kilombero/Ulanga where they refused to participate in the 2001 outlet census.

Table 5.4 Outlet survey sample size and outlets interviewed

Outlet type	Sample size			Interviewed		
	Kilombero /Ulanga DSS	Rufiji DSS	Total	Kilombero /Ulanga DSS	Rufiji DSS	Total
Government facility	9	9	18	9	9	18
Private facility	5	4	9	4	4	8
Commercial drug store	12	20	32	11	19	30
Village-run drug store	2	0	2	2	0	2
General store	135	135	270	117	119	236
Total	163	168	331	143	151	294

Background characteristics of the interviewees and outlets are presented in Table 5.5.

Table 5.5 Characteristics of outlet survey interviewees and outlets

Characteristics	General shops	Drug stores	Private facilities	Government facilities
	n=236	n=32	n=8	n=18
Interviewee				
Gender:				
Male	200 (85%)	5 (16%)	6 (75%)	12 (67%)
Female	36 (15%)	27 (84%)	2 (25%)	6 (33%)
Age in years:				
12-15	11 (5%)	0 (-)	0 (-)	0 (-)
16-24	98 (42%)	15 (47%)	0 (-)	0 (-)
25-50	118 (50%)	16 (50%)	7 (88%)	17 (94%)
>50	9 (4%)	1 (3%)	1 (13%)	1 (6%)
Role in outlet:				
Owner	116 (49%)	3 (9%)	0 (-)	0 (-)
Employee	120 (51%)	29 (91%)	8 (100%)	18 (100%)
Role in serving customers:				
Regularly	189 (80%)	31 (97%)	6 (75%)	18 (100%)
Occasionally	47 (20%)	1 (3%)	1 (13%)	0 (-)
Never	0 (-)	0 (-)	1 (13%)	0 (-)
Outlet				
Number of staff:				
1	25 (11%)	0 (-)	0 (-)	0 (-)
2	176 (75%)	27 (84%)	0 (-)	4 (22%)
3	31 (13%)	5 (16%)	2 (25%)	3 (17%)
>3	4 (2%)	0 (-)	6 (75%)	11 (61%)
Antimalarials in stock:				
Yes	30 (13%)	32 (100%)	8 (100%)	18 (100%)
No	206 (87%)	0 (-)	0 (-)	0 (-)
Location:				
In market centre	71 (30%)	15 (47%)	4 (50%)	3 (17%)
Rural village	136 (58%)	17 (53%)	4 (50%)	15 (83%)
Farming area	29 (12%)	0 (-)	0 (-)	0 (-)
DSS area:				
Kilombero	64 (27%)	11 (34%)	2 (25%)	4 (22%)
Ulanga	53 (22%)	2 (6%)	2 (25%)	5 (50%)
Rufiji	119 (50%)	19 (59%)	4 (50%)	9 (28%)

In the analysis of antimalarial prices, for ease of comparison antimalarial prices were calculated as the amount required to be purchased in order to treat a two-year-old child (Table A1.6 in Annex 1). Tablets required were rounded up to the nearest whole tablet, as fractions of tablets could not normally be purchased. Syrups and injections were costed at the price for a whole bottle or vial/ampoule, as it was not usually possible to purchase less in shops. The contents of a bottle of syrup contained more than sufficient for a child's dose, and the vials for injectables were sufficient for an initial pre-referral dose, as recommended in the National Treatment Guidelines (Ministry of Health 2000)¹⁴. As there was no fixed dose for common painkillers, prices were compared per tablet or bottle.

Drug quality testing

Samples of SP tablets stocked during the outlet survey were collected to provide a general indication of the quality of products available at the retail level. Nine or ten tablets were obtained from each lot stocked at each outlet, and analysed at CDC, Atlanta (Green et al., unpublished data, IMPACT collaboration)¹⁵. The content of sulphadoxine and pyrimethamine in each sample was assessed by high-pressure liquid chromatography under standard conditions¹⁶. Samples were classified as failing if they had less than 90% of the specified quantity of active ingredient. Any excessive quantities of active ingredient were also noted, because they could potentially lead to an increased incidence of side-effects or toxicity. However, as they contained an adequate quantity for clinical efficacy, the analysis of the results focused on those with an insufficient quantity.

5.4.7 Antimalarial Retail Audits

The retail audits were designed to estimate annual antimalarial sales volumes in the DSS areas. A specific data collection activity was required because shops did not keep good written records, and it would have been unrealistic to expect precise recall on products, doses and packaging from the household survey. Data were collected during two 2-week periods in 2002. This design was selected because qualitative interviews with providers indicated that drug sales may vary on different days of the week and at different times of year, but intra-month variation in weekly sales was rarely reported. Two weeks was considered a reasonable recall period for wholesale deliveries. The first audit took place 28th February – 6th April in Kilombero/Ulanga, and 6th-26th March in Rufiji; the second 24th June - 18th July in Kilombero/Ulanga, and 3rd-

¹⁴ in practice referral may not have taken place and the purchase of additional oral or injectable medication would have been required to achieve a full dose.

¹⁵ these results were not based on an adequate quantity of tablets for United States Pharmacopoeia (USP) standards, which require 20 tablets per test.

¹⁶ Dissolution tests were also conducted, but the results were not available at the time of writing.

23rd July in Rufiji. While additional audits would have been desirable, we were restricted to two due to logistical constraints.

The retail audit sample included outlets that stocked antimalarials during the outlet survey or the outlet census 2001. This included all facilities, all drug stores, and around half the general stores stocking antimalarials during the outlet census 2001, or 10-13% of general stores stocking any drugs. In addition, any new drug stores or facilities that had opened since the outlet survey were also included, as they were likely to be significant sources of antimalarials. New drug stores or facilities that opened between the first and second retail audit were included in retail audit 2.

For both audits in Rufiji and the first in Kilombero/Ulanga the DSS staff performed the interviews as part of their normal work. In retail audit 2 in Kilombero/Ulanga a separate team of 4 interviewers was trained because DSS staff were unavailable. Interviewers visited each outlet twice, aiming for a two-week gap between visits.

On the first visit of each audit, interviewers completed a checklist of antimalarial drugs in stock, and recorded stock levels for each one. For outlets with opened tins of loose tablets, the number of tablets in stock was estimated based on the number in a full tin and the ratio of the height of the tablets to the height of the tin (thus avoiding counting several hundred tablets and unnecessary handling of loose drugs). On the second visit interviewers again recorded stock levels, and any deliveries since their previous visit, plus any drugs that had been removed for other reasons e.g. thrown away or returned to wholesalers. Where possible, quantities received were checked using wholesale receipts, although these were rarely available.

In retail audit 1 we visited 122 outlets, and completed 115 first interviews and 112 second interviews (Table 5.6a). Of the 7 outlets where no interviews took place, 3 general shops were permanently closed, 3 were temporarily closed, and one private facility refused. In two commercial drug stores and one village-run drug store first interviews took place, but no second interview because the outlets were temporarily shut at the time of the second visit.

In retail audit 2 we added four newly opened drug stores (2 in Rufiji and 1 each in Kilombero and Ulanga), and excluded the 3 general shops permanently closed in retail audit 1, giving a total sample of 123 (Table 5b). First and second interviews were completed in 119 outlets. Of the 4 outlets where no interviews took place, 2 general shops and 1 drug store had closed down, and the private facility which declined to participate in retail audit 1 again refused.

Table 5.6 Antimalarial Retail Audit sample size and outlets interviewed**(a) Retail Audit 1**

	Sample size				Outlets where two interviews completed			
	Kilombero DSS	Ulanga DSS	Rufiji DSS	Total	Kilombero DSS	Ulanga DSS	Rufiji DSS	Total
Government facilities	4	5	9	18	4	5	9	18
Private facilities ¹	3	2	4	9	3	2	3	8
Commercial drug shops	9	2	20	31	8	2	19	29
Village-run drug shops	2	0	0	2	1	0	0	1
General stores	27	8	27	62	24	7	25	56
Total	45	17	60	122	40	16	56	112

(b) Retail Audit 2

	Sample size				Outlets where two interviews completed			
	Kilombero DSS	Ulanga DSS	Rufiji DSS	Total	Kilombero DSS	Ulanga DSS	Rufiji DSS	Total
Government facilities	4	5	9	18	4	5	9	18
Private facilities ¹	3	2	4	9	3	2	3	8
Commercial drug shops	10	3	22	35	9	3	22	34
Village-run drug shops	2	0	0	2	2	0	0	2
General stores	25	8	26	59	23	8	26	57
Total	44	18	61	123	41	18	60	119

¹since the outlet survey one mission dispensary in Kilombero had reopened and was therefore included in the retail audits, but not in the outlet survey.

In retail audit 1 there were 380 antimalarial observations, and in retail audit 2, 408. Although all the outlets selected had stocked antimalarials in either the outlet survey or the 2001 outlet census, only 25 of the general stores selected (45%) had antimalarial drugs in stock during retail audit 1, and this had fallen to 18 (32%) during retail audit 2.

The target gap between interviews was 14 days. In retail audit 1 the mean gap was 15.0, with a range of 10 to 26 days, with 97% of outlets between 10 and 21. In retail audit 2 the mean gap was 14.0, with a range of 13 to 17 days.

Calculation of antimalarial sales volumes and values

For each audit, sales of each antimalarial between the 2 visits were calculated as:

$$\text{Sales} = (\text{Total at 1}^{\text{st}} \text{ visit}) + (\text{Deliveries between 1}^{\text{st}} \text{ and 2}^{\text{nd}} \text{ visit}) - (\text{Stocks thrown away or transferred to other shops/facilities}) - (\text{Total at 2}^{\text{nd}} \text{ visit})$$

To calculate fortnightly sales, sales volumes were scaled up or down pro rata, depending on the actual number of days between interviews for each outlet. To sum across different drug types to measure total antimalarial sales, volumes were calculated in terms of purchases required for equivalent adult treatment doses, based on the adult doses shown in Table A1.6. For syrup and injectables, it was assumed that one whole bottle or vial would have to be purchased. The number of equivalent doses will be much lower than the actual number of customers, because 46% of provider visits were for patients under 14 years (household survey) who should receive a lower dose, and many people of all ages will have obtained less than the full treatment dose.

To estimate total sales volumes, data were extrapolated to cover observations with missing sales data and outlets not interviewed, using mean sales for each drug type by outlet type. To estimate yearly sales it was necessary to extrapolate from the two 2-week periods. The two audits were undertaken at different times of year with the aim of capturing seasonal epidemiological and economic variation in sales. However, the data did not show evidence of clear seasonal patterns. Annual sales were therefore estimated simply by summing the sales figures for the two surveys and scaling up pro rata to yearly sales estimates. It is possible that the timing of the 2 surveys did not capture seasonal variation at other times of year.

The value of antimalarial sales was approximated based on outlet survey data on the median price for each drug category by packaging and outlet type (e.g. median price of loose SP tablets in commercial drug stores). For three items in village health stores and two in general stores there were no appropriate price observations. Their prices were approximated with the median price from commercial drug stores. As government drugs were either heavily or completely subsidised, their value was approximated using 2002 international reference prices (IRP) from suppliers (Management Sciences for Health 2002), scaled up 15% for importation costs, and 15% for internal transport, and using an exchange rate of US\$1=Tsh950.14. Methods for the calculation of annual sales volumes and values are described in more detail in Annex 6.

5.4.8 Quantitative Data Entry and Analysis

Data from the household survey, outlet censuses, outlet survey and retail audits were double entered using FoxPro 2.6a, and checked for logical consistency and coding errors. Analysis was performed using STATA 8.

Analysis of the household and outlet surveys was performed using STATA survey commands (e.g. svytab, svylogit). Differences in proportions were tested for significance using the Pearson chi-squared statistic with the Rao and Scott second-order correction to allow for survey design (Stata Inc. 2003). In the household survey these commands were used to adjust for clustering between individuals in the same household, and for the stratified survey design (separate samples drawn from Kilombero/Ulangu and Rufiji DSS systems). With such stratification, it may be necessary to weight observations to account for differences in sampling fractions across strata. However, in this case the number of individuals interviewed as a percentage of total population was extremely close in the two strata (2.8% in Kilombero/Ulangu and 2.7% in Rufiji), so population weights were not used. Analysis of a set of key variables with and without population weights demonstrated that the use of weights would have had only a minimal impact on parameter estimates^{17,18}.

In the analysis of the outlet survey, STATA survey commands were used to adjust for the stratification of the sample between Kilombero/Ulangu and Rufiji DSS systems, and potential clustering of drug observations within outlets. As with the household survey, observations were not weighted to reflect differences in sampling fractions, as all facilities and drug stores were selected, and the sampling fractions for general stores were similar in the two strata (39% in Kilombero/Ulangu and 44% in Rufiji). Weighting general stores would have had a minimal impact on key variables¹⁹.

Population ratios were calculated using population data from the DSS systems. For consistency, all ratios were calculated on the basis of populations enumerated during the second DSS round of 2001 (May-August).

Regression models were used for multivariate analysis of variation in key outcomes. Logit models were used for the probability of obtaining appropriate antimalarials by individuals with fever/malaria. Ordinary least squares (OLS) log-lin models were used to analyse the price of antimalarial and painkillers tablets. STATA survey estimators were used for all regression analyses (svylogit, svyregress); they produce Huber/White/Sandwich estimators of variance, which control for design-based heteroscedasticity (Stata Inc. 2003).

¹⁷ for example, the percentage of individuals reporting fever was 16.34% unweighted and 16.37% weighted; the percentage of febrile individuals visiting a government facility was 22.45% unweighted and 22.47% weighted.

¹⁸ The analysis of the household survey was restricted to those variables most pertinent to the thesis objectives. Data collected on other areas, such as ITN use, adverse drug reactions, and treatment seeking costs are being analysed by other IMPACT team members. A full econometric demand model of provider and drug choice is planned using the household and outlet survey data, but is beyond the scope of this thesis.

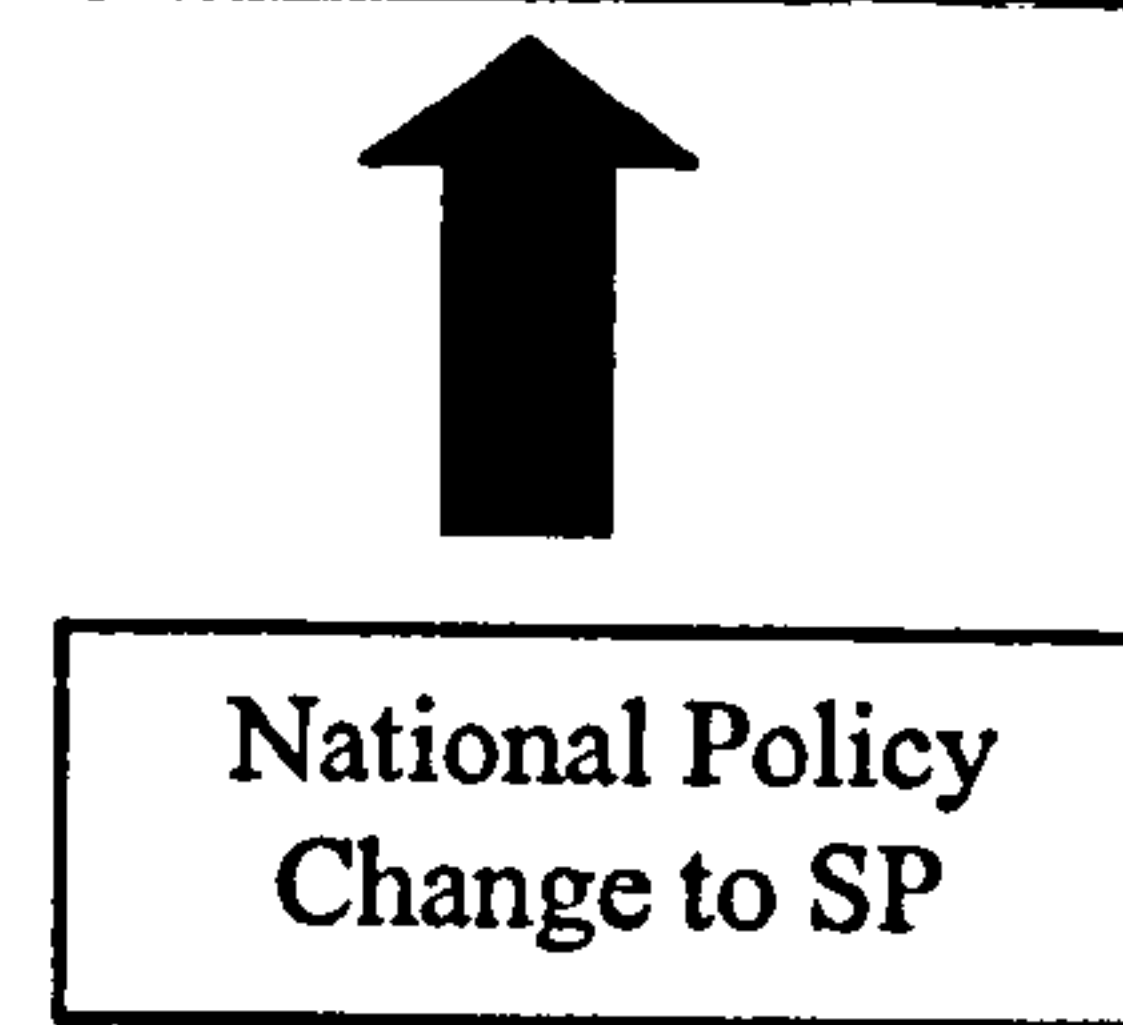
¹⁹ for example, the percentage of general stores stocking antimalarials was 14.08% unweighted and 14.13% weighted; the percentage of general store staff with more than primary education was 13.21% unweighted and 13.28% weighted.

5.4.9 Timing of Data Collection Activities

Table 5.7 clarifies the timing of the five types of data collection activity undertaken. The first outlet census was conducted in mid-2000. It was repeated in mid-2001, in tandem with the household survey. The remaining activities were undertaken sequentially over the following year.

Table 5.7 Timing of data collection activities

Data collection activity	2000				2001				2002				
	Quarter	1	2	3	4	1	2	3	4	1	2	3	4
Household survey													
Outlet censuses													
Provider qualitative interviews													
Outlet survey													
Retail audits													



The difference in the timing of the activities poses potential challenges for data analysis, as the market may experience seasonal variation, or undergo longer-term changes over time. Demand and supply may vary seasonally due to variation in malaria transmission, economic activities, cash availability, or geographical accessibility. It is therefore possible that, for example, outlet characteristics documented during the outlet survey in November/December may not reflect those faced by households during the household survey in May to September. Perhaps of even greater significance is the timing of the policy change in first line drug from chloroquine to SP, officially announced in August 2001 (Table 5.7). The household survey and outlet censuses took place almost entirely before the announcement, but the qualitative interviews, outlet survey and retail audits were spread over the following year. To complicate matters further, implementation of the policy change at facility level took place gradually and somewhat haphazardly, and was more rapid in Rufiji than in Kilombero and Ulanga. As a result the thesis is analysing a changing market, in particular with the importance of chloroquine waning, and that of SP growing over time.

A number of steps have been taken to address these potential problems. The date of each data collection activity is included in the notes to each table and figure presenting results to aid interpretation. The potential influence of changes over time are flagged up where appropriate

during the results chapters, and the methodological challenges of analysing a market under change are discussed in Chapter 11.

5.5 Summary and Plan of Analysis

The aim of the thesis is to analyse the market for fever/malaria treatment, and to draw implications for the improvement of malaria treatment obtained. The thesis is concerned with how the interplay of market structure, provider conduct, regulation and consumer demand influences treatment outcomes. Data were collected in the DSS areas of 3 rural Tanzanian districts. Data on demand were collected through a household survey. Following censuses of private providers, data on supply were collected through in-depth interviews, a structured survey, and retail audits in government and private facilities, drug shops and general stores.

The results are presented in the next five chapters. The results chapters have been organised by theme of analysis, rather than by data collection activity, in order to synthesise and triangulate data from different sources and provide a richer understanding of each theme. As a result, each chapter draws on at least three different data collection activities, and most use data from all five. The results begin in Chapter 6 with an assessment of fever/malaria treatment obtained in the study sites (Objective 1). This is followed by three chapters on the nature of competition, covering market structure (Chapter 7), product differentiation and non-price competition (Chapter 8), and pricing and price competition (Chapter 9) (Objective 2). Finally, Chapter 10 reports results on retail regulation (Objective 3). The importance of consumer demand, the final key element of the conceptual framework, is woven into these five results chapters, where appropriate. As each data collection activity is drawn on in several results chapters, the methodological strengths and limitations are addressed together after the five results chapters, in Chapter 11. Chapter 12 draws together the findings from the five results chapters and considers them in the light of the existing literature, leading to an assessment of the nature of competition and regulation, and the implications for accessibility, quality and affordability (Objective 4). The fifth and final objective is addressed in Chapter 13, which focuses on policy implications that can be drawn from the results and analysis.

PART III

RESULTS

CHAPTER 6

FEVER/MALARIA TREATMENT OBTAINED

6.1 Introduction

This chapter addresses the first objective of the thesis: to describe treatment seeking and drug purchases for fever/malaria, and assess the appropriateness of care obtained. Sections 6.2 and 6.3 set the context for this analysis. On the demand-side, Section 6.2 provides background information on the study communities, through a description of the household and individual characteristics of household survey respondents, and the prevalence of malaria parasitaemia and reported fever/malaria episodes. On the supply-side, Section 6.3 reports outlet census data on the range and number of drug providers in the study areas, and outlet survey data on the fever/malaria products available.

Sections 6.4 and 6.5 describe treatment seeking and drug purchase for fever/malaria, using two data sources. Section 6.4 analyses patterns of treatment seeking reported in the household survey; Section 6.5 reports retail audit data on the volume and value of antimalarials dispensed. A key feature of both sections is an analysis of the relative importance of retailers as fever/malaria treatment providers.

Section 6.6 draws on a number of data sources to assess the appropriateness of fever/malaria care. Firstly, household survey data are used to document the speed of treatment seeking and the appropriateness of drugs obtained. Drug samples collected during the outlet survey are used to assess antimalarial packaging, labelling and drug quality. Finally, retail audit data are used to explore the appropriateness of total antimalarial drug volumes at a community level. Variation in the choice of provider and appropriateness of drugs obtained are explored through bivariate analysis with a range of household and individual characteristics. For two key variables, the probability of obtaining an antimalarial and of attaining a minimum antimalarial dose, multinomial logit regression analysis is also employed.

Section 6.7 highlights key similarities and differences between the three DSS areas in their demand and supply characteristics. Finally, Section 6.8 concludes by summarising key findings of the analysis, and setting the agenda for the remaining results chapters.¹

6.2 Characteristics of Households and the Prevalence of Fever and Malaria

Basic characteristics of households and individuals interviewed for the household survey are presented in Table A1.7². Farming was by far the most common main occupation for household heads in all areas, and education levels were generally low, with only 13% of household heads having more than primary education. Religious affiliation was strikingly different between the three areas: over 90% of households in Rufiji were Muslim, compared with 57% in Ulanga, and only 19% in Kilombero, where the majority were Christian. Education levels were significantly lower in Rufiji, where 44% of household heads had no education, compared with 18% in Kilombero, and 16% in Ulanga, although the percentage with more than primary education was slightly higher in Rufiji (15% versus 12% in Kilombero and 9% in Ulanga). Off-farm work was more frequently mentioned in Rufiji (17% compared with 11% in Ulanga and 6% in Kilombero), reflecting a higher number of people citing small business and formal sector jobs as their main occupation³. There were no significant differences across the DSS areas in the proportion of households in each SES third, or in the mean PCA score.

Of individuals completing the household survey, 16% reported a fever/malaria episode in the previous two weeks (Table A1.8). Fever/malaria prevalence was similar in Rufiji and Kilombero DSS areas, but significantly lower in Ulanga (11%). There was also significant variation by age group: episodes were most likely to be reported for under fives (28%), followed by adults (16%), and least likely for older children (5-14 years) (10%). Of all episodes reported, 27% were in under fives, 18% in older children, and 55% of adults. There was no difference in reported fever/malaria by gender or socio-economic group, but individuals with more educated household heads were significantly more likely to report an episode, although the difference was not large (2.8 percentage points)⁴.

¹ data on key measures of the appropriateness of treatment are included as tables or figures in the text. Background and supplementary data are described in the text, and presented as tables or figures in Annex 1 (prefixed by A1).

² data are presented only for households which completed the detailed survey (Group A). There were no significant differences between Group A households and the Group X households which completed the less detailed survey in terms of household head's religion, education, main job or SES.

³ our analysis indicated that it would have been preferable to ask whether households had any source of off-farm income, rather than asking about the household head's main occupation. This would have highlighted all households with other income-generating activities undertaken by any household members, even where the household head's main activity was farming. The question has been rephrased in this way for subsequent IMPACT surveys.

⁴ only household head education was collected during the survey. One might have expected a stronger relationship between health or treatment choice variables and education of the individual for adults or the caretaker for children (Filmer, 2002).

Of 3,329 individuals with microscopy data, 23% tested positive for *P. falciparum* malaria on the day of interview. Parasitaemia was most common in Rufiji DSS (25%), followed by Ulanga (22%), and lowest in Kilombero (20%). Parasitaemia was significantly more likely in people under 15 years, with a prevalence of 41% in under fives, 38% in older children, and 10% in adults. Individuals in the better-off third of households were significantly less likely to be parasitaemic (18%) than those in the middle third (26%) or poorest third (25%). There was no significant variation across gender or household head's education. There was no difference in parasitaemia prevalence between those with a fever/malaria history and those without (24% compared with 23%). Conversely, of those with parasitaemia, only 18% reported fever/malaria. This is not surprising, as many fevers would have stemmed from non-malarial causes, and some patients who had experienced malaria in the previous two weeks would not have been parasitaemic by the day of interview. Others who were parasitaemic on the day of interview may have had low-density asymptomatic infections, that may or may not have led subsequently to fever.

6.3 Providers Stocking Drugs

In the DSS areas manufactured pharmaceuticals were provided by health facilities, drug stores and general shops/stalls. The study areas contained 27 facilities: 18 government facilities (4 health centres and 14 smaller dispensaries), 9 private facilities (7 mission dispensaries⁵, 1 mission hospital and 1 commercial dispensary) (Table A1.9). There were no Part I pharmacies in the DSS areas, but drugs were very widely available from other retail outlets. During the outlet census in mid-2001 there were 32 Part II drug shops; 30 were commercially owned, and two were recently opened village-run stores. We also identified 535 general retailers with drugs in stock on the day visited. An additional 28 general retailers had no drugs on the day of interview but reported having stocked drugs within the previous 2 months⁶. All commercial drug stores, general stores and the commercial dispensary were run on a for-profit basis, and all government facilities, mission facilities and village-run drug stores on an officially not-for-profit basis.

During the outlet census 2001 there was one general retailer stocking drugs for every 262 people, compared with one drug store for every 4386, and one health facility for every 5198. Drug stores tended to locate relatively close to facilities, and were generally limited to the more

⁵ One of the mission dispensaries in Kilombero was open during the outlet census and retail audits, but temporarily closed at the time of the outlet survey because the DHMT believed it to have been contravening its licence. In addition there was a first-aid post run by a construction company in Rufiji which provided services to the company's workers only.

⁶ Seven general retailers could not be interviewed and their drug stocking patterns were therefore unknown.

populous areas and main roads. General shops were much more scattered, reaching right out to remote communities. Coverage of private facilities was very patchy, and they were often located in the same area as government facilities.

Data on fever/malaria drugs stocked are reported from the outlet survey (Nov/Dec 2001), which included all facilities and drug stores in the DSS areas, and a sample of general stores stocking drugs^{7,8}. Full details of stocking patterns are presented in Table A1.10. Of outlets stocking fever/malaria drugs all but one (a government health centre) had painkillers. The most commonly stocked were aspirin and paracetamol tablets, with many commercial shops also selling paracetamol syrup and combination tablet products containing aspirin+caffeine or aspirin+paracetamol+caffeine. Other painkillers stocked regularly in facilities and commercial drug shops included ibuprofen, diclofenac and indomethacin.

Antimalarials were stocked by all facilities and drug stores, but by only 14% of general stores stocking drugs. The antimalarials available were chloroquine and quinine as tablets, syrups and injectables; SP and amodiaquine as tablets and syrup; and artesunate as tablets⁹. SP tablets were the most widely stocked in facilities and commercial drug shops, with chloroquine, amodiaquine and quinine tablets also common. Many facilities and commercial drug shops also stocked chloroquine and quinine as injectables, and many private facilities and commercial drug shops stocked a range of antimalarial syrups. Artesunate was very rare, only found in tablet form in one drug store. By contrast chloroquine was the only antimalarial available in the two village-run drug shops, demonstrating that more than three months after the official change to SP, the policy was not yet implemented at this level. Chloroquine tablets were also the antimalarial most commonly found in general stores (9%), followed by amodiaquine (3%), with other antimalarials stocked by less than 1% of these outlets, and none stocking artemisinin derivatives.

The stocking patterns reflect the situation in late-2001, but these patterns were not static. Over the period of data collection we witnessed a dramatic decline in chloroquine availability, with the percentage of commercial drug stores stocking chloroquine falling from 96% during the first outlet census in mid-2000 to 88% during the second outlet census in mid-2001, 60% during the outlet survey in late 2001, 48% during the first retail audit in early 2002 and 29% during the

⁷ the sample of general stores for the outlet survey was drawn from those stocking drugs during the 2001 outlet census. By the time of the outlet survey, 23 (10%) no longer had any fever/malaria drugs in stock and were therefore excluded from these figures.

⁸ data on drugs stocked were also collected during the outlet census, but data from the outlet survey are reported, because they are likely to be more reliable due to the use of a more comprehensive drug checklist and better trained staff.

⁹ the following antimalarials were not permitted in shops: quinine and artesunate tablets, SP and quinine syrup, and all injectables. In addition, chloroquine was officially withdrawn in August 2001. The prevalence of illegal activity in shops is discussed in Chapter 10 on retail regulation.

second retail audit in mid-2002. Over the same period the availability of SP, amodiaquine and quinine increased in all outlet types

6.4 Choice of Fever/Malaria Treatment Provider

Of the 628 individuals reporting fever/malaria during the household survey, 90% of under fives and 83% of older children and adults sought some kind of treatment (Table 6.1). Three-quarters sought treatment from a health care provider. Retailers were the most frequent source: 28% had attended a health facility, while 54% had visited shops. Both types of retail outlet were important sources, with 26% visiting drug stores and 29% general shops. Reported use of traditional healers and community health workers was very rare. Only four visits to traditional healers were reported, and in 3 of the 4 cases, one or two other providers were visited first, indicating that traditional healers may be used after other strategies were perceived to have failed. Drugs were obtained from home or neighbours by 13% of individuals reporting episodes. Obtaining drugs from home/neighbour was significantly more likely for individuals in Ulanga (22%) than in Kilombero or Rufiji (both 11%).

Table 6.1 Sources of treatment for individuals reporting fever/malaria episode
(% of individuals reporting fever/malaria using the specified source of treatment)

	Under 5 years	Over 5 years	Total
N	172	456	628
Any treatment	154 (90%)*	377 (83%)*	531 (85%)
Any provider visit	131(76%)	337 (74%)	468 (75%)
Government facility	60 (35%)*	81 (18%)*	141 (22%)
Private facility	18 (10%)*	22 (5%)*	40 (6%)
Drug store ¹	42 (24%)	124 (27%)	166 (26%)
General shop	35 (20%)*	150 (33%)*	185 (29%)
Traditional healer	2 (1%)	2 (0.4%)	4 (0.6%)
Community health worker	0 (-)	2 (0.4%)	2 (0.3%)
Lymphatic filariasis project ²	0 (-)	2 (0.4%)	2 (0.3%)
Drug from home/ neighbour	28 (16%)	52 (11%)	80 (13%)

*significant difference between over and under 5s (chi² test with Rao and Scott correction, p<0.05)

¹ it was not possible to distinguish between commercial and village-run drug stores from household survey data

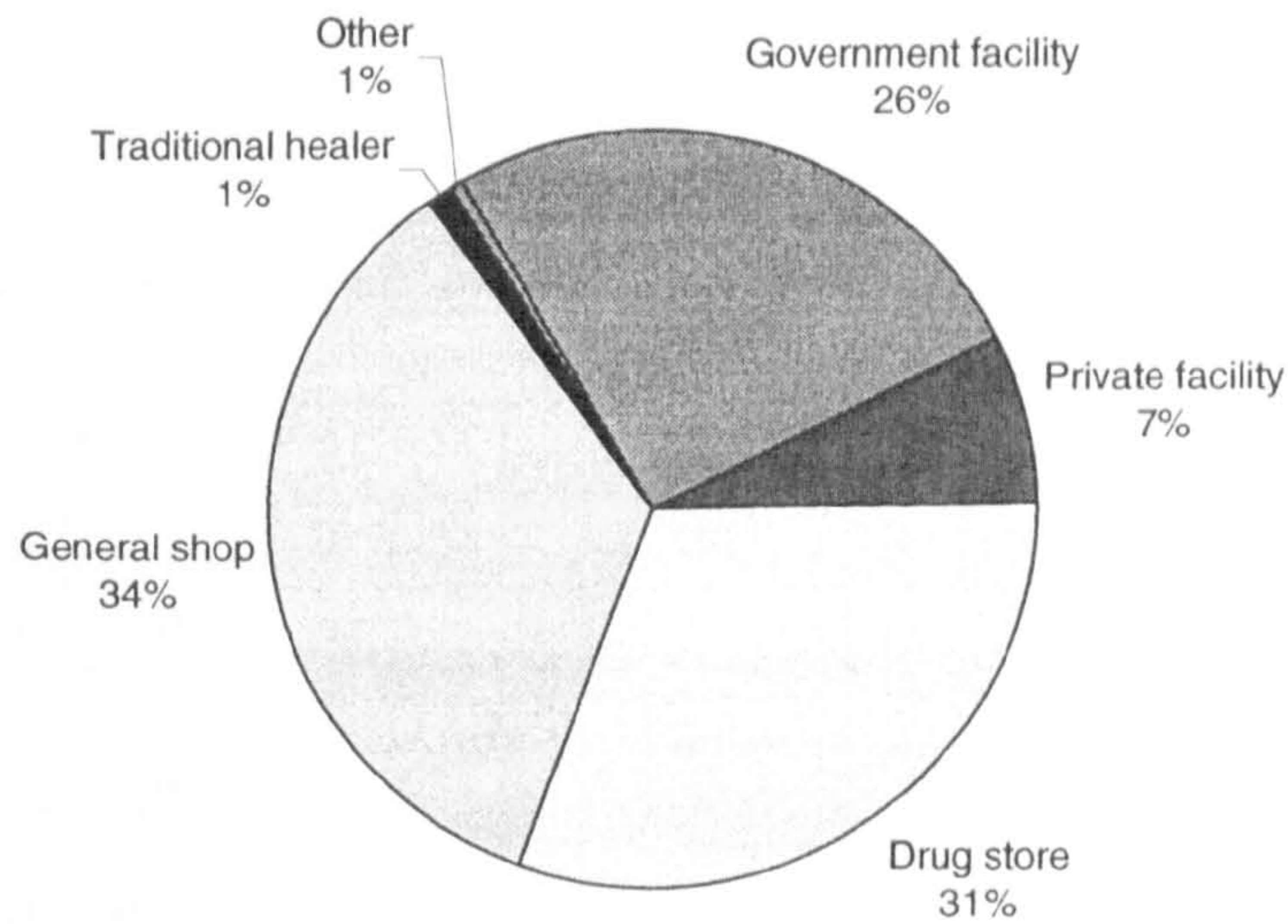
² patient visited by project workers at home.

Source: Household Survey May-Sep 2001.

Only 13% of individuals visited more than one provider, although two children made 5 visits each (Table A1.11). By far the most common pattern for multiple visits was to visit a health facility first followed by a drug store, and the second most common to visit a general store followed by a health facility.

Of total visits, 65% were to shops, and 33% to facilities (Figure 6.1). Government facilities accounted for over three-quarters of facility visits. Dispensaries, the lowest level of care, were responsible for 70% of facility visits, compared to 27% at health centres, and only 3% at hospitals.

Figure 6.1 Breakdown of provider visits for fever/malaria by provider type



n=577 visits to providers for fever/malaria

Source: Household Survey May-Sep 2001

Government facilities were most frequently visited in Ulanga DSS, drug stores in Kilombero, and general shops in Rufiji although there was a very slight overlap in 95% confidence intervals for drug and general stores across DSS areas (Table 6.2). Christian households were more likely to use drug stores, and Muslim households were more likely to use general stores, reflecting the greater proportion of Muslims in Rufiji. There was no difference by household SES in the probability of visiting government facilities, drug stores and general stores, or in obtaining drugs from home/neighbour. However, households in the better-off third were significantly more likely to use a private facility (13% of individuals reporting fever/malaria, compared with 3% in the poorest and middle thirds). The knowledge of the household head was significantly associated with choice of provider; individuals were more likely to visit private facilities and drug stores if the head had completed primary education, or if the head knew that SP was more effective than chloroquine.

Table 6.2 Variation in choice of provider by household and patient characteristics
(% of individuals reporting fever/malaria visiting specified provider)

	n ¹	Providers visited			
		Government facility	Private facility	Drug Shop	General Shop
Characteristics of household					
DSS area:					
Kilombero	203	35 (17%)*	18 (9%)	67 (33%)	47 (23%)
Ulanga	85	28 (33%)*	8 (9%)	25 (29%)	23 (27%)
Rufiji	340	78 (23%)	14 (4%)	74 (22%)	115 (34%)
Religion²:					
Christian	220	42 (19%)	21 (10%)	70 (32%)*	47 (21%)*
Muslim	407	99 (24%)	19 (5%)	95 (23%)*	138 (34%)*
SES:					
Poorest third	179	43 (24%)	5 (3%)*	51 (28%)	53 (30%)
Middle third	212	45 (21%)	7 (3%)*	51 (24%)	72 (34%)
Better-off third	208	48 (23%)	27 (13%)*	57 (27%)	54 (26%)
Household head education:					
Less than primary	328	67 (20%)	7 (2%)*	72 (22%)*	106 (32%)
Completed primary or more	300	74 (25%)	33 (11%)*	94 (32%)*	79 (26%)
Household head perception of relative efficacy of SP:					
SP better	211	53 (25%)	22 (10%)*	70 (33%)*	57 (27%)
Chloroquine better, both equal or don't know	417	88 (21%)	18 (4%)*	96 (23%)*	128 (31%)
Characteristics of patient					
Age of patient:					
Under 5 years	172	60 (35%)*	18 (10%)*	42 (24%)	35 (20%)*
Over 5 years	456	81 (18%)*	22 (5%)*	124 (27%)	150 (33%)*
Gender of patient:					
Male	208	46 (22%)	12 (6%)	64 (31%)	65 (31%)
Female	277	70 (25%)	19 (7%)	67 (24%)	82 (30%)
Perceived severity of illness:					
Life in danger	162	50 (31%)*	14 (9%)	59 (36%)*	44 (27%)
Life not in danger	414	90 (22%)*	24 (6%)	96 (23%)*	121 (29%)

¹ individuals reporting a fever/malaria episode for which relevant characteristics were known

² excludes one individual following traditional religion.

*significant difference in visiting given provider type across specified household/patient characteristics (chi² test with Rao and Scott correction, p<0.05).

Source: Household Survey May-Sep 2001.

There was significant variation between over and under fives in providers visited, but no significant variation between older children and adults. Of children under five with fever/malaria, 44% visited a health facility compared with only 22% of over fives. The probability of visiting a drug store did not vary significantly by age group, but general shops were less likely to be used for children under five, although this was still common (20%). These age patterns meant that under fives made up 44% of visits at government facilities, 45% at private facilities, 26% at drug stores and 20% at general stores (implying that the majority of cases seen at all outlet types were not in this vulnerable group). Of the other patient characteristics, there was significantly greater use of government facilities and drug stores for episodes perceived as life-threatening, but no significant differences by gender.

6.5 Antimalarial Drug Volumes and Values

During the antimalarial retail audits in 2002, sales were documented of tablets and syrup formulations of chloroquine, SP, amodiaquine and quinine, and injectable formulations of chloroquine and quinine. It was estimated that 233,606 equivalent adult antimalarial doses were dispensed per annum from all facilities and shops in the 3 DSS areas, equivalent to 1.7 doses per capita (Table A1.12). The total value of antimalarials dispensed was estimated at Tsh103,225,647 (US\$108,643), equivalent to \$0.77 per capita.

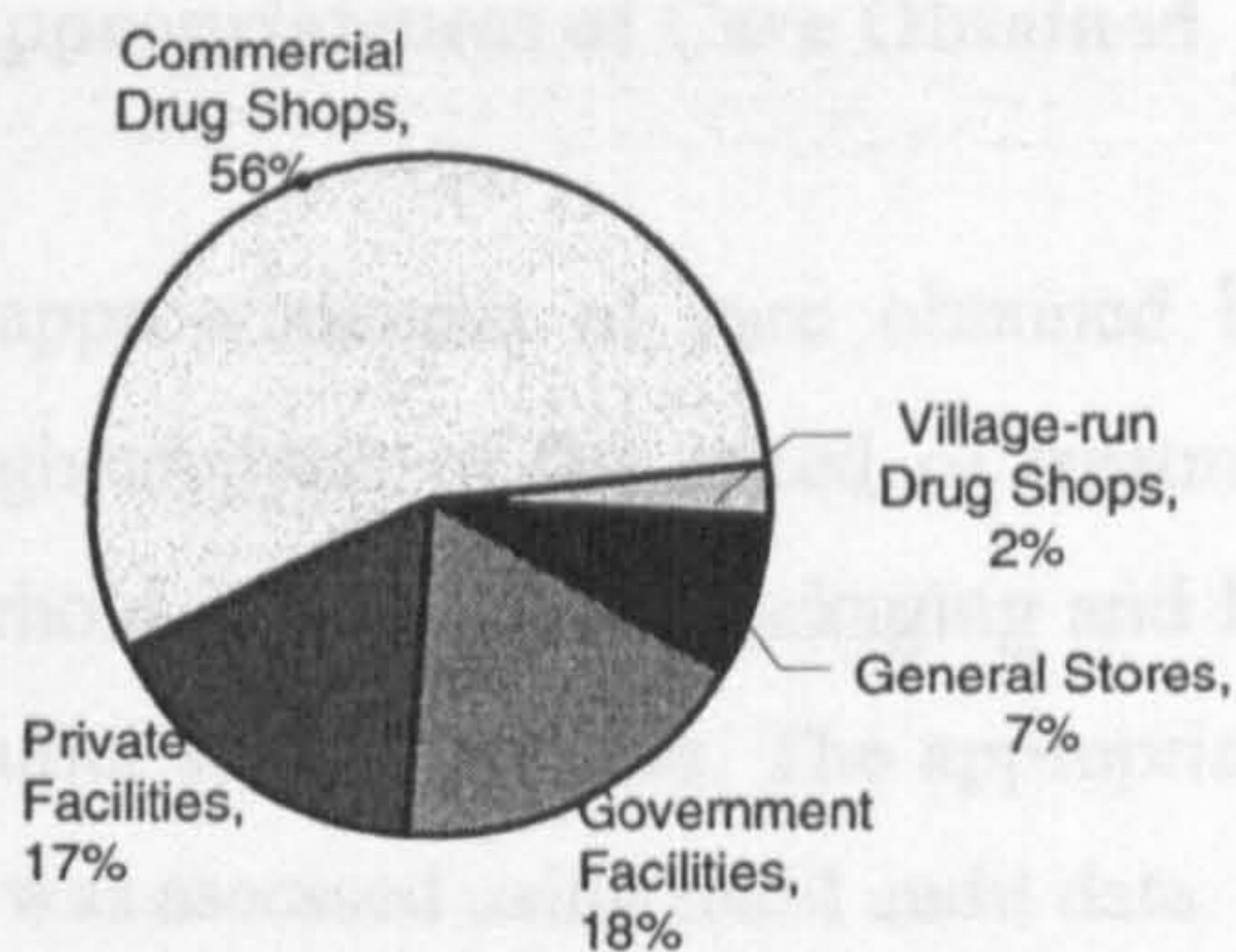
SP and amodiaquine accounted for 69% and 17% of antimalarial volumes, with all other drug types responsible for less than 5%. This breakdown was similar for facilities or drug stores alone, but not for general stores where chloroquine still made up more than half antimalarial volumes (Table A1.13). The results in value terms were quite similar, although the share for quinine tablets was considerably higher than with volumes (21% compared with 4% of all sales), reflecting its relatively high cost per dose, and giving it the second highest sales value after SP tablets.

Figure 6.2 shows the breakdown of antimalarial volumes by provider type. Pooling data across all three DSS areas, the government was the biggest individual supplier, followed by commercial drug stores and then private facilities. The private sector as a whole was very important, supplying 58% of antimalarial volumes, mostly through the retail sector which accounted for 39% of total antimalarial volumes. Within the retail market, commercial drug stores were the main suppliers, providing 88% of drug volumes, and this percentage was fairly constant across DSS areas. However, there were important differences between the areas. The private sector supplied 80% of antimalarial volumes in Kilombero, two-thirds in Ulanga and approximately half in Rufiji. The role of the retail sector was also larger in Kilombero and Ulanga (66% and 52% respectively) than in Rufiji (23%).

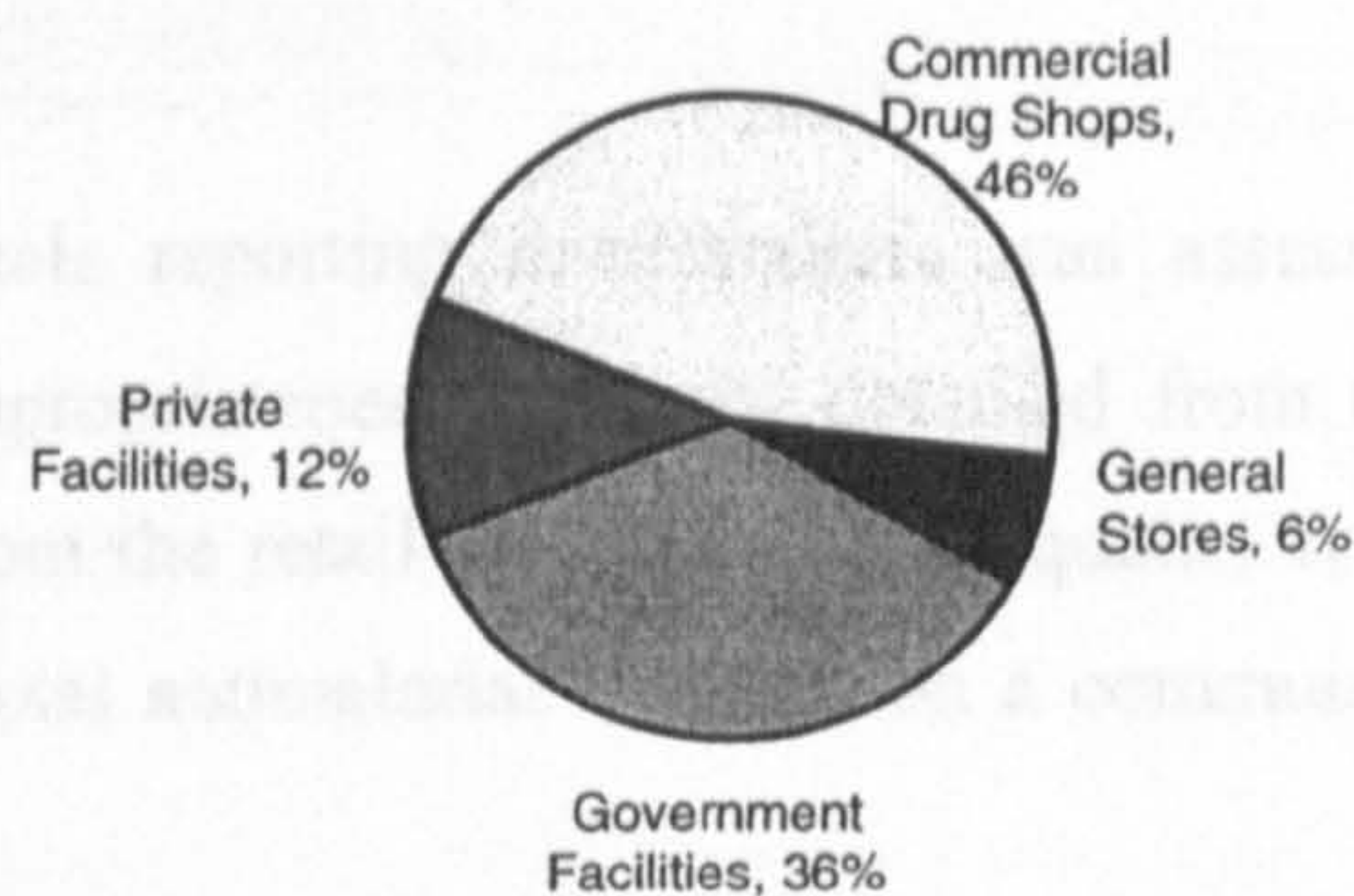
In value terms, the private sector supplied 90% of antimalarials and its retail component, 60% (Figure A1.2). Private and retail market shares were greater in value than in volume terms, reflecting the different mix of antimalarials provided in the public and private sectors, and the valuation of government antimalarials which assumed zero markup over international reference prices and delivery costs. Within the retail market, commercial drug stores supplied 90% of antimalarials in value terms

Figure 6.2 Antimalarial volumes dispensed by source (% of equivalent doses)

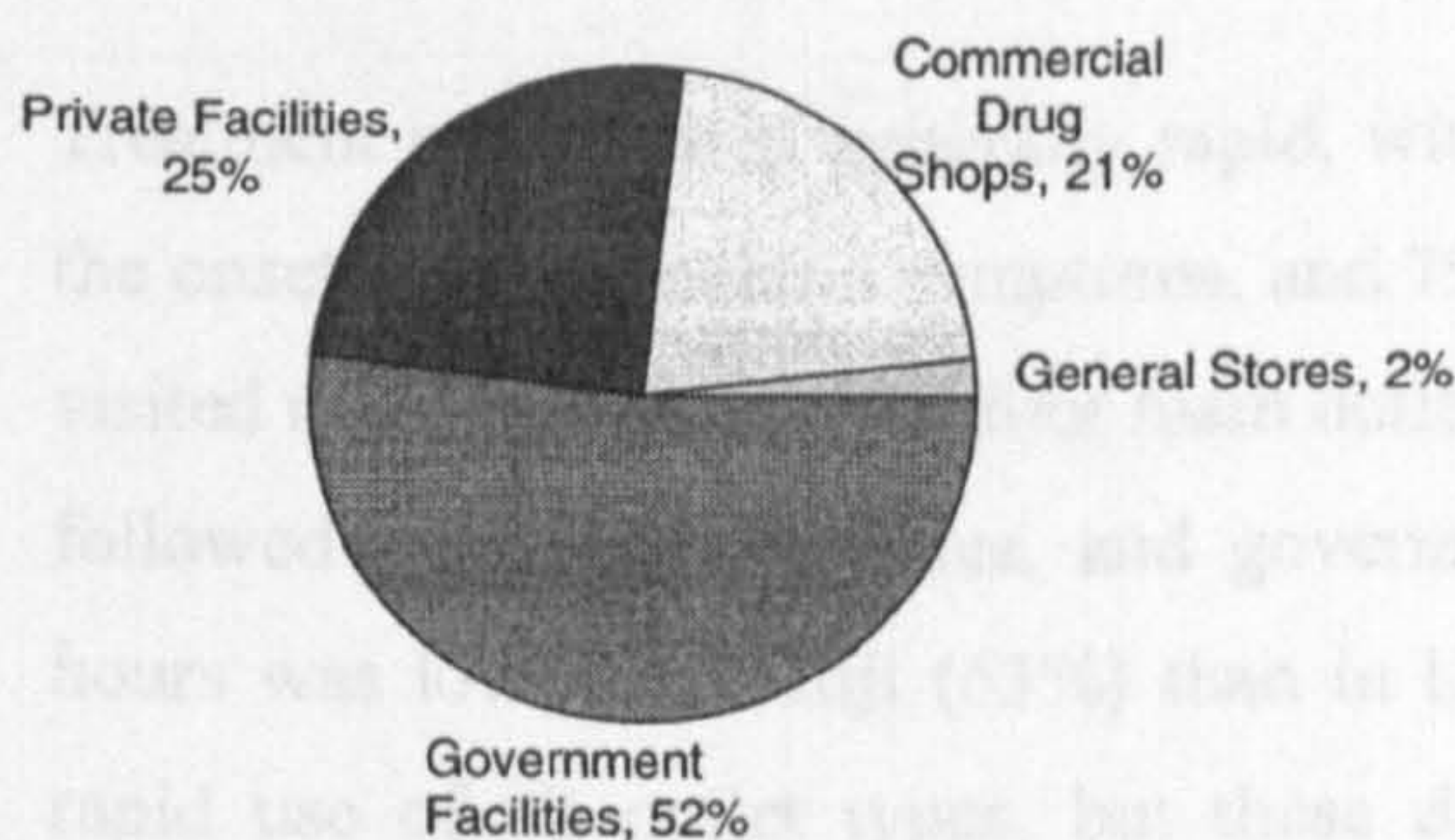
Kilombero DSS



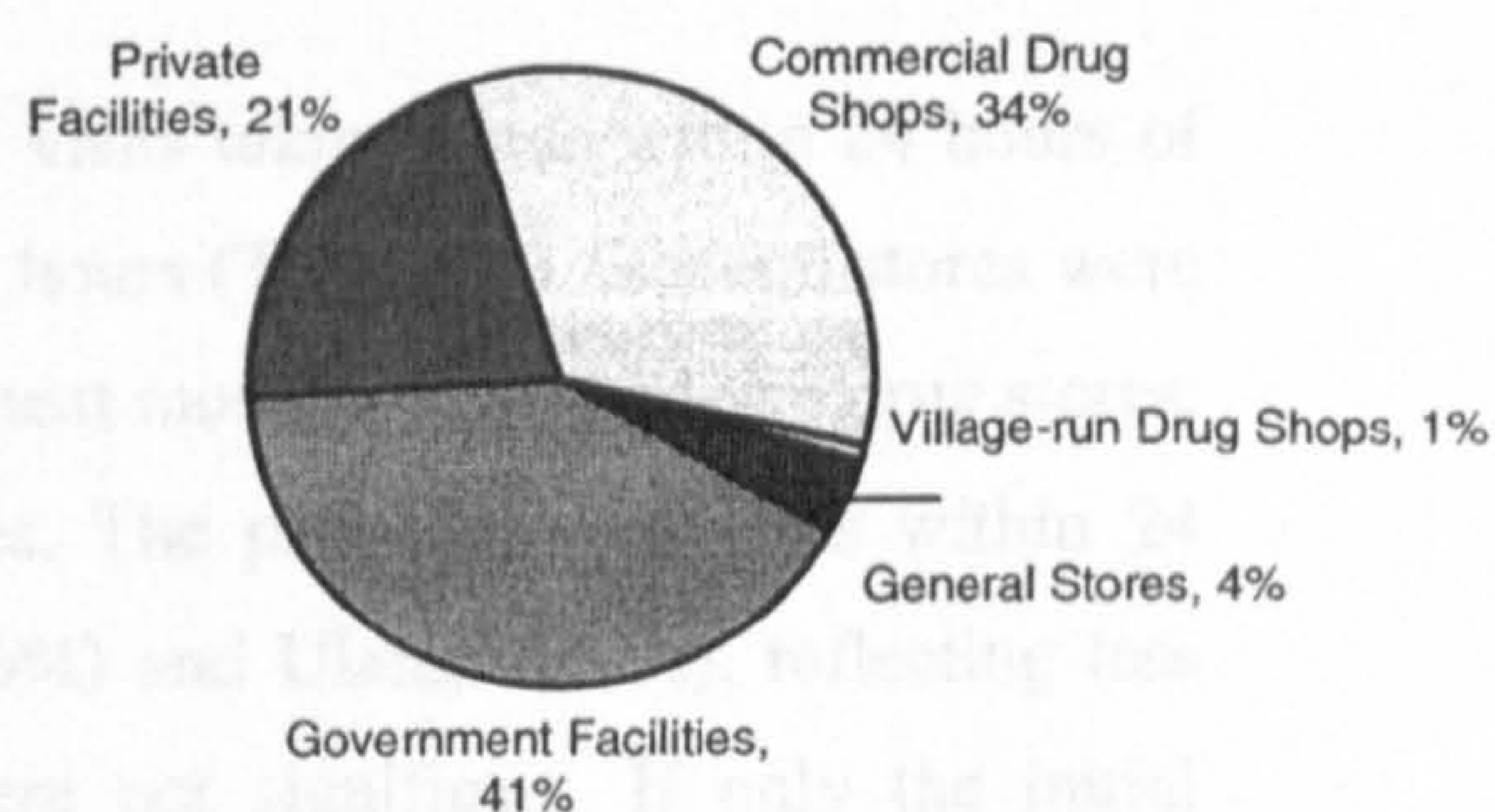
Ulanga DSS



Rufiji DSS



Total



Source: Retail Audits Feb/Apr & Jun/Jul 2002

Mean antimalarial volumes per outlet per annum in Rufiji were highest for private facilities (8,580), followed by government facilities (8,129), which both dispensed more than six times as many doses as the average commercial drug shop (1,325) (Table A1.14). However, in Kilombero and Ulanga commercial drug shops had the highest average volumes per outlet (3,893 and 4,784 respectively), 1.4 and 2.1 times mean government facility volumes respectively, and 2.9 and 3.6 times greater than commercial drug stores in Rufiji. Overall, general stores stocking antimalarials sold a mean of 74 doses per annum, meaning that on average a commercial drug store sold 31 times as many antimalarials as a general store stocking antimalarials. In value terms, a commercial drug store sold antimalarials of an average value of Tsh1,644,423 (US\$1,731) per year, 46 times that of general stores stocking antimalarials which averaged Tsh35,681 (US\$38).

Retail audit data were not collected for painkillers, but rough estimates of sales volumes obtained during qualitative interviews suggested that commercial drug stores also had much higher painkiller sales per outlet than general stores, on average selling 6 times as many aspirin tablets and 12 times as many paracetamol. However, as there were 17 times as many drug-stocking general stores as drug stores, it was not surprising that the overall share of painkillers

reported in the household survey from general stores exceeded the drug store share (45% vs 28%).

6.6 Appropriateness of Care Obtained

The appropriateness of care obtained by individuals reporting fever/malaria was assessed through analysis of the speed of treatment and appropriateness of drugs obtained from the household survey, tablet packaging and labelling from the retail audits, and drug quality from the outlet survey samples. The appropriateness of total antimalarial volumes on a community level was assessed using retail audit data.

6.6.1 Speed of Treatment Seeking

Treatment seeking was generally rapid, with 69% of all visits taking place within 24 hours of the onset of fever/malaria symptoms, and 79% within 48 hours (Table 6.3). General stores were visited most promptly of the four main outlet types. The next most rapid group were drug stores, followed by private facilities, and government facilities. The proportion of visits within 24 hours was lower in Rufiji (63%) than in Kilombero (76%) and Ulanga (74%), reflecting less rapid use of all outlet types, but these differences were not significant. If only the initial provider visited were considered, the percentage of visits within 24 hours increased for each outlet types, with general stores, drug stores and private facilities all over 80%.

Table 6.3 Speed of treatment seeking: all visits and first visits to outlets taking place within 24 hours of symptom onset (as a % of all visits to each outlet type)

	All visits		First visits	
	n ¹	Visits within 24 hours of fever/malaria onset	n ¹	First visits within 24 hours of fever/malaria onset
Government facility	136	83 (61%)	108	74 (69%)
Private facility	38	26 (68%)	30	24 (80%)
Drug store	160	112 (70%)	116	96 (83%)
General shop	184	141 (77%)	159	131 (82%)
Community health worker	2	2 (100%)	2	2 (100%)
Traditional healer	4	0 (-)	1	0 (-)
Lymphatic filariasis project	1	0 (-)	1	0 (-)
Total	525	364 (69%)	417	327 (78%)

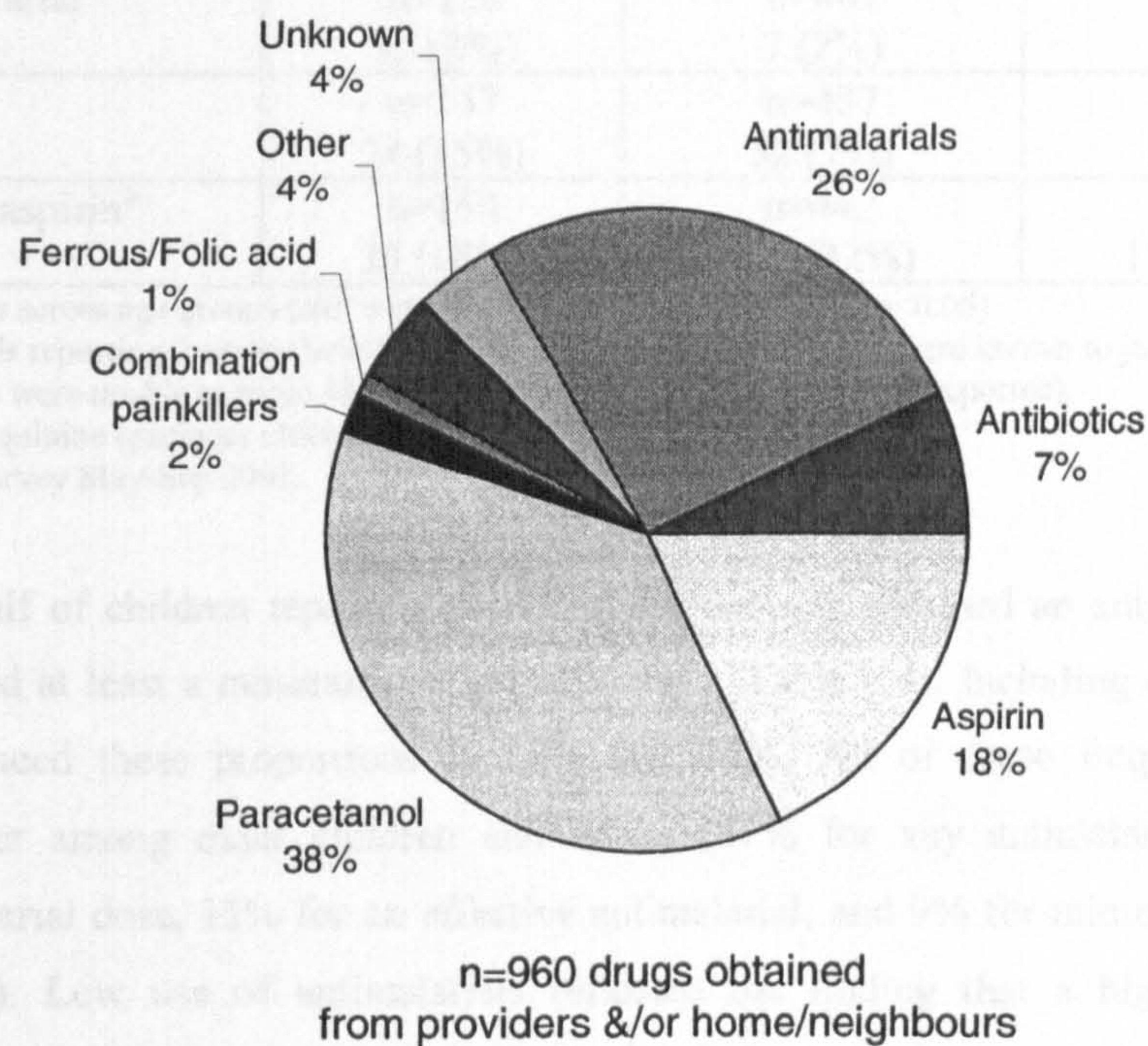
¹ Number of provider visits for which time of symptom onset and provider visit recorded.

Source: Household Survey May-Sep 2001.

6.6.2 Drugs and Doses Obtained

Obtaining manufactured drugs of some kind was very common, reported for 89% of under fives and 82% of over fives with fever/malaria. Antimalarials accounted for 35-37% of manufactured medicines obtained for fever/malaria treatment from facilities and commercial drug stores, but only 10% from general stores, meaning that overall antimalarials made up 26% (Figure 6.3). The majority of drugs obtained were simple painkillers, such as paracetamol (38%), aspirin (18%), or combinations of aspirin, caffeine and paracetamol (2%). Anti-anaemia drugs such as ferrous sulphate and folic acid were rarely obtained (1%). Antibiotics accounted for 7%, including co-trimoxazole, amoxicillin, ampicillin, cloxacillin, chloramphenicol, doxycycline, erythromycin, metronidazole and tetracycline. Only locally prepared medicines were obtained at the 4 reported visits to traditional healers. A further three individuals used traditional remedies at home.

Figure 6.3 Manufactured medicines obtained for fever/malaria treatment reported during the household survey



Source: Household Survey May-Sep 2001

The appropriateness of drugs obtained was assessed using the household survey indicators described in Section 5.4.3: the proportion of individuals reporting fever/malaria obtaining an antimalarial and a minimum antimalarial dose (for all antimalarials, and effective antimalarials only (SP, amodiaquine and quinine)); the proportion obtaining injectable antimalarials and

antibiotics, and the proportion of these likely to be inappropriate; the proportion of under fives obtaining aspirin; and the proportion of non-febrile individuals obtaining antimalarials (data were not collected on the quantity and timing of drugs actually consumed). The results are shown by individual in Table 6.4 (including all providers visited during the episode), and by provider visit in Table 6.5.

Table 6.4 Drugs obtained by patients for fever/malaria treatment
(% of individuals reporting fever/malaria obtaining specified drugs over the course of the episode¹)

Drugs obtained	Under 5 years	Over 5 years	Total
Any manufactured drugs*	n=172 153 (89%)	n=456 375 (82%)	n=628 528 (84%)
Painkillers only*	n=153 45 (29%)	n=436 187 (43%)	n=589 232 (39%)
Antimalarial*	n=160 84 (53%)	n=440 138 (31%)	n=600 222 (37%)
At least minimum dose of antimalarial*	n=157 65 (41%)	n=439 93 (21%)	n=596 158 (26%)
Effective antimalarial*	n=159 45 (28%)	n=438 53 (12%)	n=597 98 (16%)
At least minimum dose of effective antimalarial* ²	n=156 29 (19%)	n=438 41 (9%)	n=594 70 (12%)
Injectable antimalarial	n=158 12 (8%)	n=441 7 (2%)	n=599 19 (3%)
Any antibiotic*	n=157 24 (15%)	n=437 32 (7%)	n=594 56 (9%)
Drugs containing aspirin*	n=154 28 (18%)	n=442 142 (32%)	n=596 170 (29%)

*significant difference across age groups (chi² test with Rao and Scott correction, p<0.05)

¹ n refers to individuals reporting fever/malaria for whom sufficient drugs obtained were known to judge the specified variable (interviewees were unable to name 41 (4.3%) of the 960 manufactured drugs reported).

² SP, amodiaquine or quinine (excludes chloroquine).

Source: Household Survey May-Sep 2001.

Only just over half of children reporting fever/malaria under 5 obtained an antimalarial, and only 41% obtained at least a minimum antimalarial dose (Table 6.4). Including only effective antimalarials reduced these proportions to 28% and 19%. All of these frequencies were significantly lower among older children and adults (31% for any antimalarial, 21% for minimum antimalarial dose, 12% for an effective antimalarial, and 9% for minimum effective antimalarial dose). Low use of antimalarials reflected the finding that a high percentage obtained painkillers only (29% of under fives, 43% of over fives).

Consumers obtained painkillers only at 85% of visits to general stores, 33% to drug stores, 14% to private facilities and 13% to government facilities (Table 6.5). No drugs at all were obtained at 17% of visits to government facilities, but only 5% to private facilities, and less than 1% of general and drug stores.

Table 6.5 Drugs obtained during provider visits
 (% of visits to providers of each type were specified drugs obtained¹)

Drugs obtained	Government facility	Private facility	Drug Store	General Store
Any drugs	n=149	n=42	n=178	n=199
Under 5 years	55 (83%)	19 (100%)	46 (100%)	40 (100%)
Over 5 years	68 (82%)	21 (91%)	131 (99%)	158 (99%)
Total	123 (83%)	40 (95%)	177 (99%)	198 (99.5%)
Painkillers only	n=136	n=36	n=165	n=199
Under 5 years	3 (5%)	0 (-)	12 (28%)	35 (88%)
Over 5 years	14 (18%)	5 (24%)	42 (34%)	134 (84%)
Total	17 (13%)	5 (14%)	54 (33%)	169 (85%)
Antimalarial	n=139	n=37	n=168	n=199
Under 5 years	32 (53%)	13 (87%)	30 (67%)	5 (13%)
Over 5 years	40 (51%)	12 (55%)	62 (50%)	19 (12%)
Total	72 (52%)	25 (68%)	92 (55%)	24 (12%)
At least minimum dose of antimalarial	n=138	n=37	n=166	n=199
Under 5 years	25 (42%)	12 (80%)	20 (47%)	5 (13%)
Over 5 years	28 (36%)	10 (45%)	46 (37%)	7 (4%)
Total	53 (38%)	22 (59%)	66 (40%)	12 (6%)
Effective antimalarial ²	n=138	n=37	n=168	n=199
Under 5 years	16 (27%)	10 (67%)	19 (42%)	1 (3%)
Over 5 years	14 (18%)	7 (32%)	30 (24%)	1 (0.6%)
Total	30 (22%)	17 (46%)	49 (29%)	2 (1%)
At least minimum dose of effective antimalarial	n=138	n=37	n=166	n=199
Under 5 years	11 (18%)	9 (60%)	9 (21%)	1 (3%)
Over 5 years	12 (15%)	6 (27%)	22 (18%)	0 (-)
Total	23 (17%)	15 (41%)	31 (19%)	1 (0.5%)
Injectable antimalarial	n=137	n=36	n=165	n=199
Under 5 years	4 (7%)	2 (13%)	6 (14%)	0 (-)
Over 5 years	2 (3%)	2 (10%)	3 (2%)	0 (-)
Total	6 (4%)	4 (11%)	9 (5%)	0 (-)
Antibiotic	n=137	n=37	n=166	n=199
Under 5 years	10 (17%)	8 (53%)	5 (11%)	0 (-)
Over 5 years	11 (14%)	6 (27%)	17 (14%)	1 (0.6%)
Total	21 (15%)	14 (38%)	22 (13%)	1 (0.5%)
Any drug containing aspirin	n=140	n=36	n=165	n=199
Under 5 years	7 (12%)	2 (13%)	3 (7%)	15 (38%)
Over 5 year	34 (42%)	1 (5%)	24 (20%)	76 (48%)
Total	41 (29%)	3 (8%)	27 (16%)	91 (46%)

¹ n refers to provider visits reported for fever/malaria for which sufficient drugs were known to judge the specified variable (interviewees were unable to name 41 (4.3%) of the 960 manufactured drugs reported).

² SP, amodiaquine or quinine (excludes chloroquine).

Source: Household Survey May-Sep 2001.

Of the outlet types, private facilities performed best on the antimalarial indicators (Table 6.5). At least a minimum antimalarial dose was obtained at 59% of visits for fever/malaria to private facilities, 40% to drug stores, 38% to government facilities, and 6% to general stores (significant difference between general stores and all others). Under fives were more likely than over fives to obtain a minimum antimalarial dose at each outlet type, but not significantly so. One might expect antimalarials to be more frequently provided at higher-level government

facilities, but in fact they were less frequently obtained at government health centres than at government dispensaries (43% and 57%, difference not significant). The proportion of antimalarials dispensed as under-doses was 21% from private facilities, 29% from government facilities and drug shops, and 50% from general stores (differences not significant) (Table A1.15). Quinine tablets were by far the most likely to be obtained from providers as under-doses (86%). Roughly a third of chloroquine tablets and amodiaquine tablets were under-doses, but only 13% of SP tablets. All patients obtaining chloroquine syrup or chloroquine injections obtained at least the full dose¹⁰.

Considering only effective antimalarials widened the gap between government facilities and private outlets (Table 6.5). An effective antimalarial was obtained at 46% of visits for fever/malaria to private facilities, 29% to drug stores, 22% to government facilities, and 1% to general stores. At least a minimum dose of an effective antimalarial was obtained at 41% of visits to private facilities, but at only 19% to drug stores, 17% to government facilities, and 0.5% to general stores.

One would expect the share of antimalarials in the "effective" category to have increased since the 2001 household survey, as chloroquine was phased out. This has been borne out by preliminary analysis of the 2002 IMPACT household survey, which showed that one year later, the percentage of individuals obtaining an antimalarial remained constant at 37%, but the percentage obtaining an effective antimalarial had increased from 16% to 34% (Kachur et al., unpublished data, IMPACT collaboration). This explains the differences between the results of the 2001 household survey and retail audits conducted in 2002. While chloroquine tablets were the most common antimalarial obtained during the 2001 household survey (44% of antimalarials reported), by the second retail audit in mid-2002, chloroquine was responsible for only 6% of total antimalarial sales volumes (although it was still available in nearly a third of commercial drug stores and 44% of government facilities)¹¹.

The antibiotic co-trimoxazole was obtained by patients at 4% of visits for fever/malaria to government facilities and 6% to private facilities, but not at any visits to shops. While not generally prescribed for malaria, cotrimoxazole does have an antimalarial action. Adding cotrimoxazole drugs to the "effective antimalarials" group increased the proportion obtaining an effective antimalarial to 25% in government facilities and 51% in private facilities.

¹⁰ only an initial pre-referral dose was deemed to be required for injectables, according to the National Treatment Guidelines.

¹¹ Audit volumes were calculated in equivalent doses, so one would expect, *ceteris paribus*, drugs frequently under-dosed to have a smaller share in retail audit sales volumes than in household data on the number of times obtained. This may to some extent explain the difference in the share of chloroquine tablets between the household survey and second retail audit (see Table A1.15 on under-dosing by antimalarial).

As it was particularly surprising to find the proportion of under fives obtaining an antimalarial to be so low at government facilities, the case histories were explored in more depth for the 25 children under five concerned for whom all drugs were known. In 12 cases (48%) an antimalarial was obtained from a drug shop on the same day, after the government facility visit, strongly suggesting antimalarial stockouts at government facilities. In a further 11 cases other drugs such as antibiotics, salbutamol or oral rehydration solution (ORS) were dispensed at government facilities, or obtained the same day from other outlets, suggesting that health workers had made a non-malarial diagnosis. However, in nine of these 11 cases during free-listing of symptoms the respondents volunteered one of the terms generally associated with a high temperature (*joto/chemchem/kuchemka/homa*), suggesting that a malaria diagnosis should not have been ruled out.

The possible inappropriate procurement of antimalarials, antibiotics and aspirin was also considered. Twenty individuals obtained antimalarials but did not report a fever or malaria episode, representing 7% of all antimalarials obtained. Of these 20, 19 had obtained the antimalarial from a government facility, and one from a private facility. One might expect this to be due to the use of prophylaxis during pregnancy, but 15 of these 20 were either male and/or under 15 years.

Children under five with fever/malaria were given injectable antimalarial treatment at 13% of visits to private facilities and 14% to drug stores (Table 6.5). The proportion of all antimalarial treatments in injectable form was 8% in government facilities, 9% in drug stores and 12% in private facilities. No injectable antimalarials were obtained at general stores. Of the 19 individuals who received injections, 10 (53%) did not report any symptoms of severe febrile illness indicating that an injection might be warranted (vomiting, unable to eat, convulsions, or loss of consciousness).

Rates of antibiotic dispensing at private facilities were high, provided at 53% of visits for under fives and 27% for older children and adults with fever/malaria (Table 6.5). Antibiotic provision was significantly less common in government facilities and drug stores (15% and 13% respectively), and very rare at general stores. Of the 56 individuals who received antibiotics, 24 (42%) did not report any symptoms suggesting that an antibiotic might be warranted (cough, fast breathing, diarrhoea or severe febrile illness).

It was disturbing to note that aspirin was obtained for 18% of under fives with fever/malaria (Table 6.4). This was particularly common at general store visits (38%), but aspirin was also supplied at over 10% of government and private facility visits for under fives (Table 6.5).

The above analysis included all fever episodes, regardless of whether they were completed. Some individuals were still ill on the day of interview, and others who felt well, may have subsequently suffered a recrudescence. Restricting the analysis to individuals reporting feeling well on the day of interview made little difference to measured treatment quality. The percentage of individuals obtaining an antimalarial was 40% for completed episodes, compared to 37% for all episodes, and the percentage obtaining at least a minimum antimalarial dose was 28% for completed episodes and 26% for all episodes.

Variation in drugs and doses obtained

Bivariate analysis showed that patients with fever/malaria were significantly more likely to obtain antimalarials if the household was in the better-off third than in the poorest third (Table 6.6). This reflected greater use of private facilities where antimalarials were more often obtained, and less use of general stores, rather than a significant difference in the probability of obtaining antimalarials by SES at a given outlet type. Patients were also significantly more likely to get an antimalarial if the household was Christian, had a better educated household head, or if the household head knew that SP was more effective. Patients in Rufiji DSS were significantly less likely to get antimalarials than those in Kilombero or Ulanga, mainly reflecting less frequent dispensing of antimalarials at shops. In terms of individual characteristics, patients were more likely to get an antimalarial if they were under five, or if the illness was perceived as life-threatening. Males were more likely to obtain an antimalarial, but not significantly so. Similar patterns were observed for obtaining an effective antimalarial and for minimum doses.

The importance of the same household and patient characteristics was evaluated in a multinomial logit regression of the probability of patients with fever/malaria obtaining an antimalarial, specified in Table 6.7. The household PCA score was used as an independent variable, rather than dummy variables for each SES third, in order to maximise variation in household status captured. Age was left as the categorical variable of being under five, as it was hypothesised that there was likely to be a dichotomous difference in treatment obtained between young children and adults, rather than a linear relationship across all age groups. Results are shown in Table 6.8.

Table 6.6 Appropriateness of treatment obtained per episode: variation by household and patient characteristics

(% of individuals reporting fever/malaria obtaining specified treatment)

	Drugs obtained ¹			
	Antimalarial	At least min. antimalarial dose	Effective antimalarial	At least min. dose of effective antimalarial
Characteristics of household head				
DSS area:	(n=600)	(n=596)	(n=597)	(n=594)
Kilombero	88 (45%)*	63 (33%)*	35 (18%)	24 (13%)
Ulanga	39 (48%)*	28 (34%)*	15 (19%)	11 (14%)
Rufiji	95 (29%)*	67 (21%)*	48 (15%)	35 (11%)
Religion²:	(n=599)	(n=595)	(n=596)	(n=593)
Christian	95 (45%)*	66 (31%)	38 (18%)	24 (11%)
Muslim	126 (33%)*	91 (24%)	59 (15%)	45 (12%)
SES:	(n=572)	(n=568)	(n=569)	(n=566)
Poorest third	53 (31%)*	38 (23%)	18 (11%)*	14 (8%)*
Middle third	70 (34%)	47 (23%)	25 (12%)	13 (6%)*
Better-off third	91 (46%)*	68 (35%)	48 (24%)*	38 (19%)*
Education:	(n=600)	(n=596)	(n=597)	(n=594)
Less than primary	87 (28%)*	60 (19%)*	34 (11%)*	25 (8%)*
Completed primary or more	135 (47%)*	98 (34%)*	64 (22%)*	45 (16%)*
Household head perception of relative efficacy of SP:	(n=600)	(n=596)	(n=597)	(n=594)
SP better	105 (53%)*	70 (36%)*	55 (28%)*	35 (18%)*
Chloroquine better, both equal or don't know	117 (29%)*	88 (22%)*	43 (11%)*	35 (9%)*
Characteristics of patient				
Age of patient:	(n=600)	(n=596)	(n=597)	(n=594)
Under 5 years	84 (53%)*	65 (41%)*	45 (28%)*	29 (19%)*
Over 5 years	138 (31%)*	93 (21%)*	53 (12%)*	41 (9%)*
Gender of patient:	(n=461)	(n=457)	(n=458)	(n=455)
Female	94 (36%)	59 (23%)*	38 (15%)	25 (10%)*
Male	84 (43%)	64 (33%)*	42 (21%)	31 (16%)*
Perceived severity of illness:	(n=549)	(n=545)	(n=546)	(n=543)
Life in danger	73 (49%)*	61 (42%)*	39 (26%)*	33 (23%)*
Life not in danger	144 (36%)*	94 (24%)*	57 (14%)*	36 (9%)*

¹ n in each case refers to individuals reporting a fever/malaria episode for which relevant characteristics and drugs were known.

² excludes one individual following traditional religion.

* significant difference in % of individuals obtaining specified treatment across household head or patient characteristics (chi² test with Rao and Scott correction, p<0.05)

Source: Household Survey May-Sep 2001.

Table 6.7 Definition of variables for logit models of the probability of patient with fever/malaria obtaining an antimalarial and a minimum dose of an antimalarial

Variable	Definition	Mean
Dependent variables		
Obtain_AM	=1 if antimalarial obtained	0.37
Obtain_mindose_AM	=1 if at least minimum dose of antimalarial obtained	0.27 ¹
Independent continuous variables		
PCA	Household PCA SES score	0.07
Education	Years of education of household head	4.44
Independent dummy variables		
DSS area of residence: Kilombero (omitted)	=1 if individual in Kilombero DSS	0.32
Rufiji	=1 if individual in Rufiji DSS	0.54
Ulanga	=1 if individual in Ulanga DSS	0.14
Religion of household head ² : Muslim (omitted)	=1 if household head is Muslim	0.65
Christian	=1 if household head is Christian	0.35
SP_better	=1 if household head perceived SP to be more effective than chloroquine	0.34
Under_5	=1 if patient is under 5 years	0.27
Gender	=1 if patient is male	0.43
Life_threat	=1 if illness perceived as life threatening	0.28

¹ figure slightly different to the percentage reported in Table 6.4 because individuals without complete data on all independent variables were excluded from the regression analysis.

² excludes one individual following traditional religion.

Source: Household Survey May-Sep 2001.

Table 6.8 Logit regression of probability of obtaining an antimalarial
Number of observations=381¹; F<0.001

Explanatory variables	Regression results			Marginal effects		
	Logit coefficient	Standard error	p-value	dy/dx ²	Standard error	p-value
PCA	0.138	0.063	0.029*	0.033	0.015	0.029*
Education	0.039	0.040	0.332	0.009	0.009	0.331*
Rufiji	-0.894	0.378	0.019*	-0.206	0.083	0.013*
Ulanga	-0.032	0.371	0.931	-0.008	0.088	0.930
Christian	-0.143	0.316	0.651	-0.034	0.075	0.650
SP_better	0.619	0.259	0.017*	0.148	0.062	0.016*
Under_5	1.067	0.259	<0.001*	0.258	0.061	<0.001*
Gender	0.129	0.219	0.557	0.031	0.052	0.557
Life_threat	0.762	0.242	0.002*	0.184	0.059	0.002*
_cons	-1.004	0.425	0.019*	-	-	-

* coefficient significant at the 5% level.

¹ 247 observations dropped because of missing data for 28 observations on Obtain_AM, 143 on gender, 52 on life_threat, 36 on education, 29 on PCA, and 1 on religion.

² dy/dx is for discrete change of dummy variable from 0 to 1.

Source: Household Survey May-Sep 2001.

The variables significantly associated with obtaining an antimalarial were being under five, perceived severity of illness, household head's perception of SP efficacy, SES and DSS area. Marginal effects analysis showed that perceiving the illness as life-threatening increased the

probability of obtaining an antimalarial by 18 percentage points, knowing that SP was more effective by 15 percentage points, and being under five by 26 percentage points. An increase of 1 in the household PCA score increased the probability by 3.3 percentage points. A quadratic education term was tested, but found to be insignificant. To investigate the potential for collinearity between explanatory variables, the pairwise correlation matrix was calculated. The only pairwise correlation with a correlation coefficient greater than 0.5 was between district and religion ($r=0.7$). However, dropping either of the correlated variables from the model made no significant difference to the remaining coefficients, nor to their significance at the 5% level. The number of observations was limited by missing variables, particularly due to missing data on gender for 143 individuals reporting fever/malaria. However, dropping gender from the regression, and so increasing the number of observations to 492, made no difference to the variables found significant, and led to minimal changes in logit coefficients.

The results for a regression on the probability of obtaining at least a minimum antimalarial dose were similar, with the exception that DSS area and perception of SP efficacy were no longer significant (Table 6.9).

Table 6.9 Logit regression of probability of obtaining at least a minimum dose of an antimalarial

Number of observations=378¹; $F<0.001$

Explanatory variables	Regression results			Marginal effects		
	Logit coefficient	Standard error	p-value	dy/dx ²	Standard error	p-value
PCA	0.156	0.064	0.016*	0.030	0.012	0.015*
Education	0.044	0.046	0.335	0.009	0.009	0.332
Rufiji	-0.712	0.427	0.096	-0.134	0.077	0.081
Ulanga	-0.259	0.414	0.533	-0.048	0.074	0.513
Christian	-0.277	0.364	0.448	-0.054	0.070	0.5443
SP_better	0.366	0.271	0.178	0.073	0.054	0.181
Under_5	1.037	0.263	<0.001*	0.221	0.059	<0.001*
Gender	0.282	0.254	0.267	0.055	0.050	0.269
Life_threat	1.063	0.260	<0.001*	0.225	0.057	<0.001*
_cons	-1.490	0.471	0.002*	-	-	-

* coefficient significant at the 5% level

¹ 247 observations dropped because of missing data for 32 observations on Obtain_mindose_AM, 143 on gender, 52 on life_threat, 36 on education, 29 on PCA, and 1 on religion.

² dy/dx is for discrete change of dummy variable from 0 to 1.

Source: Household Survey May-Sep 2001.

6.6.3 Antimalarial Tablet Packaging and Labelling

From a public-health perspective packaged tablets are preferable to those sold loose for several reasons. The consumer is more likely to take away information on the name and dosing of the drugs; tablets are less likely to be damaged or subject to degradation; and shopkeepers are less

likely to decant tablets into other containers. However, of antimalarial tablets dispensed, only 9% of sales volumes were sold packaged (Table 6.10). In value terms packaged tablets made up 16% of the antimalarial tablet market. Packaging was particularly rare at government facilities (less than 1% of antimalarial volumes and values). According to the regulations, all tablets sold in shops should be in unit packs, but packaged tablets made up only 22% of tablet sales volumes in the retail sector. At commercial drug stores they accounted for less than 20% of tablet volumes, and less than 25% of tablet values, although they formed a larger share of tablets sold from general shops (39% and 44% respectively). Packaged sales were more common in shops in Rufiji DSS than in Kilombero or Ulanga.

Table 6.10 Percentage of antimalarial tablet sales volumes and values packaged

	Kilombero DSS	Ulanga DSS	Rufiji DSS	Total
Sales Volumes				
Government facility	4.4%	0%	0.6%	0.9%
Private facility	1.6%	13.0%	3.2%	3.3%
Commercial drug shop	10.1%	12.1%	36.8%	18.7%
Village-run drug shop	74.4%	-	-	74.4%
General shop/stall	47.3%	0%	100%	39.0%
Total	12.1%	5.6%	8.7%	9.3%
Sales Values				
Government facility	1.9%	0%	0.5%	0.7%
Private facility	0.7%	4.7%	1.3%	1.5%
Commercial drug shop	12.6%	14.3%	46.5%	24.2%
Village-run drug shop	59.2%	-	-	59.2%
General shop/stall	52.5%	0%	100%	44.1%
Total	14.4%	8.0%	20.1%	16.4%

Source: Retail Audits Feb/Apr & Jun/Jul 2001, Outlet Survey Nov-Dec 2001

Drug products purchased over-the-counter (OTC) should at a minimum include information on their international non-proprietary name (INN), strength, indication, route of administration, warnings and age-specific dosing, in a way that is understandable to the average consumer (Medicines and Healthcare products Regulatory Agency 2003). At drug stores loose tablets were generally taken away in home-made paper envelopes, labelled with a handwritten abbreviated drug name and dose, which was often illegible. In general stores they were often provided unlabelled in just a twist of newspaper. Even on packaged drugs, labelling was woefully inadequate. Labelling was assessed for the 20 packaged SP tablet products on the market (15 branded, 5 unbranded), in the form in which tablets were usually sold for an adult dose. The government communications campaign accompanying the change in drug policy used the abbreviation SP, but this was printed on only one of the products. The others had the generic or INN in full, often in such small letters that it was very difficult to read. Moreover, the generic name varied for different types of SP, meaning that customers were left to make sense of the long and variable names of "sulphadoxine pyrimethamine", "sulphamethoxypyridazine pyrimethamine" and "2-sulphanilamido-5-methoxy-pyrazine pyrimethamine"! Much bigger

letters were used for the 15 different SP brand names. Secondly, dosing instructions were inadequate and inconsistent. Ten of the products gave no guidance on dosing, stating only "as directed by your physician". Of the products with dosing instructions, one had no information for children below school-age, and only one gave the dose for a 2-year-old in accordance with the national guidelines. Thirdly, few people spoke good English in the study sites, yet there were no instructions in KiSwahili on any of the tablets. This situation may be even worse in practice, as if adult packs are broken up to sell smaller doses for children, the outer packaging is separated from the foil wrapped tablets, and any instructions not written on the base packaging are lost.

6.6.4 Antimalarial Drug Quality

Samples of all SP tablets stocked were collected during the outlet survey, and 70 samples were tested for quantity of active ingredient. All the samples contained some quantity of sulphadoxine and pyrimethamine, and therefore none appeared to be deliberate fakes. However, the sulphadoxine content ranged from 17% to 110% of the specified amount, and pyrimethamine content from 81% to 128% (Green et al., unpublished data, IMPACT collaboration). Of the samples evaluated, 7% has less than 90% of the specified content for pyrimethamine, and 33% for sulphadoxine. All those with an insufficient quantity of pyrimethamine also had insufficient sulphadoxine, meaning that the overall failure rate was 33% for either chemical. A further 36% of samples had an excessive quantity of pyrimethamine.

Tables 6.11 shows the proportion of samples with an insufficient quantity by outlet type, country of manufacture and type of packaging. It was not possible to draw firm conclusions from these data, because the number of tablets analysed per sample was inadequate for USP specifications. However, in general it appears that poor quality tablets were common in all outlet types¹², for both packaged and loose tablets, and for many different countries of manufacture, including Europe.

6.6.5 Assessing the Appropriateness of Total Antimalarial Drug Volumes

The assessment so far has considered appropriateness of drugs on the basis of individual patient characteristics. It is also of interest to compare total antimalarial sales volumes from the retail audits with estimated need at a community level. The total quantity of antimalarials consumed, and the frequency of poor quality drugs and under-dosing, are believed to be linked to drug pressure and the development of resistance (Basco 2004; White et al. 1999).

¹² In September 2001 SP supplied to public facilities were found to include a locally produced product that had failed quality tests conducted by the NMCP. The drugs were recalled, but implementation of this instruction took some time.

Table 6.11 Number of SP samples containing an insufficient quantity of active ingredient (% of samples tested with <90% of specified active ingredient)

	n	Failures		
		Pyrimethamine	Sulphadoxine	Either Pyrimethamine or Sulphadoxine
Total	70	5 (7%)	23 (33%)	23 (33%)
Outlet type				
Government facility	17	0 (-)	3 (18%)	3 (18%)
Private facility	27	1 (4%)	9 (33%)	9 (33%)
Commercial drug store	24	3 (13%)	10 (42%)	10 (42%)
General store	2	1 (50%)	1 (50%)	1 (50%)
Country manufacture¹				
Tanzania	42	2 (5%)	13 (31%)	13 (31%)
Other Africa	14	3 (21%)	4 (29%)	4 (29%)
Asia	4	0 (-)	0 (-)	0 (-)
Europe	9	0 (-)	6 (67%)	6 (67%)
Type of packaging				
Packaged	23	2 (7%)	10 (43%)	10 (43%)
Loose	47	3 (6%)	13 (28%)	13 (28%)

¹ Country of manufacture data were missing for one sample.

Source: Green et al, unpublished data, IMPACT collaboration (samples from Outlet Survey Nov-Dec 2001).

From the 1.7 equivalent adult antimalarial doses dispensed per annum one could estimate that roughly 2.04 age-adjusted doses were dispensed (assuming 40% of doses are for children with on average a half dose), although the frequency of under-dosing implies that the number of people receiving any antimalarials will be considerably higher. It is difficult to judge whether these volumes represent under- or over-treatment. The overall annual fever rate per person for Tanzania can be estimated at 5.2, based on 180,781,000 fevers (Snow, Eckert and Teklehaimanot 2003) in a population of 34,837,000 (World Population Prospects Population Database, 2002 Revision¹³). However, many of these febrile episodes will not have been malarial, and particularly in adults it may not be appropriate to treat every febrile case with antimalarials. It is also possible to compare with data on malaria incidence. Snow et al. estimate 1 clinical attack of malaria per child 0-4 years, 0.25 per child aged 5-14 years, and 0.4 per adult per annum in stable endemic African settings (Snow et al. 1999), providing a weighted average of 0.46 episodes per person per year in Tanzania (based on the population age structure from World Population Prospects Population Database, 2002 Revision). This would imply that the number of antimalarial doses dispensed in our study sites was over 4 times the number of malaria cases but under half the number of fevers. However, it is not possible to tell whether the antimalarial drugs were taken by those people with malaria, still leaving the question unresolved of whether this indicates over- or under-treatment.

¹³ <http://esa.un.org/unpp/>

6.7 Comparison of DSS areas

The markets for fever/malaria treatment in the three DSS areas had many important similarities. In terms of household characteristics, the populations were all rural, and in all areas, household heads were mainly engaged in farming activities and had relatively low levels of educational attainment. The SES distribution was also similar across DSS areas. However, there were significant differences in religious affiliation, and fever prevalence was somewhat lower in Ulanga than Rufiji or Kilombero.

On the supply-side, the three areas had the same categories of provider, and the range of painkiller and antimalarial products in the market and patterns of availability across provider types were similar. There were differences between the areas in the role of the retail sector. The retail sector had a more important role in antimalarial supply in Kilombero and Ulanga than in Rufiji. Retailers provided nearly two-thirds of antimalarial volumes in Kilombero and half in Ulanga but just under a quarter in Rufiji, with government facilities taking a larger share. However, in terms of provider visits for fever/malaria, the share of the retail sector in Rufiji was as high as Kilombero (both 67%), and higher than Ulanga (57%). This discrepancy reflected differences in the type of retailer visited. In Kilombero and Ulanga more than half of retail visits were to drug stores, but in Rufiji 61% were to general stores, where antimalarials were less likely to be obtained. This appeared to be the main factor behind the lower probability of obtaining an antimalarial in Rufiji (29%), compared with 45% in Kilombero and 48% in Ulanga.

6.8 Summary and Conclusions

The first objective of the thesis is to describe treatment seeking and drug purchase for fever/malaria, and assess the appropriateness of care obtained. This chapter has described treatment-seeking patterns, and shown that coverage of some kind of treatment was high, with 85% of patients reporting fever/malaria seeking care, either from a provider or home/neighbour. It has demonstrated that retailers were an important source of fever/malaria drugs. Of visits for fever/malaria, 65% were to shops, and all socio-economic groups were equally likely to visit drug and general stores. Shops supplied 38% of antimalarial sales volumes and 60% of antimalarial sales values, the lion's share of retail sales being through commercial drug stores.

Treatment seeking was generally rapid; 69% of visits took place within 24 hours of symptom onset, and 79% within 48 hours. However, most individuals with fever/malaria obtained inappropriate or inadequate treatment.

Ten key concerns on the quality of care obtained have been identified:

1. **A relatively low share of patients received an antimalarial --** only half of under fives and less than a third of over fives.
2. **Antimalarial under-dosing was common --** a third of all antimalarials were dispensed as under-doses.
3. **Frequent use of ineffective chloroquine in mid-2001 --** during the household survey chloroquine was frequently obtained from all provider types, despite its low efficacy. While chloroquine use declined following the change in first line drug policy, this demonstrates the persistence of retail demand for familiar antimalarials, even when severely compromised by drug resistance.
4. **Poor treatment quality at both retail outlets and government facilities --** general stores were least likely to dispense antimalarials, but they were only dispensed at just over half of visits to drug stores and government facilities. Similarly, 50% of antimalarials from general shops were dispensed as under-doses, and 29% from both drug stores and government facilities.
5. **Inequitable access to antimalarials--** patients in the better-off SES third were most likely to obtain appropriate antimalarials and correct doses because they more frequently visited private facilities, where appropriate treatment was most frequently obtained.
6. **High share of treatment visits for adults --** over fives are less vulnerable to severe disease, but accounted for the majority of visits at all outlet types. However, over fives were less likely than under fives to visit facilities or to obtain antimalarials.
7. **Indications of inappropriate drug use --** although firm judgments could not be made, it appeared likely that there was unnecessary provision of antibiotics and injectable antimalarials. Despite its potential harmful effects, 18% of under fives obtained aspirin, the majority from general stores.
8. **Inadequate drug labelling and packaging --** labelling of the INN and dosing regimen was inadequate on SP packaged products, and never in KiSwahili; the problem was even more severe for unpackaged tablets, which accounted for 91% of total antimalarial tablet volumes
9. **SP tablets of poor quality --** 33% had an insufficient quantity of active ingredient.
10. **Potential unnecessary contribution to drug pressure --** although firm conclusions could not be drawn, it is possible that frequent under-dosing, poor quality antimalarials, and unnecessary antimalarial use were contributing to the development of antimalarial drug resistance.

These problems indicate the presence of substantial market and/or government failures in the provision of fever/malaria treatment. The remaining four results chapters explore potential causes for these failures, through an analysis of the nature of market structure, price and non-price competition and regulation.

CHAPTER 7

MARKET STRUCTURE

7.1 Introduction

The second objective of the thesis is to analyse the nature of competition in the fever/malaria treatment market. As specified in the conceptual framework, the nature of competition arises from the interaction of market structure, provider conduct and consumer demand. This chapter analyses market structure, building on the description of the range of sellers and products provided in Chapter 6.

A preliminary step in any analysis of market structure is to identify the competitors which make up the market, or to define the market. This is addressed in Section 7.2, drawing on Tirole's definition of a market as a group of buyers and sellers of a set of products in sufficiently close contact for their transactions to affect the terms on which the others buy or sell (Tirole 1988). Market definition is considered along product and geographical lines. Product definition can be considered from the perspective of substitutability in demand or supply (Zwanziger, Melnick and Eyre 1994). As the focus of the thesis is on treatment for a specific set of health problems, the analysis focuses on substitutability in demand. In other words, the products should be good substitutes for fever/malaria treatment from the consumer's perspective. This is assessed in Section 7.2.1 in terms of both the providers and products making up the market. The assessment is based primarily on evidence from the household survey on sources and products widely used for fever/malaria treatment. This is supplemented with evidence from qualitative interviews with providers on the outlets perceived as close competitors.

The next step in Section 7.2.2 is to define the geographical boundaries of competition between providers. As described in Chapter 3, geographical definition is subject to many methodological and empirical challenges (Zwanziger, Melnick and Eyre 1994). The most straightforward methods are based on political boundaries or fixed radii, but can be misleading. To investigate this, the suitability of different administrative boundaries, such as the village, ward and DSS area, are considered using the insights of the shipment method (Zwanziger, Melnick and Eyre 1994). This method evaluates whether a given area is a "self-contained" market based on the proportion of the population in the market area using providers outside it, and the proportion of customers using providers in the market area who live outside it. It was not possible to evaluate the latter, as the household survey was restricted to the DSS areas and exit interviews were not undertaken, so the assessment was based on the former, using the village of residence and

location of provider visits reported in the household survey. The analysis of geographical definition leads to the division of the DSS areas into 12 sub-markets.

An essential element of market structure is the degree of market concentration, which provides an important indication of the potential for the exercise of market power. This is considered in Section 7.3 using antimalarial retail audit data. Section 7.3.1 considers antimalarial concentration among providers for each geographical sub-market. As described in Chapter 3, a number of different concentration measures exist. Three measures are used in this analysis, the simplest being the number of drug providers per capita. However, this gives no indication of the relative size or importance of different outlets, so two additional summary measures are employed. The 3-firm concentration ratio is selected because of its ease of interpretation, and the Hirschman-Herfindahl index (HHI) is calculated, as it summarises information across all firms, and the results can be compared with anti-trust guidelines. The degree of vertical integration between providers is also assessed, based on ownership links and any evidence of long-term coordination. In Section 7.3.2 concentration is considered briefly from a different perspective -- that of the drug manufacturer. This is assessed by evaluating the total number of antimalarial products in the market, and the 3-firm concentration ratio by brand.

The methods used to assess market definition and concentration are based on current patterns of utilisation, but the nature of competition may also be shaped by the contestability of the market (Baumol, Panzar and Willig 1988). Section 7.4 therefore considers barriers to entry and exit for fever/malaria treatment providers. In Section 7.4.1 barriers are assessed on a descriptive basis using evidence from qualitative interviews on providers' perceptions. Section 7.4.2 explores indirect evidence for entry and exit barriers by analysing evidence on the turnover of retail outlets over the one-year period between the first and second outlet census.

Most of the analysis in the thesis focuses on the providers directly serving fever/malaria patients. However, the wholesale supply market may also have an important influence on competition. Section 7.5 therefore briefly considers the structure of the wholesale market supplying retailers in the study sites, in terms of the type of providers, market concentration and turnover. Retail audit data were not collected at the wholesale level, but it was possible to get some indication of concentration through analysis of the number of retailers reporting use of each wholesale source.

Regulatory systems, which can also be considered as part of market structure, are covered in Chapter 10

7.2 Market Definition

The definition of the market for fever/malaria treatment is considered along product and geographical lines.

7.2.1 Product Definition

The product definition specifies the providers and products forming part of the same market. Household survey data showed that government and private facilities, drug stores and general stores were all widely used to obtain fever/malaria treatment (Table 6.1), indicating some degree of substitutability in demand across these providers. Other potential sources of competition were not important. Itinerant vendors were never mentioned during the household survey. Community health workers (CHWs) accounted for only 2 visits (0.4% of all visits), both from the same household. Traditional healers accounted for five visits (0.9%) and did not provide any manufactured drugs. The only other source was a lymphatic filariasis project in Rufiji which accounted for two home visits. CHWs, traditional healers and other projects were never volunteered as important competitors during qualitative interviews with providers. When probed specifically on traditional healers, interviewees at all three dispensaries said they received fever/malaria patients who had already visited traditional practitioners and not recovered, indicating that there may be some competition between traditional healers and dispensaries for complicated cases. However, most shopkeepers said they were not competitors because very few people visited them now that faith in modern medicines had replaced traditional beliefs. Others said that traditional healers did not treat fever/malaria, but were more concerned with problems related to supernatural causes, such as satans, devils and bewitchment. As retailers were the main focus of this analysis and use of traditional healers was very rarely reported during the household survey, traditional practitioners were not included in the product definition. As a result, the product definition for providers was set as government and private facilities, drug stores and general stores.

However, from qualitative interviews it was clear that the relative intensity of competition varied between different outlet types. When asked who they considered to be their main competitors for customers for the treatment of fever/malaria, interviewees at drug stores mentioned nearby drug stores and/or local public and private facilities. Only one drug store seller mentioned general stores, with others explaining that they were not key competitors because they stocked a much more limited range of drugs or had few drug customers. General shopkeepers mainly mentioned other general stores as their competitors; a few also mentioned drug stores but none mentioned facilities. However, it was clear from household survey data that these provider categories were all widely used for fever/malaria. Moreover, in qualitative

interviews fever/malaria was said to be the most common, or one of the most common, health problems bringing customers to all outlet types. The differences in the relative intensity of competition were therefore considered as indications of product differentiation, rather than evidence of distinct product markets.

In terms of the products forming part of the same market, the household survey showed that 88% of all identified drugs obtained for fever/malaria were painkillers or antimalarials (Figure 6.3). The share of other drug categories was relatively small (e.g. 7% for antibiotics, 1% for ferrous/folic acid). The product definition was therefore set as antimalarials and painkillers stocked in facilities, drug stores and general stores. Other related services such as diagnosis and consultation were considered as complements. Inevitably there would have been some substitutability and complementarity with providers and products outside this definition, but it is argued to capture the main axes of competition.

7.2.2 Geographical Definition

The main competitors specified by all interviewees during qualitative interviews were located nearby, generally in the same market centre or village, and most general stores did not report wider competition. However, definition of completely distinct geographical market areas would be unrealistic because outlets had overlapping catchment areas, which varied in size by outlet type. Some drug store customers were reported to travel for several hours if they had no closer drug store, and all dispensary interviewees said people travelled long distances. A few interviewees from both general and drug stores reported receiving customers from farming areas, generally located several hours' walk from the main roads, who bought substantial quantities of drugs to keep as a reserve at home. One mission dispensary received customers from the whole district and even some patients from a neighbouring district, although this appeared to be rare.

Household survey data on the village of residence and location of providers visited were used to consider the suitability of the DSS area, ward (2-8 villages) and village as guides to geographical definition. Table 7.1 shows the proportion of visits to facilities, drug stores and general stores which took place outside the care seeker's own village, ward and DSS area. Only 4% of visits took place outside the DSS area of residence. Of the sources mentioned outside the DSS areas, only three outlets were mentioned more than once: St Francis Hospital (four times), and two drug stores (both twice), all of which were located in Ifakara Town. Kilombero and Ulanga DSS areas were clearly part of separate markets, despite their proximity. No one was ever reported to travel between the two for care, reflecting their separation by the Kilombero River, and the necessity of passing through Ifakara in order to reach the only ferry crossing. By

contrast, movement within each DSS area was relatively easy: it was possible to travel between all parts without leaving the DSS area, and they were designed so that all villages were within two hours' drive of the research bases.

Table 7.1 Proportion of provider visits taking place outside the careseeker's own village, ward, sub-market and DSS area by outlet type
(as a % of all visits to providers of this type)

	n ²	Outside own village	Outside own ward	Outside own sub-market ¹	Outside own DSS area
Government facilities	149	79 (53%)	26 (17%)	6 (4%)	3 (2%)
Private facilities	42	26 (62%)	17 (40%)	12 (29%)	5 (12%)
Drug stores	178	79 (44%)	28 (16%)	17 (10%)	10 (6%)
General stores	199	39 (20%)	8 (4%)	7 (4%)	2 (1%)
Total	568	223 (39%)	79 (14%)	42 (7%)	20 (4%)

¹ defined as equivalent to ward with the following exceptions:

- Mavimba village from Minepa ward in Ulanga was included in Lupiro Area
- Ikwiriri, Umwe and Mgomba wards in Rufiji were combined into Ikwiriri Area
- Bungu ward was separated into Bungu Area (villages of Bungu A, Bungu B, Nyambunda and Pagae) and Jaribu Area (villages of Jaribu Mpakani, Mjawa and Uponda)

² Number of visits to outlets within product definition

Source: Household Survey May-Aug 2001.

Use of the DSS area as the market definition would however overstate market size, as 86% of visits took place in the ward of residence. The smaller category of village could not be considered a self-contained market, as while the majority of visits were to outlets within the village of residence, 39% were to other villages. Leaving the village was more common for visits to facilities and drug stores than for general stores, but even for the latter 20% of visits were outside the village of residence.

The ward was therefore judged the most appropriate administrative boundary as a starting point for geographical definition, but some adjustments were made to account for local circumstances. First data from each ward were analysed to identify any self-contained areas of two or more villages within a ward, which were then defined as a separate sub-market¹. As a result Bungu ward was divided into Bungu Area and Jaribu Area, as no careseekers reported travelling between the two. Secondly, in any cases where more than 15% of visits from a given ward were to another ward, the geographical definition was examined in more detail. This affected three of the 13 wards (Mgomba, Umwe and Minepa), and as a result Ikwiriri, Mgomba and Umwe wards in Rufiji were combined into Ikwiriri Area, and Mavimba village in Ulanga was included in Lupiro Area, rather than Minepa Area, although it is located in Minepa Ward.

¹ the use of a single village as a sub-market was deemed inappropriate as, even where it appeared self-contained from household survey data, this may have reflected the small number of provider visits reported for some villages.

In all other cases geographical markets were defined on the basis of wards. This gave a total of 5 sub-markets in Rufiji DSS, 3 in Kilombero, and 4 in Ulanga (Table 7.2). On this basis 93% of visits took place within the local sub-market (92% in Kilombero and Rufiji and 96% in Ulanga). The percentage was over 90% for each sub-market with the exception of Mchukwi in Rufiji. Any shipment cut-off point is essentially arbitrary, and current utilisation patterns do not necessarily reflect contestability. It was accepted that there would be some competition with providers outside these areas (e.g. St Francis Hospital in Ifakara), and that some outlets within them would not consider themselves as direct competitors, but these sub-markets are argued to capture the vast majority of geographical competition, and therefore formed a good basis for the estimation of market concentration.

Table 7.2 Provider visits outside careseeker's own sub-market (by sub-market)
(as a % of all visits by careseekers resident in that sub-market)

Sub-markets	Population ¹	n (no. of visits by careseekers resident in sub-market)	Provider visits outside careseeker's own sub- market ²
Kilombero			
Idete	10511	62	6 (10%)
Mbingu	9523	40	3 (8%)
Mchombe	17030	70	5 (7%)
Ulanga			
Minepa	7861	23	1 (4%)
Lupiro	12037	55	3 (5%)
Iragua	4353	7	0 (-)
Kichangani	5188	4	0 (-)
Rufiji			
Ikwiriri	19232	56	0 (-)
Kibiti	24244	117	4 (3%)
Mchukwi	9029	46	12 (26%)
Bungu	12627	64	6 (9%)
Jaribu	8707	24	2 (8%)
Average	11695	568	42 (7%)

Sources:

¹ DSS systems, May 2001

² Household Survey May-Sep 2001 (for providers within product market definition).

The vast majority of outlets operated all year-round in a fixed location. However, outlet census 2001 data showed that 21 of the 277 general stores in Kilombero and Ulanga (8%) reported either moving to another location, or closing down for part of the year, mainly in response to population movement during the main farming seasons². Some shopkeepers closed their shops while they were away working on their fields, and others moved their shops to the farms to serve the migrant population. For analytical purposes they were considered as part of the geographical sub-market where they were located at the time of interview.

² questions on seasonal operation did not appear well understood in general. Moreover, the questions were only asked of the smaller general shops considered by data collection staff to be "kiosks/stalls", so some seasonal changes in the operation of larger shops could possibly have been missed, although field staff believed this to be very unlikely.

7.3 Market Concentration

7.3.1 Concentration by Provider

To assess the market power of private providers, concentration is considered by sub-market to reflect geographical market definition. The concentration measures are also based on the product definition of the market, in that they include all facilities, drug stores and general shops. However, they are calculated on the basis of antimalarial sales alone, excluding painkillers. Retail audit data were collected for antimalarials only because they were of greatest importance in public health terms for malaria treatment, and the inclusion of all painkillers would have made the audit logistically infeasible. Concentration in the market for drugs for fever/malaria treatment in general is likely to have been lower than that for antimalarials alone, because painkillers were more widely supplied by general stores.

Concentration is considered in terms of three measures: the number of drug providers per capita, the 3-firm concentration ratio and the HHI. The latter two measures allow an assessment of the relative size of firms. The 3-firm ratio is defined as the percentage of antimalarial sales accounted for by the three largest providers. The HHI is calculated as the sum of the squared market shares of each firm, and therefore depends on both market share inequality and firm numbers, ranging from 0 (large number of competitors with small market shares) to 1 (single monopoly supplier).

To calculate the concentration ratio and HHI, sales values rather than volumes were used, to more closely reflect turnover, profitability and commercial decisions. All private outlets were included, but not government facilities, as their large market shares would have obscured the impact of private sector concentration on private outlets, which was assumed to be the most important factor influencing their competitive decisions. By contrast, government facilities were assumed not to compete on a local basis, but instead to follow models of service provision and prices set institutionally by their District Health Management Team (DHMT), or more centrally by the MOH. There was at least one government facility in each sub-market, so private providers were likely to have faced a similar residual private market in each area.

Results were calculated by owner, rather than by outlet, as there was some degree of horizontal integration in the market, and outlets with common ownership were likely to be run as single businesses. The owners of 58% of commercial drug stores and 11% of general stores interviewed in the outlet survey had more than one shop, but in most cases the other shops were located outside the DSS areas. However, two drug store owners owned multiple shops within

the DSS areas; one had two drug stores in Kilombero DSS and another six drug stores in the Rufiji DSS. Three general store owners in Rufiji also owned two general shops each in the DSS areas. All mission facilities in the DSS areas of Kilombero and Ulanga were owned by the Roman Catholic Church, and two of the facilities in Rufiji were owned by the Pentecostal Church.

Table 7.3 shows the population per antimalarial stockist in each sub-market, which was highly variable, ranging from 414 in Mbingu Area to 1729 in Kichangani Area. Of the 35³ outlets listed in the top 3 private antimalarial providers in each sub-market, 20 were drug stores, 8 general stores and 7 private facilities. Only 2 of the 9 private facilities were not listed in the top 3 in their area. Drug stores were the top provider in 8 of the 12 sub-markets, private facilities in 3, and general stores in one.

Table 7.3 Concentration measures by sub-market

Sub-markets	Population /antimalarial stockist ¹	% antimalarial sales values from private outlets ²	3-firm concentration ratio for private antimalarial sales values by owner ²	HHI for private antimalarial sales values by owner ²
Kilombero				
Idete	657	79%	90%	0.35
Mbingu	414	87%	87%	0.33
Mchombe	473	98%	69%	0.24
Ulanga				
Minepa	786	98%	89%	0.72
Lupiro	1204	94%	96%	0.57
Iragua	544	77%	93%	0.74
Kichangani	1729	7%	100%	1.00
Rufiji				
Ikwiriri	712	92%	92%	0.47
Kibiti	1276	86%	87%	0.34
Mchukwi	1003	73%	98%	0.87
Bungu	601	60%	85%	0.28
Jaribu	512	85%	75%	0.24
Average	826	78%	88%	0.51

Sources:

¹ Outlet Survey Nov/Dec 2001

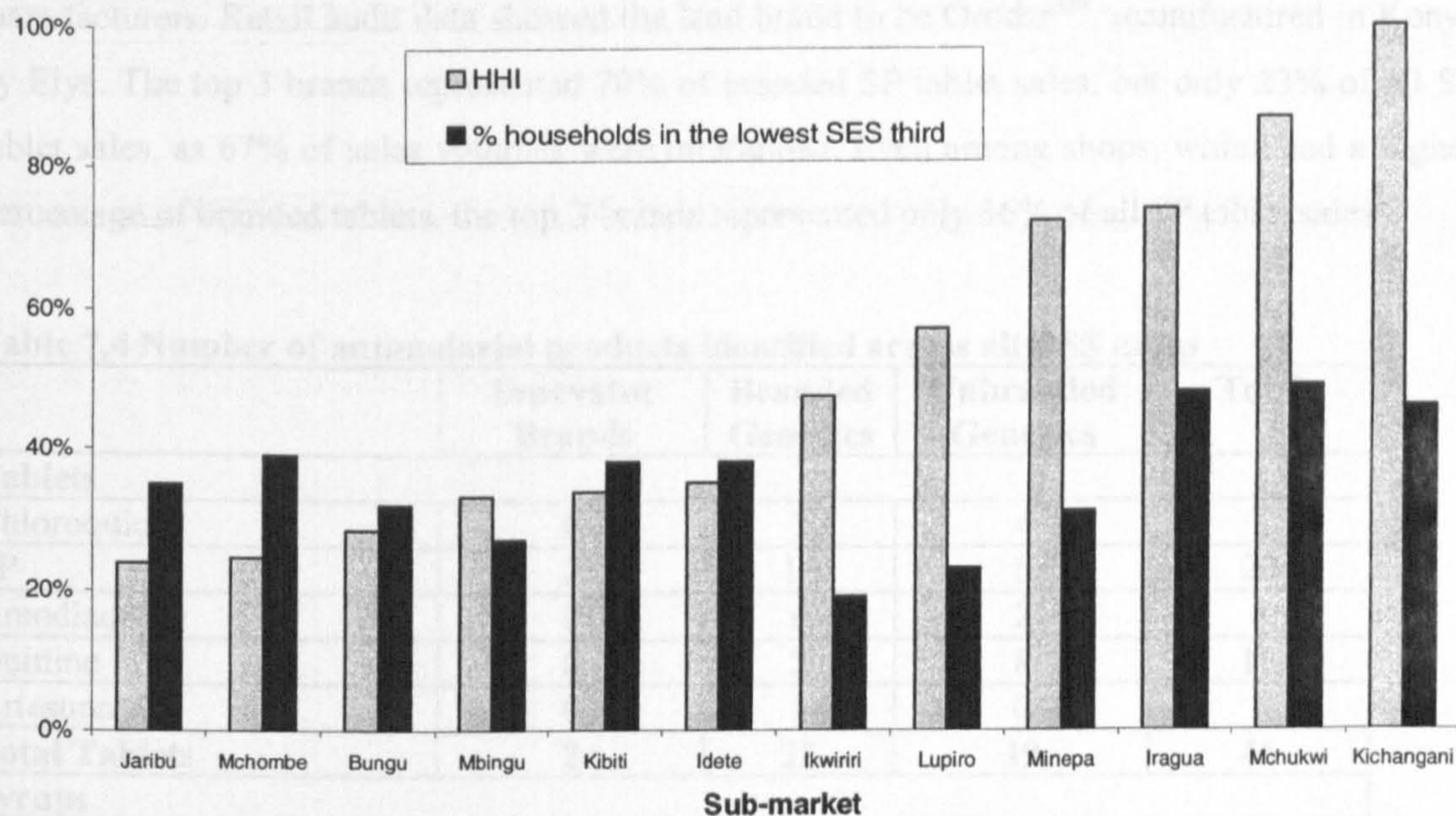
² Retail Audits Feb/Apr & Jun/Jul 2002

The 3-firm ratios and HHIs indicate high levels of concentration among private sellers in each sub-market. As a rough guide, US anti-trust guidelines state that an HHI below 0.1 is considered unconcentrated, 0.1 to 0.18 moderately concentrated, and greater than 0.18 is highly concentrated (Gaynor and Vogt 2000). On this basis, all the sub-markets would be considered highly concentrated, although there was considerable variation. Some areas were relatively close to the 0.18 cut-off (Bungu and Jaribu Areas in Rufiji, and Mchombe Area in Kilombero),

³ In Kichangani only 2 antimalarial providers were documented in total

while others were at or close to a monopoly situation. The relationship between SES and antimalarial concentration was unclear, although the 3 most concentrated sub-markets also had the highest percentage of households in the lowest SES third (Figure 7.1).

Figure 7.1 Socio-economic status and concentration in private sector antimalarial sales by sub-market



Source: Household Survey May-Sep 2001, Retail Audits Feb/Apr & Jun/Jul 2002.

Provider market power could also be influenced by vertical integration, but this was not observed between DSS retailers and their wholesalers or distributors⁴. The degree of vertical coordination was also very limited; there were no examples of long-term contracts or product tie-ins. A couple of shops reported receiving recommended retail prices from distributors, but this was not a practice passed on by the more commonly used static wholesalers.

7.3.2 Concentration by Product

The main focus of the thesis is competition between providers directly serving customers in the DSS areas, but competition could also be considered between drug manufacturers. A brief assessment of concentration by antimalarial product is therefore provided. The geographical market definition for competition between manufacturers is inevitably much broader than that for competition between fever/malaria treatment providers, operating on a regional, national or even international scale. The concentration by product was therefore considered across the

⁴ one drug store owner in Rufiji also owned a general wholesalers, but the drug store did not usually obtain its supplies through this wholesaler.

combined DSS areas, including all public and private providers. The concentration was investigated using the total number of antimalarial products in the market, and the market shares by brand.

The total number of antimalarial products identified during the outlet survey was 81, of which 47 were branded and 34 unbranded (Table 7.4). The number was particularly high for SP tablets for which there were 15 different brand-named products, plus 5 unbranded versions by different manufacturers. Retail audit data showed the lead brand to be OrodarTM, manufactured in Kenya by Elys. The top 3 brands represented 70% of branded SP tablet sales, but only 23% of all SP tablet sales, as 67% of sales volumes were unbranded. Even among shops, which had a higher percentage of branded tablets, the top 3 brands represented only 36% of all SP tablet sales⁵.

Table 7.4 Number of antimalarial products identified across all DSS areas

	Innovator Brands	Branded Generics	Unbranded Generics	Total
Tablets				
Chloroquine	0	3	4	7
SP	2	13	5	20
Amodiaquine	0	6	2	8
Quinine	0	2	8	10
Artesunate	0	1	0	1
Total Tablets	2	25	19	46
Syrups				
Chloroquine	0	2	4	6
SP	0	4	0	4
Amodiaquine	0	6	0	6
Quinine	0	2	2	4
Total Syrups	0	14	6	20
Injectables				
Chloroquine	0	3	8	11
Quinine	0	3	1	4
Total Injectables	0	6	9	15
Total Antimalarial Products	2	45	34	81

Source: Outlet Survey Nov/Dec 2001

Definitions:

Innovator brand -- the product first authorised worldwide for marketing

Branded generic -- a product which is not the innovator brand, but is marketed under a brand name.

Unbranded generic -- a product marketed under the International Non-Proprietary Name (INN) only.

7.4 Barriers to Entry and Exit

Two approaches are taken to investigate the importance of entry and exit barriers. Firstly, in Section 7.4.1 barriers are assessed on a descriptive basis using evidence from qualitative interviews on providers' perceptions. Secondly, Section 7.4.2 explores indirect evidence for

⁵ it was not possible to calculate concentration ratios or the HHI by product as data on the manufacturer of unbranded antimalarials were not collected during the retail audits.

entry and exit barriers, by analysing evidence on the turnover of retail outlets over the one-year period between the first and second outlet censuses.

7.4.1 Providers' Perceptions of Entry and Exit Barriers

During qualitative interviews the most commonly mentioned barrier to entry for both drug and general stores was access to funds to set up the shop.

"The first problem is the availability of capital, struggling to get capital." General shopkeeper #3

No interviewees were aware of any governmental or formal local institutions from which a loan could be obtained. Credit might be available from some wholesalers, but only for retailers who were already established and well-known. In general it was therefore necessary to rely on savings from other activities to establish a shop. Most general shopkeepers were also farmers, and they usually relied on profits from farming cash crops such as cashews, oranges or rice to generate capital.

Other entry barriers less frequently mentioned included the high cost of taxes and licences, and the problem of identifying trustworthy sales staff. There was the occasional mention of regulatory hurdles, but most interviewees did not volunteer them as a key problem. However, in drug stores we mainly interviewed sellers who may not have understood all the regulatory barriers owners faced in obtaining permits and complying with regulations on premises and serving staff (see Chapter 10).

Despite these barriers, most interviewees thought entry by other retailers was likely, and that many people were interested.

"Now anyone who wants to do it does it, so the number of shops increases every day." General shopkeeper #3

"They will start and there will be many of them." Drug store seller #2

Most interviewees agreed that exit was also common. General and drug store interviewees mentioned the erosion of capital as a key cause for shop closure. This might arise due to poor management, for example reckless expenditure, overgenerous credit policies, or handing over control to irresponsible relatives or employees, or due to high expenditures, such as school fees or health care costs. In some cases there was a circular flow of funds, with the agricultural surplus being used as capital for the shop, and some of the shop's profits being reinvested in farming. A bad harvest might lead to a break in the cycle and force the closure of the shop. A

couple of drug store interviewees and one general store interviewee also mentioned the potential risk of being closed down for contravening business or drug regulations, although no specific examples of such closures were provided.

7.4.2 Turnover of retail outlets

The interviewees' perceptions of high levels of entry and exit were borne out by evidence of turnover. Data comparing the outlet censuses in 2000 and 2001 for commercial shops stocking drugs are shown in Table 7.5 and Figure 7.2⁶.

Table 7.5 Turnover of commercial drug shops and general retailers stocking drugs between mid-2000 and mid-2001 (as % of shops functioning in mid-2000 in brackets)

(a) Commercial Drug Shops

	Ulanga DSS	Kilombero DSS	Rufiji DSS	Total
Total functioning in mid-2000	2 (100%)	8 (100%)	13 (100%)	23 (100%)
Of which by mid-2001:				
Still functioning	2 (100%)	7 (88%)	12 (92%)	21 (91%)
Closed	0 -	1 (13%)	1 (8%)	2 (9%)
New shops functioning by mid-2001	0 -	1 (13%)	8 (62%)	9 (39%)
Total shops functioning in 2001	2 (100%)	8 (100%)	20 (154%)	30 (130%)

(b) General Retailers stocking drugs

	Ulanga DSS	Kilombero DSS	Rufiji DSS	Total
Total functioning and stocking drugs in mid-2000	106 (100%)	146 (100%)	229 (100%)	481 (100%)
Of which by mid-2001:				
Still functioning and still stocking drugs	65 (61%)	94 (64%)	144 (63%)	303 (63%)
Still functioning but not stocking drugs	10 (9%)	12 (8%)	13 (6%)	35 (7%)
Still functioning and not interviewed	1 (0.9%)	0 -	2 (0.9%)	3 (0.6%)
Closed	30 (28%)	40 (27%)	70 (31%)	140 (29%)
New shops functioning and stocking drugs by mid-2001	50 (47%)	54 (37%)	112 (57%)	216 (45%)
Shops started stocking drugs by mid-2001 (open but not stocking drugs in 2000)	6 (6%)	6 (4%)	2 (0.9%)	14 (3%)
Stocking drugs in mid-2001 and open but not interviewed in mid-2000	1 (0.9%)	1 (0.7%)	0 -	2 (0.4%)
Total shops functioning, interviewed and stocking drugs in 2001	122 (115%)	155 (106%)	258 (113%)	535 (111%)

Source: Outlet Censuses May-Sep 2000 & 2001.

⁶ any outlets incorrectly omitted during either census would be erroneously included as entries or exits. These figures may therefore slightly overestimate turnover.

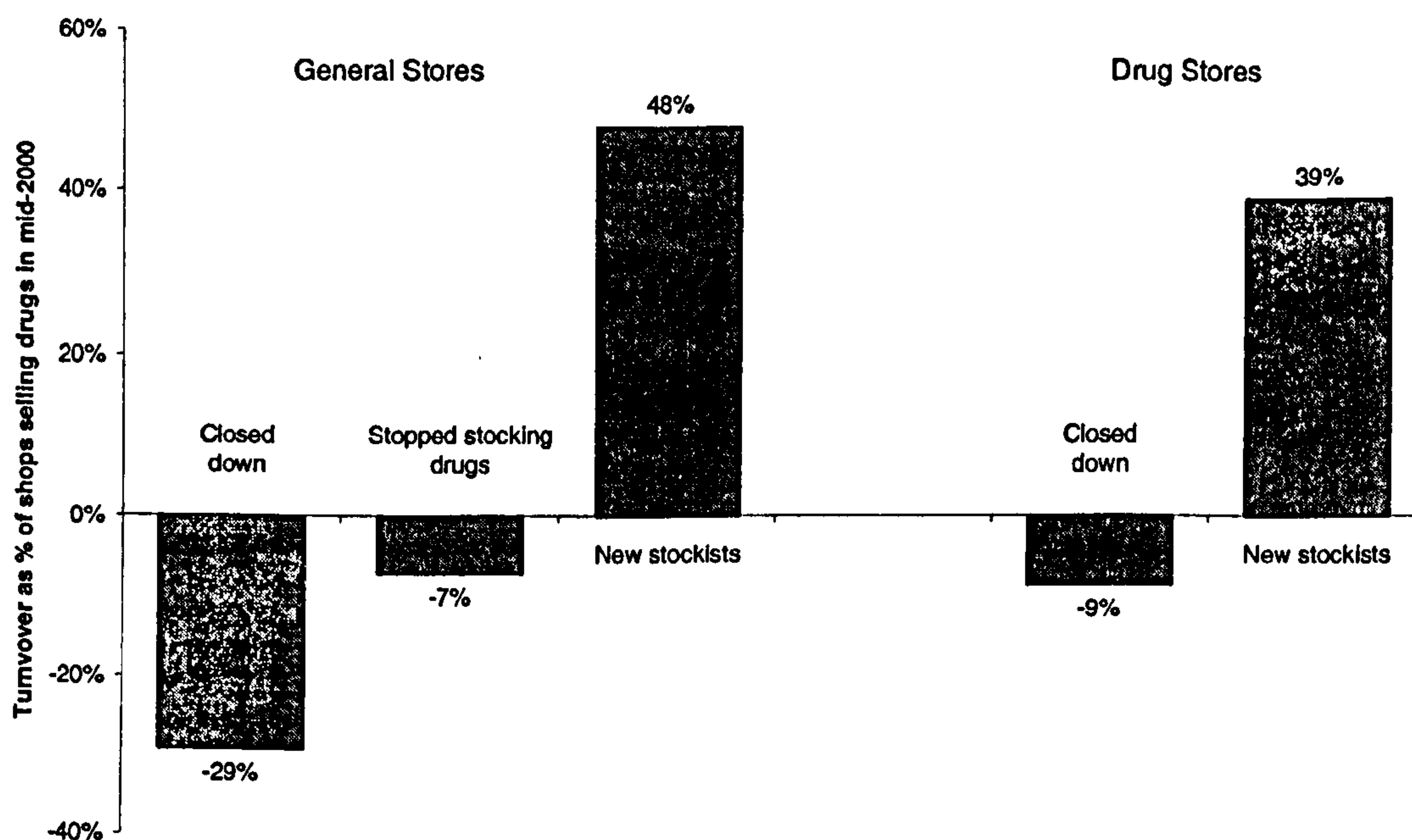
Of the 23 commercial drug stores operating in 2000, 2 had closed down by 2001 (1 each in Kilombero and Rufiji). Over the same period 9 new drug stores had opened, 8 of which were in Rufiji, and 1 in Kilombero, giving a total of 30 in 2001, reflecting the more than 50% increase in Rufiji. After the 2001 outlet census the number of commercial drug stores continued to grow. By the second retail audit in mid-2002 a further five new commercial drug stores had opened (2 in Kilombero, 1 in Ulanga and 2 in Rufiji), with only one closure in Kilombero.

The antimalarial stocking patterns of commercial drug stores in Kilombero and Ulanga remained fairly constant between the two outlet censuses, but there was a sizeable increase in the antimalarial range stocked in Rufiji, with the proportion stocking SP rising from 23% to 88%, amodiaquine 23% to 81%, and injectable antimalarials from 23% to 69%. The median number of antimalarial products stocked in Rufiji increased from 3 to 7.5, but was unchanged in the other areas. These changes did not indicate that the retail market was relatively developed in Rufiji by mid-2001. Rather the widening of antimalarials stocked reduced the differential between Rufiji and Kilombero/Ulanga, and the expansion in the number of stores brought the population per drug store in Rufiji close to that in Kilombero (3692 and 3706 respectively), while Ulanga remained much the worst served (14,720 people per drug store).

There was very high turnover among the general retailers. In mid-2000, 481 general retailers stocking drugs were identified. By mid-2001, only 63% were still stocking drugs; 29% had closed down, and 7% were open but no longer stocked drugs. These reductions were more than compensated for by new stockists. By mid-2001 an additional 216 general retailers stocking drugs had opened, and 14 existing shops had started stocking drugs, giving an overall increase in the number of general retailers stocking drugs of 11% over the year. These patterns were similar across the 3 DSS areas.

The proportion of general retailers stocking drugs which stocked antimalarials in the two censuses was constant in Kilombero and Ulanga (at 15% and 37% respectively) but fell in Rufiji from 30% to 22%. These general trends disguise even greater variation in the stocking patterns of individual shops. Of the 138 general retailers stocking antimalarials in mid-2000, only 40% were still stocking antimalarials in mid-2001; 49% were still open but not stocking antimalarials, and 12% had closed down. Of the 76 stocking antimalarials in 2001 but not in 2000, 40 had operated in 2000 but not stocked antimalarials, and 36 were new startups.

Figure 7.2 Turnover of retail outlets stocking drugs between mid-2000 and mid-2001



Source: Outlet Censuses May-Sep 2000 & 2001.

7.5 Market Structure among Wholesale Suppliers

As the wholesale market may also influence competition among retailers, wholesale market structure is briefly considered in this section, through an assessment of the type and patterns of wholesale supply, concentration and turnover.

During the outlet censuses, all shops stocking drugs were asked about their sources of wholesale drug supplies, which demonstrated that the distribution chains were quite different for drug and general stores (Table 7.6). Drug shops generally used dedicated drug suppliers, with 65% of sources specified being drug wholesalers or Part I pharmacies, and 21% other Part II drug shops. There were no dedicated drugs wholesalers in the study districts, so their suppliers were nearly all located several hundred kilometres away in Dar es Salaam, generally closely gathered in the Kariakoo area within 200m of each other. In qualitative interviews, drug shop staff explained that they did not always visit the same wholesaler, but shopped around for the best prices. Most drug stores used public buses or trains to obtain their supplies, restocking at least once a month.

Table 7.6 Type and location of retailers' wholesale sources for drug supplies¹
(% of all sources/locations specified)

	Drug shops	General retailers stocking drugs
Type of wholesale source²:		
General wholesaler or retailer	5 (15%)	729 (92%)
Drugs wholesaler or Part I pharmacy	22 (65%)	8 (1%)
Part II drug shop	7 (21%)	37 (5%)
Distributor	0 (-)	16 (2%)
Total sources specified	34 (100%)	790 (100%)
Location of wholesale source²:		
Dar es Salaam	31 (91%)	84 (11%)
District/Regional Headquarters	2 (6%)	250 (32%)
Local market centre	1 (3%)	454 (58%)
Total locations specified	34 (100%)	788 (100%)

¹ interviewees were asked to name up to two sources of drug supplies for their shop

² there was a significant difference between drug shops and general retailers in type and location of wholesale sources (Chi², p<0.001)

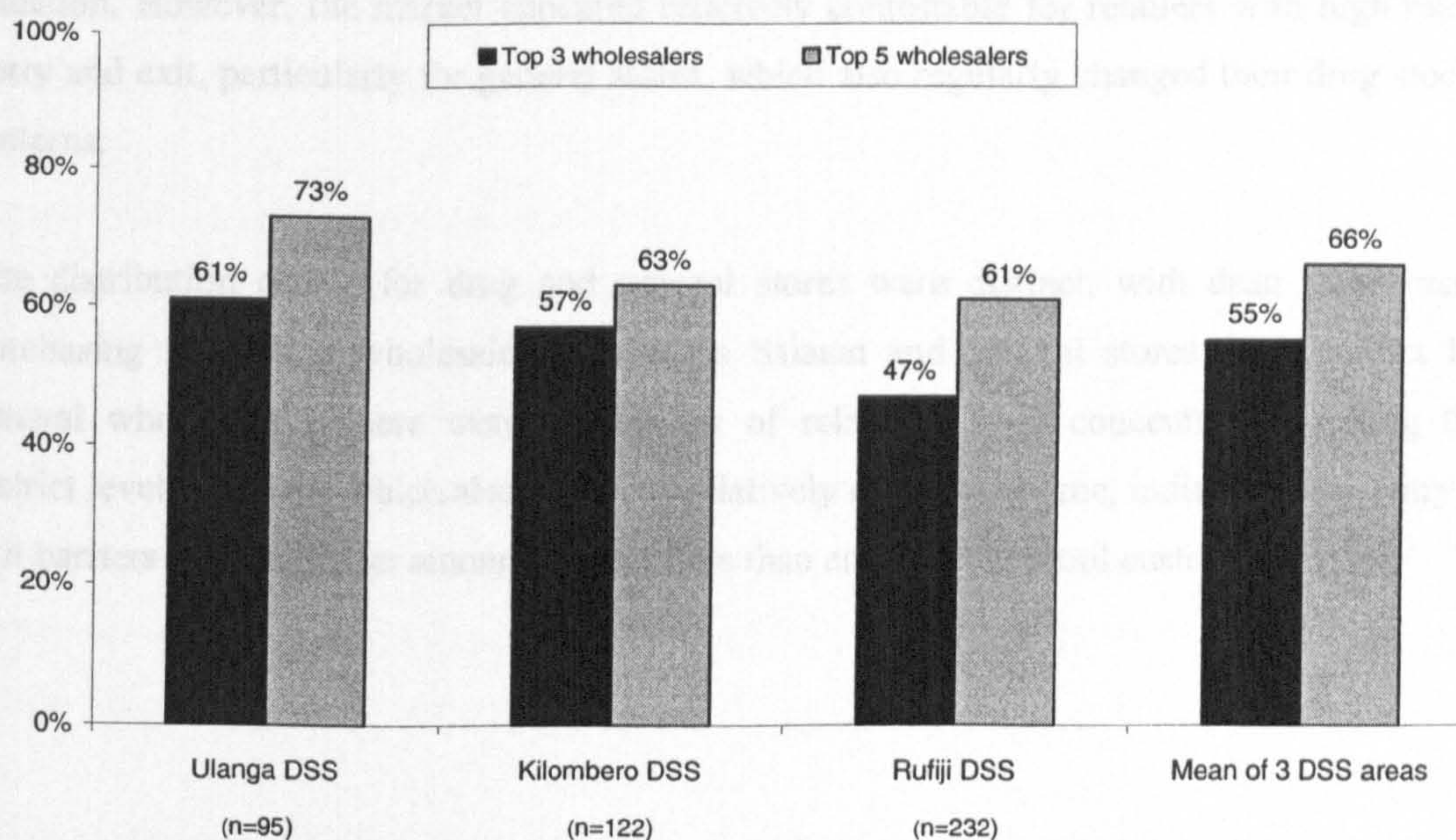
Source: Outlet Census May-Sep 2001.

By contrast, general stores restocked with drugs much less frequently; the majority had no special schedule and just purchased whenever their stocks ran out. This was rarely in under a month, and might be as infrequent as every two or even three to four months. In the outlet census, 92% of sources mentioned by general retailers were general wholesalers, which stocked a wide range of other products. General retailers stocking antimalarials were not significantly more likely to use drug wholesalers than those that did not. General retailers' sources were usually located in local market centres (58%), or in District or Regional headquarters (32%). They generally fetched their supplies by bicycle, with the round-trip taking anything between a few minutes and half a day. The main criteria for choosing between wholesalers was proximity, and they also preferred larger shops stocking the whole range of products that they sold, and shops where they were well-known and therefore more likely to get good deals. Although they mentioned price as an important factor in choosing local outlets, they generally agreed that prices were the same across all the district-level general wholesalers. They knew that prices were lower in Dar es Salaam, but felt unable to cover the cost of transport to the city because their capital was so small. Mobile distributors who travel from retailer to retailer were never mentioned at drug shops, and were not a common source for general retailers (2% of sources specified).

In addition to providing products, wholesalers and distributors were also the most important source of information for shopkeepers about new drugs, mentioned by 43% of outlet survey interviewees at drug stores and 57% at general stores. The next most common source was the radio (40% at drug stores and 46% at general stores), with newspapers, health care workers and drug shop owners also often cited.

Although general retailers mentioned a large number of different wholesalers, a few accounted for a high proportion of all sources cited. In the Kilombero DSS area for example, 122 general retailers named a specific source, with a total of 40 different wholesalers mentioned. However, a high proportion of the retailers mentioned at least one of the 5 most frequently specified wholesalers (Figure 7.3). Moreover, two of the wholesalers in the Kilombero top five purchased their supplies from other wholesalers in the top five. Averaging across the DSS areas, the proportion of general retailers mentioning at least one of the top 3 wholesalers in their DSS was 55%, and of the top 5 wholesalers, 66%. Although these data do not necessarily reflect the volume of wholesale purchases, they are indicative of high levels of concentration in the wholesale market for general stores.

Figure 7.3 General retailers with drugs in stock mentioning at least one of the top 3 and top 5 wholesale sources for general retailers



n = number of general retailers with drugs in stock mentioning at least one wholesale source
Source: Outlet Census May-Sep 2001.

The pattern of wholesale supply to general retailers appeared to be relatively stable, with little change in the top 5 wholesale sources in each DSS area between the 2000 and 2001 outlet censuses. In Ulanga the same 5 wholesalers were in the top 5 in 2000 and 2001, and in Rufiji and Kilombero 4 of the top 5 were the same.

For drug stores, data were available on specific wholesale sources for 14 retailers only, making wholesale concentration difficult to assess. However, these 14 sellers mentioned 15 different suppliers, indicating that in relation to these specific study sites there was no rapid narrowing of the number of suppliers at the next level of the distribution chain. However, as these Dar es

Salaam wholesalers served drug shops from most areas of the country, the wholesale market may be highly concentrated at a national scale.

7.6 Summary and Conclusions

This chapter aimed to analyse the structure of the market for fever/malaria treatment in the study sites. The definition of the market for fever/malaria treatment was considered on a product and geographical basis. The product definition was set as antimalarials and painkillers stocked in facilities, drug stores and general stores. For the geographical definition local sub-markets were defined based mainly on wards but adjusted where necessary using the shipment method. There were many different antimalarial products on the market, and concentration by product did not appear particularly high. Concentration of antimalarial sales by provider was high; all sub-markets could be considered as highly concentrated, with some approaching a monopoly situation. However, the market appeared relatively contestable for retailers with high rates of entry and exit, particularly for general stores, which also regularly changed their drug stocking patterns.

The distribution chains for drug and general stores were distinct, with drug stores mainly purchasing from drug wholesalers in Dar es Salaam and general stores from district level general wholesalers. There were indications of relatively high concentration among these district level suppliers, which also appeared relatively stable over time, indicating that entry and exit barriers may be higher among the suppliers than among their retail customers.

CHAPTER 8

PRODUCT DIFFERENTIATION AND NON-PRICE COMPETITION

8.1 Introduction

This chapter continues the analysis of the nature of competition in the fever/malaria treatment market (Objective 2 of the thesis). Market structure was considered in Chapter 7; the analysis now turns to an assessment of provider conduct. Conduct has been divided into two key elements, reported in separate chapters. Product differentiation and non-price competition are considered in this chapter, pricing and price competition in Chapter 9. (In addition, response to regulation is covered in Chapter 10). It might be considered more conventional for an economic analysis to address price before non-price competition. However, assessing non-price competition first facilitates the generation of hypotheses about likely sources of price variation, which are explored in the following chapter.

Competition over non-price attributes of fever/malaria treatment reflects perceived differentiation between products or between outlets, leading buyers to prefer one firm's product over a rival's at the given price (Scherer 1970). Perceived differentiation may result from inherent characteristics, or be deliberately engineered by the provider to enhance their competitive position. It is a key influence on treatment obtained because competition between retailers is likely to enhance only those product/service features that consumers view as important. Moreover, non-price competition can temper price competition by endowing certain sellers with market power.

The importance and nature of non-price competition will vary across markets. The key axes of differentiation in the fever/malaria treatment market were therefore identified empirically, by asking providers during qualitative interviews what factors were important in attracting customers to their outlet, and what factors led customers to seek care elsewhere. The most commonly mentioned issues concerned the range and reliability of drug stocks, expertise of staff, convenience, credit availability and good consumer relations.

In this chapter, qualitative data from provider interviews are used to explore each of these issues in some depth, and assess their likely influence on consumers' ranking of different outlet types. Hypotheses about the ranking by outlet type generated from these qualitative discussions are tested where possible using quantitative data from the household survey, outlet censuses, and outlet survey. From this analysis, a body of evidence is constructed which allows the provider types to be compared across each key issue. The findings are summarised in Section 8.7, where

rough rankings are assigned for 8 key non-price characteristics, and the relative overall performance by provider type is illustrated using spider diagrams^{1,2}.

8.2 Product Range and Reliability

During qualitative provider interviews, the most frequently raised issues said to affect choice of provider concerned drugs, in terms of the drug product range, stock reliability and perceived drug quality. These are discussed below. From a technical perspective of treatment quality, one would also expect the availability of confirmed diagnosis and injectable antimalarials to influence preferences for providers. The reasons why these aspects were not volunteered are also explored.

8.2.1 Drug Product Range

Consumers were said to choose a drug store or facility instead of a general store because of the wider range of drug products, which were not limited to painkillers. This is corroborated by outlet survey data which showed that in terms of most drug availability measures, private facilities ranked highest, followed by drug stores, with government facilities ranked as third, and general stores last. As described in Chapter 6, antimalarials were available in only 14% of general stores stocking drugs, meaning that to be confident of obtaining an antimalarial customers needed to visit facilities or drug stores. In total, general shops had a median of 3 fever/malaria drugs³, compared with 7 in government facilities, 11.5 in private facilities and 13.5 in drug stores. Of those outlets stocking antimalarials, private facilities had the widest choice, with a median of 7 antimalarial products, compared to 6 in drug shops, 5 in government facilities and only one in general stores (Table 8.1). General shops usually had only chloroquine, whereas SP, amodiaquine and quinine were frequently found in facilities and drug stores, and many drug stores stocked several brands of each antimalarial type.

¹ Chapters 8 and 9 explore price and non-price competition between government facilities, private facilities, commercial drug stores and general stores. The village-run drug stores were excluded from the analysis in these two chapters as there were only two in the study areas, making it difficult to generalise from their results, and both were located in the same sub-market, meaning that they were only practical options for 10% of the study population.

² Unless otherwise stated, only general shops stocking drugs at the time of the interview are included in outlet survey results.

³ defined to include painkillers and antimalarials.

Table 8.1 Number of antimalarial products stocked per outlet (for outlets stocking at least one antimalarial)

	n	Minimum	Maximum	Mean	Median
Government facilities	18	1	11	4.9	5
Private facilities	8	3	10	6.8	7
Commercial drug shops	30	1	17	6.9	6
General stores	30	1	3	1.3	1

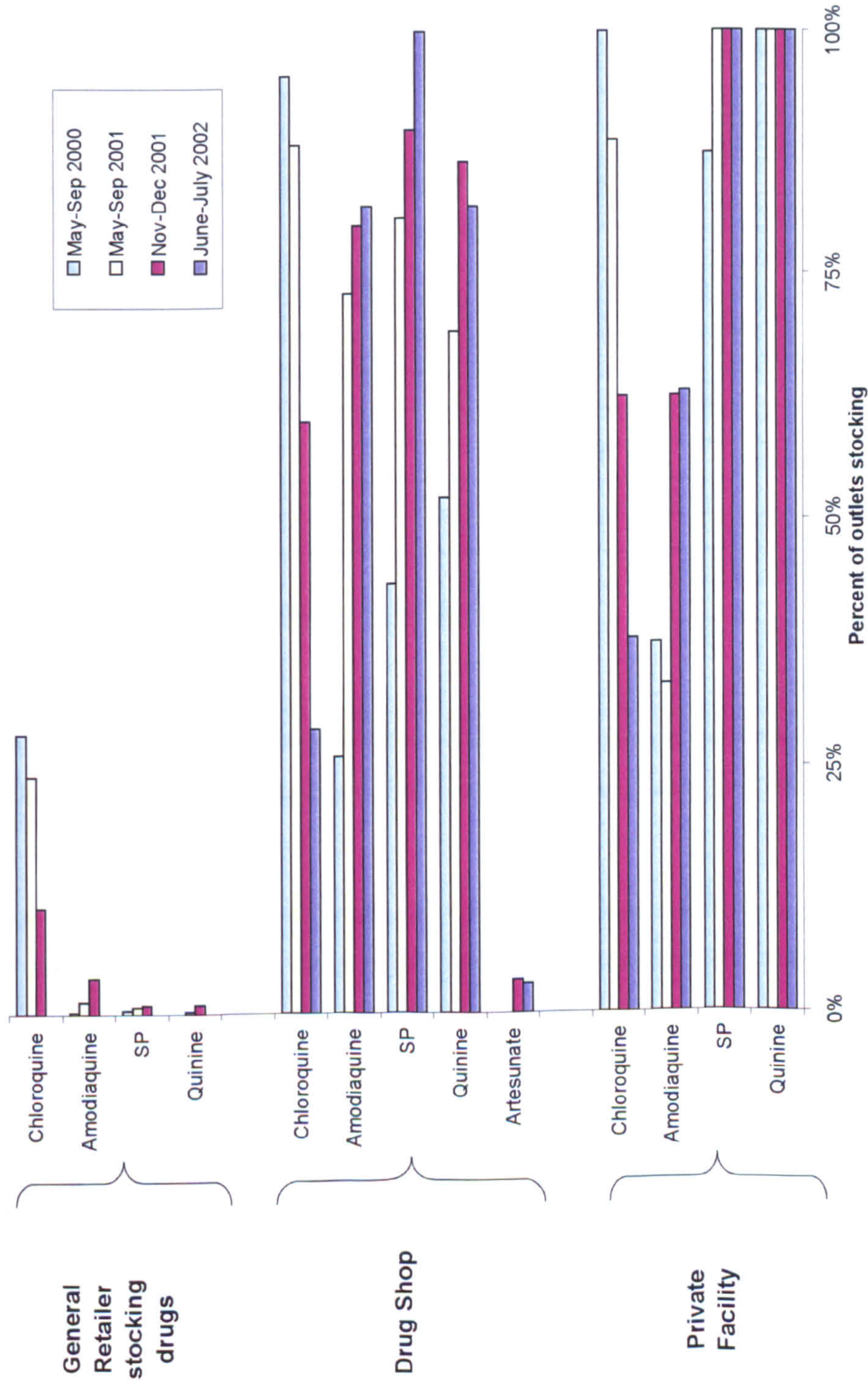
Source: Outlet Survey Nov/Dec 2001.

The availability of amodiaquine and quinine in commercial drug stores and private facilities was better than in government facilities, and the wide availability of SP in these private outlets predated the national change in first line policy in August 2001 (Figure 8.1). During the 2001 outlet census just before the policy change, SP was already available (illegally) in 81% of commercial drug shops, and (legally) in all private facilities. More than a year earlier during the 2000 outlet census it was available in 43% of commercial drug stores and 88% of private facilities. The new second line, amodiaquine, was already stocked by 26% of commercial drug stores and 38% of private facilities in mid-2000, and 73% and 33% respectively in mid-2001. By contrast, at the time of both censuses, chloroquine was the only antimalarial in the core drug kit in government primary health care facilities, with a sub-set of facilities receiving only a very limited amount of SP and quinine.

Bivariate analysis indicated that general stores were significantly more likely to stock antimalarials if they possessed a business licence, and if they stocked garments, the latter probably acting as an indicator of a relatively high stock value (Table 8.2). There were also indications that antimalarial stocking was more likely if the shop had better educated staff, a permanent building, and was on the main road (differences not significant).

The low level of antimalarial stocking in general stores leads one to question why they do not try to compete with drug stores to meet antimalarial demand. The stated reasons why general retailers did not stock chloroquine or SP are shown in Table 8.3. The most frequently given reasons were that they were not permitted, a shortage of customers, the high cost of purchase, their lack of expertise, and problems with wholesale availability. For SP, many respondents also said they did not know the drug.

Figure 8.1 Antimalarial stocking patterns in private outlets between mid-2000 and mid-2002 (all formulations)



Source: May-Sep 2000 – Outlet Census 2000; May-Sep 2001 – Outlet Census 2001; Nov-Dec 2001 – Outlet Survey; June-July 2002 – Retail Audit 2 (excluding general shops for June-July 2002 as a representative sample was not obtained).

**Table 8.2 Characteristics of general shops stocking antimalarials
(as a % of all general shops stocking drugs¹)**

	Number stocking antimalarials (%)
DSS area (n=213):	
Kilombero	12 (22%)
Ulanga	3 (7%)
Rufiji	15 (13%)
Licence status (n=209):	
Licensed	25 (23%)*
Unlicensed	5 (5%)*
Location (n=213):	
Market centre	7 (11%)
Rural village	19 (15%)
Farming area	4 (17%)
On main road (n=213):	
Yes	20 (19%)
No	10 (10%)
Regular serving staff with at least primary education (n=205):	
Yes	27 (16%)
No	2 (6%)
Length of time shop has been open (n=143):	
Less than one year	6 (16%)
More than one year	13 (12%)
Wall construction² (n=213):	
Permanent	22 (20%)
Temporary	8 (8%)
Stocks mosquito nets (n=213):	
Yes	5 (33%)
No	25 (13%)
Stocks garments (clothes, cloth, kanga or kitenge) (n=213):	
Yes	17 (29%)*
No	13 (8%)*

¹ variations in n reflect differences in the number of interviewees able to supply the relevant information

² permanent = stone, cement, bricks; temporary = wood, iron sheets, mud, mud & sticks, coconut palms, grass, cardboard.

* significant difference across specified characteristics (Chi² with Rao and Scott correction, p < 0.05)

Source: Outlet Survey Nov/Dec 2001.

The proportion of general stores stocking antimalarials had declined over time in all DSS areas, from 29% of general stores stocking drugs in the 2000 outlet census and 24% in the 2001 outlet census to 14% in the outlet survey, and there was no evidence of a resurgence in antimalarial stocking in the retail audits in 2002. This reflected the official withdrawal of chloroquine, the main antimalarial stocked in general stores, but almost no move to start stocking the new first line, SP, and only very limited adoption of the new second line, amodiaquine. As a result, general shops were becoming less and less competitive on drug range over time.

Table 8.3 Reported reasons why chloroquine and SP were not stocked by general retailers

Reasons why drug not stocked ¹	Chloroquine	SP
	No. responses (%)	No. responses (%)
Not allowed to sell	83 (37%)	45 (18%)
No or few customers	40 (18%)	54 (22%)
High cost or lack of capital to buy	37 (16%)	40 (16%)
Don't have expertise to sell	22 (10%)	39 (16%)
Not available at wholesalers	21 (9%)	24 (10%)
It can have harmful or dangerous effects	8 (4%)	3 (1%)
Does not work well	7 (3%)	0 (0%)
Not yet bought new stocks	3 (1%)	2 (1%)
Don't know where to buy it	3 (1%)	8 (3%)
People buy from nearby drug stores/facilities	2 (1%)	4 (2%)
Don't know this drug	0 (-)	26 (11%)
Other	1 (-)	4 (2%)
Total Responses	226 (100%)	245 (100%)

¹ interviewees could specify more than one reason.

Source: Outlet Survey Nov/Dec 2001.

8.2.2 Stock Reliability

During qualitative interviews almost every interviewee reported that consumers avoided government facilities because of their frequent drug stockouts of both antimalarials and painkillers.

"They come here for drugs that are not available there (at the government dispensary). It's not that they prefer it, it's that they can't get drugs." General shopkeeper #3

This was borne out by household survey data which showed that no drugs were obtained at 17% of visits to government facilities (compared with 5% at private facilities and less than 1% at drug and general stores). The use of shops as a drug source when government facilities had stockouts had been semi-formalised through the use of *cheti*, informal prescriptions from government staff. These were normally written in exercise books, and described the drug and dose required. During qualitative interviews all drug stores reported getting many customers with *cheti* for painkillers, antimalarials and antibiotics; in one drug store such patients made up around half of their customers. This was also reflected in the most common pattern for multiple provider visits documented in the household survey, a health facility visit followed by a drug store. *Cheti* were quite rare in general stores, but many general shops said sales increased at times of government stockouts, because patients were sent to shops by health care workers, or chose to go directly to shops once news of the stockout had spread. A couple of general stores had even started stocking syringes to cater for demand when government stocks ran out. Two drug stores and one general store linked their weekly sales patterns to patients directed from government facilities, with sales peaking on the days when the facility had most customers.

In contrast stockouts were never mentioned as a problem in private facilities. This was backed up by outlet survey data on drug stockouts in the previous month⁴. Stockout data were collected for chloroquine, SP, aspirin and paracetamol tablets. Data for chloroquine are not presented as it had been officially withdrawn by this time, so a stockout may have reflected a decision to discontinue this product. Data on SP are presented, but may not be representative of typical stock reliability at government facilities, as it had been introduced in most of the public sector only in the previous two months, meaning that their stocks may have been atypically high at the time of the survey. Much higher government stockout rates for chloroquine were observed across Tanzania when it was still the first line drug (Abdulla 2001).

Table 8.4 shows that on average private facilities were the most reliable stockists. Drug stores were the next most reliable; although they had frequent stockouts, they were half as likely as general stores to run out of aspirin or paracetamol, and one sixth as likely for SP. Respondents in qualitative interviews suggested that general stores were used because of high stockout rates in government facilities, but outlet survey data showed them to be equally unreliable themselves, with average stockout rates for aspirin and paracetamol of 34% in general stores and 36% in government facilities, although in most areas patients would have had the option of trying several general shops. General stores in farming areas were particularly likely to have aspirin and paracetamol stockouts (46% and 48% respectively). However, stockouts in drug and general shops were remedied relatively rapidly, usually in three or four days, in contrast to government facilities where the median stockout period was over a week.

Table 8.4 Outlets reporting stockouts of tablet products in the previous month¹

	Outlets reporting stockout (as % of those stocking in previous month) ²			Median number of days out of stock (where stockout took place) ³		
	Aspirin	PCL	SP	Aspirin	PCL	SP
Government facilities	5 (28%) n=18	8 (44%) n=18	1 (6%) n=16	8 n=5	8 n=8	7 n=1
Private facilities	2 (25%) n=8	0 (-) n=8	0 (-) n=8	7 n=2	n/a	n/a
Commercial drug shops	5 (17%) n=29	5 (17%) n=30	3 (11%) n=28	3 n=5	3 n=5	3 n=3
General stores	59 (31%) n=183	77 (37%) n=209	3 (60%) n=5	4 n=57	4 n=77	7 n=3

PCL=Paracetamol

¹ stockouts were defined as any occasion when the provider completely ran out of a product, even if it was restocked on the same day.

² n= number of outlets which have stocked this product in the previous month and where interviewee knew whether stockouts had taken place.

³ n=number of outlets with stockout in previous month.

Source: Outlet Survey Nov/Dec 2001.

⁴ Stockout data were collected for outlets which currently stocked the relevant product, or had stocked it in the previous month, and therefore include some general shops with no drugs in stock at the time of the interview, which were excluded from other analysis. Stockouts lasting more than a month were not captured.

8.2.3 Perceived Drug Quality

Concerns over drug quality, and expired drugs in particular, were said to lead consumers to avoid certain outlets, especially general stores.

"People tell you that you can buy drugs from a certain individual and even if you are given the whole tub and you swallow them all, they will not be helpful." General shopkeeper #12

Although advertising or marketing of drugs was very rare in these rural areas, restricted to the odd, often out-dated poster, consumers were said to have well-developed views about the relative merits of different products. In qualitative interviews, three drug characteristics were reported to be associated with higher quality, and to command price premiums: the country of origin, packaging and brand name. Most antimalarials were manufactured in Tanzania, followed by other African countries (mainly Kenya), Asia (mainly India), with the smallest percentage coming from Europe (mainly Belgium and Italy). In general, those from Europe were perceived to be the highest quality. For example, one interviewee explained that British drugs were believed to be best, followed by those from Kenya, with Indian and Tanzanian products seen as the poorest quality. As with drug availability in general, private facilities had the highest proportion of European products (21% of products stocked), followed by drug stores (19%), compared with only 3% in general stores (Table 8.5). Government facilities were particularly likely to have Tanzanian products, with more than half of all their antimalarials being domestically manufactured.

Table 8.5 Proportion of drugs stocked having characteristics argued to be associated with high quality

	Antimalarials manufactured in Europe ¹ (% ²)	Antimalarial tablets packaged (% ³)	Painkiller tablets packaged (% ⁴)	SP tablets innovator brands (% ⁵)
Government facilities	11 (13%) (n=86)	1 (2%) (n=49)	0 (-) (n=33)	0 (-) (n=19)
Private facilities	11 (21%) (n=53)	7 (20%) (n=35)	4 (13%) (n=32)	2 (11%) (n=19)
Commercial drug shops	39 (19%) (n=206)	85 (67%) (n=127)	52 (37%) (n=142)	14 (23%) (n=61)
General stores	1 (3%) (n=37)	25 (76%) (n=33)	484 (60%) (n=811)	0 (-) (n=2)

¹ n=number of antimalarial products where country of manufacture was known

² as a % of all antimalarials stocked

³ as a % of all antimalarial tablets stocked

⁴ as a % of all painkiller tablets stocked

⁵ as a % of all SP tablets stocked

Source: Outlet Survey Nov/Dec 2001.

Tablets packaged in foil or paper were said to be perceived as more valuable than those sold loose. Packaged drugs were particularly rare in government facilities, representing only 2% of antimalarials (Table 8.5). Shops were much more likely to stock packaged items, which accounted for 67% of antimalarials in drug shops and 76% in general stores. Similar patterns were observed for painkiller tablets.

Certain brands were reportedly viewed as of superior quality. For SP tablets the innovator brands of FansidarTM and MetakelfinTM were best known, and perceived as of higher quality⁵. These brand names made up almost a quarter of SP products in drug shops, compared with 11% in private facilities, and were never found in government facilities or general stores (Table 8.5). Other well-known brands were often imitated by other companies, who chose brand names, presentations and packaging very similar to the original product. For example, SmithKline Beecham in Kenya produced PanadolTM (paracetamol) and CafenolTM (aspirin + caffeine), two leading painkiller brands, which had been imitated by a much less well-known Zambian firm with its two products, PanadoTM and CafemolTM.

Shopkeepers argued that customers placed considerable weight on country of manufacture, packaging and brand in assessing product quality. However, the basic SP tablet content tests reported in Table 6.11 provided no evidence that these attributes were associated with better quality drugs. Many packaged and loose tablets were found to fail, as were products manufactured in Europe, including one innovator brand.

8.2.4 Availability of Injections and Confirmed Diagnosis

One might have expected facilities to attract custom through the provision of products/services that could not be provided in shops, notably antimalarial injections and malaria microscopy, but this type of non-price competition was never mentioned in qualitative interviews. This was not surprising as injectable antimalarials were at least as widely available in drug stores, being stocked by 80% of drug stores, compared with only 61% of government facilities (although they were stocked by all private facilities). All shopkeepers stated that they did not administer injections, and that patients had to go to the health facility to be injected. When pressed about what the patient would do if they needed an injection when the health facility was shut, one drug store said they might be able to help, and another said there was a local health worker who could assist. However, we did not see any evidence of drug stores providing injections on a routine basis.

⁵ innovator brands are those first authorised worldwide for marketing (normally as a patented product); such brands did not exist for other common antimalarials

Only 4 of the 18 government facilities and 5 of the 8 private facilities had functioning microscopy services, with no functioning services at all in the Ulanga DSS area. The most common reason for the lack of microscopy was that the facility did not have a microscope, with other problems being the lack of supplies and appropriate staff, and that the microscope did not work (Table 8.6). Even where facilities did offer microscopy, it was typically not provided on a routine basis for all suspected malaria cases, and the protocols on which patients should receive laboratory confirmation were unclear. There were no private laboratory services in the study sites⁶.

Table 8.6 Reasons for lack of microscopy in public and private facilities (n=number of facilities without functioning microscopy¹)

	Facilities reporting (n=17 facilities)
No microscope	7 (41%)
No supplies for microscopy	5 (29%)
No laboratory staff	6 (35%)
Microscope does not work	4 (24%)
No electricity for microscope	1 (6%)
Lack of appropriate building	1 (6%)
Don't know / Not specified	3 (18%)
Total responses	27 (100%)

¹ several interviewees gave more than one reason
Source: Outlet Survey Nov/Dec 2001

8.3 Staff Expertise

Staff expertise was not said to be seen as crucial by all fever/malaria patients. Many participants in qualitative interviews commented that customers did not feel the need to visit a facility because malaria was common, they could self-diagnose, and knew which drugs they required. They therefore felt confident in obtaining treatment directly from shops.

However, all interviewees from dispensaries and drug stores believed their expertise attracted custom, and some general storekeepers volunteered their lack of knowledge as a reason why customers preferred to go elsewhere. Variation across outlet type in perceived expertise was reflected in the agency roles played by staff⁷. Household survey data showed that 100% of drugs obtained in government facilities were selected by the provider, and 91% in private facilities, compared with 47% in drug stores and less than 4% in general stores.

In general stores the role of owner/manager/seller was combined and taken by one person, a husband and wife team, or group of men. Their reported agency roles were normally very

⁶ although a private laboratory opened after the study in 2002 in Ulanga DSS, and there were several in Ifakara Town

⁷ Providers may act as an agent for the consumer, advising on appropriate health care demand if providers are perceived as better informed than their customers.

limited because in most cases customers knew what drugs they wanted, and general shopkeepers did not perceive themselves to have the expertise to provide advice.

"Customers themselves come and ask for the drugs specifically. I depend on the drugs customers ask for." General shopkeeper #5

One general shopkeeper said persuading a customer to buy a different drug would be akin to persuading him to buy trousers instead of a shirt. When prompted, some said they would give advice on drug choice only if a customer requested it, or the drug they wanted was not available. They did not perceive themselves to have the expertise to advise on a regular basis:

"The biggest sellers for these drugs are the drug stores, because most of us believe that the sellers there have education about drugs, so they sell more than we do." General shopkeeper #12

In drug stores the role of seller and owner was nearly always split. Owners rarely served in shops, but were responsible for stock choice, price setting and the purchase of supplies. The sellers manned the shop and perceived their expertise as important in attracting custom.

Interviewer: "How do you attract more customers to come to your shop?"

Drug store seller #16: "The fact that this is a drug store and the seller here has studied medicines, she is an expert. That is a sufficient criterion."

One seller encouraged this association by wearing a nurse's uniform to signal her expertise. Their agency role depended on the customer, but many clients requested advice, treating sellers with the respect due to medical experts. The seller often effectively took a short history, asking about the nature and duration of symptoms, the age of the patient, and which drugs had been used in the past, and then advised on drug choice and dosage. When a patient came with a *cheti*, the seller often explained it, and helped them prioritise if their money was insufficient.

Customers reportedly visited health facilities in order to consult a *daktari*, which literally means doctor, but in this context referred to a range of lesser-qualified health-care workers. Health dispensary staff noted that patients visited them if they were still sick after taking shop-bought drugs, presumably because the greater expertise of a *daktari* was perceived to be required with treatment failures. Some drug stores were owned by a *daktari*, and their occasional presence was seen as a particular draw.

Facility staff said that some patients asked for specific drugs, but that the final decision rested with the health care worker. By contrast in drug stores if a customer insisted on a certain drug,

the seller would give it to them. One seller said if a customer requested chloroquine, he would advise against it because of drug resistance, but if they insisted he would happily sell it, in the knowledge that he was using up his stock.

These perceived differences in expertise across outlet type were reflected to some degree in provider knowledge and qualifications. Interaction during qualitative interviews showed that drug store staff were familiar with the drug categories of painkillers, antimalarials and antibiotics, and with common brands, and aware of antimalarial resistance and the change in first line drug. By contrast many general shopkeepers were unable to categorise the drugs they sold by generic type, and had not heard of the recent policy change nor its justification. Three general store interviewees had never even heard of SP. General shopkeepers also seemed easily influenced by brand names; for instance we were told that MifupenTM (aspirin + caffeine) was the best drug for body pains (*mifupa* means bones in KiSwahili). HedexTM was argued to be best for headaches, and MaraMojaTM, meaning immediately, was said to be particularly fast acting (both HedexTM and MaraMojaTM contain paracetamol + aspirin + caffeine).

In terms of the qualifications of staff regularly serving customers, the results for facilities and drug stores were quite similar (Table 8.7). With the exception of one government dispensary, they all had at least one staff member with health qualifications. However, this did not imply that customers were always treated by a qualified person; the percentage of regular serving staff lacking health qualifications was 3% in drug shops, 17% in private facilities and 28% in government facilities. Government facilities also performed more poorly than private facilities and drug stores in terms of total years of education, with a median of 12 years in private facilities, 11 in drug stores, and 8 in government facilities. Of those with health-related qualifications, staff in private facilities on average had the most training, with a mean of 2.8 years, compared with 2.7 years in government facilities (both having a median of 2.0 years). The mean was 1.4 in drug shops, where most staff were Nurse Assistants, with one year's training. More than a quarter of drug shop owners had no health-related qualifications.

Education levels were much lower in general stores, with a median of seven years total education. While 83% of general stores had a member of staff serving regularly with at least primary education, only 14% had one with more than primary education, and none had a regular server with health qualifications. Thirty general store staff regularly serving customers (11%) had no education at all. It has been argued that general stores are frequently staffed by children, but we found this to be rare. Only 11 children under 16 years served regularly, and 11 occasionally (4.2% of regularly serving staff and 2.7% of all serving staff for whom age was known).

Table 8.7 Qualifications of staff who regularly served customers¹

	% of shops with at least one staff member regularly serving customers with:			% staff regularly serving customers with:	Of staff regularly serving customers with health qualifications:
	At least primary education	More than primary education	Any health qualification	Any health qualification	Mean years of health training
Government facilities	18 (100%) n=18	17 (94%) n=18	17 (94%) n=18	70 (72%) n=97	2.7 n=66
Private facilities	8 (100%) n=8	8 (100%) n=8	8 (100%) n=8	40 (83%) n=48	2.8 n=38
Commercial drug shop	30 (100%) n=30	29 (100%) n=29	30 (100%) n=30	36 (97%) n=37	1.4 n=34
General stores	171 (83%) n=205	27 (14%) n=191	0 (-) n=236	0 (-) n=265	n/a

¹ variations in n reflect the number of interviewees able to supply the relevant information

Source: Outlet Survey Nov/Dec 2001

Staff expertise was also evaluated through shopkeeper knowledge of the correct dose of chloroquine and SP tablets for a 2 year old child in shops where these drugs were stocked⁸ (Table 8.8). Knowledge was deemed correct if interviewees knew both the total number of tablets required and the timing of the dose⁹. No general store interviewees gave the correct dose of either drug. Knowledge was better in drug shops, but although most drug store staff had health qualifications, only 27% gave the correct chloroquine dose and 42% the correct dose of SP. Better performance for SP may have reflected the influence of promotional materials distributed at the time of the policy change. In general, confusion was greatest over the number of tablets, reflecting over-doses in all 15 of the incorrect chloroquine responses, but under-doses in 10 of the 13 incorrect SP answers. Knowledge was better in Rufiji District than in Kilombero or Ulanga for the SP dose (although not significantly so), but not for chloroquine, perhaps reflecting that some seminars for drug store staff on the policy change to SP had been held in Rufiji.

⁸ Not evaluated at facilities.

⁹ For chloroquine, one to two 250mg tablets over a three-day period (Ministry of Health 1997); for SP, one 500/25mg tablet in a single dose (Ministry of Health 2000).

Table 8.8 Knowledge of antimalarial doses for a two-year-old by interviewees in shops stocking chloroquine and/or SP tablets

	Chloroquine				SP			
	n ¹	% specifying correct dose			n ²	% specifying correct dose		
		No. of tablets	Timing of dose	Both correct		No. of tablets	Timing of dose	Both correct
Commercial drug shops	11	3 (27%)	11 (100%)	3 (27%)	26	13 (50%)	21 (81%)	11 (42%)
General stores	10	2 (20%)	4 (40%)	0 (-)	2	2 (100%)	0 (-)	0 (-)

¹ excludes 10 general store interviewees who said chloroquine tablets should not be sold for a child of this age because the drug or formulation was inappropriate or because the child should see a doctor or be weighed first.

² excludes one commercial drug shop where the interviewee said they would not give SP tablets to a child of this age
Source: Outlet Survey Nov/Dec 2001.

8.4 Convenience

Providers gave several reasons why shops were nearly always more convenient than facilities. Firstly, people were said to prefer nearer outlets and, as general shops were much more numerous and widely dispersed, they were usually the closest source of drugs, and the only source in remote farming areas. Population ratios indicate clearly the relative accessibility of drug retailers and general stores in particular, with one general retailer stocking drugs for every 262 people, compared with one drug store for every 4386, and one health facility for every 5198 (Table A1.9). The data from the household survey showed that 63% of households could reach a general store stocking drugs within 15 minutes, compared with only 27% for government facilities, 24% for drug shops, and 12% for private facilities (Table 8.9). Painkillers were therefore available very close to the home for most people, and some smaller general stores even relocated temporarily to remote farming areas during the main cultivation months.

Table 8.9 Travel time to nearest outlet of each type reported by household heads

	No. of households	<15 minutes	15-60 minutes	1-2 hours	> 2 hours	Not aware of any outlet of this type
Government facilities	1060	282 (27%)	493 (47%)	184 (17%)	101 (10%)	0 (-)
Private facilities	1055	122 (12%)	382 (36%)	221 (21%)	184 (17%)	146 (14%)
Commercial drug shops	1047	251 (24%)	447 (43%)	186 (18%)	116 (11%)	47 (4%)
General stores	1053	659 (63%)	271 (26%)	21 (2%)	5 (0.5%)	97 (9%)

Source: Household Survey May-Sep 2001.

However, as general stores rarely stocked antimalarials, longer average journeys to drug stores or facilities would have been required to obtain these drugs. Travel time did not give drug stores a comparative advantage over facilities; times were very similar, and in fact government

facilities were reachable within an hour for a slightly higher proportion of the population. The similarity in travel times was not unexpected as government facilities and drug stores were roughly equal in number and drug stores tended to locate close to facilities. However, other factors were argued to make both drug and general stores more convenient than facilities. Service in shops was quick, while visiting facilities was perceived to be highly time-consuming, as there were long waiting times and patients had to go through the many time-consuming steps of registration, consultation, lab tests (in some facilities), prescription and dispensing.

"There is a queue there (at the government health centre). One can go in the morning and not get treatment till 2pm." Drug store seller #9

This was clearly demonstrated by household survey data on the time customers spent at outlets in order to obtain treatment (Table 8.10). General stores were the quickest with 98% spending less than 15 minutes, and service was also fast in drug shops with 85% within 15 minutes and 98% within an hour. By contrast, 40% of visits to government facilities and 38% to private facilities took over an hour.

Table 8.10 Time spent at outlet to obtain treatment during provider visits for fever/malaria (excluding travel time)

	Number of provider visits	<15 minutes	15-60 minutes	1-2 hours	> 2 hours
Government facilities	143	22 (15%)	64 (45%)	23 (16%)	34 (24%)
Private facilities	42	7 (17%)	19 (45%)	8 (19%)	8 (19%)
Commercial drug shops	162	138 (85%)	20 (12%)	2 (1%)	2 (1%)
General stores	173	170 (98%)	3 (2%)	0 (-)	0 (-)

Source: Household Survey May-Sep 2001.

Shop opening hours were much longer than those for facilities (Table 8.11). All outlets opened every weekday, but less than half the facilities opened on both Saturday and Sunday compared with all drug shops and nearly all general stores. Typically facilities were open from 7:30am till 3.30pm, drug stores from 7.30/8am to 9pm, and general stores from 6/7am to 9pm. As one general shopkeepers said:

"Some customers come back from the fields late, at 7.30 or 8pm, but if they come here they'll still be in time." General shopkeeper #1

The median number of hours open per week was more than twice as high in drug shops as in facilities. General stores were open for longer than drug stores, with the median 7 hours higher per week.

Table 8.11 Opening hours of providers

	n	Open both Saturday and Sunday	Median number of hours open per week
Government facilities	18	8 (44%)	40
Private facilities	8	4 (50%)	44
Commercial drug shops	30	30 (100%)	91
General stores	213	210 (99%)	98

Source: Outlet Survey Nov/Dec 2001.

Shops can also be more convenient because other people can make the visit on the patient's behalf. The patients themselves did not travel to the provider in 68% of visits to general stores and 49% to drug stores, but only 14% to private facilities¹⁰ and one visit (0.7%) to government facilities. Moreover, for 15% of general shops visits, only a child was sent to buy treatment (compared with 2% at drug stores, and zero at facilities).

8.5 Strategies to Increase Affordability

Many sellers cited credit as an important strategy for attracting business, with careseekers argued to choose shops where they were known as regular customers, who were trusted, believed to have the means to repay, and could be followed up if they defaulted.

It might be assumed that shops were more likely to offer credit than facilities, but we found no significant difference across outlet type. Staff reported offering credit to fever/malaria patients at 57% of government facilities charging fees and 75% of private facilities, compared with 57% of drug stores and 60% of general stores. General shops were more likely to offer credit if they were unlicensed, located off a main road, or in farming areas.

However, household survey data showed that credit was very rarely obtained in practice, being received for only five of the recorded visits (less than 1%), 4 of which were to drug shops (2 from households in the better-off SES third, 2 in the poorest third), and 1 to a government facility (in the better-off third). This leads to the conclusion that in practice credit was not an important point of competition for uncomplicated fever/malaria patients. Another potential strategy to increase affordability, payment-in-kind, was never volunteered by interviewees as important. Only one incident of payment-in-kind was recorded in the household survey, which was a supplementary payment to government facility staff in addition to cash payments for drug and non-drug fees.

A more common strategy for improving affordability may be to provide a less than complete drug dose, or just painkillers. As described in Chapter 6, household survey data showed that

¹⁰ all visits to one private facility which also (illicitly) acted as a drug store

painkillers only were obtained at 33% of visits to drug stores and 85% to general stores (Table 6.5). Of antimalarials purchased at shops, 29% were under-doses at drug stores and 50% at general stores (Table A1.15), although it was not clear whether this reflected poor customer and/or seller knowledge or problems of affordability. Although interviewees did not raise under-dosing as a way of attracting customers, when prompted they agreed it was common in both drug and general stores, but private dispensary staff said they insisted on providing a full dose. Only one drug store seller said they would not sell an under-dose, but this applied to painkillers only, and was to reduce the need for small change, rather than to ensure treatment efficacy! All other shops were happy to sell any number of tablets; customers bought as much as they could afford at the time, with no guarantee that they would return for the rest.

8.6 Consumer Relations

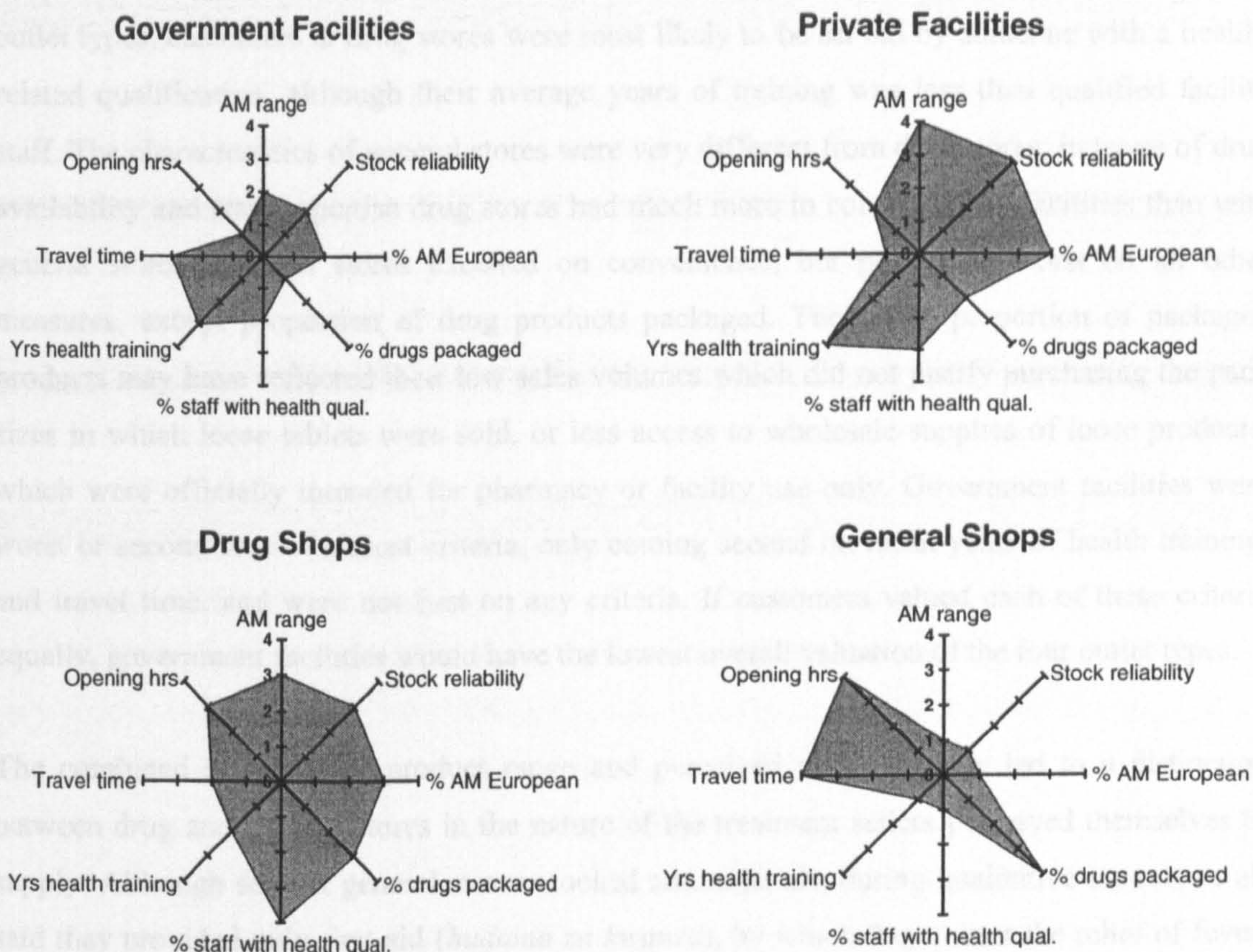
Finally, sellers in all types of outlet considered good relations with their customers to be key to increasing demand. They emphasised that people visited outlets where staff were welcoming and spoke warmly and pleasantly, and that they frequented the shops of their friends and relatives, or those where they were well-known. Once customers had established such a local and regular outlet they tended to come back repeatedly.

"You know, the customer is like any beast you keep, once he is accustomed to something it is very difficult to change him." General shopkeeper #12

8.7 Summarising Non-Price Characteristics by Outlet Type

The relative performance of the four outlet types across 8 key non-price characteristics is shown in Figure 8.2, with outlet types ranked from 4 (best) to 1 (worst) on each characteristic. The characteristics selected were those highlighted as important during qualitative work, which could be quantified across outlet type. They could therefore be considered as quantifiable proxies for perceived quality. The characteristics comprise two elements of drug availability (number of antimalarial products stocked, and stock reliability), two proxies/signals for perceived drug quality (percentage of antimalarials manufactured in Europe and percentage of fever/malaria products packaged), two proxies for staff expertise (percentage of serving staff with health qualifications, and mean years of health-related training), and two measures of convenience (travel time to nearest outlet and weekly opening hours). A number of limitations of this presentation should be noted: the selection may exclude other important non-price factors (e.g. potential to buy a sub-optimal dose; availability of microscopy); the measures may not capture the proxies most frequently used by customers to determine perceived quality; and the relative weighting of these characteristics is likely to be unequal, and to vary across consumers.

Figure 8.2 Ranking by outlet type on key dimensions of non-price competition



Key to Figure 8.2

Characteristic	Definition	Source
AM (Antimalarial) range	Median number of antimalarial products stocked	Outlet Survey (Table 8.1)
Stock reliability	1 - (average stockout rate) for aspirin, paracetamol and SP tablets	Outlet Survey (Table 8.4)
% AM (antimalarial) European	European products as percentage of all antimalarial products stocked	Outlet Survey (Table 8.5)
% drugs packaged	Packaged products as percentage of all fever/malaria tablet products stocked	Outlet Survey (Table 8.5)
% staff with health qual.	Percentage of staff often serving customers who have a health qualification	Outlet Survey (Table 8.7)
Yrs health training	Mean years of health-related training of staff often serving customers who have a health qualification	Outlet Survey (Table 8.7)
Travel time	Percentage of households reporting that the nearest outlet of this type can be reached in under an hour	Household Survey (Table 8.9)
Opening hours	Median number of hours open per week	Outlet Survey (Table 8.11)

Figure 8.2 shows that private facilities performed best on the drug measures, and were also strong on staff expertise, but weak on convenience. Drug stores came second on all drug measures. Bearing in mind that private facilities were not easily accessible for all DSS residents, drug stores were likely to be the best local fever/malaria drug source for many people. Of all outlet types, customers at drug stores were most likely to be served by someone with a health-related qualification, although their average years of training was less than qualified facility staff. The characteristics of general stores were very different from drug stores; in terms of drug availability and staff expertise drug stores had much more in common with facilities than with general stores. General stores excelled on convenience, but performed worst on all other measures, except proportion of drug products packaged. Their high proportion of packaged products may have reflected their low sales volumes which did not justify purchasing the pack sizes in which loose tablets were sold, or less access to wholesale supplies of loose products, which were officially intended for pharmacy or facility use only. Government facilities were worst or second worst on most criteria, only coming second on mean years of health training, and travel time, and were not first on any criteria. If customers valued each of these criteria equally, government facilities would have the lowest overall valuation of the four outlet types.

The combined influence of product range and perceived staff expertise led to a distinction between drug and general stores in the nature of the treatment sellers perceived themselves to supply. Although several general stores stocked antimalarials, during qualitative interviews all said they provided only first-aid (*huduma za kwanza*), by which they meant the relief of fever, headache and stomach ache usually with common painkillers and anti-acids. By contrast, drug store interviewees said they provided both first-aid and complete treatments/cures (*tiba kabisa*). However, no drug or general shopkeepers reported treating severe cases of fever/malaria, and all stated that if they did get such a patient they would direct them to a health facility.

Distinctions across outlet type conceal some variation within types. For example, general stores varied between those with several fever/malaria products including antimalarials, operating out of permanent well-established shops, to roadside stalls with just the odd painkiller. Some drug stores were owned by a respected health worker, and had a very wide range of drugs, with over a dozen antimalarial products, while others had just a handful of items, and a minimally trained nurse assistant. However, the evidence showed much more variation between outlet types than within them.

A key dimension of provider conduct and competition not included in Figure 8.2 is price, which we now turn to in Chapter 9.

CHAPTER 9

PRICING AND PRICE COMPETITION

9.1 Introduction

Chapter 8 highlighted the key dimensions of non-price competition in the market for fever/malaria treatment. However, in a community of poor consumers, where obtaining care is mainly based on out-of-pocket payment, price is likely to be a key factor affecting treatment choice. This chapter explores the second key dimension of provider conduct, pricing and price competition, which is central to an analysis of the nature of competition (Objective 2 of the thesis).

The chapter describes the prices of antimalarial and painkiller drugs, and sources of price variation, and investigates the intensity of price competition. Background information on the presentation of price data is provided in Section 9.2. Section 9.3 compares median prices for each antimalarial and painkiller across outlet type. The implications for total patient expenditure by outlet type are discussed, taking into account the additional non-drug fees charged at many facilities.

The subsequent sections assess the intensity of price competition faced by retailers. The extent of price competition is closely linked with the location of the market on the monopoly-perfect competition continuum. Under perfect competition firms cannot raise price above marginal cost, and are price-takers, all charging the same market price for a given product. Under monopolistic or oligopolistic competition price may exceed marginal cost because each provider has some market power.

In a market characterised by strong price competition one would therefore expect shopkeepers to report little or no leeway in setting their prices, and to see relatively low retail markups, and uniform prices for a given product. These hypotheses are tested in Sections 9.4, 9.5 and 9.6. Section 9.4 describes the price setting behaviour reported by retailers themselves during qualitative interviews. Their responses are analysed to assess whether they view themselves as price-takers or as having discretion over the prices they set. In Section 9.5 gross markups for antimalarials and painkillers are evaluated. Two measures of markups are employed: total markups over international reference prices, and retail markups over wholesale costs. Markups which appear excessive compared with suggested benchmarks are argued to be potential indicators of market power. In Section 9.6 price variation for given products is analysed to assess whether common market prices exist.

Substantial diversion from the competitive model is indicated by the analysis in Sections 9.5 and 9.6. A range of possible explanations are considered, including geographical segmentation, high concentration, product differentiation and collusion. Finally, in Section 9.7, a statistical analysis of drug prices is presented, using OLS regression to investigate the relative importance of product characteristics, outlet characteristics and market concentration on retail prices.

9.2 Reporting Price Data

Data on antimalarial and painkiller drug prices were drawn from the outlet survey. In presenting price data, the aim was to facilitate comparison across products and outlet types.

Prices are generally summarised by their median because of the skewed nature of much of the price data. Median prices were not weighted by sales levels, and therefore indicate the average price faced by consumers, not the average price paid. In many cases outlets stock more than one product in each generic category, and the most relevant price for comparing affordability across outlet type may therefore be the average minimum price rather than median price. However, comparing average minimum prices by outlet type made very little difference to relative prices for antimalarials or painkillers, so the analysis was conducted on the median price alone.

As described in the outlet survey methods (Section 5.4.6), antimalarial costs have been calculated as the purchase required in order to treat a two-year-old child, as a key measure for affordability and public health (with syrups and injections costed at the price for a whole bottle or vial/ampoule, as it was not usually possible to purchase less in shops). As there was no fixed dose for common painkillers, prices are compared per tablet or bottle.

Price variation was explored in more detail for the most common antimalarials and painkillers. The four most common antimalarial products were the tablet formulations of SP, amodiaquine, chloroquine and quinine, which together made up over 95% of total antimalarial volumes and values. The most common painkillers were the tablet forms of aspirin, paracetamol, aspirin+caffeine, and aspirin+paracetamol+caffeine.

As the sample was stratified by DSS system, and drug observations may be clustered within outlets, standard tests for significant differences between medians, such as the Wilcoxon Rank Sum test, are not valid. Statistical significance is therefore explored through regression analysis.

9.3 Average Prices by Provider Type

Table 9.1a shows median prices of antimalarials by outlet type. Of the antimalarial tablets, chloroquine was the cheapest and quinine the most expensive at all outlet types. For example, in drug stores, amodiaquine was ten times the price of chloroquine, SP more than 12 times, and quinine 55 times. Syrup and injectable formulations were considerably more expensive than tablet formulations of the same drug.

Median prices for common painkillers are shown in Table 9.1b¹. The cheapest per tablet was generally aspirin, followed by paracetamol. Combinations of aspirin and caffeine, or aspirin, paracetamol and caffeine were considerably more expensive.

For all antimalarials which they supplied, the three government facilities which reported charging drug fees had the lowest median price. Moreover the table excludes the remaining 15 government facilities which did not report charging for drugs, emphasising that on average government facilities should be the cheapest source in terms of antimalarial costs. Drug stores tended to be more expensive than private facilities, with higher median prices for 7 of the 10 antimalarials. The relative prices of general stores compared with facilities and drug stores did not follow a clear pattern, although the scope for comparison was limited by the small number of observations. For chloroquine tablets, the most frequently stocked antimalarial in general stores, the median price was significantly higher in general stores than in all other outlet types.

Similarly for painkillers, reported prices from government facilities were the cheapest or equal cheapest source for the two products they stocked. The median prices for private facilities, drug stores and general stores were similar, although private facilities had higher prices for aspirin tablets.

¹ excluding junior versions of painkillers as the quantity of active ingredient differs from the regular versions.

Table 9.1 Antimalarial and painkiller prices by outlet type (Tsh)
(a) Median price of antimalarial purchase required to treat a two-year-old child
(n=number of products identified)

	Government facility with drug fees ¹		Private facility		Commercial drug store		General store	
	n	Median	n	Median	n	Median	n	Median
Tablets								
SP	2	68	19	200	61	250	2	150
Amodiaquine	1	126	4	140	31	200	7	200
Chloroquine	4	14	1	20	10	20	23	60
Quinine	1	275	8	550	22	1100	1	440
Syrup								
SP	0	-	1	800	9	1500	0	-
Amodiaquine	0	-	2	575	18	1000	1	1000
Chloroquine	3	125	3	300	9	700	2	725
Quinine	0	-	1	2000	10	2000	0	-
Injectables								
Chloroquine	0	-	1	800	8	700	1	500
Quinine	0	-	9	300	23	500	1	700

(b) Median price of common painkillers per tablet / bottle
(n = number of products identified)

	Government facility with drug fees ¹		Private facility		Commercial drug store		General store	
	n	Median	n	Median	n	Median	n	Median
Tablets								
Aspirin	3	5	8	8	34	5	206	5
Paracetamol	3	5	9	10	41	10	290	10
Aspirin + Caffeine	0	-	0	-	6	45	77	35
Aspirin + Caffeine + Paracetamol	0	-	0	-	13	40	208	40
Syrup								
Paracetamol	0	-	4	500	44	500	5	400

¹ price data are for the 3 government facilities which reported charging for drugs; the remaining 15 government facilities reported providing drugs for free. If all government facilities were included, the median price was zero for all antimalarials and painkillers.

Source: Outlet Survey Nov-Dec 2001.

Although facility antimalarial prices were generally lower than those in drug stores, total expenditure per patient would in some cases have been higher, as in many facilities consumers paid non-drug fees for registration, consultation, laboratory tests or contributions for kerosene, in addition to fees for drugs. Table 9.2 shows the fee charging practices reported by government and private facilities. No fees were reported by staff at any government facilities in Rufiji, nor at the two health centres in Kilombero and Ulanga. All Kilombero dispensaries reported charging drug and non-drug fees, and all Ulanga dispensaries non-drug fees only. Of these 7 dispensaries in Kilombero/Ulanga, 6 reported providing exemptions to the poor, 5 to the disabled, 2 to under fives, and one each to schoolchildren, the elderly, and the seriously ill. All private facilities

reported charging for drugs, and half reported charging non-drug fees as well. For facilities charging non-drug fees, the median fee for an adult outpatient with fever/malaria was reported to be Tsh 100 in government facilities and Tsh 500 in private facilities (Table 9.2). In addition, patients were required to make the one-off purchase of an exercise book for their health records in 14 of the government facilities and 4 of the private facilities, which cost Tsh 50-100 in local shops.

Table 9.2 Fee charging policies reported by facility staff

	Government facilities	Private facilities
Number of facilities	18	8
Drug fees charged	3	8
Non-drug fees charged	7	4
Median (range) non-drug fees for adult outpatient for fever/malaria where non-drug fees are charged	Tsh 100 (Tsh 50-400)	Tsh 500 (Tsh 200-1100)
Facilities requiring patients to bring exercise book for health records (cost Tsh50-100 in local shops)	14	4

Source: Outlet Survey Nov-Dec 2001

However for government facilities, actual practices documented during the household survey were rather different (Table 9.3). Although no government facility staff reported charging fees in Rufiji, 20% of visits to government facilities were reported by households to have incurred non-drug fees, at 6 different facilities, with a median charge of Tsh 60. Drug fees were not reported by consumers at Rufiji government facilities. However, they were reported in 33% of visits in Ulanga, and 37% in Kilombero, including the health centres in each district, although the Kilombero health centre, and all government facilities in Ulanga, claimed not to charge for drugs. Although patients over five years were more likely to be charged fees than children under five (62% compared with 38%), charging for children was still common, including one facility which stated during the outlet survey that under fives were exempt.

In sum, fee charging policies of facilities were extremely varied and, even where care was officially free, unofficial non-drug and drug fees were commonly charged. However, government drug and non-drug fees paid remained considerably lower than those at private facilities. Non-drug fees in private facilities meant that, of all facility and shop types, the total treatment cost would usually have been highest at these outlets, more than compensating for any higher antimalarial prices in shops. Although government facilities had free drugs, or the cheapest reported drug prices where they charged, this advantage would have been partially or totally cancelled out by the payment of non-drug fees in many cases. Moreover, variability in unofficial charges and exemption implementation was likely to have led to considerable uncertainty among consumers about the full prices they would face.

Table 9.3 Facility fees paid by patients reporting fever/malaria

	Kilombero DSS	Ulanga DSS	Rufiji DSS	Total
Government facility visits				
n ¹	35	30	81	146
Paid drug fees (%)	13 (37%)	10 (33%)	0 (-)	23 (16%)
Paid non-drug fees (%) ²	15 (52%)	14 (50%)	16 (20%)	45 (33%)
Median (range) drug fees (when drug fees charged)	Tsh 200 (60-1150)	Tsh 100 (50-1000)	n/a	Tsh 100 (50-1150)
Median (range) non-drug fees (when non-drug fees charged)	Tsh 100 (50-550)	Tsh 100 (50-250)	Tsh 60 (50-100)	Tsh 100 (50-550)
Private facility visits				
n ¹	19	8	14	41
Paid drug fees (%)	11 (58%)	4 (50%)	1 (7%)	16 (39%)
Paid non-drug fees (%) ³	3 (16%)	1 (17%)	3 (50%)	7 (23%)
Median (range) drug fees (when drug fees charged)	Tsh 220 (50-3000)	Tsh 380 (140-800)	Tsh 1000 (-)	Tsh 380 (50-3000)
Median (range) non-drug fees (when non-drug fees charged)	Tsh 300 (200-400)	Tsh 1500 (-)	Tsh 950 (100-5000)	Tsh 400 (100-5000)

¹ visits to facilities within the DSS areas.

² excludes 6 visits in Kilombero and 2 in Ulanga where respondent did not know if non-drug fees were paid.

³ excludes 8 visits in Rufiji and 2 in Ulanga where respondent did not know if non-drug fees were paid.

Source: Household Survey May-Sep 2001.

The remainder of the chapter assesses prices in drug and general stores in more detail, exploring price setting, sources of variation, and the intensity of price competition. The focus is on retailers because the potential at facilities for cross-subsidisation between drug and non-drug costs complicates the interpretation of drug prices.

Under intense price competition one would expect shopkeepers to perceive themselves as price-takers, retail markups to be low, and prices for given products to be uniform. These three hypotheses are tested below.

9.4 Price Setting in the Retail Sector

This section uses qualitative interview data to investigate how shopkeepers themselves perceived their price-setting behaviour. When asked how they set their retail drug prices, nearly all shopkeepers said they selected prices themselves, based on their wholesale costs. When asked how they chose their retail markups, they said prices were based on those charged by similar shopkeepers, indicating that they viewed themselves as price-takers. They were slightly less sure about the comparability of prices with outlets of other types, but reported that prices were the same for all neighbouring outlets of a given type, even for those located some distance from the main road. Any variation was said to lead to complaints from well-informed, price-sensitive customers.

"If you add a high profit customers will flee and buy elsewhere. If you are any different you will end up with nothing." General shopkeeper #3

Recommended retail prices (RRP) from manufacturers and distributors were rare for drugs, although this practice was common for other products such as cigarettes and soft drinks. RRP were reported for drugs from two neighbouring general stores only, purchased from a mobile distributor, and were never said to be passed on by static wholesalers².

Although shopkeepers generally said retail prices were fixed, they occasionally reported varying the price of drugs, as a function of the quantity purchased (second-degree price discrimination), or the characteristics of the purchaser (third-degree discrimination). Second-degree price discrimination was reported to take place in just over half the shops, either at large general shops where discounts were given to customers buying wholesale for their smaller outlets, or to any retail customer buying several different drugs or many tablets. Some traders said they used the *zawadi* (gift) custom of giving one or two extra tablets, in the way they might for a purchase of tomatoes or sweets. In terms of third-degree discrimination, all drug store interviewees and about half of those in general stores said they gave discounts or free drugs to poor customers. However, it seems likely that social desirability bias influenced these responses, especially as interviewees often only said that they gave such discounts after considerable probing. What is clear is that any third-degree discrimination was *ad hoc*, and for a few isolated cases.

As described above, shopkeepers described a market with a high degree of price competition. If this were the case, one would expect to see uniform prices across retailers, and low retail markups, indicating that prices were close to marginal cost. These hypotheses are investigated below.

9.5 Price Markups in the Retail Sector

Under intense price competition one would expect to find low retail markups. This section evaluates the level of markups using two methods. Firstly, total markups are reported over international reference prices (IRPs), and secondly, retail markups are reported over wholesale costs.

Total markups of average shop prices over IRPs are shown in Table 9.4 and Figure 9.1. IRPs were based on the median supplier price per tablet/capsule from the International Drug Price Indicator Guide, 2001 (Management Sciences for Health 2001). IRP were reported for loose

² other data collection by the author has found that RRP were used to some degree further up the distribution chain.

tablets. As packaging costs vary, a range of 5-25% was added to estimate IRPs for packaged drugs³. Total markups were generally high; only loose chloroquine in drug stores, and loose quinine in general stores, had overall markups under 100%. The retail price for loose SP tablets was almost six times the IRP, and for packaged tablets, 9 to 10 times. For amodiaquine the retail price of packaged and loose tablets was 4 to 6 times the IRP. In several cases we observed local wholesale prices lower than the IRP, e.g. loose chloroquine at a wholesale price of Tsh 3.5 per tablet, compared with an IRP of Tsh 7.1. This may reflect the small number of suppliers included in the IRP estimates⁴. It implies that the drugs stocked came from a cheaper source than those used in the IRP calculation, and total markups were therefore even higher in practice. There is no standard rule of thumb for an appropriate total markup, but Srinivasen argues that a 250% markup over the government tender prices should be seen as "very liberal", and for an off-patent medicine a total markup over IRP greater than 100% has been described as a cause for concern (Srinivasan 1999; WHO & HAI 2003).

Table 9.4 Average total markups in shops (median shop retail price over median IRP)

		IRP per tablet ¹ (Tsh)	Total markup over IRP ²	
			Drug stores	General stores
Antimalarial tablets				
Loose	SP	21.5	599%	599%
	Chloroquine	7.1	40%	111%
	Amodiaquine	13.9	621%	-
	Quinine	25.4	175%	57%
Packaged	SP	22.5-26.8	899%-1089%	-
	Chloroquine	7.5-8.9	-	293%-368%
	Amodiaquine	14.6-17.3	477%-586%	477%-586%
	Quinine	26.7-31.8	214%-274%	-
Painkiller tablets³				
Loose	Aspirin	1.5	238%	103%
	Paracetamol	2.7	273%	273%
Packaged	Aspirin	1.6-1.9	1522%-1831%	1251%-1509%
	Paracetamol	2.8-3.4	496%-610%	1093%-1320%

¹ Loose Tablets: Median supplier price per tablet/capsule, International Drug Price Indicator Guide, 2001; Packaged Tablets: IRP for loose tablets plus 5% - 25% to cover packaging costs; converted using an exchange rate of \$1=Tsh925 (<http://www.oanda.com> for 1st Dec 2001).

² total markup of median retail prices from Outlet Survey over IRP.

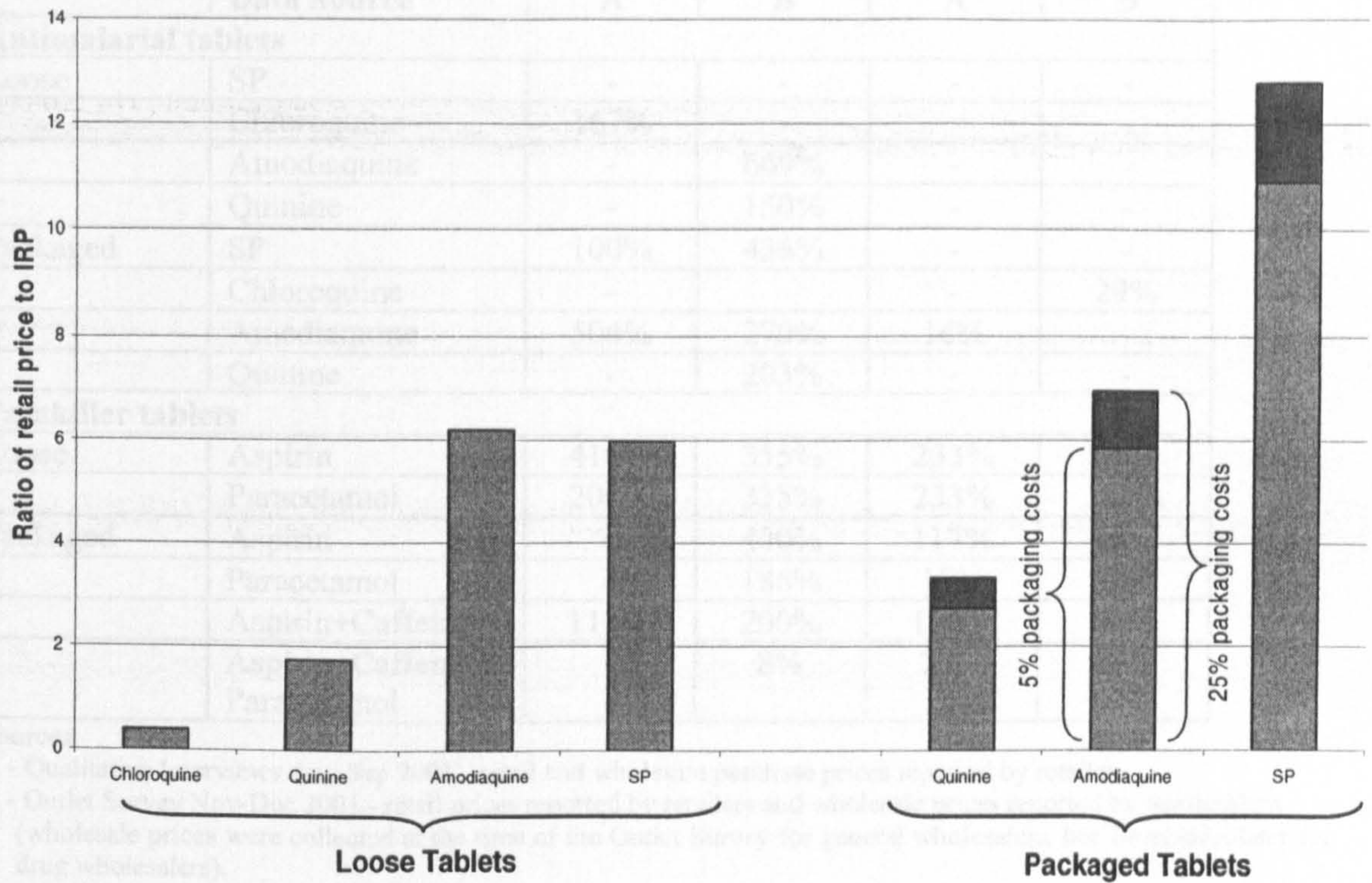
³ IRP were not available for combination painkillers.

Source: Outlet Survey Nov-Dec 2001 and International Drug Price Indicator Guide, 2001

³ pers. comm.: Julie McFadyen, Management Sciences for Health; Ian Boulton, GlaxoSmithKline

⁴ 6 for SP, quinine and paracetamol, 5 for aspirin, 2 for chloroquine, and 1 for amodiaquine

Figure 9.1 Average ratio of retail prices to IRPs for antimalarials in commercial drug shops



Source: Table 9.4

Retail markups form part of total markups and are the component most likely to be influenced by local competitive conditions. Data on retail markups over wholesale prices for common antimalarial and painkiller tablets were assembled from two sources. Firstly, data on wholesale purchase prices and retail sale prices were obtained during qualitative interviews from 9 general stores and 2 drug stores (n=56 products) (Source A). As we found knowledge of wholesale purchase prices to be poor among interviewees, this method was not used for the outlet survey. Instead wholesale prices were collected from wholesalers, and retail prices from retailers, and median wholesale and retail prices compared (Source B). Data collection from 11 general sub-wholesalers, which mainly supplied general stores, was undertaken at the time of the outlet survey (n=50 wholesale price observations). Data collection from drugs wholesalers (mainly supplying drug stores) was delayed for logistical reasons and did not take place until September/October 2002 (8 drugs wholesalers; n=200 wholesale price observations). The delay of 10 months between retail and wholesale price data collection makes estimation of these markups less robust.

Table 9.5 Average retail markups over wholesale drug costs in shops

		Drug Stores		General Stores	
Data Source		A	B	A	B
Antimalarial tablets					
Loose	SP	-	-	-	-
	Chloroquine	167%	-	-	-
	Amodiaquine	-	669%	-	-
	Quinine	-	150%	-	-
Packaged	SP	100%	436%	-	-
	Chloroquine	-	-	-	29%
	Amodiaquine	504%	270%	16%	-
	Quinine	-	203%	-	-
Painkiller tablets					
Loose	Aspirin	410%	355%	233%	67%
	Paracetamol	208%	335%	233%	100%
Packaged	Aspirin	-	400%	117%	16%
	Paracetamol	-	186%	17%	18%
	Aspirin+Caffeine	118%	200%	106%	33%
	Aspirin+Caffeine+Paracetamol	-	8%	25%	40%

Sources:

A - Qualitative Interviews Aug-Sep 2001 - retail and wholesale purchase prices reported by retailers

B - Outlet Survey Nov-Dec 2001 - retail prices reported by retailers and wholesale prices reported by wholesalers

(wholesale prices were collected at the time of the Outlet Survey for general wholesalers, but 10 months later for drug wholesalers).

It is clear from Table 9.5 that retail markups were highly variable within shop type, both across data sources and across drugs. There was no evidence of a standard percentage markup, and in fact markups appeared quite *ad hoc*, with no indication that there was a systematic difference between antimalarials and painkillers. In general, retail markups were high. The majority of drugs had retail markups of more than 50% over wholesale prices, and for two-thirds the estimates exceeded 100%. There was an indication that markups were higher in drug stores, with a mean estimate for drug stores across data sources of 312% for antimalarials and 278% for painkillers, compared with 23% and 84% respectively in general stores. One drug store had markups of 233% for chloroquine tablets, 300% for quinine injections, and 669% for aspirin tablets. As with overall markups, there is no standard appropriate retail markup, but as a point of reference, gross retail markups averaged 25% in the US during much of the 20th-century (Larson and Rosen 2002). A request on the e-drug listserv for information on retail markups elicited responses for developing countries of between 25% and 50% as the level recommended by pharmaceutical companies or governments⁵.

There are a number of possible explanations for these high markups. It is possible that they reflected high overhead costs such as staff salaries, transport, buildings and taxes, and were not necessarily indicative of high profit margins. It was not possible to collect such overhead data, but the above comparisons with rules of thumb for total and retail markups indicate that

⁵ E-drug listserv archive: <http://www.essentialdrugs.org/edrug/archive/200301/msg00012.php>

markups were probably far in excess of overhead costs, even if such costs were relatively high in these remote areas. High markups may reflect a lack of competition due to high local market concentration. As demonstrated in Chapter 7, in terms of private sector antimalarial sales all sub-markets could be considered as "highly concentrated" on the basis of the HHI, and some areas were close to a monopoly situation.

Higher markups in drug stores than in general stores might have reflected higher overhead costs, or the lower wholesale prices drug stores could obtain from drugs wholesalers in Dar es Salaam, which were not passed on to consumers. Drug stores may also have had the ability to charge higher retail prices because of market power derived from product differentiation in outlet or drug characteristics.

All but one interviewee firmly rejected explicit price collusion.

"There is no cooperation or debate amongst us on this. Everyone sets his own price." General shopkeeper #3

However, it is possible that higher markups reflected implicit collusion, with sellers unwilling to antagonise their fellow businessmen, or start a price war. This was suggested by the observation that many interviewees were uncomfortable discussing other shopkeepers as "competitors", which appeared to have negative, aggressive connotations, preferring to use the more neutral term "fellow sellers".

Two other factors were mentioned during qualitative interviews, which might have made prices "sticky" downwards. Several shopkeepers said they could not make minor price reductions because change was not available in denominations under Tsh 5. One seller also remarked that consumers might see a price below the market rate as a signal that there was something wrong with the drugs.

9.6 Retail Price Variation

In a market characterised by strong price competition one would expect uniform prices for given products. This section explores the degree of price variation across given products in shops. For each common antimalarial, Table 9.6 shows the total price range in drug shops, interquartile range (IQR) and quartile coefficient of variation, a non-parametric dispersion measure standardised by absolute price⁶ (Owen and Jones 1990). The evidence indicates considerable variation in price for each drug category, with for example the price of a child's dose of

⁶ Quartile coefficient of variation = $50 \cdot \text{IQR} / \text{Median}$

packaged SP tablets ranging from Tsh 167 to Tsh 750, and of packaged amodiaquine tablets from Tsh 100 to Tsh 400.

Table 9.6 Price dispersion for antimalarial tablets in drug shops (child's dose in Tsh)

		n ¹	Median	Range	IQR	Quartile coefficient of variation ²
Loose	SP	9	150	100-300	50	17%
	Chloroquine	10	20	20-20	0	0%
	Amodiaquine	12	200	100-300	200	50%
	Quinine	9	770	550-1100	330	21%
Packaged	SP	52	268	167-750	200	37%
	Chloroquine	0	-	-	-	-
	Amodiaquine	19	200	100-400	0	0%
	Quinine	13	1100	660-2640	220	10%

¹ number of products identified.

² Quartile coefficient of variation = 50*IQR/Median.

Source: Outlet Survey Nov-Dec 2001

There are a number of possible explanations, including geographical segmentation, and weak price competition due to product differentiation or imperfect information. While geographical segmentation may well have played a part, considerable variation remained among shop prices within each sub-market, with for example ranges for packaged SP of Tsh 167-350 in Mchombe Area, and Tsh 200-750 in Ikwiriri Area.

One might expect higher price variation for products that are relatively new to the market or with small market shares, with variation decreasing as they become more established in the market, and as the intensity of price competition increases. Chloroquine which was historically the most established antimalarial was sold at a uniform price, which might suggest that SP dispersion would decrease over time as it became established as the new first line.

The influence of product and outlet characteristics on drug prices is explored in Section 9.7 below. However, some variation in price remained even if the same brand in the same packaging was considered in the same sub-market and outlet type. For example, five sub-markets had more than one observation in drug shops for packaged OrodarTM, the most popular SP brand, but in three of these the price varied between drug shops, for example between Tsh 167 and Tsh 200 in Mchombe Area. The price for the two most popular painkillers, loose unbranded aspirin and loose SheladolTM (paracetamol) tablets in general stores varied in 7 of the 12 sub-markets, for example in Kibiti between Tsh 2.5 and Tsh 5 per tablet for aspirin and Tsh 5 and Tsh 10 for SheladolTM. Such residual variation could have reflected unobserved outlet differentiation, changes in wholesale prices over time, or imperfect information and/or price insensitivity on the part of consumers.

9.7 Regression Analysis of Retail Prices

Tables A1.16 and A1.17 in Annex 1 provide bivariate analysis of antimalarial and painkiller drug prices, and a range of outlet and product characteristics. Antimalarial prices tended to be higher for packaged products than loose tablets, and there was a premium attached to innovator brands of SP over branded generics. Imported drugs tended to be more expensive, and for SP and quinine, prices were higher for those from Europe. Some similar patterns were observed for painkillers. For aspirin and paracetamol tablets, prices were higher for packaged products and for branded generics compared to unbranded ones. Prices for combination painkillers were higher in rural villages than in market centres.

The interpretation of this bivariate analysis is complicated by the considerable correlation between drug and outlet characteristics (e.g. packaged antimalarials were significantly more likely to be found in Rufiji than in Kilombero or Ulanga). This makes it difficult to assess the relative importance of different factors, or the magnitude of their marginal impact. The influences on prices charged for antimalarials and painkillers by drug and general stores were therefore explored using regression analysis.

An OLS log-lin regression model for the price of a child's dose of antimalarial tablets is specified in Table 9.7. The dependent variable was logged to reflect the skewed nature of price distribution. It was regressed on the generic drug type, type of packaging, country of manufacture, brand status, DSS area, outlet type and outlet location, and market concentration as measured by the HHI for private outlets in the sub-market (Table 9.8)⁷. The `svyregress` command was used to allow for clustering of drug prices within shops, and the stratification of the sample between the two DSS systems of Kilombero/Ulanga and Rufiji.

⁷ The HHI is calculated from retail audit data collected in 2002, 2-8 months after the price data used as the dependent variable.

Table 9.7 Definition of variables for model of the price of antimalarial and painkiller tablets in shops

Variable	Definition	Means for antimalarial regression	Means for painkiller regression
Dependent variables			
Log_price_AM	Log of price for child's dose of antimalarial tablets (Tsh)	5.29	
Log_price_PK	Log of price per painkiller tablet (Tsh)		2.72
Independent continuous variables			
Antimalarial market concentration: HHI	Hirschman-Herfindahl index for antimalarial sales value by sub-market, for all private sector sales	0.38	0.43
Independent dummy variables			
Antimalarial type: Chloroquine (omitted) Amodiaquine Quinine SP	=1 if antimalarial is chloroquine =1 if antimalarial is amodiaquine =1 if antimalarial is quinine =1 if antimalarial is SP	0.22 0.24 0.14 0.40	
Painkiller type: Aspirin (omitted) Paracetamol Asp+Caf Asp+Caf+Par	=1 if painkiller is aspirin =1 if painkiller is paracetamol =1 if painkiller is aspirin+caffeine =1 if painkiller is aspirin+caffeine +paracetamol		0.28 0.38 0.09 0.25
Type of packaging: Loose (omitted) Packaged	=1 if tablets are sold loose =1 if tablets are sold packaged	0.31 0.69	0.45 0.55
Country of Manufacture ¹ : Tanzania (omitted) Other_africa Asia Europe	=1 if manufactured in Tanzania =1 if manufactured in another African country =1 if manufactured in Asia =1 if manufactured in Europe	0.37 0.40 0.08 0.15	
Brand Status: Unbranded_generic (omitted) Innovator Branded_generic	=1 if unbranded generic =1 if innovator brand =1 if branded generic	0.25 0.09 0.66	0.26 0 0.74
DSS area: Kilombero (omitted) Ulanga Rufiji	=1 if in Kilombero DSS area =1 if in Ulanga DSS area =1 if in Rufiji DSS area	0.29 0.07 0.64	0.22 0.14 0.64
Outlet Type: Drug store (omitted) General_store	=1 if outlet is a commercial drug store =1 if outlet is a general store	0.79 0.21	0.11 0.89
Outlet location: Market_centre (omitted) Rural_village Farming_area	=1 if outlet is in market centre =1 if outlet is in rural village =1 if outlet is in farming area	0.55 0.43 0.02	0.32 0.60 0.08

¹ Country of manufacturer data were not collected for painkillers.

Source: Outlet Survey Nov-Dec 2001, HHI from Retail Audits Feb/Apr & Jun/Jul 2002.

Table 9.8 OLS log-lin regression of antimalarial and painkiller tablet prices for shops

Explanatory variables	Antimalarials ¹ n=154; F<0.0001; R ² =0.9057			Painkillers n=875; F<0.0001; R ² =0.9376		
	Coefficient	Standard Error	p-value	Coefficient	Standard Error	p-value
HHI	1.017	0.325	0.003*	0.023	0.052	0.660
Amodiaquine	1.711	0.139	<0.001*			
Quinine	3.497	0.140	<0.001*			
SP	1.939	0.124	<0.001*			
Paracetamol				0.463	0.048	<0.001*
Asp+Caf				0.353	0.574	<0.001*
Asp+Caf+Par				0.559	0.050	<0.001*
Packaged	0.381	0.092	<0.001*	1.651	0.047	<0.001*
Other_africa	-0.141	0.105	0.184			
Asia	-0.031	0.151	0.840			
Europe	0.103	0.139	0.460			
Innovator	0.555	0.167	0.002*	-	-	-
Branded_generic	0.159	0.104	0.129	0.240	0.058	<0.001*
Ulanga	-0.322	0.156	0.044*	0.029	0.042	0.489
Rufiji	0.117	0.091	0.200	-0.362	0.030	<0.001*
General_store	0.388	0.129	0.004*	-0.201	0.057	0.001*
Rural_village	0.076	0.087	0.386	0.004	0.025	0.859
Farming_area	-0.344	0.181	0.063	0.060	0.051	0.238
_cons	2.670	0.153	<0.001*	1.672	0.064	<0.001*

¹Five observations were dropped because of missing data on country of manufacture or tablet size.

* coefficient significant at 5% level.

Source: Outlet Survey Nov-Dec 2001.

The antimalarial model had an R² of 0.9. Antimalarial prices were significantly affected by HHI, generic type, packaging, brand status, DSS area and outlet type. Compared with a baseline of chloroquine tablets, a child's dose of amodiaquine had a mean price 1.7 times higher, SP 1.9 times higher and quinine 3.5 times higher. Being sold from a general store rather than a drug store increased the price by 39%. Packaging increased the price by 38% compared with loose tablets. The price of innovator brands was 55% higher than unbranded generics, and innovator brands were also significantly more expensive than branded generics (F test: p=0.035). Prices in Ulanga were significantly lower than in Kilombero (p=0.044) or Rufiji (p=0.009). Country of origin and location type were not significant. Higher market concentration led to higher prices, with a 0.1 increase in the HHI leading to a 10% increase in antimalarial prices. However, it is possible that the HHI may have been correlated with remoteness, and that higher prices in more concentrated areas reflected higher transport costs rather than less intense competition. This was difficult to assess as all the sub-markets contained some areas on and off main roads.

A similar model for the price of the most common painkiller tablets in private outlets is also specified in Table 9.7, with results presented in Table 9.8. In the absence of a measure of market concentration for painkillers, that for antimalarials was used. The R² was 0.94. Painkiller prices were significantly affected by generic type, packaging, brand status, outlet type and DSS area. Compared with a baseline of aspirin, the mean price of paracetamol was 46% higher,

aspirin+caffeine 35% higher and aspirin+paracetamol+caffeine 56% higher. Packaging increased the price by 165%, and prices of branded generics were 24% higher than those for unbranded products. Prices were significantly lower in Rufiji DSS than in Kilombero and Ulanga (F test: $p < 0.0001$). In contrast to antimalarials, painkiller prices in general stores were significantly lower than in drug stores by 20%.

The HHI for antimalarial sales did not have a significant impact on painkiller prices, which was not surprising as painkillers were much more widely available through general stores than antimalarials, and market concentration was therefore likely to differ for the two groups of drugs.

9.8 Summary and Conclusions

This chapter has assessed the price of antimalarial and painkiller drugs across provider types, and analysed the degree of price competition faced by retailers. Government facilities had the cheapest drug prices, and antimalarial prices tended to be higher at drug stores than at private facilities. Total expenditure at government and private facilities was increased by non-drug fees, which were highly variable across facilities. Unofficial drug and non-drug fees were commonly charged where care should have been free. The provision of exemptions appeared *ad hoc* and haphazard. Once fees were included, government facilities may no longer have been cheaper than drug and general stores. Private facilities were likely to be the most costly source of care.

Although retailers argued that they faced stiff competition on price, this was not backed up by analysis of prices. There was considerable evidence of both high retail markups, and price variation for given products, features of a market characterised by weak price competition.

A number of potential explanations are proposed, including geographical segmentation, high concentration, imperfect consumer information, and collusion. It is not possible to draw firm conclusions on the sources of weak price competition, but in statistical analysis, higher prices were linked to market power arising from product differentiation, differentiation by outlet type, and for antimalarials, the level of market concentration.

CHAPTER 10

RETAIL REGULATION

10.1 Introduction

The third objective of the thesis, to assess the impact of government regulation on the operation of retailers, is addressed in this chapter.

Shops were regulated for both business and health-related purposes. Business regulation was undertaken by district authorities for large shops, or village authorities for small shops and stalls. Business regulation encompassed approving the operation of the outlet, granting business licences, and collection of a range of taxes. Health-related regulation had two components. Firstly, all retailers should have been inspected regularly by an environmental health officer, generally a health assistant based at the local health centre. Their remit was to approve the outlet premises, and inspect the safety and appropriate storage of products, including expiry dates on drugs and foodstuffs. In addition, drug stores fell under the jurisdiction of the Pharmacy Board, and the 1978 Pharmaceuticals and Poisons Act. They were required to obtain a Pharmacy Board permit each year from the Regional Commissioner, and to meet certain specific conditions, related to the premises, qualifications of the seller and products stocked (Ministry of Health 1998). Drug shops should have been inspected on a quarterly basis by an appointed representative of the Pharmacy Board.

Drug stores were permitted to stock only Part II drugs and basic medical supplies. Part II drugs were over-the-counter medicines, so classified because they were relatively safe, used for minor and self-limiting conditions, and their use was well understood by the public. Part I (prescription-only) drugs were not permitted. This category included painkillers such as diclofenac, indomethacin and nimesulide; antimalarials such as artesunate and quinine; all non-topical antibiotics; and injectables of any kind. The legal position on the drugs that general stores could stock was unclear because they were not covered under the 1978 Pharmaceuticals and Poisons Act. Discussions with staff responsible for drug regulation at a national and regional level indicated that strictly general stores were not allowed to stock any drugs, but in practice were permitted to sell some over-the-counter medicines, such as common painkillers. Chloroquine was generally permitted when it was the first line antimalarial, and one might therefore expect SP to be permitted following the change in policy.

All Part II medicines were required to be sold in unit packs, accompanied by the manufacturer's instructions for use. In addition, all imported drugs were required to be registered with the

Pharmacy Board (locally manufactured drugs were exempt from registration at the time of data collection). There was no regulation on drug pricing. The health-related regulation of retailers was a purely government activity, with no role taken by professional or consumer organisations.

This chapter begins by assessing regulatory compliance at drug and general stores. In Section 10.2 the coverage of business licences is assessed. This element of business regulation was investigated because of its potential importance for identifying retailers that could be involved in fever/malaria treatment interventions in the future. Compliance with health-related regulation is considered in Section 10.3. The regulations investigated were selected as those most likely to affect the quality of fever/malaria treatment, and the potential for future collaboration or interventions. In drug stores this covered the presence of a Pharmacy Board permit, and the qualifications of selling staff. In all retailers, infringements of regulations on drugs stocked were assessed, in terms of the stocking of Part I drugs, unpackaged tablets, and unregistered or expired antimalarials. The assessment draws mainly on outlet survey data, supplemented by information from the outlet censuses, household survey and retail audit. Finally, data from qualitative provider interviews are used to assess the extent of drug leakage from government facilities.

Widespread infringements of a number of regulations are demonstrated below, the most ubiquitous being the stocking of Part I medicines in drug stores. Understanding why this takes place has the potential to shed light on implementation by regulatory staff, the response to regulation by shopkeepers, and the relationship between regulators and regulatees. The reasons for this infringement are therefore explored in Section 10.4, which uses data from the outlet survey and qualitative interviews to assess possible explanations, covering poor knowledge of regulations, lack of inspections, lack of sanctions, successful concealment of Part I products, and tacit permission by regulatory staff.

10.2 Business Licences

All drug stores were required to have a business licence from the District authorities, renewed annually and displayed in the shop. During the outlet survey 4 drug shops (13%) had no licence, 3 of which were new start-ups, having opened within the previous year. The median fee paid by drug stores for business licences was Tsh100,000 per annum (US\$108).

As licence fees vary depending on stock value, they were on average much lower at general stores, where the median was Tsh20,000 per year (\$22), although it ranged between Tsh8000 and Tsh200,000 (US\$9-\$216). Of the general stores stocking drugs, 49% said they were licensed. General retailers were significantly less likely to be licensed if they were located in

farming areas (8%, chi² test with Rao and Scott correction, p<0.001). The lack of a licence did not necessarily imply that they were operating illegally. General retailers are divided into two groups for the purpose of business regulation: *dukas* (larger shops) which are required to be licensed, and *genges* (smaller shops or stalls), which can operate unlicensed with the permission of the Village authorities. During qualitative interviews, many unlicensed retailers expressed concern about being reclassified as a *duka* because of the higher taxes and licence fee. The level of tax paid and classification between *duka* and *genge* were blurred and involved considerable negotiation with Village and District officials. Interviewees variously suggested the defining characteristics of *dukas* as that they had more goods, a permanent structure, used weighing scales, or sold manufactured goods (which would imply that *genges* could not officially stock drugs). General shops stocking antimalarials, or cloth/garments were significantly more likely to be licensed (83% and 70% respectively, p<0.001). However 20% of those one would expect to be categorised as *dukas* because they stocked cloth/garments and had permanent roof and wall structures remained unlicensed, suggesting that a significant minority evaded this regulation. However, it appeared unlikely that any shop could operate completely without the knowledge of the authorities for long; as a *genge* owner explained, the sub-village chairman would know all the outlets operating in his area.

10.3 Health-Related Regulation

Violations of a range of regulations are assessed below, related to Pharmacy Board permits and staff qualifications in drug stores, and to drugs stocked by all retailers (Table 10.1).

Table 10.1 Infringement of health-related regulation
(% of shops infringing regulations)

	Drug shops (n=30)	General shops (n=213)
Pharmacy Board permit not displayed	11 (37%)	
Regular selling staff not appropriately qualified ³	30 (100%)	
Stocked Part I painkillers	16 (53%)	0 (-)
Stocked Part I antimalarials ¹	27 (90%)	3 (1%)
Stocked unregistered imported antimalarials ²	19 (63%)	2 (1%)
Stocked loose painkillers	29 (97%)	195 (92%)
Stocked loose antimalarials	22 (73%)	7 (3%)
Stocked expired antimalarials	4 (13%)	3 (1%)

¹ excluding oral chloroquine formulations.

² excluding all chloroquine formulations.

³ defined as having less than 4 years medical training.

Source: Outlet survey Nov/Dec 2001.

Drug store permits

In addition to a business licence, drug stores required a permit issued annually by the Pharmacy Board, at a cost of Tsh10,000 (US\$11). Such permits were displayed in only 19 drug stores (63%). Of the 9 drug stores with permits in Kilombero and Ulanga, 2 were out-of-date, and in 7

shops the registered seller specified on the permit was not working there¹. During a qualitative interview, an owner explained that it was easier to get a renewal if you did not change the names of the owner or seller.

Drug store staff qualifications

Drug store serving staff were required to have a “basic knowledge of pharmaceutical science, medical science, veterinary science, agricultural science or to be a dispenser approved by the Pharmacy Board” (Ministry of Health 1998). In a meeting with the Regional Pharmacist for Morogoro, he interpreted this to mean a minimum of four years training (e.g. nurse, pharmacy assistant). However during the outlet survey, none of the 37 regular serving staff had such qualifications, and the median years of health training was one year.

Stocking of Part I medicines

Neither drug stores nor general shops were permitted to stock any Part I drugs. However, outlet survey data showed that stocking of Part I medicines was very common in drug stores, with 53% stocking Part I painkillers, and 90% Part I antimalarials². By contrast this was very rare in general stores. None stocked Part I painkillers, and only 3 stocked Part I antimalarials (1%), all of which were located in Kilombero, 2 in farming areas, and one in a village. Data on antibiotics were not collected during the outlet survey, but outlet census data from mid-2001 showed they were stocked by 92% of drug stores and 11% of general retailers stocking drugs. These rates of stocking Part I products should be considered as minimum estimates: while Part I products were sometimes openly displayed, they were usually concealed from view in a side room or in a box under the counter and interviewees may not always have revealed their presence during the survey. The illegal stocking patterns in drug stores were also reflected in household survey data, which showed, for example, that patients reporting fever/malaria obtained injectable antimalarials at 5% of drug store visits and antibiotics at 13% (Table 6.5).

Stocking loose tablets

According to the regulations, all drugs sold in shops should be in “unit packs” i.e. packaged as single doses. However, the sale of loose tablets from pots was found to be widespread during the outlet survey, with 97% of drug stores and 92% of general stores selling loose painkillers, and 73% of drug stores and 3% of general stores selling loose antimalarials. Retail audit data showed that packaged drugs made up only 39% of antimalarial sales volumes in general stores and 19% in drug stores (Table 6.10).

¹ the Rufiji permits did not display these details.

² oral chloroquine formulations were not included in Part I products for these estimates because they had been removed from the Part II list only 3–4 months before the survey, and shops were still using up their remaining stocks during this transition period.

Stocking of unregistered imported antimalarials

Stocking of imported antimalarial brands unregistered in Tanzania was also common. Unregistered imported antimalarials were found in 63% of drug shops and 1% of general stores, including unregistered brands of SP tablets and syrup, amodiaquine tablets and syrup, quinine tablets and artesunate tablets³.

Stocking expired antimalarials

Expired antimalarials were found in 4 drug shops (13%) and 3 general stores (1%). Each shop had only one expired product, representing 3% of all retail antimalarial products; for a further 3% of products no expiry date was shown. However, expired antimalarials were not found only in shops; while none were observed in private facilities, they were found in 26% of government facilities, accounting for 5% of all antimalarial products in government stocks.

The remaining shelflife of unexpired antimalarials was also investigated, showing that 21% of products in general stores were within one year of their expiry date, but only 3% in drug stores (Table 10.2). Time since manufacture is also potentially important, particularly as new antimalarials may have a shorter shelflife, such as the two years for artemether-lumefantrine. Only 2% of antimalarials in drug stores had been manufactured more than two years previously, but this was much more common in general stores (29%).

Table 10.2 Shelflife of antimalarial products (all formulations)
(% of antimalarial products in each shelflife category)

	Drug shops (n=208 products)	General shops (n=38 products)
Time to expiry:		
Expired	4 (2%)	3 (8%)
=<1 year	6 (3%)	8 (21%)
>1 year	191 (92%)	26 (68%)
Not shown	7 (3%)	1 (3%)
Time since manufacture:		
>2 years	5 (2%)	11 (29%)
=<2 years	177 (85%)	19 (50%)
Not shown	26 (13%)	8 (21%)

Source: Outlet Survey Nov/Dec 2001.

Leakage of drugs from government facilities

A form of illegal behaviour much discussed by researchers and commentators working in the region is the leakage (i.e. theft and illicit sale) of drugs from government health facilities to private shops. During qualitative interviews, the majority of interviewees said they had never come across such behaviour, although this was obviously a sensitive area, where they could have had strong incentives to conceal information. One general shopkeeper said that because

³ excluding all chloroquine formulations as they were not included in the new registration system.

government health facilities ran out of drugs quickly, some people might erroneously assume that the drugs had been stolen when this was actually due to genuine shortage. Such suspicions had affected another general shopkeeper who had started to sell syringes because the local dispensary had such frequent stockouts but had been forced to stop because local people suspected they had been leaked from the dispensary.

Three interviewees reported having heard of specific incidents of leakage, including one general shopkeeper who had been offered drugs himself by a health worker from the local dispensary. He said he had refused, noting that he would have been in danger of being caught because the logo of the government's drugs might have been recognised, and he would not have had receipts for their wholesale purchase.

No direct evidence of leaked drugs was observed during data collection, but it would have been difficult to detect, as many government drugs were not labelled with the Government or Medical Stores Department (MSD) logo on the packet or tablet. This leads to the tentative conclusion that drug leakage was not an everyday occurrence, but may have taken place from time to time.

Perhaps a more common financial relationship between facilities and shops was the referral of patients by health care staff to shops for drug purchase. Although in some cases this reflected actual stockouts at government facilities, during qualitative interviews many customers were observed coming with *cheti* from the local government health centre for SP, while independent sources reported that the health centre still had SP in stock. Possible explanations could be conservation of drug supplies by government health workers for particular groups of patients, or arrangements between health workers and drug store owners in order to increase the business of the latter, but in the absence of more detailed investigation it was not possible to draw firm conclusions.

10.4 Explaining Infringements of Pharmaceutical Regulation

The potential causes for these frequent infringements of health-related regulations are explored below, particularly the stocking of Part I medicines in drug stores, to assess whether this could be attributed to poor knowledge of regulations, lack of inspections, lack of sanctions, successful concealment of products, or the tacit permission of inspectors.

Knowledge of regulations

Poor knowledge of regulations was reflected in the considerable confusion among shop staff about which drugs they were allowed to stock. At that time, chloroquine had been withdrawn,

yet more than half the drug store staff still thought they could stock chloroquine (Table 10.3). Of drug shop interviewees, 90% knew they were allowed SP. For general shop interviewees, the percentages who thought they could stock chloroquine or SP were both low, reflecting the general confusion about the legality of general store antimalarial sales.

Table 10.3 Shop interviewee knowledge of whether they were allowed to stock chloroquine and SP¹

(% of interviewees believing they could stock specified drug)

	n	Chloroquine			SP		
		Yes	No	Don't know	Yes	No	Don't know
Drug shops	30	18 (60%)	8 (27%)	4 (13%)	27 (90%)	2 (7%)	1 (3%)
General stores	236	17 (7%)	175 (74%)	44 (19%)	15 (6%)	165 (70%)	56 (24%)

¹ At the time of the study chloroquine had been withdrawn; SP was allowed in drug shops, and the legal position was unclear for general stores.

Source: Outlet survey Nov/Dec 2001.

Confusion was also evident during qualitative interviews. Most general shopkeepers were vague about the drugs they could stock, generally suggesting that they were allowed painkillers, first-aid, or *baridi* drugs, but not antibiotics or strong medicines. All drug store sellers knew they were only allowed to sell *baridi* drugs but they were not clear which products this included. *Baridi* is the KiSwahili term used informally for over-the-counter Part II products. It literally means cool or cold, or could be translated as weak or mild. When asked what they understood by *baridi*, no shopkeepers interpreted it to mean specifically over-the-counter or non-prescription. Some said it meant drugs that were for first-aid, or were not powerful or poisonous/harmful. Others said they were termed *baridi* because they cool down the patient's fever, were not bitter tasting (chloroquine is very bitter), or did not need refrigeration (being already cold!). Staff knew that common painkillers were *baridi*, and that antibiotics were prohibited, but were unclear on the status of antimalarials:

"They're not antibiotics, so that's OK isn't it?" Drug store seller #16

While some of the drug store staff had copies of the Pharmacy Board regulations (often outdated), none of the general shopkeepers had any written regulations on which drugs were allowed, and new shopkeepers tended to just copy the stocking patterns of similar shops.

"I just trusted because I saw them being sold in other shops and so I also bought them." General shopkeeper #5

This confusion may explain to some degree the widespread availability of oral quinine, although one would expect any Part I products to have been removed during inspections. Furthermore, antibiotics were widely stocked, although all sellers knew they were prohibited.

Frequency of regulatory inspection

Both drug stores and general stores were supposed to receive regular environmental health inspection visits from the Ward Health Assistant, known locally as "*Bwana Afya*" (literally "Mr Health"). During qualitative interviews the main concerns of *Bwana Afya* were said to be the cleanliness of the shop, building conditions, food storage, and expiry dates for products including drugs. They were not reported to have any other drug-related role.

Environmental health inspections were reported to take place quite regularly in general. In the outlet survey, over three-quarters of drug shops and general stores recalled being visited by *Bwana Afya*, and this percentage did not vary across DSS areas (Table 10.4). Of interviewees who recalled the date of the visit, 35% reported a visit in the last three months, 56% within the last six months, and 68% within the last year. Shops were significantly less likely to recall a visit if they were located in farming areas (54%), if their roof was constructed from temporary materials (56%), or if the outlet was categorised by interviewers as "poorly built" (62%), or "dirty" (33%). It was unclear whether inspectors were less likely to visit these less formal outlets, or whether the poor standards of building and cleanliness were the outcome of a lack of environmental health inspection.

Table 10.4 Regulatory inspection: visits by Environmental Health and Drug Inspectors recalled by interviewees
(% of interviewees recalling any visit)

	Environmental Health Inspectors		Drug Regulatory Inspectors	
	n ¹	Ever visited (%)	n ¹	Ever visited (%)
Drugs shops	29	22 (76%)	30	24 (83%)
General stores	223	172 (77%)	227	12 (5%)

¹ variations in n reflect the number of interviewees able to supply the relevant information.

Source: Outlet survey Nov/Dec 2001.

In addition to visits from *Bwana Afya*, drug stores should have received drug regulatory inspections on a quarterly basis. In the study sites responsibility for these inspections was delegated to the District Health Management Teams (DHMT). The inspectors reportedly looked for prohibited products, as well as checking drug expiry dates, the permit, and the competence of the seller. 83% of drug shop interviewees recalled such a visit (94% in Rufiji, 78% in Kilombero, but neither interviewee in the two drug stores in Ulanga DSS). Of the drug shops

where the interviewee recalled the date of the visit, 15% reported a visit in the last three months, 56% within the last six months, and 70% within the last year⁴.

No clear patterns were detected to indicate that either type of regulatory inspection had a constraining impact on regulatory violations. There were no significant relationships between the frequency of visits by *Bwana Afya* or drug inspectors and the probability of outlets stocking Part I drugs, unregistered antimalarials, expired antimalarials, loose antimalarial or painkiller tablets, or lacking a pharmacy board permit⁵.

Imposition of sanctions

In theory a failure to comply with regulations could lead to the outlet being fined or closed down. During the outlet survey, 5 of the 30 drug store interviewees said that inspectors had reprimanded them for stocking Part I drugs during their most recent visit; in two stores such drugs had been confiscated, and one store had been fined. At the time of the study the maximum fine for drug stores was still set at the nominal level fixed at the time of the 1978 Pharmaceuticals and Poisons Act of Tsh5,000 (\$5). During qualitative interviews, none of the interviewees knew of specific examples of shops being closed down. In sum, it appeared that the penalties of being caught were low because no heavy sanctions were implemented, and the cost of confiscation of a few bottles of antibiotic syrup was small compared with the profits to be made from selling these high-value and popular products.

Concealing Part I products

Widespread stocking of Part I drugs could have reflected inspectors' imperfect information about retailer operation. However, although sellers hid some Part I drugs, their availability was well-known, particularly by customers, and presumably by inspectors, who were also local District residents.

"I sell them (antibiotics) via the back door, and they know that we sell via the back door. In fact you can tell someone openly that you sell them." Drug store owner #10

⁴ for Kilombero the frequency of inspection over the previous six months may have been higher than usual. The District Medical Officer informed us that between May and October 2001 Pharmacy Board officials from Dar es Salaam visited Ifakara twice to look for counterfeit drugs and Part I products. Such visits were extremely unusual.

⁵ the lack of statistical significance may reflect the small sample sizes of only 31 drug stores and 30 general stores stocking antimalarials.

Tacit permission

It is possible that there was an element of regulatory capture. Of the 30 drug stores, 10 owners had jobs in the formal health sector, the majority being health-care workers at local government facilities. Inspectors may also have been personal acquaintances of shop staff, as in this case:

"When they come I know how to deal with them.....I know the Regional Pharmacist, I know the District Pharmacist well. We have eaten *ugali* and beans together....." Drug store owner #10

Perhaps more importantly, inspectors may have given their tacit permission, recognising that shops met a genuine need in communities without Part I pharmacies, in particular acting as a reserve drug source for government facilities. As one seller noted:

"I normally have (cotrimoxazole⁶) syrup because it is prescribed to many people and it is not available in the health centre." Drug store seller #9

Finally, inspectors may have recognised that eliminating such a widespread and popular practice would have been infeasible. As one drug store owner said:

"They should make changes because they forbid things which cannot be forbidden. For instance, they say Part II drug stores should not sell antibiotics, but the truth is that people are selling them and they are bought a lot." Drug store owner #10

10.5 Summary and Conclusions

The health-related regulatory infringements investigated were relatively uncommon in general stores, with the exception of stocking loose tablets. General stores very rarely stocked Part I medicines, or unregistered or expired antimalarials, reflecting the low frequency of antimalarial stocking in these outlets in general. However, only around half of general shops were licensed, possibly limiting the potential for interventions or collaboration with these retailers; some were too small to require a licence, but others appeared to have evaded the regulation.

Although most drug stores had business licences, infringement of health-related regulation was extremely common in these outlets. Many lacked Pharmacy Board permits and several others had permits which were invalid in some way. It was the norm for drug stores to stock Part I medicines and loose tablets, most stocked unregistered products, and a minority had expired antimalarials. All drug store serving staff were underqualified.

⁶ Part I antibiotic

Potential explanations for widespread infringement of the regulations concerning Part I drugs were investigated. Knowledge of regulations was quite poor, but it was well-known that certain Part I products, such as antibiotics, were prohibited. It appeared more likely that infringement reflected a combination of relatively infrequent regulatory inspections, a failure to ever implement heavy sanctions, successful concealment of Part I products by drug store staff during inspections, and the tacit permission of local regulatory staff.

The implications of these findings are explored in more depth in Chapter 12, which considers the evidence from the results chapters in the light of the existing literature, leading to an analysis of the nature of competition and regulation in the fever/malaria treatment market. Before turning to this discussion, the methodological strengths and weaknesses of the study are considered in Chapter 11.

PART IV

DISCUSSION, POLICY IMPLICATIONS AND CONCLUSIONS

CHAPTER 11

METHODOLOGICAL STRENGTHS AND LIMITATIONS

11.1 Introduction

This chapter reviews the methods and data used in the five results chapters, and explores their strengths and weaknesses. It begins with the strengths, looking in Section 11.2 at insights gained from the conceptual framework, and in Section 11.3 at the strengths of the data collection methods. Section 11.4 raises a number of concerns about the reliability and validity of the study data, focusing on the small sample sizes for some analyses, and the dangers of relying on reported behaviour and characteristics. Three areas subject to particular measurement problems are discussed: SES, the appropriateness of treatment obtained, and market concentration. Section 11.5 on data gaps identifies a number of areas where additional information would have been beneficial to aid the analysis. Finally, Section 11.6 addresses three key methodological challenges; developing appropriate market definitions, understanding behaviour in the context of relatively homogeneous study areas, and analysing a market changing over time.

11.2 Insights from the Conceptual Framework

The use of an explicitly economic framework, based on market structure, provider conduct and consumer demand, is argued to have provided fruitful lines of inquiry and interesting insights into fever/malaria treatment. Considering treatment provision as a market led to analytical choices which can be seen as key strengths of this research. Firstly, both the demand and supply sides of the market were considered, allowing for validation of findings, and an understanding of the way providers and consumers respond to one another's preferences, incentives and decisions. Secondly, the full range of consumers and competitors were included. The demand analysis considered all age groups, in contrast to most similar household surveys which have focused on children under five; although children are the most biologically vulnerable group, in this setting the majority of fever/malaria patients treated were over five, which through their purchasing power therefore influence providers' behaviour and overall market development.

On the supply-side, collection of comparable data on all provider types, from formal health centres to roadside stalls, allowed comparison of their advantages and disadvantages from both the consumer and public-health perspective. Including government facilities and private providers demonstrated that they acted as both substitutes and complements for one another, and highlighted the extent of government failure in service provision. In previous studies, general shops and drug shops have often been grouped under the broader categories of "retail" or "no treatment" (i.e. no formal health facility treatment). In this analysis they were clearly distinguished in demand and supply analyses, thus highlighting the major differences in services offered and treatment provided.

Viewing providers explicitly as economic agents facilitated incorporation of their wide range of financial and non-financial incentives, and shed light on the force and limitations of price and non-price competition. Economic concepts argued to have provided particular leverage include product differentiation by outlet and drug, and market concentration, both of which can influence private provider market power, and the accessibility, affordability and quality of treatment. Other market failures highlighted by the research arose from imperfect information and consumption externalities. At the same time, the inclusion of regulatory considerations showed how rule-based regulations interacted with financial incentives, and demonstrated that government failure was prevalent in regulation as well as provision.

11.3 Data Collection Strengths

On a more practical level, a key strength of the data collection was its foundation on reliable sampling frames, drawn from the DSS systems for demand and the outlet census for supply, facilitating the selection of representative samples of households and outlets for quantitative surveys, and an informed sample for qualitative provider interviews. Data on treatment seeking were based on reported behaviour for actual episodes, which is more reliable than responses to hypothetical scenarios (McCombie 1996). The DSS systems provided excellent background information, their staff were knowledgeable about the study areas, and the household survey and outlet census were undertaken by their experienced local field staff. We benefited from extremely high participation rates, even among commercial retailers. These high rates were likely to have reflected the skilful and sensitive invitations to participate provided by local DSS field staff. Working within the IMPACT partnership allowed the organisation and management of the household survey to be shared, widening the potential scope for thesis data collection. In addition, the author benefited from advice on data collection and analysis from more experienced team members.

The comparison of data collected through five different activities allowed for considerable triangulation, with identification of discrepancies between sources leading to a better understanding. For example, user fees reported by government facility staff proved very different from those said to have been paid in practice by household survey respondents. Credit was widely argued by shopkeepers to be an important competitive practice during qualitative interviews and the outlet survey, but the household survey indicated that it was very rarely given in practice. Despite the insistence of shopkeepers in qualitative interviews that they faced stiff price competition, the outlet survey revealed high markups and variable prices. On the other hand, the utility of qualitative methods, relatively rarely used by economists, was demonstrated in the in-depth discussions of, for example, relationships with regulators, and the interdependence of drug stores and facilities, which could not have been gleaned from structured surveys.

11.4 Reliability and Validity Concerns

Despite these benefits of triangulation, a number of concerns about the reliability and validity of study data remain. Firstly, some sample sizes were relatively small. Qualitative data from the semi-structured interviews were based on only 18 private providers. Even for the larger scale quantitative outlet survey and retail audits, the number of facilities and drug stores was constrained by the total number operating in the DSS areas, although all were selected. Within the outlet survey, the number of antimalarial products in general stores was very low because they were so rarely stocked. Had the detailed household survey been administered to all households sampled rather than just Group A, the sample sizes for the analysis of treatment seeking behaviour would have been doubled. However, concern about the potential time requirements led us to restrict the more detailed survey to 50% of households interviewed. The size of the samples for these quantitative surveys of both households and outlets limited the potential to demonstrate statistical significance for some comparisons.

Nearly all data collection relied on interviews with householders or providers, about their opinions and reported behaviour. For a number of reasons these data may not be a valid guide to actual behaviour. Reported behaviour may be affected by poor recall. Even for the two-week period used in the household survey, respondents may have struggled to remember exact details of all illness episodes and drugs obtained (McCombie 2002). Mild or untreated illnesses may be most likely to be forgotten. Recall on drug use has been improved in some settings by using photo-illustrated drug charts, or a tray of samples of common medicine brands (Amin et al. 2003; Hamel et al. 2001). These memory aids were felt to be impractical in this setting, where there were 81 different antimalarial products alone, in addition to painkillers, antibiotics and other drugs. Moreover, as 91% of antimalarial tablets were dispensed loose, and most tablets

looked very similar, packaging would have been of limited use as a memory aid. Recall on drug quantities obtained might be expected to be particularly poor, calling into question the validity of estimates of minimum antimalarial doses obtained. In some cases this might have been improved through reference to patient-held records of facility care, but such documentation would not have been available for non-facility visits. Providers were asked for longer recall periods for some questions, for example one month for drug stockouts, and even longer for regulatory visits. In addition, in many general stores and most drug stores we interviewed the main seller, who was frequently not the owner. These interviewees were knowledgeable about the day-to-day running of the outlet, but may not always have been well-informed about topics such as sources of capital, wholesale supplies and regulatory compliance. Finally, some qualitative interviews were long, with several exceeding two hours, which may have led to respondent fatigue, and therefore less accurate or complete responses.

Even for householders with good recall, there is some controversy over whether caretakers can accurately recognise fever in children. The evidence suggests that the sensitivity of identifying fever is relatively high, but specificity may be low in some settings. In Ghana, 22% of children with a report of fever were afebrile (Dunyo et al. 2000). In Guinea, 55% of children reported as febrile had a normal temperature, and a high temperature was found in 38% of children identified as sick but afebrile, and in 13% of children considered healthy (Diallo et al. 2001). In the Tanzanian setting, these issues were potentially compounded by the interpretation of the question on whether individuals had experienced *homa au maleria* (fever or malaria). The term *homa* can apply to a broader range of symptoms, which may not necessarily be associated with a high temperature (Winch et al. 1994). For example, it may be used for respiratory conditions (*homa za vifua*) or gastrointestinal illnesses (*homa za matumbo*) (Tarimo et al. 2000). We also recorded specific symptoms free-listed by respondents, which included a code for a number of terms used to signify high temperature (*chemchem / joto / kuchemka / homa*). Of those responding positively to *homa au maleria*, 35% did not specifically report a high temperature during free-listing. This percentage was much lower in under fives (11%) than in over fives (43%). This might have indicated more frequent use of *homa* to describe non-febrile illness in older patients. On balance it is possible that a significant minority of the illness episodes analysed were non-febrile. It should also be noted that all fever episodes are not commensurate in their nature or severity. Despite the inclusion of information on whether the illness was perceived as life-threatening, the analysis may not have controlled adequately for disease severity in choice of provider or drug.

Even with good knowledge and recall, respondents may deliberately misrepresent their behaviour or views, perhaps with the aim of meeting the interviewer's approval. This social desirability bias might, for example, have led consumers to under-report use of traditional

healers, or led providers to overstate the help they provided to the poorest consumers or the severely ill.

Other topics covered with providers were sensitive for commercial and/or legal reasons, especially those related to regulatory infringements. We tried to address this problem by emphasising that we were unconnected with any regulatory body, and by asking more sensitive questions on business and health regulation towards the end of the outlet survey and qualitative interviews, once a reasonable rapport had been developed. As a result it proved feasible to raise these issues, and many interviewees were very open in their discussion. However, concerns about participation were clearly expressed by a sub-set of interviewees; some required considerable reassurance before consenting, or refused to answer certain questions. Reported rates of illegal behaviours should therefore be considered a minimum.

To some degree qualitative interviews with providers ensured a conducive forum to probe these issues in more depth than was feasible during structured surveys. However, no qualitative data collection was undertaken with householders, so the qualitative assessment of factors influencing consumer demand has relied on provider perceptions. For providers themselves, the social distance between the interview team and interviewees was much greater for the qualitative interviews, conducted by the author and two Tanzanian university graduates, than for quantitative data collection undertaken by local field staff. Many interviewees, particularly those in smaller shops, had never talked to a European at any length before, and the Tanzanian qualitative research assistants were also outsiders, being highly educated, relatively wealthy, urban residents, from other areas of Tanzania. The seller in one drug store was reluctant to allow the tape recording of discussion about the drugs she could legally stock; and at one general shop the interview was cut short after the landlord became suspicious about the purpose of questions relating to revenue and staff pay.

All data collection focused on the DSS areas in the three districts, but for policy-makers the district itself would be a more appropriate unit of implementation. Care should be taken in generalising these results to the whole district, as the DSS areas excluded the towns where district headquarters were located, and some of the most remote locations.

Three specific areas were subject to particular measurement problems: SES, the appropriateness of treatment obtained, and market concentration. The SES index has not been validated against consumption or income measures in these areas. Validation of similar indices has been undertaken in other settings (Filmer and Pritchett 2001; McKenzie 2003), although neither consumption or income provide a gold standard, as both are subject to significant measurement problems. Concerns remain over how well such indices represent true variation in wealth,

especially in these relatively homogenous and poor communities, where the range of assets may not be broad enough to differentiate SES across all households (Filmer 2002). Even with a valid index, the assessment of variation in fever prevalence by wealth may be compromised if some assets contributed independently to fever risk (e.g. water supply), or if SES groups had different propensities to report ill health they had experienced (Filmer 2002). An oft-cited advantage of asset indices is that they are not subject to the seasonal variation that affects consumption and income measures (McKenzie 2003). However, this may have been a disadvantage in this analysis, if treatment choice was influenced by seasonal variation in cash availability at the household level. Finally, we have explored variation in treatment seeking by individual household SES only. However, Filmer found that levels of wealth in the community in which the household lived influenced treatment more than the wealth of the household itself, and for Tanzania, Khan et al. found that community wealth had an independent effect on health status as measured by Body Mass Index and height-for-age (Filmer 2002; Khan et al. 2003).

Variation in the appropriateness of treatment obtained proved difficult to assess. As described in Chapter 5, it was not possible to judge quality definitively for individual patients from the household survey because of recall and social desirability bias, problems in accurate identification of febrile cases and completed episodes, and because in the absence of a clinical examination it was frequently unclear what the ideal treatment should have been. If such weaknesses were randomly distributed across reported episodes, comparison of quality across outlet type or socio-economic group would have remained valid. However, it was possible that, for example, in high SES groups recall of symptoms and drugs obtained may have been better, or that social desirability bias may have been higher. In addition, data were collected only on drugs obtained; if adherence to doses obtained varied across outlet type, relative performance may have differed for the quality of treatment obtained and that actually consumed. On the other hand, in comparing outlet survey data on quality indicators across provider type, the analysis was restricted to the use of proxies, such as staff qualifications and drug range. It was not possible to assess their validity as proxies for perceived quality, and their impact on technical treatment quality is not clear.

On concentration, it was reassuring that the HHI and r-firm ratios gave similar indications of relative concentration (correlation coefficient across sub-markets of 0.79, t test, $p=0.002$). However, they suffered from empirical limitations, as sales data had to be extrapolated for one facility and the majority of general stores (Annex 6). Extrapolations based on mean sales for each category are likely to have biased the HHI through an underestimation of sales variation, and may also have affected the r firm ratio if total sales estimates were inaccurate.

11.5 Data Gaps

Data on some important factors influencing provider behaviour were not included in the analysis. Firstly, information on private provider cost structure proved too sensitive to collect, even in qualitative interviews. Such data are required to move from an assessment of gross price markups to one of retail profit margins, which would provide a better guide to the intensity of price competition. This is likely to require long-term data collection activities, which allow the development of a trusting rapport with shopkeepers.

The main focus of the study was the retailers themselves. They are the most visible part of the market, but depend on their wholesale suppliers, who have a major influence over the prices and availability of products in retail outlets, and are also an important source of information for retail sellers. Particularly for general stores, there may be relatively little choice over product range, which is determined further up the distribution chain. Data have been gathered on the supply chain serving the study retailers, and their analysis will form the next phase of this project.

Inclusion of additional data collection activities, such as observation in outlets, exit interviews or undercover care-seekers could have added value by providing more robust measures of treatment quality, and addressing the deliberate misrepresentation of true views and practices during interviews. These activities were not pursued for a number of reasons. Observation and exit interviews potentially suffer from the Hawthorne effect of influencing participant behaviour through the very presence of the researchers. This effect may diminish as participants become accustomed to the researcher's presence, but time constraints prohibited long-term study in individual outlets. In addition, many general shops saw relatively few fever/malaria patients, and so would have required long study periods to obtain a sufficient number of relevant encounters. Undercover care-seekers raise both ethical and practical issues in the maintenance of deception (Madden et al. 1997), and were considered inappropriate in this setting, where any discovery could have damaged working relations for the whole IMPACT project, and the long-standing DSS systems themselves.

11.6 Key Methodological Challenges

This section considers three key methodological challenges faced in the analysis: the definition of markets, the relative homogeneity of the study areas, and the changing nature of the market under analysis.

11.6.1 Market Definitions

Product and geographical market definitions were inevitably not clear-cut. It is always difficult to distinguish between separate markets and segmentation/product differentiation within a single market. On the geographical side, the shipment cut-off points used for definition of sub-markets were essentially arbitrary, and the reliance on household survey data meant they reflected current utilisation patterns only, and not contestability. For example, two outlets may be in competition but consumers may only visit one of them if it is perceived as superior value for money.

The focus on treatment for fever/malaria led to a product definition around antimalarials and painkillers. This excluded antibiotics, which made up only 7% of drugs obtained for fever/malaria. However, as relatively expensive medicines, they may have been more significant in terms of private sector profits. The focus on fever/malaria was chosen to reflect the consumer and public health perspectives, but from a provider perspective the market may be defined around the products, whether they are used for fever treatment or not. While only 7% of antimalarials were obtained by non-febrile patients, the percentage of painkillers used for other reasons was much higher (36%), and the focus on fever/malaria therefore entails only a partial market analysis for these drugs from the provider's perspective.

11.6.2 Homogeneity of Study Areas

The potential to understand factors underlying the nature of competition was restricted by the lack of variation across the study areas. The sites were chosen deliberately to be relatively similar and homogenous to serve the purposes of the main IMPACT evaluation. As a result, the lack of variation in variables such as SES and market concentration restricted the leverage to explore their influence on competition. While some significant relationships were discovered, these variables would be likely to emerge as more important in a Tanzania-wide analysis, incorporating district and regional towns, and very remote locations.

11.6.3 Analysing a Changing Market

The timing of data collection activities was highlighted in Section 5.4.9 and Table 5.7. The outlet censuses were conducted in May-September 2000 and 2001, the latter in tandem with the household survey. The qualitative provider interviews took place in August/September 2001, the outlet survey in November/December 2001, and the retail audits in February/April and June/July 2002. The activities were scheduled in this way for logistical reasons, and to allow the results of each activity to inform the design of subsequent data collection. The timing poses two

potential challenges for data analysis, related to seasonal variation, and long-term changes in the market.

One could expect seasonal variation in fever incidence, parasitaemia prevalence, cash availability, farming activities and physical accessibility (Sauerborn et al. 1996). There are generally two rainy seasons in the study districts: the short or light rains in October to December, and the long and heavy rains from March to May. Particularly during the heavy rains, road travel may become difficult, although villages within the DSS areas are rarely inaccessible. Malaria transmission is perennial, but may vary seasonally. An active case detection study in under fives in Ifakara Town in 2000/2001 found a peak in both fever and clinical malaria in January, one month after the light rains had begun, and a peak in parasitaemia prevalence in March (Schellenberg et al. 2003). However, the authors note that transmission in Ifakara Town is lower than that in the surrounding rural areas, where the thesis study sites were located. It is also possible that the timing of peaks varies from year to year, depending on the rains. The timing of agricultural activities varies among the different crops cultivated. However, the major rice harvest takes place mid-year. In the run-up to the harvest, income levels tend to be at their lowest (the hungry season), and agricultural activity is most intense, with many people moving temporarily to their *shamba* (farm). One might therefore expect higher need for fever/malaria treatment during the first six months of the year, but demand to be tempered towards the end of this period by accessibility problems during heavy rains, low cash availability and the high opportunity cost of time pre-harvest.

Such seasonal variation could imply that the data collected through each activity were not representative of the whole year. Moreover, the thesis is structured by presenting the fever/malaria treatment obtained, and then aiming to explain these findings in the light of market analysis; there is a risk that, for example, outlet survey data on provider characteristics, such as drugs stocked or stock reliability, do not reflect the conditions faced by consumers at the time of the household survey. On the other hand, the staggered timing of the activities provides some leverage to investigate seasonal variation in demand and supply. In addition, the retail audits were conducted at two different points, and questions about seasonal variation were asked during the second outlet census, and the qualitative provider interviews.

On the supply side, there was seasonal variation in the operation of a small minority of smaller general shops, with 8% of kiosks/stalls in Kilombero and Ulanga DSS areas reporting moving to another location, or closing down for part of the year (Section 7.2.2). However, the vast majority of outlets operated all year round in a fixed location. Stocking patterns also did not appear subject to seasonal variation. For example, a wide range of antimalarials and painkillers were available from drug stores during the outlet censuses, outlet survey and both retail audits,

which in combination spanned most months of the year. Prices were only recorded during the outlet survey, but there were no indications from qualitative work that these varied at different times of year, nor of seasonal changes in outlet staffing or wholesale supplies.

One might expect greater variations in demand. The household survey stretched over four months, from mid-May to mid-September, allowing some limited analysis of demand over time. Comparison of households interviewed during the first half of the survey (up to July 25th) with households in the second half, showed that the prevalence of reported fever/malaria was slightly, but significantly, higher during the first half (19% vs 13%, χ^2 with Rao and Scott correction, $p < 0.0001$). This might be expected, as the first half more closely followed the long rains. Of those reporting fever/malaria, there were no differences in the probability of obtaining appropriate antimalarials, or of visiting different provider types, between the first and second half of data collection, with the exception of private facilities, which were less commonly used during the second half (8% vs 3%, $p = 0.047$). There was therefore no evidence to suggest that the hungry, harvest season, at its peak during the first half of the survey, led to less use of more expensive providers, or avoidance of longer journey times. However, the SES of households interviewed in the first half was significantly higher than in the second half, which may have obscured such effects.

The retail audits were conducted deliberately at two different times, to attempt to capture seasonal variation in antimalarial sales, but the findings were inconclusive. Sales in June/July were 82% higher than in February/April in Kilombero DSS, but almost the same in Rufiji, and 35% lower in Ulanga (Annex 6). During qualitative interviews, drug store staff said that sales of fever/malaria drugs did vary seasonally, with most reporting peaks during the heaviest rains (March/April), and a few also mentioning a smaller increase post-harvest (July to October). This tallies with routine data from sentinel government facilities in Kilombero and Ulanga in 2002, which showed a peak in malaria outpatient diagnoses in April. It is possible that the audits were not well timed to distinguish this peak period.

In sum, there did not appear to be strong seasonal variation in supply. Seasonal variation in demand was more likely, but firm conclusions could not be drawn. Seasonality patterns may vary between years depending on the rains, which were relatively good in 2001 and 2002; national agricultural growth was over 5% in both years, largely due to good weather conditions, compared with an average of 3% in the previous four years (Government of Tanzania 2004). Comparison with IMPACT household survey data from 2000 and 2002 did not indicate that 2001 was atypical in terms of parasite prevalence or reported fever/malaria (Kachur 2004).

There was strong evidence of longer-term changes taking place in the market during data collection. The number of drug stores was expanding over time, particularly in Rufiji; from a starting point of 13 drug stores in the Rufiji DSS area in mid-2000, the number grew to 20 in mid-2001, and 22 in mid-2002. Another key change was in antimalarial stocking patterns, in reaction to the official change in policy to SP in August 2001. The outlet censuses and household survey were undertaken before the change, but the other data collection activities took place during the year in which it was gradually implemented in the public sector. Most drug stores and private facilities had been stocking SP well before the official change, but this became universal by June/July 2002, with amodiaquine and quinine stocks also increasing. The stocking of chloroquine dramatically declined in facilities, drug stores and general shops over this period. As few general shops began to stock SP or amodiaquine instead, the proportion stocking any antimalarials was falling over time.

There were therefore some important long-term changes taking place in the market during the period of data collection. The thesis has attempted to highlight these were possible, but their implications for the nature of competition are difficult to gauge. For example, antimalarial competition is likely to have been increased by an expansion in the number of drug stores, but reduced by a fall in general stores stocking antimalarials. This dynamism is an inherent issue in the analysis of markets, which can and do change rapidly over time, particularly where entry and exit barriers are relatively low, as in this setting. Change has obviously continued since the study, and the implications of these subsequent developments for drawing policy lessons from the thesis results are considered in Chapter 13.

11.7 Conclusions

Key strengths of the analysis included the insights provided by the economic framework, the quality of sampling frames, and the potential for triangulation across data collection tools. A number of limitations and omissions have been discussed. The most important relate to concerns about unvalidated proxies for SES and treatment quality, and the reliability of some provider and consumer responses. For some variables, such as doses obtained or travel time, one would expect the error in responses to be random, but for others systematic bias may have been introduced. In particular, the interpretation of *homa* is likely to have led to an overestimation of fever, and fear of regulatory sanctions probably resulted in an underestimation of illicit provider behaviours.

CHAPTER 12

DISCUSSION

12.1 Introduction

This chapter draws together the findings of the five results chapters, and considers them in the light of the literature on fever/malaria treatment reviewed in Chapter 2, and the literature on markets and competition in Chapter 3. Section 12.2 briefly summarises the evidence presented in the thesis on the relative roles of retailers and facilities. Section 12.3 compares these and other findings with available evidence from the literature on fever/malaria treatment in sub-Saharan Africa. The chapter then turns to the fourth objective of the thesis, to analyse the implications of competition and regulation for the accessibility, quality and affordability of fever/malaria care obtained. The nature of competition is considered in Section 12.4, through an assessment of the market's place in the monopoly-perfect competition continuum, and potential insights from models of monopolistic and oligopolistic competition. The links between competition and treatment accessibility, quality and affordability are analysed, leading to the identification of a number of market failures. Finally, Section 12.5 discusses the nature of regulation, and the extent to which the regulatory system controlled for market failures.

12.2 The Relative Roles of Retailers and Facilities

The majority of provider visits for fever were to retail outlets. Although the proportion due to malaria was unknown, it was likely to have been a significant cause. Shops treated only relatively mild cases, but as the treatment of uncomplicated malaria affects the probability of progressing to severe disease (Greenwood et al. 1987), they were likely to have had an important indirect effect on severe disease and mortality.

There were a number of reasons for the popularity of shops, reflecting the interplay of market structure, provider conduct, demand and regulation. Retailers offered long opening hours, friendly and courteous service, and the potential to avoid the non-drug fees charged at most facilities. In addition, drug stores attracted consumers through the perceived expertise of their staff, and the reliability of their drug stocks. Partly as a result of the lack of regulatory enforcement, they generally stocked a wider range of products than government facilities. They were also more likely to stock antimalarials perceived to be of higher quality due to their packaging or country of manufacture. General stores had the advantage of proximity for most households, and their convenient but unspecialised services were seen as adequate for common fevers, which were not perceived as serious illnesses.

By contrast, government facilities had longer waiting times, shorter opening hours, and much longer travel times than general stores. They had a more limited drug range than drug stores, mainly consisting of poorly perceived domestically manufactured products, and were known for their frequent stockouts. However, as demonstrated in Chapter 8, no one outlet type was clearly perceived to be of higher quality all round. Despite their limitations, government facilities remained responsible for 26% of fever/malaria visits, perhaps reflecting the perception that they were appropriate providers for more severe disease, especially in children, combined with their highly subsidised or free drugs. However, their affordability was likely to have been undermined by their frequent official and unofficial non-drug fees, and the indirect costs of waiting time. Private facilities generally had better drug ranges and stock reliability, and more frequently had functioning microscopy services. However, they mainly served the better-off households, reflecting the high level of their drug and non-drug fees.

In sum, retailers were very important providers in the fever/malaria treatment market. They acted as both substitutes for government facilities, and as complements in providing a supplementary drug source for government facility patients. In addition, there were other links between the two sectors, with a third of drug shops owned by MOH personnel, and drug and general store staff frequently citing public facility staff as sources of information on drugs.

12.3 Comparison with the Literature on Fever/Malaria Treatment

No comparative studies were identified analysing the nature of competition in African fever/malaria treatment markets. However, there were many overlaps in the data collected with studies describing features of both demand and supply. The thesis results are compared with their findings below, beginning with other studies within Tanzania, and then broadening the comparison to the rest of sub-Saharan Africa.

It is possible to identify a number of common features with other Tanzanian studies in terms of treatment-seeking behaviour and market structure. Several studies also found that traditional practitioners are rarely used for mild malaria symptoms, but that retailers are an important source (Alilio et al. 1997; Nsimba et al. 1999; Okoli 2001). Comparison of treatment obtained within Tanzania is restricted by the limited number of community-based household surveys reporting treatment seeking during actual episodes. A similar survey in the thesis study districts (plus Morogoro-Rural) for the evaluation of IMCI found slightly lower use of antimalarials in febrile under fives (42% compared with 53% in this study) (Armstrong Schellenberg et al. 2003), perhaps reflecting that the IMCI survey covered all rural areas of the districts, rather than just the DSS sites, and therefore included more remote locations. Nationally representative data

are provided by the Demographic Health Surveys (DHS), which found that in 1999, 52% of children under five with fever had received an antimalarial, a figure very close to that obtained in this study (National Bureau of Statistics Tanzania and Macro International Inc. 2000).

On the supply-side, the characteristics of drug and general stores in terms of staff and stocking patterns seem relatively standard in other studies, although they are insufficiently detailed for a comprehensive comparison (Alilio et al. 1997; Masseur et al. 1993; Nsimba et al. 1999; Okoli 2001). Similar inadequacies in regulatory implementation were reported in drug shops in Dar es Salaam, where 85% of undercover caretakers obtained prescription-only drugs without a prescription from drug stores and pharmacies (Kumaranayake et al. 2003). Government failures in public sector provision have been widely reported across Tanzania, such as drug stock-outs, long waiting times, poor geographical accessibility and corruption (Abdulla 2001; Abel-Smith and Rawal 1992; Gilson, Kitange and Teuscher 1993; Gilson, Magomi and Mkangaa 1995). However, the geographical focus of Tanzanian studies is quite limited, almost entirely restricted to the eastern half of the country, with only one small study identified from western Tanzania (Okoli 2001).

Household and outlet surveys elsewhere in Africa demonstrate a number of similarities in the market for fever/malaria treatment across countries. The problems of poor quality of public facility care are echoed by the similar issues raised in consumer-focused research from many areas (Williams and Jones 2004). Studies in a wide variety of settings cite similar advantages with retailers, including accessibility, speed of service, potential to purchase by proxy, drug availability, friendly staff and lower costs (Adome, Whyte and Hardon 1996; Kachur et al. unpub. report; McCombie 1996; Molyneux et al. 1999; Snow et al. 1992; Van der Geest 1987; Williams and Jones 2004).

The problems with retail treatment quality found in this study have also been described in other settings. From a review of the literature, McCombie estimated that overall only a third to a half of febrile illnesses were treated with antimalarials, meaning that this study's figure of 37% is fairly typical (McCombie 2002). Frequent antimalarial underdosing has also been widely reported (Amin et al. 2004; Marsh et al. 1999; McCombie 2002), although it is not possible to compare the thesis figures for drugs obtained directly with those for drugs consumed from other settings. Persistent demand for chloroquine, even when it is highly ineffective, was also observed in Malawi, even after their official policy change to SP (Kachur et al. unpub. report). Other studies have also shown frequent use of inappropriate drugs. Similar rates of aspirin use in children were documented in coastal Kenya (Marsh et al. 1999). Much higher rates of antibiotic provision from drug shops for childhood fevers were observed in Uganda (48% vs 11% in this study) (Nshakira et al. 2002). However, antibiotic use appeared slightly greater than

in Burkina Faso, where only 4% of drugs provided were antibiotics, compared with 7% in this study (Muller et al. 2003). The illegal stocking of prescription medicines by retailers is very widely observed across the literature (Adikwu 1996; Adome, Whyte and Hardon 1996; Fassin 1988; Geissler et al. 2000; Murray et al. 1998; Oshiname and Brieger 1992; Van der Geest 1987), and poor quality antimalarials on the private market have also been documented in many countries (Amin et al. 2004; Basco 2004; Minzi et al. 2003; Ogwal Okeng, Okello and Odyek 1998; Risha et al. 2002; Shakoor, Taylor and Behrens 1997; Taylor et al. 2001).

The high total markups over IRP reported in this study have also been found in surveys using the WHO/Health Action International medicine pricing methodology in private retail pharmacies, although evidence from non-pharmacy outlets is very limited (WHO & HAI 2003). In Kenya, the median ratio of retail prices to IRPs for a range of essential drugs in private pharmacies was 17 for innovator brands, and 4 for the lowest priced generic in each drug category (Madden 2004). In Ghana these ratios were 14 and 3. This compares with a ratio of 6 for loose SP and 10 for packaged SP reported in this study.

The limited evidence available also indicates some similarities in market segmentation, with households with higher education levels also more likely to obtain an antimalarial in Malawi (Slutsker et al. 1994), and higher SES associated with greater use of private facilities across sub-Saharan Africa, but little variation by SES in use of lower-level government facilities or shops (Filmer 2002). The higher use of facilities for children than for adults reported in this study followed patterns in other endemic settings (Agyepong and Manderson 1994; Geissler et al. 2000; Krause and Sauerborn 2000), in contrast to the relative homogeneity of treatment seeking patterns across age groups reported in epidemic-prone regions (Guyatt and Snow 2004; Lindblade et al. 2000).

However, the evidence demonstrates some important cross-country variation, particularly in the frequency of shop use, and the types of retailers. The percentage of care-seekers using shops during recent childhood illness ranged from 15% to 82% across Africa (Brieger et al. 2004). In the thesis study sites 44% of under fives used shops, locating the market in the middle of this range, similar to areas of Kenya, Somalia and Nigeria, but much higher than the Gambia, Zambia and Zimbabwe.

There were also some important differences in the types of retailer involved in drug selling. In Uganda, drug and general shops were the main retail suppliers, as in the thesis study sites, but drugs were also sold in markets (Adome, Whyte and Hardon 1996). In coastal Kenya, a higher percentage of general retailers stocked antimalarials (73%, compared with 14% in this study in late 2001), perhaps due to the absence of drug stores in those rural areas (Molyneux et al. 1999).

In West Africa, itinerant vendors are often an important retail supplier of drugs (Djimde et al. 1998; Faye et al. 1996; Oshiname and Brieger 1992; Van der Geest 1987), but these were never observed in this study.

There were some similarities in the patterns of wholesale supply documented by other East African studies, particular in the use of general wholesalers by general retailers, and wholesale pharmacies by drug stores (Adome, Whyte and Hardon 1996; Marsh et al. 2004; Tavrow, Shabahang and Makama 2003). In contrast, mobile vendors frequently supplied rural shops/kiosks in Western Kenya, and in Nigeria, sales reps from pharmacies and pharmaceutical companies were a principal source of drugs (Adikwu 1996).

In sum, the evidence indicates many similarities in the demand and supply of fever/malaria treatment within other settings in Tanzania and elsewhere in Africa. However, there are some important cross-country differences in the market structure of the retail sector and its importance for fever/malaria treatment. The potential for comparison with the existing literature was very limited for a number of the study findings, such as those concerning market definition, market concentration, entry and exit and price competition. These are closely related to the nature of competition, to which the analysis now turns.

12.4 The Nature of Competition

12.4.1 How Competitive is the Market for Fever/Malaria Treatment?

At first glance the market for fever/malaria treatment might appear relatively close to the competitive end of the monopoly-perfect competition continuum. Each DSS area had a high number of drug providers, with the prevalence of microenterprises reflecting the structure observed in markets for other products elsewhere in Africa (Fafchamps 1997). The shops sold a wide range of antimalarial and painkiller products. The drugs were largely based on standard formulations and therefore were potentially relatively homogenous goods, and none of the products were on patent. Households obtained treatment regularly, so repeat purchases should have allowed consumers to become familiar with products and prices. The service was relatively simple, and most drug treatments were fully tradable after purchase (in contrast for example to inpatient care). Consumers were likely to be price sensitive because of their low SES and the overwhelming predominance of out-of-pocket payment. In such settings, the role of providing a financial safety net is likely to have fallen to extended family and/or other informal structures, which were unlikely to have nearly such a significant impact on price elasticity of demand as formal insurance. With the exception of two village drug stores, all retail outlets were run on a commercial basis, and therefore would be expected to reflect profit-maximising objectives. The

agency role of the provider was less important than in other health care markets; consumers had a free choice of provider and in shops were free to choose their own treatment if they wished. Contestability was relatively strong in the retail market, especially for general stores which experienced extremely high turnover. General shopkeepers frequently combined shop-trading with other activities, such as farming, a pattern frequently observed by small-scale traders elsewhere (Fafchamps 1997). In fact it appeared that any farmer who could raise a little capital from cultivation could become a small general shopkeeper almost overnight. Once established as a general trader, it was very easy for shopkeepers to add or subtract commonly available drugs from their product range. Despite the regulations on establishing drug stores, high levels of entry were taking place for these outlets as well. We did not witness attempts by providers to change market structure through, for example, large advertising campaigns, predatory pricing policies, or horizontal integration. Finally, the degree of vertical integration or coordination with providers further up the distribution chain was very limited; there were no examples of long-term contracts, product tie-ins, or aggressive detailing by pharmaceutical company reps, and only a couple of shops reported receiving recommended retail prices from distributors.

However, closer examination highlighted a number of reasons why the competitive model is inappropriate. Markups were high, and there was considerable evidence of product differentiation and segmentation by geographical area and product and provider type, as commonly observed in other health care markets (Dranove and Satterthwaite 2000).

The evidence presented in Chapter 9 demonstrated considerable price variations and high retail markups, especially in drug stores. It was not possible to assess how far this reflected the high overhead costs of running remote outlets. In addition, consumers may have limited their investigation of relative prices due to search-related costs, which would be relatively high when treatment was needed for an urgent illness. However, it seemed likely that to some degree prices diverged from marginal cost due to the exercise of market power derived from strong product differentiation and high sub-market concentration.

In practice, drugs were far from homogenous goods. As in much of the pharmaceutical industry, we observed considerable deliberate product differentiation on the basis of formulation, packaging and brand name, with significant price premia attached to superior characteristics. Strong product differentiation reduces the cross-price elasticity of demand between different providers and between different products, thus tempering the intensity of price competition. For SP we observed the situation described as the "generic competition paradox" (Scherer 2000), where the post-patent market was segmented, with innovator brands (FansidarTM and MetakelfinTM) maintaining a price premium, although in theory other SP products were identical in technical terms. It was presumably more profitable for their producers to serve relatively

price insensitive consumers at a high price, than to lower the price to attract those with a more price elastic demand. However, SP was the exception; such innovator brands were not found in the market for other antimalarials, although there remained considerable variation across brands.

The product market definition for uncomplicated fever/malaria treatment was set as antimalarials and painkillers supplied by facilities, drug stores and general stores. However, the intensity of competition varied across these outlet types, with greater perceived competition between facilities and drug stores than with general stores. The perception of drug stores as providers for "complete cures" with qualified staff and good quality drugs, compared with general stores for "first aid" only, may have enhanced quality by directing customers to more knowledgeable sellers, but also restricted competition by encouraging the view of drug stores as the only appropriate retail source for antimalarial treatment. Competition between general stores may also have been reduced by the tendency of consumers to use local shops where they were well known and had good relations with the owner or serving staff.

Even within DSS areas, the market was strongly geographically segmented, with the majority of sub-markets having populations under 10,000. Such segmentation or fragmentation has been observed in many African markets (Jones, Lindauer and Roemer 1991). As a result, competitive conditions differed for the supply of antimalarials and painkillers. Antimalarial availability had become increasingly restricted over time in general stores, and concentration based on antimalarial sales was high in all geographical sub-markets. The significant link between private sector concentration and antimalarial retail prices suggested that concentration was an important factor raising price above marginal cost. It was notable that general store prices were higher than those in drug stores for antimalarials, but lower for painkillers. This also pointed to the important influence of concentration on price, as the general store market segment had much lower concentration for painkillers than for antimalarials. However, although there were many alternative painkiller sources in most sub-markets, evidence indicated a rapid narrowing of the number of providers involved in general store supply as one moved up the distribution chain.

12.4.2 The Relevance of Models of Monopolistic and Oligopolistic Competition

Monopolistic competition was likely to have been an appropriate characterisation for the market for painkillers in most geographical sub-markets. In these settings of relatively low concentration, there were a substantial number of firms whose services were good but not perfect substitutes. In the short-run, shops may have made economic profits. In the long-run these would have been eroded by entry of new shops but, even in long-run equilibrium, price would have remained above marginal cost because shops were likely to have faced downward-sloping demand curves.

However, in other geographical and product segments, the potential for oligopolistic behaviour clearly existed. It has been suggested that where the 4-firm ratio exceeds 40%, oligopoly is likely to occur (Scherer 1970). For antimalarials, even the 3-firm ratio was 69% or above in all sub-markets. With such high concentration and significant barriers to entry for drug stores, private firms were likely to consider the behaviour of their competitors in making decisions on price and quality, the defining characteristic of oligopolistic competition. Even for painkillers, oligopoly conditions may have prevailed in some sub-markets which had relatively few drug outlets overall, or among the wholesalers serving general retail stores.

A potentially oligopolistic market structure does not determine the type of competitive interaction that will take place. Several oligopoly models may provide insights, especially those modelling the firm's choice of price (as opposed to quantity supplied), as this most closely reflects the reality of retail competition.

One might expect facilities to be the market leader(s) in each sub-market, drawing on oligopoly models of price leadership (Varian 1999). Unlike leaders in conventional models, government facilities were unlikely to take retail behaviour into account in setting their prices or capacity, which were generally fixed by the government to meet goals unrelated to profit-maximisation. However, one could consider retailers as conventional followers, taking facility price and capacity as given, and proceeding to set their own prices to maximise profits. Standard price leadership models assume homogenous goods, and therefore that followers are obliged to behave as perfect competitors, charging the price set by the leader. As retail products in these markets were differentiated by product and outlet characteristics, retailers would have had more discretion over their prices, and may have chosen to exceed or undercut those of facilities.

In view of the inequality of sales volumes across retailers, drug stores may have played a leadership role within the retail sector. As profit maximisers, they would then set their price given the likely supply of general retailers at each drug store price, and general stores would have set prices given the choice of the leading drug store. This would lead to a tiered model, with price and product range set by drug stores taking facility decisions as given, and by general stores given both facility and drug store choices.

The kinked demand model (Clarke 1985) may provide some insights into the high retail markups observed. Once a substantial markup was established in the market it may have resisted erosion if retailers believed their competitors would match their price cuts, but not their price increases. As a result, relatively large falls in wholesale costs would be required before retailers would cut prices.

Finally, models of tacit collusion among retailers may also be of use (Chamberlin 1933). Several factors argued to be conducive to the prevention of cheating in cartels were present in the retail sub-markets. The number of outlets was small, and it would be relatively easy to observe cheating, as retailers could obtain information on competitors' prices from customers, or by visiting the shops themselves. In addition, general stores had "multi-market" contact (Tirole 1988), so general retailers may have avoided price cuts on drugs if competitors were likely to retaliate on other household goods. Even with the narrower product range of drug stores, the number of different drugs sold may have led them to fear a damaging price war across their product range if they dropped the price on one popular item. If such collusion did prevail, one would have expected firms to act collectively to maximise total market profits, and therefore price could have been set as high as the monopoly level.

The models of competition described above are based on the underlying assumption that providers have profit-maximising objectives. One might expect this to be a central objective for commercial shop owners, but the full picture is likely to be more complicated. Ownership was separated from control of day-to-day selling in most drug stores, although owners generally retained control of pricing and product range. However, both owners and serving staff may have included variables other than profits in their objective functions, such as their reputation in the community, the assistance of vulnerable groups, or good relations with their fellow traders (Goel et al. 1996). While there was no explicit system of professional ethics among drug or general store staff, there were likely to be informal social constraints at the community level in these small rural settlements. Moreover, they may have followed the norms of cooperation, rather than competition, as observed among other African microenterprises (Fafchamps 1994; Tripp 2003). As a result, retailers may not have fully exploited their market power to raise prices even where this potential existed.

It is not possible from the data collected to say that any one model is most appropriate in these markets. Both monopolistic and oligopolistic conditions existed in different market segments, and a range of non-collusive and (tacitly) collusive/cooperative pricing strategies were probably employed. It might be considered surprising that shopkeepers argued in qualitative interviews that price competition was very strong. A similar discrepancy was observed in work by Amin, who found that Bangladeshi hospital owners perceived their markets to be very competitive, although the markets were highly concentrated (Amin 2002). He argues that this may reflect a lack of consideration of market segmentation and unequal market shares by owners, or a fear of competition heightening its perception.

12.4.3 Competition and Treatment Accessibility

Retail competition clearly increased the geographical and temporal accessibility of drugs in the DSS areas. In comparison with facilities, shop opening hours were longer, visits were less time-consuming, and it was not necessary for the patient themselves to attend. In addition, general shops were very numerous and widely dispersed, meaning that painkillers were available close to the home for most households, even in remote farming locations. However, antimalarial accessibility was much more restricted. This reflected the product range of general stores and the location of drug stores, which tended to be very close to facilities. According to Hotelling Models of product differentiation, there may be maximal or minimal differentiation, depending on the market characteristics (Hotelling 1929). The minimal geographical differentiation in this case may have reflected the economics of agglomeration in locating in areas where demand was greatest, and the weakness of price competition (Tirole 1988). Perhaps more importantly, drug stores often acted as complements rather than substitutes for facilities on the frequent occasions when government facilities experienced drug stockouts, and therefore benefited from being as close as possible to attract the frustrated consumers. The lack of antimalarials in general stores reflected a mixture of supply side, demand side and regulatory influences. Antimalarials were difficult to obtain from their normal wholesalers, expensive to purchase given the limited capital of shopkeepers, and rarely requested by their customers. Shopkeepers argued that they lacked the expertise to sell these drugs, and a high proportion believed it was illegal for them to do so. These influences resulted in significant barriers to entry into antimalarial supply, reducing contestability in this market segment.

12.4.4 Competition and Treatment Quality

Treatment quality depends on many factors: prompt care-seeking, accurate diagnosis, staff expertise, availability and quality of drugs, drug packaging, appropriate dosing, and the likelihood that staff act in the patient's best interests. Non-price competition could lead to higher quality standards if providers competed over characteristics correlated with these aspects of technical quality. While the evidence demonstrated that non-price competition was important for shops, it will lead to improved outcomes only if consumers can observe quality, value it, and have the ability to pay for it.

Consumers were reported to base their choices on some easily observable quality attributes, such as drug availability, proximity, opening hours and waiting time. As discussed above, shop competition over these attributes had no doubt increased the relative accessibility of care. To a large extent this explains the high coverage of treatment of some kind, and the promptness of treatment seeking.

Consumers were also reported to base their choices on perceptions of drug quality, and the expertise and trustworthiness of staff, which one might expect to be positively correlated with technical quality. However, in practice we noted widespread use of inappropriate drugs and doses and poor quality SP. This reflected in part the information characteristics of fever/malaria treatment. Painkillers and antimalarials have some characteristics of experience goods which consumers can judge after consumption, such as taste and minor side-effects. In general, however, they would better be characterised as credence goods, as quality is difficult to observe even after treatment, because there are many other influences on treatment outcome (Darby and Karni 1973). Even if appropriate malaria treatment were recommended, the patient may not recover if the illness was not caused by malaria, the patient did not adhere to the dosing regimen, or they succumbed to another infection. On the other hand, if the patient makes a full recovery this may be attributed to the most recent therapy used, when in reality it was a result of acquired immunity or the delayed action of drugs taken earlier. Finally, there is potential for confusion over the antipyretic and antimalarial effects of some products; chloroquine reduces fever independently of its antimalarial action, and may therefore be perceived as effective against non-malarial febrile illnesses. It is thus hard for consumers to make informed decisions on whether to re-visit a provider or re-use a given product in the event of a recurrence or future episode, and repeat purchases therefore fail to discipline the market. This problem was evident from the persistently high demand for chloroquine up until the change in first line drug policy, even though resistance levels were extremely high.

Where consumers cannot assess quality directly, they tend to use observable proxies. Customers were said to use several proxies for drug quality including outlet type, packaging, country of manufacture and brand name. Some consumers were willing to pay significantly more for well-known brands, reflecting the accumulated goodwill and reputation of these products, combined with concern over the quality of other products. However, the potential for branding to communicate useful information may have been compromised for three reasons. Firstly, the importance of well-known brands led other manufacturers to locate their products as close as possible to lead brands in product space, in order to "borrow" the product's reputation. Secondly, the sheer number of branded generics, particularly for SP and amodiaquine, is likely to have caused confusion in itself, making it difficult for consumers to remember their reputation or even which active ingredient they contained. This could lead to a situation analogous to the "increasing monopoly" model (Pauly and Satterthwaite 1981), with an increase in the number of brands decreasing consumer experience and information about each one, making them less price sensitive and providing established providers with greater market power. Thirdly, these drug quality proxies clearly conferred significant price premia on certain drugs, but evidence on their correlation with actual quality is very limited. In Cameroun, packaged

antimalarials were much better quality than loose tablets (Basco 2004). However, in the basic tests of content for SP tablets reported in Chapter 6, there was no clear relationship between quality in terms of the proxies of packaging, country of manufacture, outlet type or brand. If these proxies and their associated price premia do not reflect true quality differences, the market will be inefficient, and the economic burden on poor consumers will be unnecessarily increased.

For staff expertise, customers were reported to rely partially on the proxy of outlet type, leading some to favour drug stores over general stores, or to use facilities more for severe cases and treatment failures. We found this to be only partly justified. Consumers would be correct on average to assume that drug store sellers were better informed than general shopkeepers. However, the trust placed in drug store sellers may in some cases have been misplaced; they often had minimal pre-nursing training and made basic errors in dosage recommendations. Although the average length of training was longer for government staff, consumers were actually more likely to be served by someone with a health qualification in a drug store than in a government facility. The poor quality of government facility treatment in terms of appropriateness of drugs and doses may have been influenced to some degree by drug availability, but was also likely to have reflected poor provider knowledge, which has been documented in similar facilities elsewhere (Clarke et al. 1992; Massele et al. 1993).

Even where providers have greater expertise than their clients, they may not use this asymmetry of information in the interest of their patients. There may be a temptation to engage in supplier-induced demand, recommending unnecessary costly treatments. This did not appear to be a key problem in this market. For general shopkeepers, it was unlikely because their agency role was so limited. In government and mission facilities, staff did not officially have financial incentives to induce demand, but this may have occurred where unofficial fees were charged or official fees diverted to individuals. It is possible that supplier-induced demand contributed to the frequency of antibiotic and injectable antimalarial provision in drug stores. However, household survey data did not indicate that these drugs were more likely to be selected by the drug store seller, as opposed to the consumer, than other medications supplied. Sellers in drug stores may have chosen not to exploit the potential for demand inducement where it existed for ethical reasons, or to preserve their reputation among customers and fellow sellers.

Other elements of non-price competition may be negatively correlated with technical quality. Quality may be reduced by competition on strategies to increase convenience for customers, such as the potential to avoid waiting for consultations and lab tests, or the potential to purchase on the patient's behalf, which makes it harder for providers to judge the appropriateness of treatment. Competition over strategies to increase affordability may have a similarly negative effect, with financial incentives leading shopkeepers to supply antimalarial under-doses or just

painkillers. Only 6% of visits for fever/malaria to general stores are estimated to have led to patients obtaining at least a minimum antimalarial dose, and only 40% at drug stores (although the latter was still greater than the proportion at government facilities).

Finally, consumers may have chosen to under-dose or over-use antimalarials and antibiotics, because most of the costs of such behaviour in terms of drug pressure fall on other community members, not the individual concerned (Hanson 2004). Such negative consumption externalities may accelerate the development of antimicrobial resistance.

Analysis of developed country health care markets, such as the US hospital market, has frequently focused on models of quality competition, where the equilibrium level of quality is potentially excessive in efficiency terms, and an increase in competition may result in a rise in price due to the cost of high quality, rather than a fall (Dranove and Satterthwaite 2000). This is believed to reflect consumers who are quality sensitive but insensitive to price. However, in this market the reverse appeared to hold, with concentration and price being positively linked, as one would expect from standard economic theory. In this setting of imperfectly observable quality and price sensitive consumers, the fear is that there will be a "rush to the bottom", where providers are unable to demonstrate their superior quality so a "market for lemons" emerges in which "low price -- low quality" practitioners compete better quality providers out of existence (Akerlof 1970; Leonard 2000). While there were elements of this characterisation in the fever/malaria treatment market, these tendencies appeared tempered to some degree. This may have reflected some level of consumer information on this common cause of illness, the willingness to rely on provider advice, and the broader incentives of providers to serve the community well, rather than to aim purely for short-term profit maximisation.

12.4.5 Competition and Affordability

The level of price markups on drugs substantially increased the absolute differential between antimalarial and painkiller prices. For example, a child's dose of SP cost on average Tsh200 compared with a couple of paracetamol tablets at Tsh20. This was likely to be a strong explanatory factor in the use of painkillers alone in 39% of fever cases. Differences in percentage markups between chloroquine and SP also contributed to the more than sixfold difference in their median prices, partly explaining why although 37% of fever cases obtained an antimalarial, the drugs were only categorised as "effective" for 16%. However, preliminary analysis of the IMPACT 2002 household survey did not indicate that the official introduction of SP as first line drug and the decline in chloroquine availability had led to the fall in antimalarial utilisation one might expect; in fact the percentage of fever/malaria patients receiving an antimalarial remained constant at 37%, of which 34% were classified as effective (Kachur et al,

unpublished data, IMPACT collaboration). This appeared to reflect a decrease in the probability of getting an antimalarial at shop visits, combined with an increase in the proportion of patients visiting facilities and drug stores, where antimalarials were more often supplied. Further analysis is warranted to investigate why treatment seeking patterns changed, and whether the economic burden on households has increased.

A range of institutional and market-based mechanisms should have been in place to protect the poorest from the costs of treatment seeking, but in practice they did not function well. In government facilities, fees were often charged for services which should have been provided free, and in government and private facilities, implementation of exemptions appeared limited and haphazard. Moreover, the uncertainties surrounding total fees for consumers at these facilities may have led risk averse consumers to choose retailers instead, even if average shop costs were similar or higher.

In the private sector, credit was rarely given in practice for fever/malaria treatment, and third-degree price discrimination was restricted to a few *ad hoc* discounts. There was no systematic sliding scale, analogous to that used historically by private doctors in the West (Jacobs 1997). This was not surprising in view of the potential for arbitrage with highly tradeable goods such as fever/malaria drugs, in contrast to more complex medical treatments which tend to be embodied in the treated patient.

It was therefore not surprising that the appropriateness of treatment obtained and SES were significantly linked; individuals from households with higher SES were more likely to get an antimalarial and to get at least a minimum dose. However, even in the better-off third only 19% of individuals obtained an adequate dose of an effective antimalarial, indicating that price was likely to have been an important barrier to all groups, no doubt reflecting that nearly all households in the DSS areas were poor by absolute standards.

12.5 The Nature of Regulation

This section considers whether regulation provides an efficient solution to the market failures identified. The impact of regulation should be considered in terms of both its costs and benefits, including outcomes such as accessibility, consumer safety, quality, price and equity (Jan, Palmer and Mills 2004; Kirkpatrick 2001). Regulatory costs were not evaluated in this study, but some general observations can be made. Including drug issues in environmental health inspections was likely to have added little to government implementation costs. However, drug store inspections involved separate visits by DHMT staff, and consumed scarce professional

time and transport resources at district level. The opportunity cost of drug store regulation may have included less facility supervision and fewer district planning activities.

Regulatory systems may benefit consumers and facilitate competition through rules controlling for the market failures that endanger treatment quality and consumer safety. However, such strategies may also provide market power to certain providers, potentially restricting price and non-price competition. The regulatory system had this double-edged effect in this market through the barriers to entry for establishing drug stores. Official designation as a drug store acted as a signal of quality, clearly differentiating drug stores from general stores, because the former were seen as sources of medical expertise and better quality drugs. To a limited degree this addressed the market failure of imperfect information, but also provided market power to incumbent drug stores.

In many countries, legal entry for an entrepreneur is very time-consuming and expensive because of the number, nature and cost of the procedures involved (Djankov et al. 2000). For drug stores, the health-related regulatory entry barriers were relatively high. They were required to obtain a Pharmacy Board permit, which involved a fee and a complex process, with permission required from the village authorities, the District Medical Officer, the Regional Pharmacist, and the Regional Pharmacy Board, before the permit was signed by the Regional Commissioner. To be approved they were required to meet a set of conditions covering the shop premises and qualifications of the seller. Although rarely adhered to precisely, they were generally met partially, and were likely to have incurred significant costs for owners, and therefore restricted the total number of drug stores, and reduced contestability. However, the rapid growth in the number of drug stores during the study period demonstrated that overcoming these barriers was frequently considered worthwhile. In theory drug shops were allowed to open only in areas currently "under-served". This was clearly not universally enforced, as we found many closely located drug stores and some market centres with clusters of five or six. However, to the degree it was followed it could effectively have provided existing drug stores with a local monopoly, and may have discouraged potential entrants, rather than diverting them to other areas. In contrast, regulatory entry barriers were relatively insignificant for general stores, especially those operating on a small-scale. This was demonstrated by the very high turnover of general retailers, indicating a highly contestable market. During qualitative interviews general retailers very rarely mentioned regulatory hurdles as a key barrier to entry, and were much more likely to raise the problem of obtaining capital. Neither general nor drug store interviewees volunteered difficulties in entering the market due to corruption or bribery, although this has been found to be of great significance in other settings (de Soto 1990).

Beyond these eligibility requirements, health-related regulation at the retail level was not designed to influence directly the majority of the public health concerns arising from market failure; it did not cover pricing, dosing, increasing drug accessibility, or address drug quality at the retail level beyond the checking of expiry dates. Instead, as with most drug regulation, it focused on preventing the harmful use of medicines by restricting their availability to outlets with suitably qualified staff. Even in these terms, the benefits for treatment quality appeared small. Health-related inspections of general stores were limited to the environmental health visits of the Ward Health Assistant, who had very narrow responsibilities concerning drugs, limited to checking cleanliness and expiry dates. Moreover, the lack of clarity in the regulatory system over which drugs were allowed in general stores may have had a negative impact on antimalarial accessibility.

Most drug stores were regularly inspected on drug matters, but this activity seemed unlikely to affect treatment quality significantly. Inspections did not ensure that the registered individual staffed the outlet, nor control the sale of prohibited or inappropriately packaged drugs. Inspections may have had a role in reducing the prevalence of expired products, but retail inspectors had no way of assessing other potential causes of sub-standard drugs, such as poor manufacturing quality. They could have checked whether brands were registered in Tanzania and had therefore been approved by the Pharmacy Board, but this was never raised as part of the inspection. Government failure in regulation therefore contributed to the sale of inappropriate medicines and packaging, and unregistered products of unknown quality. While this failure may have contributed to poor quality treatment and increased antimalarial and antibiotic drug pressure, to some degree it also had important benefits for treatment accessibility, as drug supplies were more reliable and varied in shops than in facilities. For example, effective antimalarials were stocked illegally in drug stores before the policy change to SP when most government facilities had only ineffective chloroquine.

Drug stores had strong financial incentives to operate partially outside official regulations, and to make a good living may have been obliged to do so. Although government officials went through the motions of performing inspections and occasionally confiscating openly displayed antibiotics, we concluded that they did not seriously attempt to eliminate these practices. This probably reflected imperfect information about retailer behaviour, and some element of regulatory capture, with vested self-interests successfully influencing regulatory implementation. Perhaps more importantly, inspectors may have viewed elimination as infeasible, and/or harmful to community drug access. A similar approach to regulatory infringements has been documented among pharmacy inspectors in Sri Lanka, who took a "passive role" in their dealings with unlicensed pharmacies in remote areas, because they felt the service provided had important social benefits (Attanayake and Siyambalagoda 2003). In the

Tanzanian study sites, tacit permission of infringements led to a division between the official *de facto* regulations, and a locally legitimate *de jure* version, creating uncertainty for retail staff, who were never sure whether they would be apprehended, and giving an adversarial tone to inspections. This contrasted with the quarterly supervisions of private dispensaries by the same DHMT team, which were seen in a positive light by staff, who commented that they were helpful and informative, a source of information on government policy, and an opportunity to discuss operational problems. No interviewees volunteered any such positive, educational aspects to drug store inspections.

12.6 Summary and Conclusions

Retailers played an important role in the treatment of uncomplicated fever/malaria, acting as both substitutes and complements to facility services. Their high use reflected a number of perceived advantages, related to their opening hours, location, courtesy, cost, expertise, product range and stock reliability. Frequent use of retailers also reflected the poorly perceived services of public sector facilities. Government failure in the provision of fever/malaria treatment in its own facilities was therefore likely to have contributed to the growth and development of the retail drug sector.

Comparison of the study findings with other literature on fever/malaria treatment demonstrated many similarities in the demand and supply of care in other settings in Tanzania, and elsewhere in Africa. However, there are some important cross-country differences. Firstly, the proportion of care seekers using the retail sector varies considerably, with this study falling roughly in the middle of the range reported. Secondly, the type of retailers selling drugs is different in some other settings where, for example, itinerant vendors play a larger role, or drug shops do not exist.

Retail providers increased the accessibility, range and reliability of drug stocks in the study areas, and were partly responsible for the high coverage of some kind of treatment and prompt treatment-seeking observed. However, the market for fever/malaria treatment exhibited a number of market failures. In their discussion of market failure and the pharmaceutical industry, Henry and Lexchin state that "Markets work well for society when there is price competition, comprehensive and accurate information, an adequate supply of drugs, where consumers are able to make informed unpressured choices between competing products, and where there are few barriers for entry to the market" (Henry and Lexchin 2002). A number of these considerations were not met in the market under analysis. Market concentration was high, price competition was weak, information on treatment quality was poor for both consumers and providers, antimalarial supplies were not easily available from general stores, and there were

important consumption externalities from inappropriate antimicrobial consumption. In addition, vulnerable patients were likely to have been excluded from more appropriate care due to an inability to pay. These failures contributed directly to many of the observed inadequacies in treatment described in Chapter 6: low antimalarial coverage, inequitable access to quality care, frequent under-dosing, and frequent use of ineffective, poor quality and poorly packaged antimalarials. Health-related retail regulation was not designed to address most of these market or equity failures. Moreover, there was clear evidence of government failure in the poor implementation and enforcement of the regulations that existed. However, although health-related regulation obviously fell far short of its own targets, its evaluation is hampered by the difficulty in assessing what would have happened in its absence. Without these inspections it is possible that an anarchic system might have prevailed, with much wider availability of Part I medicines from people with no health-related training, such as market traders and itinerant vendors, possibly passing themselves off as qualified practitioners. This degree of illegal private sector activity was not observed.

In sum, the market exhibited evidence of both market failures, and failures in government provision and regulation. The next chapter considers the implications of this analysis for policy to improve fever/malaria treatment.

CHAPTER 13

POLICY IMPLICATIONS

13.1 Introduction

This chapter addresses the fifth and final thesis objective: the identification of policy implications for improving malaria treatment, and the delivery of artemisinin-based combination therapy (ACT) in particular. The scientific and political momentum behind ACT has grown greatly over the last few years, in response to concerns about the development of resistance to monotherapies, and growing unwillingness to accept current rates of drug efficacy (Attaran et al. 2004; Institute of Medicine 2004; Kindermans et al. 2002). WHO recommends that all countries experiencing resistance to conventional monotherapies should use combinations, preferably ACTs (WHO RMB 2004). By mid-2004, 15 African countries had decided to adopt ACT, and six had begun implementation. Tanzania itself plans to introduce ACT in 2006, and has made a successful application to the Global Fund for AIDS, TB and Malaria to fund the process of policy change and initial drug costs. Although thesis data collection was undertaken in the current monotherapy era, it is therefore most relevant to consider the policy implications under a future of ACT.

This thesis is based on data collected in three neighbouring rural districts, between mid-2000 and mid-2002. The chapter begins in Section 13.2 by assessing the applicability of the analysis to the current Tanzanian policy context, in terms of generalisability beyond the study sites, and over time, as there have been a number of policy developments since data collection. Section 13.3 sets the scene by presenting potential models for ACT delivery, distinguished by where ACT is made available, and for whom. In Section 13.4 and 13.5, the implications of the thesis findings are discussed for a facility-only ACT strategy, and one encompassing the retail sector.

13.2 Applicability of Analysis to the Tanzanian Policy Context

The applicability of the analysis is considered in terms of its generalisability to other areas within Tanzania, and its generalisability over time, given any changes in the fever/malaria treatment market since data collection, or foreseen in the near future.

The malaria transmission risk in the study sites is typical of that experienced by the majority of Tanzanians (75%) (de Savigny et al. 2004). Moreover, the patchy evidence discussed in Chapter 12 indicates that there are a number of common features with markets for fever/malaria treatment

elsewhere in rural Tanzania. However, during consultancy visits to other areas the author has observed some variation (Battersby et al. 2003); for example, in Mwanza Region in northern Tanzania, mobile distributors appear to be a more common source of drugs for general retailers, and a higher proportion of antimalarial products are reportedly sourced from Kenya and Uganda. In Mtwara and Songea Regions in the south, retail drug inspection is conducted from the regional level, further restricting the capacity of inspectors to cover all drug shops. Finally, the situation is quite different in urban areas, where Part II drug stores are much more common, and Part I pharmacies, private laboratories and commercial private clinics are often found. Further investigation of rates of shop use and shop characteristics in areas previously unstudied is therefore warranted. However, one could argue that there is evidence of sufficient similarities across Tanzanian's regions to justify qualified application of the study findings.

General observation in the study sites does not indicate dramatic changes in market structure or the nature of competition since the data for this thesis were collected. However, there has been a continued decline in chloroquine stocking, and it is now very rarely available in drug or general stores. Few general stores within the study sites were found to have started stocking other antimalarials, such as amodiaquine or SP, even by mid-2004.

A number of pilot interventions have been launched at a sub-regional level with implications for fever/malaria treatment. These include the introduction of ACT in government and private mission facilities in Rufiji District in January 2003 as part of the IMPACT project. In Kilombero District the ACCESS project began a programme of provider training and consumer information to improve fever/malaria treatment in 2004. Small-scale training and community education activities have also been undertaken by CARE in Dar es Salaam and Medicins Sans Frontieres (MSF) in Kigoma. In Songea Region, the Strategies for Enhancing Access to Medicines (SEAM) project in collaboration with the Pharmacy Board established Accredited Drugs Dispensing Outlets (ADDOs) during 2003/4 (Part II drug stores which meet specified quality criteria, where staff have undergone a training programme, and which are permitted to stock some prescription-only medicines) (Sigonda-Ndomondo 2004).

There have been important changes in drug regulation since 2002. The Pharmaceuticals and Poisons Act 1978 was replaced with the Food, Drugs and Cosmetics Act in 2003, and a new Tanzanian Food and Drug Authority (TFDA) was established, which has replaced the Pharmacy Board. The new Act does not refer to Part II drug stores, making reference only to ADDOs, which the TFDA says will be introduced nationwide in the future. The legal status of Part II stores is thus somewhat ambiguous, although in practice they continue to operate and are regulated as pre-2003. The new

Act replaces the Part I/Part II drug classification with three groups: controlled drugs, prescription drugs and general sale drugs. SP, amodiaquine and common painkillers are classified as general sale, and quinine and artemisinin derivatives as prescription-only. The availability of controlled drugs is very restricted. Prescription drugs can be sold only in Part I pharmacies. The Act states that "any general sale drug may be sold either by way of retail or wholesale in an open shop", which should clearly indicate that SP and amodiaquine are permitted in both general and drug shops¹. In addition, a set of strategies to improve drug quality has been put in place by the TFDA, including training on Good Manufacturing Practice for Tanzanian pharmaceutical manufacturers, and the introduction of mini-labs at major ports of entry to test the quality of some imported drugs, including SP, quinine and artesunate (Battersby et al. 2003).

In sum, while there have been changes in official drug classification, and some shift in stocking patterns since 2002, for Tanzania in general there is not evidence of significant changes in the competitive environment nor in regulatory implementation in the retail sector for fever/malaria treatment. However, the planned nationwide introduction of ACT is likely to have major implications for the retail sector and fever/malaria treatment in general. In mid-2004, the Tanzanian Government applied to the Global Fund for AIDS, TB and Malaria for funds to introduce ACT as first line drug in public facilities in 2006 (<http://www.theglobalfund.org/en/>). Implementation plans are to date only roughly sketched out, but distribution is likely to begin in formal facilities only. Funds for operational research on the potential for increasing the use of confirmed diagnosis, and for involving the retail sector, have been requested. While plans are not finalised, the most likely ACT candidate is currently artemether-lumefantrine (AL), a patented product under the public access name CoartemTM. The use of AL is expected to increase treatment efficacy and speed of recovery. However, it will also increase the complexity of the dosing regimen (6 doses over 3 days, compared to a single dose of SP). It will increase drug costs substantially, with a change in the factory gate price of an adult dose of the first line therapy from \$0.10/\$0.15 for SP to at least \$2.00. AL is likely to be selected because it is the only co-formulated ACT currently available, and because the companion drug (lumefantrine) is not widely available in the retail sector. For some other potential companions to artemisinin, such as SP or amodiaquine, widespread use of the companion as monotherapy is expected to undermine the hypothesised higher efficacy and slower development of drug resistance on which the case for ACTs is based. The retail sector has therefore already had an important influence on policy design. Many more questions remain about its role in ACT implementation.

¹ However, in mid-2004, some regulatory officials in the IMPACT study sites were interpreting the law to mean that SP could not be stocked in general stores (S. Patrick Kachur, pers. comm.)

13.3 ACT Delivery Models

When ACT is introduced, policymakers will have to decide which antimalarials should be available where, and to whom. This could be framed in terms of two key choices (Figure 13.1). First, should ACT be available in facilities only, or more widely through community members? Secondly, where ACT is provided, should it be universally available to all suspected malaria cases, or targeted to certain groups? The default (Option 1) would be to maintain the existing status quo for antimalarial distribution, of universal provision through facilities only. ACT would simply replace SP in all public facilities. Drugs would continue to be free or heavily subsidised for all groups in the public sector, and availability outside facilities would be determined by the operation of the free retail market.

Figure 13.1 ACT delivery models

	Universal coverage	Targeted coverage
Facility-only provision	<p>Option 1. Status quo for antimalarial delivery</p> <p>Free or very subsidised public sector facility delivery for all suspected malaria cases; unsubsidised free market outside facilities</p>	<p>Option 3. Tighter targeting</p> <p>Facility provision only, targeted by confirmed diagnosis, age group, pregnancy status or area</p>
Facility and community-based provision	<p>Option 2. Widening access</p> <p>Free or very subsidised provision through public facilities and community members e.g. CHWs, trained mothers, retailers</p>	<p>Option 4. Targeted widening of access</p> <p>Free or very subsidised provision through public facilities and community members, targeted by confirmed diagnosis, age group, pregnancy status or area</p>

However, there is growing pressure for effective treatment to be available more easily and promptly (Option 2). Many argue that the best approach to reducing malaria morbidity and mortality is to make antimalarial treatment widely and freely available down to the most peripheral level (Bloland, Kachur and Williams 2003). This approach is often referred to using the umbrella term of "home-based management", although a number of intermediaries outside the home may be used to deliver care (WHO 2004). Alternative delivery channels include retailers, community health workers, trained mother coordinators, or newly established community drug stores. Implementing home-based management with ACT would be likely to increase costs substantially, but is argued by some to be essential to the achievement of Abuja treatment target (WHO 2004).

By contrast, due primarily to the high cost of ACTs, proposals to target their delivery more tightly are also being seriously considered (Option 3). Tighter targeting may also address some concerns

about drug safety, excessive drug pressure, and mis-treatment of non-malarial cases. Targeting could be based on confirmed diagnosis using microscopy or rapid diagnostic tests (RDTs). ACT could also be targeted on the basis of biological vulnerability, proxied by area of residence, age group or pregnancy status (Snow, Eckert and Teklehaimanot 2003). Targeting by region might be appropriate for epidemic-prone areas, or in areas where current monotherapies are least effective. Targeting ACT to pregnant women and children less than 5 years of age would be expected to maximise reductions in malaria-associated morbidity and mortality per treatment. This targeting approach could reduce the incremental public antimalarial budget for ACT introduction by roughly two-thirds; as this study has shown, over fives make up over half of visits for fever to government facilities, and of course consume higher antimalarial doses.

Targeting could be applied within a purely facility-based programme, but targeting and widening accessibility are not necessarily mutually exclusive strategies (Option 4). For example, ACT could be made available through community workers, but only for children under five, or through retail outlets, but only with a positive RDT result.

Sections 13.4 and 13.5 draw on the thesis findings to identify implications for policy under firstly, a facility-only model of ACT provision, and secondly a model including retail sector distribution. As mentioned above, retailers are only one possible channel for widening ACT access. Key advantages of using the retail sector are that it provides a pre-existing, self-sustaining distribution system and, as shown in the thesis, already reaches remote rural areas, and plays an important role in fever/malaria treatment. This is not to dismiss the utility of other intermediaries as alternative or complementary channels, but to recognise that consideration of these is beyond the scope of this thesis.

ACT is being adopted to improve the efficacy of the first line therapy in the short and medium-term. However, as this analysis has demonstrated, the weaknesses in fever/malaria treatment are much broader than the problems of drug efficacy, encompassing low antimalarial coverage, frequent under-dosing, poor quality drugs, inappropriate packaging and labelling, and inequitable access to better quality care. These issues may have a similar or even greater impact on public health than a decline in the efficacy of the first line medicine (Amin et al. 2004). Any plan for ACT implementation must therefore consider failures in the health system and retail market, as well as treatment efficacy.

13.4 Implications for Facility-only ACT Provision

The implications of the thesis findings for facility-only ACT provision are considered firstly, for the facility sector itself, and secondly, for a non-ACT retail sector.

13.4.1 Government Facility Quality and Utilisation

The thesis findings indicate that simply changing the first line drug policy will not address many causes of poor quality care, because government facilities are used by only a minority of patients, and drugs and doses provided in the public sector are frequently inappropriate. For example, antimalarials were obtained at only 52% of government facility visits for fever/malaria, and a minimum antimalarial dose at only 38%. If a facility-based model is adopted, it will be important to raise the technical quality of government services, and to improve their perceived quality to increase utilisation. This would be important under any model of ACT implementation, but particularly so where facilities are the only subsidised ACT source.

An assessment of strategies for improving the technical quality of public sector care is beyond the scope of this thesis, requiring detailed study of the way staff behaviour is influenced by knowledge, supervisory structures, consumer demand and financial considerations. Suffice it to say that quality problems have been widely observed over many years, and a number of strategies including training, supervision and restructured incentives have already been targeted at these complex issues. Tanzania is in the process of scaling up the Integrated Management of Childhood Illness (IMCI) to address weaknesses in technical quality, particularly for under fives. The IMPACT study districts were the site for an evaluation of this programme, with IMCI implemented in Rufiji District (and Morogoro-Rural), while Kilombero and Ulanga acted as controls. A facility-based study for the IMCI evaluation in 2000 found that children in IMCI districts were significantly more likely to be diagnosed and treated correctly than in non-IMCI districts (Armstrong Schellenberg et al. 2004). However, although Rufiji began implementing IMCI in 1997, household survey data from this thesis in 2001 showed that the probability of a fever patient under 5 getting a minimum antimalarial dose at a government facility visit did not vary significantly across DSS areas, indicating that even well-implemented IMCI may not solve these problems.

As described above, facility provision could be for all patients, or restricted to those with confirmed diagnosis, or to certain biologically vulnerable groups. This study has shown that targeting parasite positive patients only would require a major increase in the accessibility of confirmed diagnosis, as during data collection only 4 of the 18 government facilities, and 5 of the 8 private facilities in the

study sites, had functioning microscopy. Even at such facilities, most first-time patients are not tested. The use of RDTs could facilitate an expansion of confirmed diagnosis because they require less equipment and staff expertise. However, successful deployment would be dependent on the supply chain to public facilities, which this and other studies have shown to be erratic for drugs. In addition, the high rates of afebrile parasitaemia documented in the household survey lead one to question the potential for health workers to assess whether parasitaemia detected is the cause of presenting illness in these areas of high transmission.

With or without confirmed diagnosis, it will be important to ensure that a high proportion of patients actually use facility services. This study found that only 22% of patients reporting fever/malaria visited a government facility and 6% a private facility. One might expect the provision of a more effective drug to encourage a shift in utilisation to facilities. Although the credence characteristics of antimalarials could make demand insensitive to drug quality, the higher efficacy of ACT may be relatively easy to observe because artemisinin derivatives are extremely fast acting (Adjuik et al. 2004). The impact on overall utilisation will depend on the targeting policy. If targeted by biological vulnerability, no increase in utilisation would be anticipated for non-pregnant adults. The impact on utilisation of targeting by confirmed diagnosis is unclear: the opportunity for a test could attract patients, although in this study providers did not mention this as an important form of competition. On the other hand, tests could increase waiting times and non-drug fees, which interviewees emphasised to be important deterrents for patients. The thesis findings indicate that any increase in utilisation of private facilities adopting ACT is likely to be by the better-off groups, who currently make up the majority of their customers. This reflects their relatively high fees, which led private facilities to be on average the most costly source of care in the study sites.

A key strategy to increase government utilisation would be the removal of user fees, which were in the process of being gradually *introduced* in Kilombero and Ulanga Districts during data collection, and were sometimes unofficially charged in all three DSS areas. Evidence from other settings has shown that utilisation can be increased substantially when fees are removed (Yates 2004). In addition to lowering the average cost for care-seekers, such a clear policy may increase utilisation by removing the variability in fee rates and exemption eligibility described in the thesis, which would have led to considerable uncertainty for consumers. A clear policy of free care would also diminish the potential for unofficial charges, which were found to be common during the study.

Although fees at government facilities were lower in Rufiji than in Kilombero or Ulanga, the proportion of patients using government facilities was actually higher in Ulanga DSS, and only

slightly lower in Kilombero, demonstrating that user fees were not the only reason for low utilisation. The analysis of non-price competition indicates several aspects of service provision on which government facilities are perceived to perform poorly, including stock reliability, waiting times and opening hours. One might therefore expect utilisation to be increased if consumer confidence in drug availability were raised, or if opening hours were made more flexible, for example, to include some weekend hours. The importance attached to good customer relations by private providers in this study contrasts with frequent consumer complaints of rudeness and indifference at government facilities reported in other research (Gilson, Kitange and Teuscher 1993), highlighting another area where improvements could potentially be made.

Two unintended impacts of facility-only provision may be an increase in drug leakage and in counterfeit products. This study did not uncover evidence of deliberately counterfeited drugs, nor widespread theft from facilities, although the latter topic is inherently difficult to research. However, with an unsubsidised private market, the highly subsidised public provision of a drug with a high retail sector value could provide a powerful incentive for such illegal activities. One would expect these incentives to be magnified if facility provision of ACT were restricted to under fives and pregnant women. Many counterfeit artemisinin derivatives have been reported in South East Asia, where these products are more widely used (Newton et al. 2003; Newton et al. 2002; Rozendaal 2001), and the IMPACT project has already experienced several incidences of leakage of ACT to urban retail outlets (S. Patrick Kachur, pers. comm.). Evidence on regulatory ineffectiveness in general from this study suggests that the system does not have the capacity to prevent the development of such black markets. This could further harm consumer relations and stock reliability in the public sector, and the safety and efficacy of private sector products.

13.4.2 Non-ACT Treatment in the Retail Sector

There are likely to be limits to the potential for increasing government facility utilisation. The problems of poor public sector quality have proved persistent in the face of similar initiatives in the past. Moreover, shops will remain the closest and quickest sources for most people, who were said by shopkeepers to value prompt care, and to feel that febrile illness often does not require the attention of a health care worker. The retail sector is therefore likely to continue to be widely used, even for targeted groups.

Among care-seekers in an unsubsidised rural retail sector, current patterns of drug purchase indicate that the cost of artemisinin monotherapy would be likely to keep its demand very low, which could be important in maintaining the efficacy of ACT. However at free market prices, ACT utilisation

would also be very low. At current monotherapy prices, an antimalarial was obtained at only 55% of visits to drug stores and 12% to general stores. ACT at 10 to 20 times the cost would be likely to be purchased by the very wealthiest consumers only. Treatment for the vast majority of people using shops would therefore be unaffected by the policy change, and would be contrary to the new national guidelines, with nearly all retail customers using non-artemisinin monotherapies or no antimalarial at all. Moreover, in this context the government would be unlikely to embark on any major strategies to improve retail treatment quality through a communications campaign with consumers or retailer training, because such strategies would need to address the appropriate use of cheaper monotherapies. This would lead to conflicting messages, as there would be effectively two sets of treatment guidelines, one for facilities and one for shops, which would probably be seen as undesirable.

However, in the absence of such communications or training, the thesis findings suggest that significant improvements could still be made to treatment obtained from shops by improving the standard of drugs in the retail sector, in terms of their chemical quality, packaging and labelling. Insufficient quantities of active ingredient were discovered in a third of all SP tablet products, and sub-standard quality of common antimalarial monotherapies has been demonstrated by other Tanzanian studies (Minzi et al. 2003; Risha et al. 2002). Due to the credence good characteristics of antimalarials, consumers are unlikely to be able to gauge these problems, either before or after treatment, so a greater government role in quality assurance is likely to be beneficial. Several important steps towards improving quality undertaken by the Tanzanian government since 2002 were described above, but more could be done. Further reform might include regular quality testing of locally manufactured drugs; local products currently require testing prior to registration only, in contrast with imported drugs which are subject to routine tests at ports of entry. The government could consider providing reliable signals of drug quality on product packaging. This would provide an alternative to the product differentiation proxies currently used by consumers, such as packaging, brand name and country of manufacture, which this study has found to be unreliable. Products which maintain high quality standards over time could be marked with a government quality seal, and consumers advised to purchase marked products only. If lower-priced products performed well enough to receive this stamp, this strategy could erode the market power currently enjoyed by manufacturers of higher-priced products, reducing price variation and consumer costs.

Labelling and packaging quality should be treated with the same rigour as the quality of the medicine itself. Tanzania has some regulation in place on this issue, but our evaluation of SP tablets demonstrated that existing labelling was woefully inadequate. Labelling of the INN and age-specific doses were found to be incomplete and/or incorrect on most packaged products, and

instructions were only provided in English. To address this situation the government could insist that no general sale antimalarial be registered or re-registered without fulfilling the following criteria. Firstly the INN (e.g. SP, amodiaquine) should be marked in large clear letters, ideally larger than the brand name, to avoid confusion over product identity. Such a strategy was adopted for SP products in Malawi following their change in first line drug in 1993 (Marsh and Kachur 2002). Antimalarials for OTC use should require dosing instructions for all age groups, strictly in accordance with government guidelines. This would address the issue that many products observed had no instructions for young children, and resolve dosing inconsistencies. All information should be provided in KiSwahili. Currently manufacturers can use English and/or KiSwahili, but most just use English, which the majority of the rural population do not understand. Finally, manufacturers should be required to demonstrate that their labelling has been subject to user testing for comprehensibility in the relevant consumer groups.

By using the leverage of the registration process to enforce these changes, improvement in product quality and consumer information could be implemented rapidly on a nationwide scale, with costs borne largely by the pharmaceutical manufacturers. Moreover, in view of the international nature of antimalarial trade, it might be possible to develop some co-ordinated strategies with other East African governments. Additional regulations might discourage some marginal manufacturers from registering their products in Tanzania. However, in view of the very high number of antimalarial products currently on the market (81 products in our study areas alone), the loss of a few brands would be unlikely to restrict competition significantly, and might have the beneficial side-effect of reducing consumer and retailer confusion.

These improvements in labelling will do nothing to address the extremely poor information provided with loose tablets, which retail audit data showed made up 91% of all antimalarial tablets dispensed and 78% of those from shops. Enforcement of the existing regulation that only drugs in unit packs be sold over-the-counter has the potential to both improve labelling and to guard against tablet contamination and degradation. However, this may increase the cost of antimalarials to consumers, further reducing the proportion of patients who purchase at least a minimum antimalarial dose. Regression analysis showed that packaging increased antimalarial tablet prices by 38% on average. However, this was likely to reflect the market power enjoyed by manufacturers of packaged products, as well as their increased manufacturing costs. Wider competition between packaged antimalarials may therefore bring down their prices significantly. Although packaged tablets may remain somewhat more costly, this is likely to be a price worth paying for appropriate packaging and labelling, which has been demonstrated to improve treatment adherence (WHO 2004).

Improving quality, packaging and labelling standards for registered products will not address the quality of unregistered antimalarials. These were found in 63% of drug shops in the study sites, and no shopkeepers reported regulatory inspection of the registration status of the drugs they stocked. Since thesis data collection, the government has taken the important step of requiring that the registration number be printed on the outer packaging, and has provided port of entry inspectors with up-to-date registration information (Battersby et al. 2003). However, this will not cover any products imported through unofficial channels. To address this at the retail level, local regulators and shopkeepers need information on which products are registered, and the importance of the registration system in quality control. This could be achieved by providing a regularly updated checklist of all currently registered general sale products to inspectors, wholesalers and retailers, so that any drug could quickly be checked against the list. It would be particularly beneficial for Ward Health Assistants, the only inspectors of general stores, who do not have expertise in pharmaceuticals and may be unsure of even the generic category of many drugs.

Even under a model of facility-only ACT provision, some improvements could therefore be made to retail sector treatment at a relatively low-cost. However, nearly all retail consumers would continue to purchase antimalarial monotherapies or painkillers only. One way to make a more fundamental difference to the quality of care they receive would be to distribute ACT through retail outlets as well, a model we turn to in the next section.

13.5 Implications for Retail Sector ACT Distribution

This section focuses on the potential role of the retail sector in improving access to ACT. The main advantage of involving the retail sector would be to expand the coverage of ACT to the high proportion of patients not attending facilities. In addition, as this thesis has demonstrated, care seeking through shops is relatively prompt, and retailers represent an important alternative source of drugs when government stocks run out.

Home-based management through retailers or other community members has been gaining acceptance among national and international policymakers in recent years (WHO 2004). However, the change to ACT presents important practical challenges to its implementation. Governments and donors are struggling to raise funds for ACT in the public sector alone, and it is unclear whether there will be sufficient resources, or sufficient artemisinin, to cover a wider range of outlets (Institute of Medicine 2003). This section considers the implications of the thesis findings for the

design of a potential retail sector intervention in the event that international efforts to ensure an adequate and subsidised supply of medicines are successful in the medium-term.

A report by the Institute of Medicines (IOM) has proposed that ACT should be heavily subsidised at the global level at the point of pooled supra-national procurement, with subsidised drugs made available to both the public and private sectors, including retailers (Institute of Medicine 2004). If a patented drug were selected for private sector distribution, such as AL, a single product would by necessity be subsidised. Where off-patent ACTs are selected, an alternative strategy could be to support a limited number of brands. AL is currently available to developing country governments at a price of \$2.40 for an adult dose, and \$0.90 for the youngest age group, although use of alternative ACTs might reduce the price per adult dose as low as \$1.50 (Coleman et al. 2004). The IOM recommended that ACT should not cost patients more than chloroquine monotherapy, implying a 90-95% subsidy for AL (Institute of Medicine 2004). The subsidy could be provided to all age groups, or targeted to under fives through packaging in paediatric doses, and appropriate labelling and marketing. Such an approach has been used in monotherapy social marketing programmes in Nigeria and Madagascar².

The design of a comprehensive retail sector strategy is highly complex, including choices about products and sources, subsidy mechanisms, product packaging, labelling and branding, product placement, the role of diagnostics, communication with consumers, wholesalers and retailers, quality control and monitoring. This section focuses on four areas where the thesis findings may provide insights: the choice of retailers for product distribution, retail pricing, training and communications, and amendments to retail regulation.

13.5.1 Choice of Retailers for ACT Distribution

The thesis has demonstrated important differences in the characteristics and utilisation of drug and general stores, which are highly relevant to the consideration of their appropriate roles in ACT distribution. The analysis suggests that providing ACT through Part II drug stores could have a number of important advantages. They are established sources for fever/malaria treatment, responsible for 88% of retail antimalarial sales in the study areas. Sellers have some health-related education, and are perceived by consumers as a good source for advice. Stockouts of key fever/malaria medicines occurred in 10-20% of drug stores per month, but were less common than in government facilities, much rarer than in general stores, and generally relatively short-lived. One

² see PSI website at http://www.psi.org/our_programs/products/ppt.html

might have expected drug shops to be more frequently used by better-off households, but survey data showed no significant difference in the probability of visiting a drug store by SES, or in obtaining an antimalarial at a drug store visit. This implies that a subsidy on the scale suggested by the IOM should not be captured by relatively well-off groups only. However, despite recent market entry, drug shops remain sparsely located in rural areas, and are generally in market centres or on main roads, and close to facilities. As a result, only 24% of households could reach their nearest drug store in under 15 minutes, compared with 63% for general stores. Moreover, of the twelve geographical sub-markets identified, three had no drug shops, representing 13% of the total study population.

By contrast, the network of general shops was shown to reach more remote populations, including households that moved seasonally for farming activities. In addition, general shops have the longest opening hours and shortest waiting time of all outlet types. Expanding ACT distribution to include general stores would therefore increase accessibility. Moreover, evidence of a significant and positive association between the HHI and price suggests that decreasing concentration in antimalarial supply could put downward pressure on prices.

However, even if general shops are given the opportunity to stock ACT, take-up may be very low. Of general stores stocking drugs, the percentage stocking antimalarials had fallen from 29% in mid-2000 to 14% in late-2001. Analysis of the reasons why general shops did not stock antimalarials suggested that this decline could be reversible to some degree if antimalarials became more available in general wholesalers, and if the regulatory position for retailers was clarified. A more deep-rooted problem may be perceived low demand from consumers, who reportedly view general stores as a source of first aid, rather than complete cures. In addition, even if subsidised to a level similar to current monotherapies, ACT would be relatively costly for the smaller general shops with limited capital.

The thesis findings indicate several other potential disadvantages in using general stores for ACT distribution. They are relatively prone to stockouts, perhaps reflecting the erratic drug purchasing patterns they reported. The remaining shelflife of antimalarials stocked was on average shorter than in drug stores, and 8% of antimalarials in general stores had expired. For AL this may be a particular problem because of its short shelf-life of two years (compared with 5-6 years for most antimalarial tablets); in general stores, 29% of antimalarials had been manufactured more than two years previously, compared with only 2% in drug shops.

A further problem with general stores could be the calibre of their serving staff. Although 82% of staff serving regularly had completed primary education, 11% had no education at all, and none had any health qualifications. In addition, no general store sellers stocking antimalarials knew the correct doses for chloroquine or SP. General stores are not included in the pharmaceutical inspection framework, and drug-specific inspections of the thousands of general stores in Tanzania would be infeasible. If ACT stocks were kept in general stores, regulatory implementation would need to rely on the much less qualified Ward Health Assistants. Finally, in view of the sheer number of general stores, their high turnover, and frequent changes in stocking patterns documented in this study, the potential to monitor ACT retail distribution would be severely constrained.

In conclusion, restricting ACT to Part I and Part II drug stores would seem the most sensible course of action in most areas. However, some flexibility would be required in remote areas not served by drug stores. In these settings, one or two well-established general shops, with relatively educated staff and good storage conditions could also be included, perhaps at the discretion of the DHMT.

13.5.2 Retail Pricing

The level of subsidy proposed by the IOM may seem high, but it should be noted that, even at current monotherapy prices, a minimum antimalarial dose was obtained at only 40% of fever/malaria drug store visits, and 6% of general store visits. As a result, many consumers may still not purchase ACTs at the highly subsidised price.

In addition, it is possible that the subsidy will not feed down to the point of purchase. This study has strongly suggested that existing levels of competition in the fever/malaria treatment market do not ensure competitive retail prices. The high markups documented in the retail distribution chain could mean that even drugs heavily subsidised at source could end up beyond the reach of most rural customers. Synergistic strategies must therefore accompany subsidy at source to ensure that low prices are passed on to consumers. If ACT is restricted to drug stores, the potential to achieve this through competition will be limited in rural areas, because of strong geographical segmentation, and high concentration in antimalarial sales within sub-markets.

Alternative strategies could include reducing drug store overheads, the use of recommended retail prices (RRP), or price regulation. Retail overheads include staff, transport, rent, taxes, licence and permit fees. More information is needed on their relative importance, to assess whether and how they could be reduced through, for example, tax breaks to drug stores, or by reducing travel costs for drug sourcing by establishing drugs wholesalers closer to target markets. Price regulation is

unlikely to be feasible to administer, given the weak regulatory capacity documented. Moreover, it requires sensitive adjustments to changes in producer costs, as if prices are set below the competitive price, shortages are likely to arise and parallel markets with unregulated prices will develop (Bennett, Quick and Velásquez 1997).

RRP may provide a less rigid tool for achieving the same goal. Although most drug manufacturers and importers provide distributors with schedules of recommended wholesale and retail prices, these were very rarely found to feed down to the periphery, and most retailers were totally unaware of the recommendations. However, RRP are widely used for common products in general stores, such as soft drinks and cigarettes, and have been used for socially marketed products, such as ITNs and condoms. Using a similar approach, recommended prices could be printed on ACT product packaging, and price information could be included in a communications campaign.

13.5.3 Training and Communications

The thesis demonstrated a number of poor treatment practices in the retail sector that should be addressed if the benefits of expanded ACT distribution are to be achieved. At drug store visits, antimalarials were obtained by only two-thirds of under fives, and half of over fives, and 29% of antimalarial purchases were under-doses. These figures were much worse at general stores, where only 13% of under fives and 12% of over fives obtained of antimalarial, 50% of which were under-doses. There was also evidence of inappropriate drug use in under fives, with injectable antimalarials purchased at 14% of drug store visits, and aspirin at 7% of drug store visits and 38% of general store visits.

Retail sector distribution therefore needs to be accompanied by the provision of information on appropriate ACT use. The study findings indicate that key messages should include the importance of obtaining ACT for vulnerable groups; age-appropriate dosing and the importance of completing the full course, particularly in view of the complex dosing regimens of ACT; and the dangers of inappropriate use of injections and aspirin in children.

A key question is how these messages would best be delivered. One potential strategy is to use training sessions for shop staff, which could be a requirement for accreditation as an ACT stockist. There have been calls for shopkeeper training in Tanzania, some pilots have been conducted, and a draft training package has been developed by NMCP. However, the literature in this area repeatedly shows that one-off knowledge-based training alone does not lead to long-lasting behavioural change (Marsh and Kachur 2002). Key features of successful programmes which maintain knowledge and

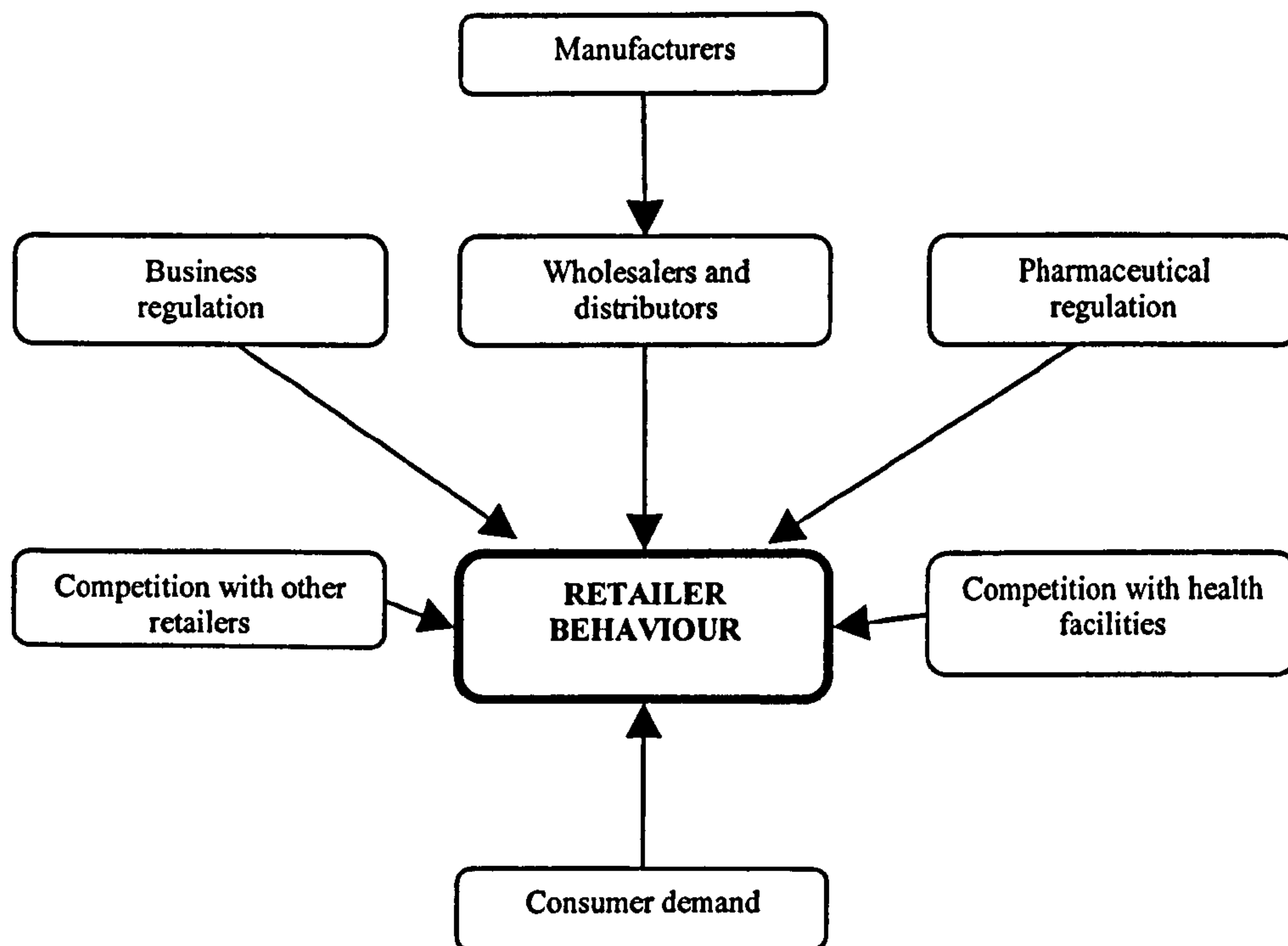
motivation are regular refresher training and monitoring visits, and complementary community mobilisation activities (Marsh et al. 2004). Such programmes are therefore not cheap, and require considerable on-the-ground implementation capacity (Goodman et al. Submitted). As a result they have tended to operate to date on a relatively small scale.

The number and turnover of general stores documented in this study indicates that maintaining a cadre of trained general store staff would be very difficult and expensive. If ACT were to be distributed mainly through drug stores, such face-to-face interaction would be more feasible, as they are relatively few in number, subject to relatively low turnover, and their staff already have some basic medical training. However, providing an effective nationwide training programme to Tanzania's 6000-plus Part II stores would still place a great financial and managerial burden on the MOH. Moreover, the poor quality of care and frequent stockouts observed in government facilities indicate that the MOH currently struggles to provide appropriate supervision and commodity supplies to its own primary care facilities. This raises the question of whether such an ambitious shopkeeper training programme would be feasible and sustainable, and whether it would distract attention from the government's core responsibility of ensuring good facility care.

However, interventions focused on retailers themselves are not the only way to improve retail care, and may not be the most efficient approach. Retailers are the most visible part of a complex market, but this analysis has shown retail behaviour to be influenced by manufacturers, distributors, regulators, facility and retail competitors, and consumer demand (Figure 13.2). It may therefore be more appropriate to place greater emphasis on the provision of information to consumers, wholesalers and regulators, rather than retailers.

The analysis demonstrated that wholesalers have an important influence on retailers through their product range and pricing, and are their most important source of information on new drugs. Working through wholesalers to spread key messages and distribute information, education and communication (IEC) materials may therefore be an effective method for reaching the retail interface, possibly building on the model piloted in western Kenya (Tavrow, Shabahang and Makama 2003).

Figure 13.2 Actors Influencing Retailer Behaviour



However, the most important target group is likely to be the patients and caretakers themselves, who have the greatest incentive to achieve a high-quality outcome. Moreover, household survey data showed that in many cases consumers do not rely on provider advice, selecting over half of drugs obtained at drug stores themselves, and over 95% at general stores. The evidence on the effectiveness of such communications strategies is very limited, as few public education interventions include impact evaluations (Fresle and Wolfheim 1997; Mills et al. 2002). When SP was introduced, the National Malaria Control Programme (NMCP) produced posters, magazines and user-friendly guidelines containing key messages. This represented a major improvement on pre-change IEC, but was mainly restricted to these print media, most of which were distributed to health facilities. Moreover, it was a one-off effort. A health issue of this importance could be argued to require an ongoing communications campaign of a different order of magnitude. A possible model would be the ITN campaign, which has successfully used mass media and local roadshows to communicate informative and persuasive messages, and been partly responsible for a substantial increase in net and insecticide treatment coverage (PSI 2003). Unlike a shopkeeper training programme, a consumer communications campaign would involve less face-to-face interaction with small groups, potentially benefiting from significant economies of scale. In the absence of formal training for retailers, drug store staff could be involved in the roadshows to ensure that they receive appropriate information, and that the public understand the place of retailers in fever/malaria treatment.

13.5.4 Retail Regulation

ACT provision in shops would require a change in the regulations, to give ACT the general sales status currently granted to SP and amodiaquine. This could provide an opportunity to address the gulf demonstrated in this thesis between the official regulations on drugs permitted and the drug range tacitly accepted in drug stores by local regulators. There are three options: the government could clamp down on illegal stocks, imposing severe penalties such as shop closure and heavy fines; it could proceed with the status quo of tacit acceptance of widespread infringements; or it could change the regulations to bring *de facto* regulatory implementation more in line with its *de jure* counterpart.

The evidence suggests that, given regulatory capacity constraints, government facility stockouts, and consumer demand, a concerted attempt to remove all prohibited drugs from drug stores would be very costly and time-consuming and probably infeasible. Moreover, the public health implications would be unclear. While it might reduce antimalarial and antibiotic drug pressure, and so slow the development of drug resistance, it would also reduce access to much-needed drugs for poor rural populations. On the other hand, remaining with the status quo of widespread regulatory contraventions could affect the potential for government or other agencies to work with retailers to distribute ACT, and perpetuate an antagonistic relationship between drug store staff and MOH personnel.

Although more investigation is warranted, there is a strong argument for widening the range of legal drug store stocks to include, for example, a small set of oral antibiotics, as permitted for ADDOs in the pilot project in Songea. Officially allowing drug stores to stock a wider range of products than general stores would reflect their far greater suitability as medicine providers. In addition, acknowledging the reality of stocking patterns would open the way to provision of supportive IEC for products frequently purchased. Concerns about treatment quality would remain, but it should be noted that according to the measures used in the study, treatment quality was no worse in drug stores than in government facilities. Wherever the boundaries are set, some infringement is likely to continue, but bringing the official and locally legitimate situations closer into line should create a more positive environment for public-private collaboration.

Such regulatory revision could pave the way for a more constructive engagement between drug store staff and regulators. In the absence of training, regulatory visits could provide an important opportunity for face-to-face contact if the role of the inspector were widened to include more

supportive activities, following the model for private facility supervision. For example, they could provide information on essential drugs, registered brands, appropriate dosing and consumer advice, and respond to queries and comments from shopkeepers.

13.6 Summary and Conclusions

This chapter has aimed to identify the policy implications of the thesis for improving malaria treatment, and in particular for the delivery of ACT, which Tanzania plans to adopt in 2006. Although there is some variation in fever/malaria treatment within Tanzania, and certain regulatory changes have taken place since the study, the thesis findings are argued to be broadly relevant to the current national policy context in rural areas.

Policymakers face two key decisions concerning the model for ACT delivery: whether ACT should be universally available or targeted at certain groups; and whether its distribution should be expanded beyond the formal health sector. If a facility-only model of ACT provision is followed, the analysis indicates that it will be particularly important to improve the quality and utilisation of government services. Nonetheless, a high proportion of patients are likely to continue to use the retail sector, purchasing antimalarial monotherapies or painkillers only. It is argued that significant and affordable improvements could be made to the treatment they receive by improving the chemical quality, packaging and labelling of retail sector drugs.

Subsidised retail sector ACT distribution has not yet been adopted by African countries changing to ACT, all of which have requested funds for the public sector only (Institute of Medicine 2004). In this chapter it has been argued that key advantages of involving retailers are that they are an important source of fever/malaria treatment, are likely to remain so in the future, and have the potential to increase the coverage of prompt ACT treatment significantly. The thesis findings suggest that Part II drug stores would be the most appropriate outlet for retail sector ACT, and that ACT distribution should be accompanied by strategies to maintain low retail prices, communicate key messages on treatment practices, and harmonise the official and tacitly accepted regulations on drugs stocked.

Ultimately the decision of whether to opt for retail sector distribution will involve wider considerations, beyond the scope of this thesis. Firstly, insufficient funding may preclude any ACT distribution outside the formal health sector. The IOM estimates that the proposed subsidy would cost \$300-500 million per year for all endemic nations. However, Snow et al. estimate that this sum would be required to cover Nigeria alone, and that achieving 60% coverage in the formal sector

would cost between US\$1.6bn and US\$3.4bn per year (Snow, Eckert and Teklehaimanot 2003). The appetite of donors for such an increase in malaria funding is as yet untested. It is possible that ACT prices will fall over time, as production capacity increases, or synthetic artemisinins are introduced, but this is likely to take time. A second fundamental concern relates to the impact on drug resistance. Increased drug pressure on ACT component drugs as a result of widening access may be seen as a major threat, especially in view of the limited number of alternative drugs available for the future. Data have not been collected systematically on the impact that widespread, easy access to antimalarials has on resistance (Bloland, Kachur and Williams 2003). In the light of current uncertainty, some policymakers may feel maximum effort should be put into increasing access to effective care now, while for others the potential risks for drug resistance may be too great.

Whatever the choice of ACT delivery model, the current importance of the retail sector, and its likely continued significance, mean that the intended role of the retail sector should be considered from the outset. To date, the government approach has been largely reactive, allowing the private market to determine the products, prices and information provided by retailers, with only limited and relatively ineffective attempts to influence this through drug registration and retail regulation. Whether policymakers plan facility-only or wider provision of ACT, it is argued to be preferable to take a proactive stance to the retail sector, deciding what balance of facility/retail utilisation is desirable, which drugs should be available OTC, and the standards drugs should meet, and then to design a set of interventions focused around these goals.

Much more work is needed to test a range of approaches to improving retail sector treatment, both with and without ACT. Intervening retailer by retailer on a national scale would present huge challenges, even for drug stores alone, in view of their sheer number and the limited government capacity. An alternative approach would be to target the bulk of resources to interventions with other actors, such as manufacturers, distributors, and consumers themselves. Such an approach may facilitate the achievement of sustainable national level interventions. In an ideal setting, the distributional power of the retail market would be harnessed, by ensuring that good quality, well-labelled, affordable products enter the top of the distribution chain, are distributed safely and efficiently around the country, and that consumers have the information to demand a high-quality, safe and appropriate service at the chain's end.

CONCLUSIONS: NEW KNOWLEDGE AND RESEARCH PRIORITIES

14.1 Policy Context

Malaria is a treatable disease that affects some of the world's most vulnerable people. Rates of appropriate treatment in Africa are scandalously low, and mortality rates appallingly high (Snow et al. 1999; WHO & UNICEF 2003), though their power to shock may have waned through their familiarity. Despite national and international efforts, malaria treatment has deteriorated in much of sub-Saharan Africa over the last two decades, due to the growth of resistance to commonly used and relatively cheap antimalarials (Bloland, Ettlign and Meek 2000). Many now feel the situation has reached crisis proportions, and that action is needed urgently to improve health outcomes (Attaran et al. 2004; Institute of Medicine 2004; Kindermans et al. 2002; Nosten and Brasseur 2002).

Particular attention is focusing on the introduction of ACTs in health facilities, but the choice of an appropriate complementary approach in the retail sector remains open to debate. Possible options range from restricting ACT to formal facilities on the basis of confirmed diagnosis, to flooding the public and private market with highly subsidised products. What is clear is that, in view of the current high use of retailers, the sector should not be ignored. Although retail outlets are widely used for fever/malaria treatment, there is considerable concern about the quality of care provided, and uncertainty about how this should be improved.

14.2 New Knowledge

This thesis has aimed to demonstrate how an economic analysis of such markets for treatment can shed light on the determinants of the demand and supply of care, and inform policy decisions. The study is the first to use the industrial organisation concepts of market structure and provider conduct to explore this type of health care market and its performance in terms of public health goals. In order to investigate the market as a whole, it encompassed all consumers and suppliers of fever/malaria drugs in the study sites, including patients of all ages, and the full range of drug providers, from formal facilities to roadside stalls. Operational methods were developed for the investigation of market definition, antimalarial sales volumes, market concentration, entry and exit, product differentiation, price competition, and substitutability and complementarity between outlet types. The study adds to the very limited number of household surveys on fever/malaria treatment seeking in Tanzania, and provides the first detailed, large-

scale study of retailers across several Tanzanian districts, and the first quantitative study of antimalarial retail sales volumes in Africa.

The study confirmed the importance of retailers as a source of fever/malaria treatment. They accounted for the majority of provider visits, and a high proportion of total antimalarial volumes. Their popularity was based on a wide range of characteristics, including drug stock range and reliability, geographical and temporal accessibility, and staff expertise and courtesy. Retailers acted as both substitutes for facility care, and as complementary drug sources following facility consultation. An important finding was that drug and general retailers should be considered separately, as their characteristics were quite distinct. The relatively small number of drug stores had a much wider product range of higher perceived quality, and more knowledgeable staff, with a much greater agency role. As a result, they were reportedly perceived as sources for complete treatment/cures, competing closely with facilities, as opposed to the ubiquitous general stores, which were seen as first aid outlets only. Regulatory entry requirements and systems of inspection were also markedly different between the two retailer types.

In many ways this market was closer to the competitive end of the monopoly-perfect competition continuum than more frequently studied health care markets, due to the number of providers and products, lack of patents, frequent repeat purchase, prevalence of out-of-pocket payment, relatively low barriers to entry, and commercial nature of the majority of providers. However, there was considerable evidence of market power and market failures, with oligopolistic competition likely to have been the norm for rural antimalarial sales. There was strong differentiation across drug products on the basis of packaging, brand name and country of manufacture. The market was heavily geographically segmented, with high concentration in antimalarial sales in each segment. It was therefore not surprising to find evidence of weak price competition in the form of considerable drug price variation and high retail markups. This is likely to have had a damaging impact on the affordability of appropriate treatment for most households in these poor communities.

Non-price competition failed to deliver high quality care because consumers had imperfect information on treatment quality, and were obliged to rely on imperfect proxies for drug quality and staff expertise. Moreover, quality may have been compromised by competition among retailers to increase accessibility and affordability for patients, at the expense of appropriate diagnosis, drugs and doses. Finally, there may have been negative consumption externalities from antimalarial over-use and/or under-dosing which contributed to the development of drug resistance.

Government failures were also in evidence, and were likely to have contributed to the development and growth of the retail drug sector. The standard of public sector treatment was poor in terms of accessibility, waiting times, stock reliability, diagnostics, and the appropriateness and doses of drugs obtained. User charges were highly variable across facilities, often unofficial, and exemptions were rarely and haphazardly applied. Governmental regulatory oversight may have been responsible for the maintenance of some degree of order within the retail market, with no evidence of drug provision through itinerant vendors, market traders, or unofficial and unqualified "street doctors". However, regulation did not adequately address the many market failures, with little or no apparent impact on drug accessibility, pricing, dosing and quality. The potential for effective engagement with retailers was undermined by the divergence between the narrow drug range officially allowed in drug stores, and that deemed acceptable at a local level to meet community needs.

Overall, the interaction of market structure, provider conduct, demand and regulation had both positive and negative implications for fever/malaria treatment. Retailers increased the accessibility, range and reliability of drug stocks, and were partly responsible for the observed high coverage of some kind of treatment, and prompt treatment-seeking. However, the nature of competition and regulation contributed to the observed quality problems in terms of low antimalarial coverage, frequent under-dosing, inequitable access to quality care, and frequent use of ineffective, poor quality and poorly packaged antimalarials.

14.3 Policy Implications

In view of the impending introduction of combination therapy in Tanzania, the thesis results were used to consider policy implications under a first line ACT regimen, although many of the findings are potentially of relevance to continued implementation of monotherapies. The policy implications were identified, firstly, for a facility-only model of ACT provision, and secondly, for a model including retail sector distribution. While a strong argument can be made for extending coverage to the retail sector, ultimately the choice of approach will depend on factors beyond the scope of this thesis, including the funding available, and the perceived threat of increasing drug resistance. Under a facility-only model, the analysis was used to argue that even if improvements in facility care were made, retail sector use was likely to remain high and of poor quality. Moreover, restriction of subsidised ACT to the public sector may encourage drug leakage and marketing of counterfeit products. The potential for improving care with the monotherapies available in shops through a communications campaign is likely to be limited by the need to maintain clarity on the national ACT policy. However, there would be potential to work with manufacturers, distributors and regulators to improve the chemical quality, packaging and labelling of drugs in the retail sector.

The IOM has proposed that ACT delivery include the retail sector, using a product heavily subsidised at a supra-national level (Institute of Medicine 2004). However, many questions remain about how the subsidised drug could be delivered safely, efficiently and equitably to the target population. The results of this thesis have been used to argue that under current regulatory and competitive conditions, the retail market is unlikely to deliver affordable drugs or appropriate treatment to the majority of its users. Key features of a retail sector strategy to address these problems could include the use of drug shops as a point of retail distribution; strategies to reduce retail prices by lowering shop overheads and the use of recommended retail prices; an on-going large-scale communications campaign; revisions to the regulations on drugs stocked in drug stores; and a more constructive role for retail regulators in improving the availability of essential drugs and appropriate advice.

14.4 Research Priorities

Before putting the above recommendations into practice, more information is needed to assess geographical generalisability, and to further investigate drug prices, drug quality and the distribution chain. The research and implementation communities will then need to collaborate on the evaluation of ACT introduction, and the assessment of potential interventions to improve ACT coverage and use.

14.4.1 Analysing Markets in Other Settings

The thesis is based on data from three rural areas in south-east Tanzania. While the literature indicates some evidence of similarities with other Tanzanian settings, it will be important to collect nationally representative data on fever/malaria treatment in the retail sector, to evaluate the generalisability of the findings at the national level. The study results may also have relevance for other African countries with similar levels of endemicity and economic development. However, the literature indicates some important sources of cross-country variation in both the demand and supply for drugs in the retail sector, emphasising the need for similar analyses of the competitive and regulatory environment in other settings.

14.4.2 Further Investigation of Drug Prices, Drug Quality and the Distribution Chain

In addition to expanding the geographical focus, there are three specific issues within the retail sector where further research is warranted: price markups, antimalarial drug quality, and the operation of the distribution chain. More information is needed on prices and the costing structure of retailers in order to calculate net retail markups. Data on retail costs proved very

difficult to collect in one-off interviews with shopkeepers, but are essential to assess the potential to reduce existing markups and costs. Such information is likely to require in-depth work with a limited number of retailers, based on longer-term relationships. These issues are of great importance in view of the proposals for subsidising ACT in the private sector, to ensure that such subsidies feed through to the consumers.

Secondly, the study added to the evidence that antimalarial quality at the retail level is often poor, and indicated that the proxies for high-quality drugs relied on by consumers are often invalid. Clear policy implications cannot be drawn from these data for several reasons: the sample size was limited, drugs were sampled from only three districts, and the evaluation methods did not meet USP standards. Moreover, since the samples were collected in 2001, the Tanzanian government has implemented a number of strategies to improve drug quality, including mini-labs to test imports at borders, and collaboration with domestic manufacturers to improve quality assurance. However, testing of retail level quality has been very limited. A representative study of antimalarial retail quality should therefore be conducted, with the aim of both documenting the extent of the problem, and understanding the causes of poor quality. These issues are likely to be of increasing importance as the market share of artemisinin-based products increases, in view of the number of reports of deliberately faked artemisinins in Asia (Newton et al. 2003; Rozendaal 2001).

In assessing both pricing and drug quality, retail providers represent only the last link in a long chain of providers who handle the pharmaceuticals as they travel from factory to consumer. Providers in this distribution chain above the retail level also have a key influence on the product range, pricing and knowledge of retailers, but our understanding of the distribution chain structure, and the characteristics of these providers, is very limited. Improving information in this area will be essential if governments are to manage successfully the introduction of new antimalarials, and the distribution of subsidised products in particular.

14.4.3 Documenting the Impact of ACT Introduction

Such analysis of existing retail markets should represent only the beginning of the wide-ranging research agenda required to address the confluence of two key policy initiatives in African malaria treatment -- home-based management and ACT. The initiatives generate a broad range of questions concerning the appropriate choice of drug, diagnostic, treatment outlet, target group and supportive interventions, in both the facility and retail sectors. Firstly, it is important that lessons are learnt from early ACT-adopters, in terms of the impact on public sector utilisation, the retail sector's drug range, quality, prices and practices, and potential leakage of public sector products. Follow-up data collection is planned in the thesis study sites to compare the retail

market in control and intervention areas after two years of ACT implementation through facilities in Rufiji. However, introduction in one district will not have the far-reaching effects of nationwide public sector implementation, and it is therefore essential that the retail sector impact is monitored following national policy changes in Tanzania and elsewhere.

14.4.4 Evaluation of Retail Sector Interventions

Much more than observation of retail sector activities is required. In order to improve the evidence base for the implementation of retail sector strategies in future, there is a need to expand the number of intervention evaluations in the retail sector, and to ensure that they are rigorous and comprehensive. The evaluations should cover a range of different strategies in a variety of settings, and should not be restricted to those focusing on retailers alone. The thesis findings suggest that it may be more feasible and efficient to improve retail care through other actors, such as manufacturers, distributors, regulators and consumers. It may also be appropriate for interventions to address a broader range of health problems, as retailers are also important providers of treatment for other illnesses, such as acute respiratory infections, sexually transmitted diseases and TB, and are actual or potential distribution points for commodities such as ITNs and contraceptives. In all evaluations, data should be collected on consumer and provider behaviour, costs, and the distribution of benefits by SES. To provide comprehensive information to policy makers, a subset of evaluations should go beyond behavioural measures, to assess the impact on health outcomes and drug resistance.

There will be significant challenges in identifying appropriate study designs for intervention evaluations. There have been calls for increased rigour in the evaluation of health service interventions through the use of randomised controlled trial methods (Editorial 2004; Victora, Habicht and Bryce 2004). This could include the use of cluster-randomisation to evaluate one or two interventions alone or in combination (Mills submitted). This approach may be appropriate for certain research questions which can be addressed on a relatively small scale, such as packaging strategies to improve patient compliance. However, interventions such as social marketing through mass media techniques, or the strengthening of distribution chains, are likely to exhibit significant economies of scale, and be most effectively implemented on a larger-scale than would be feasible under cluster-randomisation. In addition, a key issue in the choice of retail sector approach is the likely impact on antimalarial drug resistance, but it is unlikely to be possible to evaluate this through relatively short-term studies, or by comparison of neighbouring areas.

For these reasons, cluster-randomised trials may be inappropriate or impractical for much of the intervention research agenda. Possible alternatives are plausibility evaluations that do not

involve randomisation, but attempt to document impact by including a comparison group and careful documentation of confounding variables, and adequacy evaluations, based purely on documentation of time trends following the introduction of an intervention (Habicht, Victora and Vaughan 1999). In some settings, adequacy designs may be the only feasible option, but the research community should look for opportunities to use plausibility designs where possible, through partnerships with implementing agencies.

14.5 Final Conclusions

Health care markets in developing countries are highly heterogeneous, with the importance and nature of the private sector varying across geographical settings and health problems. Economic analysis of the operation of such markets is to date very limited, despite major concerns about their performance in public health terms. A considerable literature exists on hospital markets in some developed countries, which highlights the utility of economic concepts and methods in understanding their performance. This study has shown that such concepts are also of value in the analysis of treatment markets in rural, developing country settings. Moreover, the relevance of economic theories of competition may be greater in these settings, due to the commercial nature of most providers, and the lack of large institutions such as insurance providers and health maintenance organisations. While the thesis findings have immediate relevance to the improvement of malaria treatment, it is therefore hoped that the concepts and methods employed will be of use in expanding our knowledge of the structure, conduct and performance of developing country health care markets in general.

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ANNEX 1

APPENDIX OF TABLES AND FIGURES

Table A1.1 Structure, conduct and performance under standard competition models

	Structure	Conduct	Performance
Perfect competition	<ul style="list-style-type: none"> • Concentration low • Large numbers of buyers and sellers • Homogenous good • Perfect information • No barriers to entry or exit 	<ul style="list-style-type: none"> • Competition is on the basis of price • Firms face horizontal demand curve as no single firm can influence the market price • Quality competition is irrelevant with a homogenous product 	<ul style="list-style-type: none"> • In equilibrium, price will equal marginal revenue & marginal cost • Firms make normal profits only
Monopolistic competition	<ul style="list-style-type: none"> • Concentration is relatively low • Many providers & many consumers • Product may not be homogenous • Information may not be perfect 	<ul style="list-style-type: none"> • Individual firms have some market power • Firms face downward sloping demand curve • Competition may be on the basis of price & non-price characteristics • In selecting its own action each firm takes the actions of the competing providers as given 	<ul style="list-style-type: none"> • Not clear cut, but generally argued that price & profits will be higher than under perfect competition
Oligopoly	<ul style="list-style-type: none"> • Concentration is high • Relatively small number of firms • High degree of interdependence between firms • Barriers to entry 	<ul style="list-style-type: none"> • In making decisions concerning price, quality etc, firms consider the likely behaviour of their competitors • Firms may maintain high prices through collusion (although this will not necessarily be sustainable) 	<ul style="list-style-type: none"> • Not clear cut – variety of collusive and non-collusive oligopoly models lead to different predictions about price & quantity
Monopoly	<ul style="list-style-type: none"> • Concentration is at its maximum • Single firm is the sole actual & potential supplier • Industry's product has no close substitutes 	<ul style="list-style-type: none"> • Monopolist can set own price • Faces downward sloping demand curve • Market segmentation through price discrimination is possible 	<ul style="list-style-type: none"> • Monopolist will set price to ensure operation on the elastic portion of the demand curve • Higher price & lower quantity than under perfect competition • Monopolist can persistently earn excess profits

Table A1.2 Background information on study districts

Features	Rufiji District	Kilombero District	Ulanga District
Geographic characteristics	Coastal delta, flood plain, plateau	Flood plain, escarpment	Flood plain, highlands
Estimated district population in 2000	170,000	220,000	160,000
Population density / km ²	9	10	10
Population under 5	20%	16%	16%
Under five mortality rate	191 /1000	160 /1000	160 /1000
Malaria transmission & endemicity	Intense perennial	Intense perennial	Intense perennial
Severe anaemia (Hb<8g/dL) in children under 5 years	44%	37%	33%
Average household size	6	5	5
Children under 5 years sleeping under bednet	26%	63%	31%
Children under 5 years sleeping under bednet treated with insecticide in last 6 months	3%	7%	5%

Source: IMPACT-TZ proposal.

Table A1.3 Adequacy of household survey sample size for analysis of treatment seeking behaviour

Variable	Estimated proportion /mean	Estimated standard deviation	Difference detectable between 2 equally sized groups	
			All age groups pooled	Under 5s only
Proportion using formal health facilities	53% ¹	-	12% points	25% points
	34% ²	-	12% points	24% points
Number of provider visits per episode	0.91 ¹	0.52 ¹	0.13	0.26

¹ Data from IMCI 1999 household survey (for under fives only)

² Data from IMPACT 2000 household survey (adults only)

Assumptions:

- Total sample of Group A households: 1250 (625 in each group)
- Wastage: 25%
- Design effect: 2
- Fever episodes in previous 2 weeks:
 - per household: 1.34
 - per household for under fives only: 0.34
- Detectable difference based on 5% significance and 90% power

Table A1.4 Minimum antimalarial doses used to calculate adequacy of treatment reported in household survey

Product	Chloroquine tablets	SP tablets	Amodiaquine tablets	Quinine tablets	Chloroquine syrup ³	Chloroquine injection	Quinine injection
Unit size	250mg ¹ (150mg base)	500/25mg	200mg	300mg	100ml (10mg/ml)	30ml (40mg/ml)	2ml
Dose	25mg/kg	25mg/kg	25mg/kg	210mg/kg	25mg/kg	10mg/kg ²	10mg/kg ²
Age group							
2-4 months	0.8	0.25	0.75	5.25	0.125	0.06	0.5
4-12 months		0.5	1.25				1.5
1-3 years	1.8	1	1.75	10.5	0.275	0.09	1
3-5 years	2.5		2.25		0.375	0.125	1.5
5-8 years	3.5	1.5 (5-9 yrs)	3	15.75		0.16	1.75
8-11 years	4.2	2 (9-14 yrs)	4.25	21		0.2	2.5
11-14 years	6		6.25	31.5			3.5
14-16 years	8.3	3	7.5	36.75		0.4	4.5
16+ years	10		8	42			5

¹ A minority of chloroquine tablets were 150mg (90mg base), and so these doses will provide minimum estimates of chloroquine underdosing

² Chloroquine and Quinine injection doses are for initial pre-referral treatment only, as recommended in the National Treatment Guidelines. As some people will not have obtained further treatment, this provides a minimum estimates of underdosing with injectables.

³ No chloroquine syrup treatments were reported for patients over five years.

Table A1.5 Outlet survey sample size calculations

Variable	Estimated proportion /mean ²	Estimated standard deviation ²	Difference to detect ¹	Required sample size in each group ³
Frequency of stockouts of key drugs	20%	-	20%	63
Staff have some secondary education	50%	-	20%	98
Price of loose chloroquine tablet	Tsh 15	Tsh 5	Tsh 3	44
Price of loose paracetamol tablet	Tsh 7	Tsh 5	Tsh 1.4	72
Average number of drug customers per day	20	10	4	98

¹ based on 20% difference from estimated mean or 20% point difference from estimated proportion.

² based on data from qualitative interviews.

³ based on 5% significance and 80% power.

Table A1.6 Antimalarial purchase required for standard doses for a two-year-old child and an adult

Drug type	Standard unit size ¹	Purchase required to treat a two-year-old child (for comparison of antimalarial prices)	Purchase required per equivalent adult dose (for calculation of sales volumes)
Tablets			
Chloroquine	250mg ²	2	10
SP	525mg	1	3
Amodiaquine	200mg	2	8
Quinine	300mg	11	42
Syrups			
Chloroquine	100ml	1	1
SP	10ml	1	1
Amodiaquine	60ml	1	1
Quinine	100ml	1	1
Injectables³			
Chloroquine	30ml	1	1
Quinine	2ml	1	1

¹ Some products were available in different unit sizes (e.g. amodiaquine syrup in 100ml and 60ml bottles; chloroquine tablets of 250mg and 150mg). Where this occurred, doses were adjusted to the equivalent volumes of the most common unit size.

² 150mg base.

³ Chloroquine and Quinine injection doses are for initial pre-referral treatment only, as recommended in the National Treatment Guidelines. The cost of purchasing a syringe and water for injection was not included.

Table A1.7 Characteristics of household survey respondents¹

	Kilombero DSS	Ulanga DSS	Rufiji DSS	Total
Household characteristics				
Number of households²	357	228	516	1101
Education of household head:				
None	63 (18%)	37 (16%)	226 (44%)	326 (30%)
Less than primary	110 (31%)	87 (38%)	99 (19%)	296 (27%)
Completed primary only	140 (39%)	83 (36%)	116 (22%)	339 (31%)
More than primary	44 (12%)	21 (9%)	75 (15%)	140 (13%)
Main job of household head³:				
Farming	336 (94%)	204 (89%)	425 (83%)	965 (88%)
Off-farm work	21 (6%)	24 (11%)	85 (17%)	130 (12%)
None	0 (-)	0 (-)	3 (0.6%)	3 (0.3%)
Religion of household head:				
Christian	284 (80%)	95 (42%)	43 (8%)	422 (38%)
Muslim	67 (19%)	131 (57%)	473 (92%)	671 (61%)
Traditional	0 (-)	2 (1%)	0 (-)	2 (0.2%)
No religion	6 (2%)	0 (-)	0 (-)	6 (0.5%)
Household SES:				
Poorest third	130 (36%)	76 (33%)	156 (33%)	362 (34%)
Middle third	108 (30%)	69 (30%)	166 (35%)	343 (33%)
Better-off third	119 (32%)	83 (36%)	148 (31%)	350 (33%)
Individual characteristics				
Number of individuals⁴	1085	802	1964	3851
Age group:				
Under five years	172 (16%)	118 (15%)	330 (17%)	620 (16%)
Over five years	913 (84%)	683 (85%)	1632 (83%)	3228 (84%)
Gender:				
Male	501 (51%)	343 (46%)	492 (44%)	1336 (47%)
Female	485 (49%)	402 (54%)	629 (56%)	1516 (53%)

¹ for households answering the detailed questionnaire (Group A only)

² data were missing on main job for 3 households in Rufiji, and on SES for 46 households in Rufiji

³ off-farm work encompassed labourer, business, driver, craftsman, formal sector, traditional healer, lumberjack, charcoal seller and fishing.

⁴ data on age were missing for 3 individuals (2 in Rufiji and 1 Ulanga). Data on gender were missing for 57 individuals in Ulanga, 99 in Kilombero, and 843 in Rufiji. The high level of missing data in Rufiji reflected the loss of roughly one-third of Rufiji questionnaire cover sheets, where this information was recorded.

Source: Household Survey May-Sep 2001.

Table A1.8 Prevalence of reported fever/malaria episodes and *P. falciparum* parasitaemia

	Reported fever/malaria in previous 2 weeks	<i>P. falciparum</i> parasitaemia on day of interview
All individuals	(n=3,847) 628 (16%)	(n=3,329) 768 (23%)
Household characteristics		
DSS area:	(n=3,847)	(n=3,329)
Kilombero	203 (19%)*	189 (20%)*
Ulanga	85 (11%)*	147 (22%)
Rufiji	340 (17%)*	432 (25%)*
Education of household head:	(n=3,847)	(n=3,329)
Not completed primary	328 (15%)*	435 (23%)
Completed primary or more	300 (18%)*	333 (23%)
SES:	(n=3,693)	(n=3,198)
Poorest third	179 (16%)	249 (25%)*
Middle third	212 (17%)	283 (26%)*
Better-off third	208 (16%)	202 (18%)*
Individual characteristics		
Age group:	(n=3,843)	(n=3,325)
Under 5 years	172 (28%)*	226 (41%)*
5-14 years	110 (10%)*	356 (38%)*
15+ years	346 (16%)*	185 (10%)*
Gender:	(n=2,849)	(n=2,501)
Male	208 (16%)	282 (25%)
Female	277 (18%)	299 (22%)

*significant difference across household/individual characteristics (chi² test with Rao and Scott correction, p<0.05)

Source: Household Survey May-Sep 2001.

Table A1.9 Number of outlets with drugs in stock

	Ulanga DSS	Kilombero DSS	Rufiji DSS	Total
Population (mid-2001)	29,439	37,064	73,839	140,342
Health care facilities				
Government	5	4	9	18
Private	2	3	4	9
Total facilities	7	7	13	27
Retailers stocking drugs				
Commercial drug shops	2	8	20	30
Village-run drug shops	0	2	0	2
General shops stocking drugs	122	155	258	535
Total retailers stocking drugs	124	165	278	567
Population ratios				
Population per facility	4206	5295	5680	5198
Population per drug shop	14,720	3706	3692	4386
Population per general shop stocking drugs	246	239	286	262
Population per drug outlet	229	215	254	236

Source: Outlet Census May-Sep 2001

Table A1.10 Fever/malaria drugs stocked
(% of outlets in each category stocking specified medicine)

(a) Painkillers

	Government facilities	Private facilities	Commercial drug shops	Village-run drug shops	General retailers ¹
n	18	8	30	2	213
Aspirin tablets	16 (89%)	8 (100%)	29 (97%)	2 (100%)	173 (81%)
Paracetamol tablets	16 (89%)	8 (100%)	30 (100%)	2 (100%)	188 (88%)
Paracetamol syrup	-	4 (50%)	27 (90%)	2 (100%)	5 (2%)
Aspirin + Caffeine tablets	-	-	5 (17%)	-	63 (30%)
Aspirin + Paracetamol + Caffeine tablets	-	-	7 (23%)	-	114 (54%)
Other painkillers	-	7 (88%)	16 (53%)	-	1 (0.5%)
Any painkillers	17 (94%)	8 (100%)	30 (100%)	2 (100%)	213 (100%)

(b) Antimalarials

	Government facilities	Private facilities	Commercial drug shops	Village-run drug shops	General retailers ¹
n	18	8	30	2	213
Tablets					
Chloroquine	11 (61%)	4 (50%)	11 (37%)	2 (100%)	20 (9%)
SP	16 (89%)	8 (100%)	27 (90%)	-	2 (0.9%)
Amodiaquine	10 (56%)	4 (50%)	23 (77%)	-	7 (3%)
Quinine	5 (28%)	7 (88%)	20 (67%)	-	1 (0.5%)
Artesunate	-	-	1 (3%)	-	-
Syrups					
Chloroquine ²	10 (56%)	3 (38%)	8 (27%)	2 (100%)	2 (0.9%)
SP	-	1 (13%)	6 (20%)	-	-
Amodiaquine	-	2 (25%)	13 (43%)	-	1 (0.5%)
Quinine	-	1 (13%)	10 (33%)	-	-
Injectables					
Chloroquine	10 (56%)	2 (25%)	9 (30%)	-	1 (0.5%)
Quinine	10 (53%)	8 (100%)	24 (77%)	-	1 (0.5%)
Any antimalarials	18 (100%)	8 (100%)	30 (100%)	2 (100%)	30 (14%)

¹n excludes general stores not stocking any fever/malaria drugs at the time of the Outlet Survey

² including powder for syrup

Source: Outlet Survey Nov-Dec 2001

**Table A1.11 Number of providers visited per individual reporting fever/malaria
(% of individuals reporting fever/malaria making specified number of provider visits)**

Number of visits per interviewee	Total
0	160 (26%)
1	389 (62%)
2	56 (9%)
3	18 (3%)
4	3 (0.5%)
5	2 (0.3%)
Total episodes	628 (100%)

No significant difference in number of providers visited by age group (chi² test with Rao and Scott correction)
Source: Household Survey May-Sep 2001.

Table A1.12 Estimated antimalarials dispensed per annum in volume and value terms (per capita amounts in brackets)

	Kilombero DSS	Ulanga DSS	Rufiji DSS	Total
Antimalarial volumes in equivalent adult doses				
Government facilities	11,232 ¹ (0.3)	11,232 ¹ (0.4)	73,164 (1.0)	95,641 (0.7)
Private facilities	10,465 (0.3)	3,705 (0.1)	34,357 (0.5)	48,540 (0.3)
Commercial drug shops	35,035 (0.9)	14,352 (0.5)	29,159 (0.4)	78,533 (0.6)
Village-run drug shops	1,560 (0.04)	0 (-)	0 (-)	1,560 (0.01)
General stores	4,659 (0.1)	1,978 (0.1)	2,761 (0.04)	9,397 (0.1)
Total	62,951 (1.7)	31,241 (1.1)	139,415 (1.9)	233,606 (1.7)
Antimalarial sales values in US\$				
Government facilities	\$2,031 (\$0.05)	\$1,386 (\$0.05)	\$7,381 (\$0.10)	\$10,799 (\$0.08)
Private facilities	\$6,777 (\$0.18)	\$2,692 (\$0.09)	\$23,086 (\$0.31)	\$32,555 (\$0.23)
Commercial drug shops	\$26,991 (\$0.73)	\$10,094 (\$0.34)	\$21,759 (\$0.29)	\$58,844 (\$0.42)
Village-run drug shops	\$1,742 (\$0.05)	0 (-)	0 (-)	\$1,742 (\$0.01)
General stores	\$2,446 (\$0.07)	\$907 (\$0.03)	\$1,350 (\$0.02)	\$4,703 (\$0.03)
Total	\$39,988 (\$1.08)	\$15,079 (\$0.51)	\$53,576 (\$0.73)	\$108,643 (\$0.77)

Source: Retail Audits Feb/Apr & Jun/Jul 2002 (drug prices from Outlet Survey Nov-Dec 2001)

¹ It is correct that estimates for Kilombero and Ulanga government facilities are identical.

Table A1.13 Breakdown of sales volumes by antimalarial for each outlet type

	Government facilities	Private facilities	Commercial drug shops	Village-run drug shops	General shops
n (equivalent adult doses)	95,641	48,540	78,533	1,560	9,397
Tablets:					
Chloroquine	3%	2%	2%	0%	51%
SP	77%	71%	64%	73%	31%
Amodiaquine	16%	11%	24%	11%	9%
Quinine	1%	8%	4%	13%	6%
All Syrups	0%	2%	2%	3%	2%
All Injectables	3%	7%	4%	0%	0%
Total	100%	100%	100%	100%	100%

Source: Retail Audits Feb/Apr & Jun/Jul 2002.

Table A1.14 Estimated mean antimalarial sales per outlet p.a. in volumes and values

	Kilombero DSS	Ulanga DSS	Rufiji DSS	Average across DSS areas
Mean antimalarial sales volumes (equivalent adult doses)				
Government facilities	2,808	2,246	8,129	5,313
Private facilities	3,488	1,853	8,580	5,393
Commercial drug shops	3,893	4,784	1,325	2,310
Village-run drug shops	780	-	-	780
General stores ¹	91	99	50	74
Mean antimalarial sales values in Tsh (US\$ in brackets)				
Government facilities	483,893 (\$509)	263,450 (\$277)	789,242 (\$831)	575,333 (\$606)
Private facilities	2,146,313 (\$2,259)	1,278,843 (\$1,346)	4,387,000 (\$4,617)	3,093,162 (\$3,255)
Commercial drug shops	2,849,519 (\$2,999)	3,196,795 (\$3,365)	939,742 (\$989)	1,644,423 (\$1,731)
Village-run drug shops	827,398 (\$871)	-	-	827,398 (\$871)
General stores ¹	45,471 (\$48)	43,057 (\$45)	23,701 (\$25)	35,681 (\$38)

¹ General stores stocking antimalarials in 2001

Source: Retail Audits Feb/Apr & Jun/Jul 2002 (drug prices from Outlet Survey Nov-Dec 2001).

**Table A1.15 Proportion of antimalarials for fever/malaria dispensed as under-doses
(a) By provider type**

	No. of antimalarials	Underdoses (%)
Government facility	79	23 (29%)
Private facility	34	7 (21%)
Drug shop	95	28 (29%)
General shop	24	12 (50%)
Other	2	1 (50%)

(b) By antimalarial type

Antimalarial	No. of antimalarials	Underdoses (%)
SP tablets	68	9 (13%)
Chloroquine tablets	103	34 (33%)
Amodiaquine tablets	7	2 (29%)
Quinine tablets	28	24 (86%)
Chloroquine syrup	9	0 (-)
Chloroquine injection	11	0 (-)
Quinine injection	8	2 (25%)
All antimalarials	234	71 (30%)

¹ Antimalarials obtained from providers only.
Source: Household Survey May-Sep 2001.

Table A1.16 Variation in antimalarial tablet prices in shops by outlet and product characteristic (median price of 2 year old child's dose in Tsh)
(a) Commercial drug shops

Variation by:	SP		Amodiaquine		Chloroquine		Quinine	
	n	Median	n	Median	n	Median	n	Median
Outlet characteristics								
<i>DSS area</i>								
Kilombero	13	200	10	120	3	20	6	825
Ulanga	3	200	2	180	0	-	3	1100
Rufiji	45	300	19	200	7	20	13	1100
<i>Location type</i>								
Market centre	43	300	17	200	6	20	13	1100
Rural village	18	200	14	170	4	20	9	880
Farming area	0	-	0	-	0	-	0	-
Product characteristics								
<i>Packaging</i>								
Packaged	52	268	19	200	0	-	13	1100
Loose	9	150	12	200	10	20	9	770
<i>Brand status</i>								
Innovator brands ¹	14	500	0	-	0	-	0	-
Branded generics	40	200	23	200	6	20	4	935
Unbranded generics	7	150	8	200	4	20	18	1100
<i>Country of manufacture²</i>								
Tanzania	17	250	9	140	10	20	7	770
Other Africa	24	200	12	200	0	-	6	935
Asia	4	267	8	200	0	-	0	-
Europe	15	500	0	-	0	-	9	1100

¹ Innovator brands: FansidarTM for SP and MetakefinTM for SMP.

² country of manufacture missing for one SP product and one amodiaquine product.

(b) General stores

Variation by:	SP		Amodiaquine		Chloroquine		Quinine	
	n	Median	n	Median	n	Median	n	Median
Outlet characteristics								
<i>DSS area</i>								
Kilombero	2	150	1	400	10	35	1	440
Ulanga	0	-	2	250	1	20	0	-
Rufiji	0	-	4	167	12	70	0	-
<i>Location type</i>								
Market centre	0	-	4	167	3	60	0	-
Rural village	0	-	3	300	19	70	1	440
Farming area	2	150	0	-	1	30	0	-
Product characteristics								
<i>Packaging</i>								
Packaged	0	-	7	200	18	70	0	-
Loose	2	150	0	-	5	30	1	440
<i>Brand status</i>								
Innovator brands ¹	0	-	0	-	0	-	0	-
Branded generics	2	150	7	200	21	70	0	-
Unbranded generics	0	-	0	-	2	25	1	440
<i>Country of manufacture²</i>								
Tanzania	0	-	0	-	12	35	-	-
Other Africa	2	150	7	200	11	70	-	-
Asia	0	-	0	-	0	-	-	-
Europe	0	-	0	-	0	-	-	-

¹ Innovator brands: Fansidar™ for SP and Metakelfin™ for SMP.

² country of manufacture missing for one quinine product.

Source: Outlet Survey Nov-Dec 2001.

Table A1.17 Variation in painkiller tablet prices in shops by outlet and product characteristic (per tablet in Tsh)
(a) Commercial drug shops

Variation by:	Aspirin		Paracetamol		Aspirin+Caffeine		Aspirin+Caffeine +Paracetamol	
	n	Median	n	Median	n	Median	n	Median
Outlet characteristics								
<i>DSS area</i>								
Kilombero	10	5	11	10	5	50	5	50
Ulanga	3	5	3	10	0	-	1	50
Rufiji	21	5	27	10	1	25	7	35
<i>Location type</i>								
Market centre	16	5	22	10	2	28	8	38
Rural village	18	5	19	10	4	50	5	50
Farming area	0	-	0	-	0	-	0	-
Product characteristics								
<i>Packaging</i>								
Packaged	3	30	5	20	6	45	12	40
Loose	31	5	36	10	0	-	0	-
<i>Brand Status</i>								
Branded generics	7	5	31	10	6	45	13	40
Unbranded generics	27	5	10	10	0	-	0	-

(b) General stores

Variation by:	Aspirin		Paracetamol		Aspirin+Caffeine		Aspirin+Caffeine+Paracetamol	
	n	Median	n	Median	n	Median	n	Median
Outlet Characteristics								
<i>DSS area</i>								
Kilombero	44	5	70	10	18	40	31	40
Ulanga	34	5	49	10	7	50	22	50
Rufiji	128	3	171	25	52	30	155	35
<i>Location type</i>								
Market centre	58	3	85	25	26	30	63	35
Rural village	125	5	175	10	49	35	131	40
Farming area	23	5	30	10	2	60	14	40
Product Characteristics								
<i>Packaging</i>								
Packaged	45	25	126	40	77	35	208	40
Loose	161	3	164	10	0	-	0	-
<i>Brand Status</i>								
Branded generics	42	25	265	10	77	35	208	40
Unbranded generics	164	3	25	5	0	-	0	-

Source: Outlet Survey Nov-Dec 2001.

Figure A1.1 Coding scheme for analysis of qualitative provider interviews

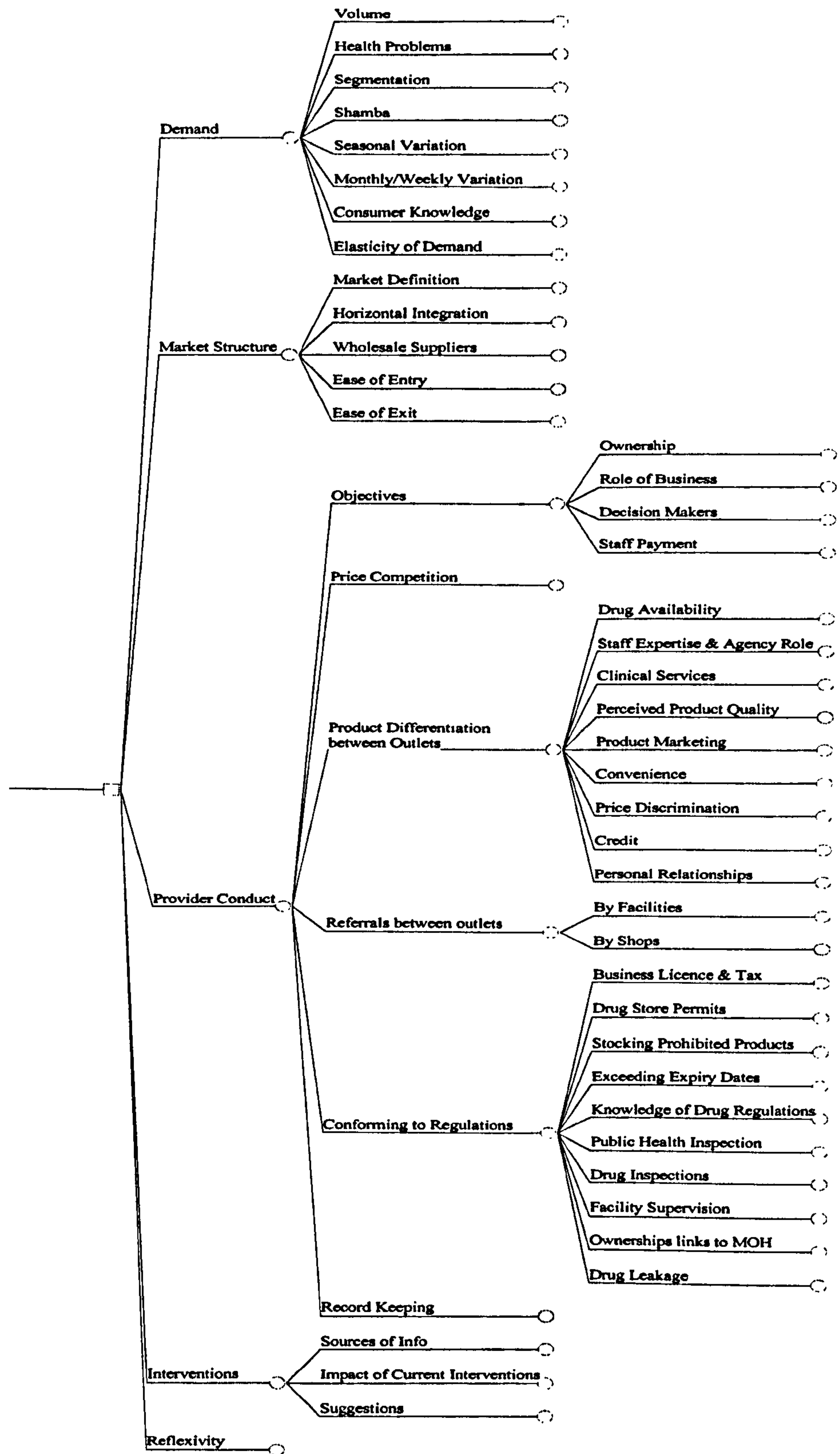
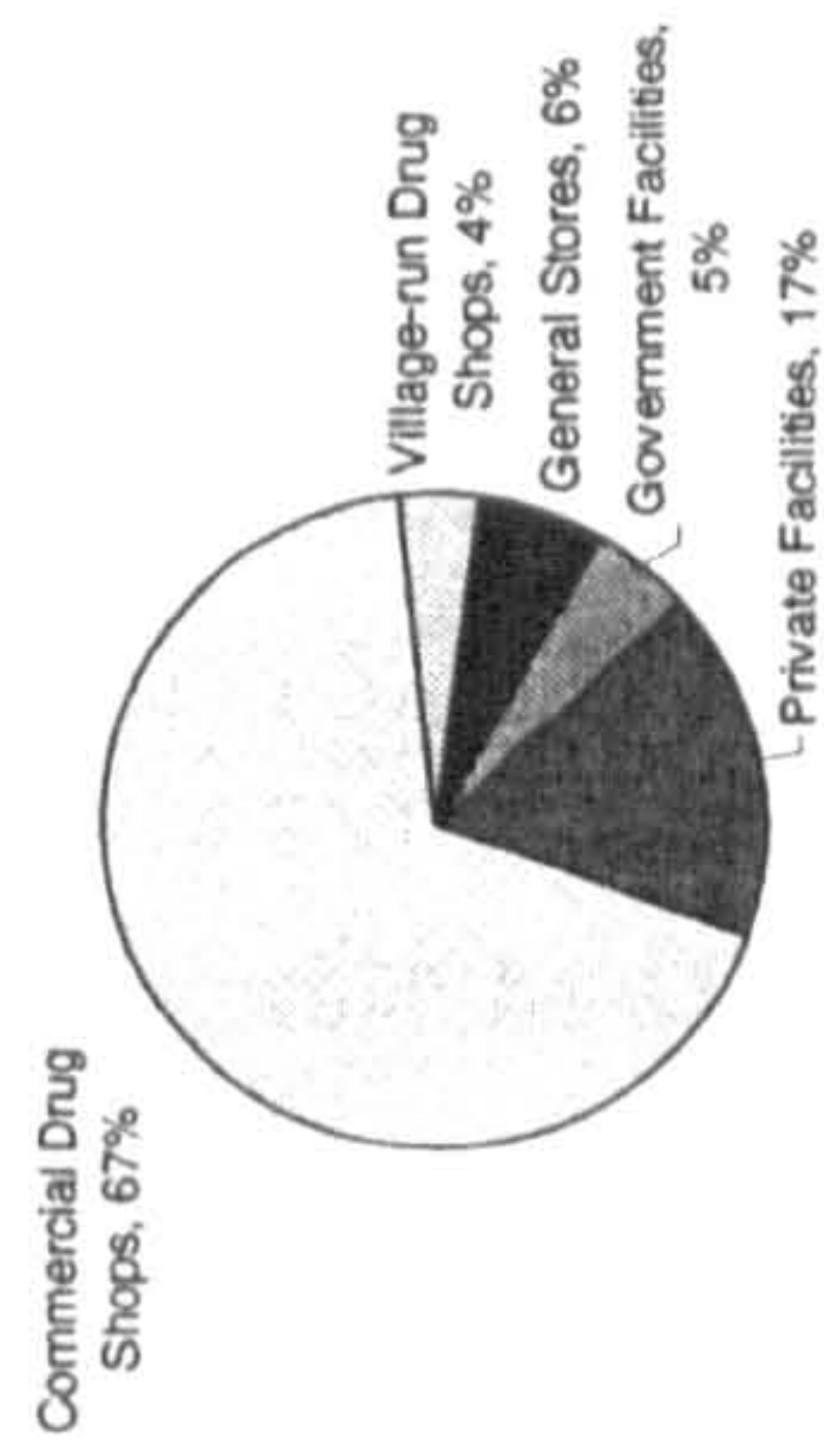
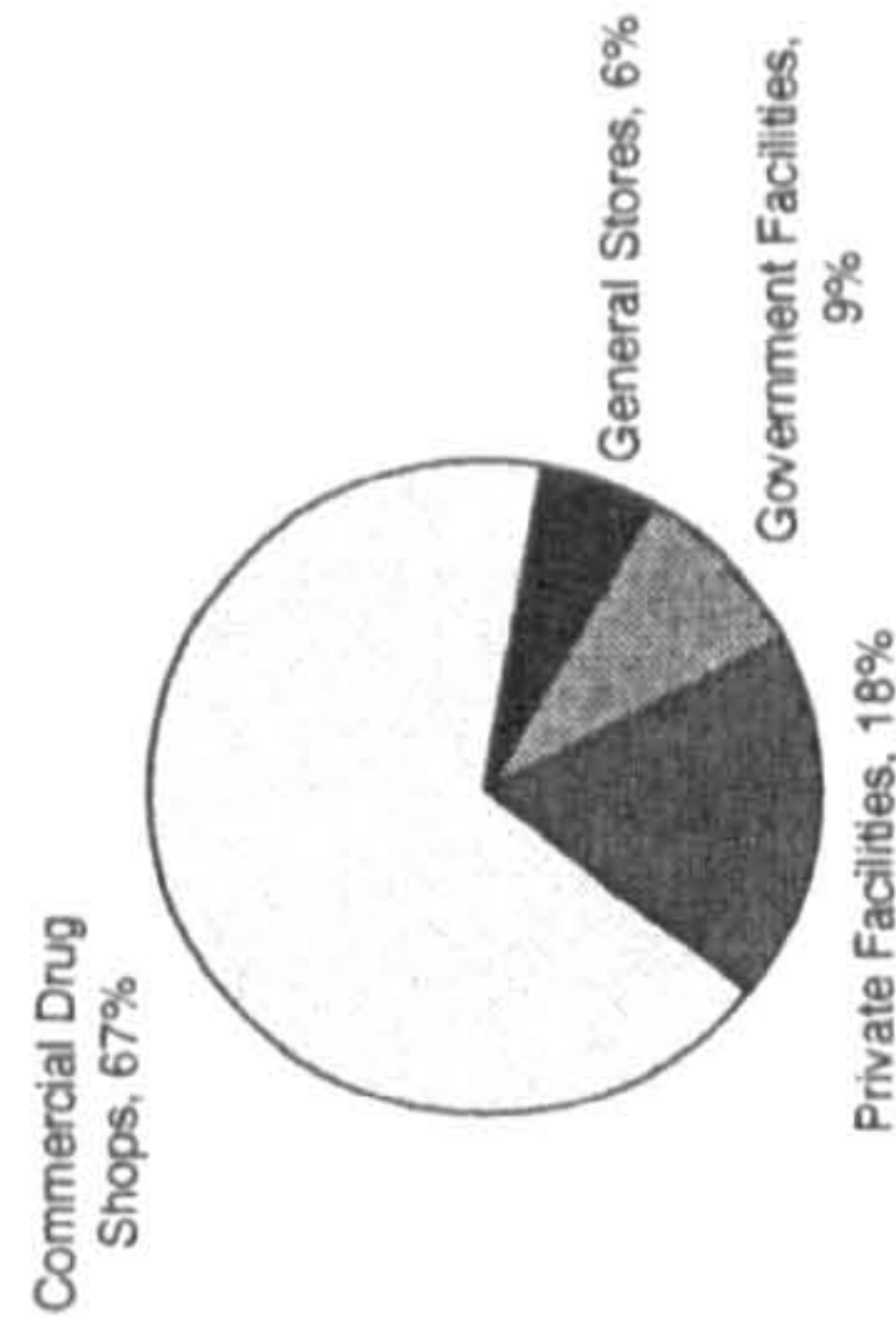


Figure A1.2 Antimalarial values dispensed by source

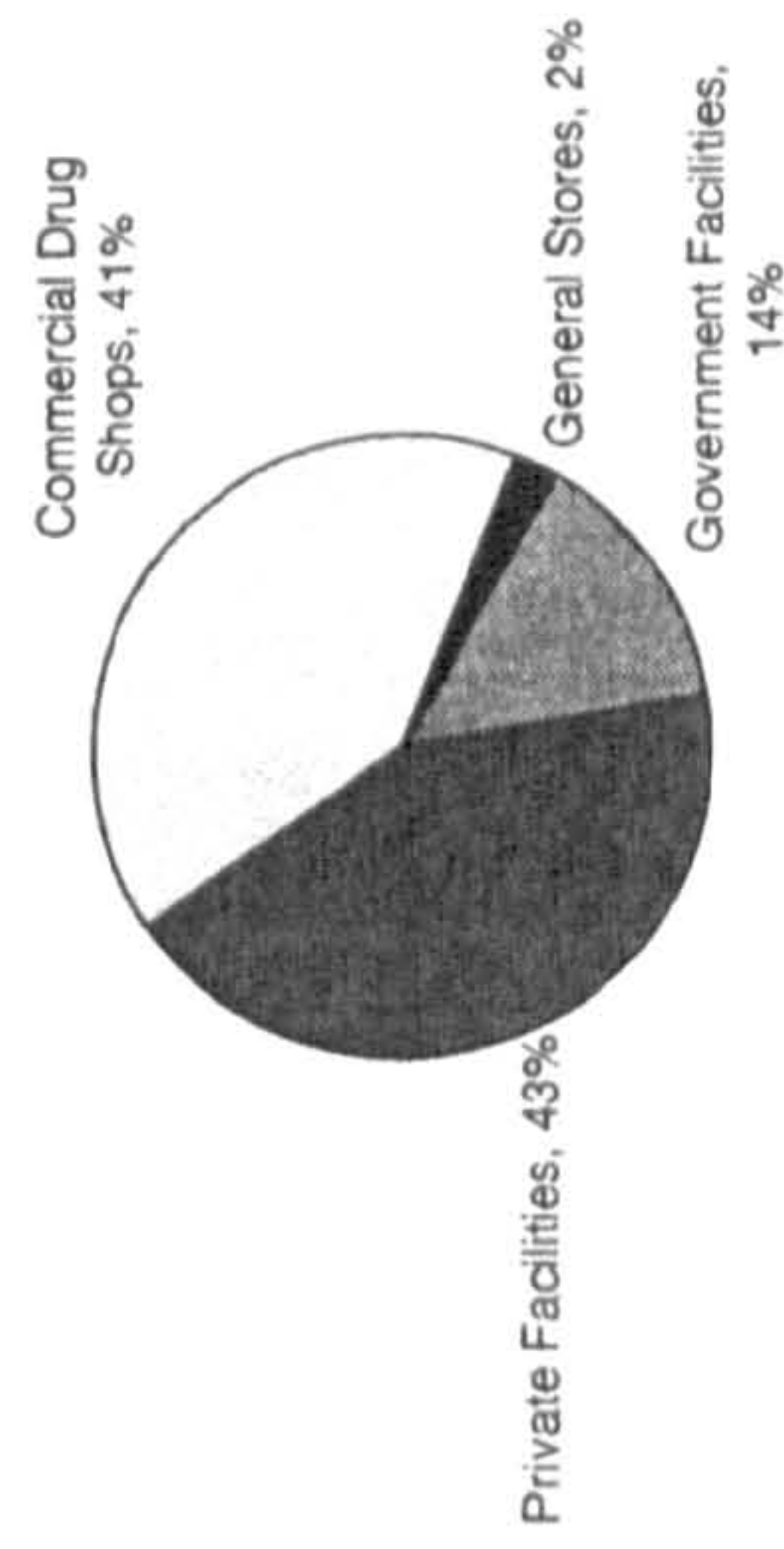
Kilombero DSS



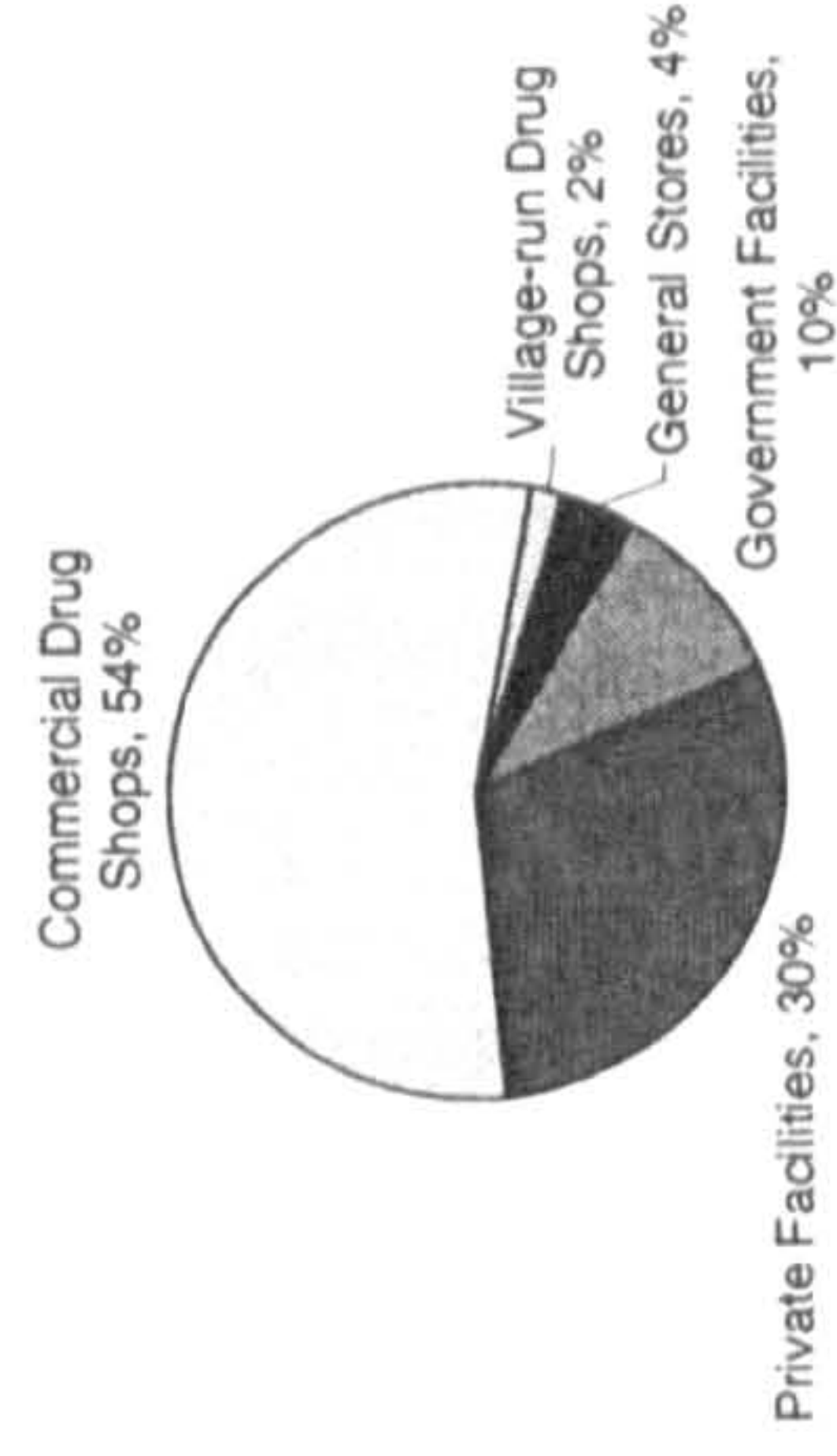
Ulanga DSS



Rufiji DSS



Total



Source: Retail Audits Feb/Apr & Jun/Jul 2002

ANNEX 2

FRAMEWORK FOR POTENTIAL DETERMINANTS OF HOUSEHOLD DEMAND AND RETAIL PROVIDER SUPPLY

1. Potential Determinants of Household Demand

Consumer knowledge and beliefs about fever/malaria and treatment efficacy:

- local illness classifications and explanatory models for malaria
- perceptions of disease severity
- knowledge of drug treatments and dosing regimens
- understanding of the difference between types of formulation, antimalarials and antipyretics, and between brand name and generic products
- perceptions of efficacy and resistance
- information characteristics of the products
- branding and promotion strategies of manufacturers and distributors

Consumer preferences for other product characteristics:

- dosage regimens
- antipyretic action
- side-effects
- taste

(noting that some apparently unpleasant characteristics are linked with greater perceived efficacy)

Consumer preferences for provider characteristics:

- accessibility and opening hours
- waiting times
- reliability and range of drug supplies
- the availability of equipment, diagnostics and examination services
- the condition of buildings
- courtesy of staff
- perceived expertise of staff
- perceived motivation of staff

Prices:

- variation across individuals, providers, drugs and formulations (including any price discrimination, market segmentation or product differentiation)
- price of complementary goods and services such as diagnosis, consultation, travel and time costs
- additional under-the-table charges
- mode of payment (credit availability, payment-in-kind)
- household income (including seasonal fluctuations)
- availability of loans or gifts

Agency role of the provider:

- degree of information asymmetry between consumer and provider
- potential for opportunistic behaviour by providers
- balance of provider /consumer roles in deciding on treatment

2. Potential Determinants of Retail Provider Supply**Provider knowledge:**

- knowledge of drug treatments and dosing regimens
- understanding of the difference between types of formulation, antimalarials and antipyretics, and between brand name and generic products
- perceptions of efficacy and resistance
- beliefs about patients' attitudes and preferences

(knowledge will be influenced by medical/pharmaceutical training, work experience, general levels of education, information provided through training programmes, provider and general public health education initiatives, and professional support)

Provider incentives:

- nature of provider goals (profit, satisficing, serving community, building reputation etc.)
- outlet ownership
- terms of staff employment and remuneration
- decentralisation of control over personnel and finance
- cost structure, taxes or regulatory fees
- promotional prospects

Competitive environment:

- market concentration
- prevalence of price and non-price competition
- information characteristics of the products and services
- whether demand is characterised by recurrent visits or one-off exchanges
- access to credit and capital
- threat of potential new entrants to the market
- threat of exit

Regulation and supervision:

- scope of government regulation or supervision
- government enforcement capability including potential for regulatory capture
- self-regulation by professional associations
- monitoring by consumer associations

Distribution chain:

- availability and prices of products to retailers
- frequency and reliability of distribution
- information provided by distributors
- mode of payment and incentive schemes
- vertical control and integration

ANNEX 3

THE IMPACT-TZ EVALUATION

The Interdisciplinary Monitoring Project for Antimalarial Combination Therapy in Tanzania (IMPACT-TZ) is a collaboration between the United States Centers for Disease Control and Prevention (CDC), the Ifakara Health Research and Development Centre (IHRDC), the National Institute for Medical Research (NIMR), the Tanzanian Essential Health Interventions Project (TEHIP), the Adult Morbidity and Mortality Project (AMMP), the London School of Hygiene and Tropical Medicine, and the Ministry of Health (PIs: Dr. Peter B. Bloland (CDC) and Dr. Salim Abdulla (IHRDC)).

The overall aim is to evaluate the effectiveness of artemisinin-based combination therapy (ACT) for malaria treatment in Tanzania. The evaluation is taking place in the four rural Tanzanian districts of Kilombero, Ulanga, Rufiji and Morogoro-Rural. Baseline data were collected in all areas between 2000 and 2002. In early 2003 IMPACT staff collaborated with the Rufiji District Health Management Team to implement ACT (SP plus three-day artesunate) as first line drug in Rufiji district. The evaluation of ACT in comparison with SP monotherapy in the other three districts is ongoing.

The objectives of IMPACT-TZ are:

1. To determine the effectiveness of combination therapy using an artemisinin derivative and SP for delaying the advent and intensification of parasitologic resistance to the separate component drugs.
2. To determine the effectiveness of combination therapy using an artemisinin derivative and SP for decreasing malaria transmission (using gametocyte carriage rates as a proxy measure).
3. To identify the range of factors which influence the use of antimalarials by patients, caretakers, and health providers, and to develop and evaluate interventions that optimize the recommended use of combination therapy through all available channels of distribution (including public, private, formal and informal sectors).
4. To investigate the costs and cost-effectiveness of the combination therapy strategy.
5. To describe the policy implications of combination therapy, including barriers to successful implementation of the policy, successful strategies for implementation, health care workers' understanding and use of the new policy, and use of information from this pilot implementation area to inform or modify policy in other districts or nationally.
6. To measure the public health impact of combination therapy when used operationally.
7. To support and promote capacity building within partner institutions in Tanzania.

IMPACT data collection includes household surveys, outpatient and inpatient facility surveys, *in vivo* and *in vitro* drug efficacy studies, assessment of compliance, qualitative assessment of illness classification, care-seeking and drug use practices, costing studies at the household, facility and district levels, analysis of the process of change and decision-making, demographic surveillance of migration, births and deaths, and adverse drug reaction / post marketing surveillance.

The evaluation is supported by a number of funders including the United States Agency for International Development, CDC, and the Wellcome Trust. This thesis contributes to the achievement of Objectives 3 and 5, and was funded primarily by the Wellcome Trust.

ANNEX 4

DATA COLLECTION INSTRUMENTS

- Household Economics Survey
 - Module A: Household data 286
 - Module B: Individual data 289
 - Module C: Source of treatment or medicine 293
- Outlet Census
 - Questionnaire 296
- Qualitative Provider Interviews
 - Guide for qualitative interviews at facilities 303
 - Guide for qualitative interviews at shops 308
 - Staffing table 314
 - Drugs table 315
- Outlet Survey
 - Questionnaire 316
 - Drug Check List 332
- Retail Audit
 - Questionnaire 335
 - Stock Table 340



Interdisciplinary Monitoring Programme for Antimalarial Combination Therapy in Tanzania.

IMPACT Second baseline household survey (Activity A, Year 2001) In Kilombero, Ulanga and Rufiji Districts.

HOUSEHOLD ECONOMICS SURVEY

MODULE B: Individual Data (Complete 1 form for each household member who is present at the time of the interview)

District Code: Village Code: DSS Household Number:

Name of individual:

DSS Permanent ID: Date of Birth: / /

Ask the following questions to each adult household member. For children under 12 years of age, ask the questions of the child's parent or primary caretaker.

19. Specify your relationship to the individual mentioned above.

- 1=self (the person is more than 11 years old)
- 2=mother
- 3=father
- 4=grandmother
- 5=grandfather
- 6=aunt/uncle
- 7=sibling
- 8=other:

20. Have you had (has your child had) a severe blistering skin rash at any time in the past 4 months?
 1=yes 2=no 9=unknown

If it the individual is a child under 3 years of age, go to question #18.

21. Have you (has your child) experienced a problem with walking or talking (as if drunk) at any time during the past 4 months?
 1=yes 2=no 9=unknown

22. During the past 14 days have you (has your child) had fever or malaria?
 1=yes 2=no 9=unknown
**If yes, go to question # 24*

Questionnaire for census of outlets selling drugs in the DSS areas*If possible interview the In-Charge or owner of the outlet***Information and invitation to participate in research: Inventory of outlets where people obtain drugs for treating fever or malaria.**

My name is, and I am an interviewer from the Ifakara Health Research and Development Centre / Rufiji Demographic Surveillance System. We would like to learn about how people from this area obtain drugs for treating fever. We would also like to know more about malaria, one of the most common causes of sickness here in Tanzania. The results of this research will help to improve the availability of drugs when they are needed by people suffering from malaria.

In order to do this we are visiting and interviewing staff in clinics, general shops, drug shops, kiosks and other outlets to ask about the types of drugs that they sell. We would like to know which drugs you stock for treating fever or malaria, which drugs people buy most often, and where you normally buy your drug supplies.

This is the second year of this activity. Last year we obtained very useful information, and this year we are visiting to update this information to see whether there have been any changes in the number or type of outlets, or changes in the types of drugs available.

We would greatly appreciate your co-operation in this research. Participation is voluntary, and you do not need to answer any question that you do not want to answer. The interview will only last a few minutes. The information obtained from this interview will be confidential, and is for research purposes only. Your name and the name of your business will not appear in any report that comes out of this study. Information from this research will be used for improving services only and will not be passed to any drugs regulatory authorities.

Do you have any questions? Do you agree to participate?

Code Number: |__|__|__|__|
(From the outlet list. If the outlet is new, write 8888)

District Code: |__|__|__| **Village Code:** |__|__|__|

Name of Kitongoji: _____

Date of first visit: |__|__|/|__|__|/|__|__|__|__|
(day/month/year)

1. Type of provider: |__|

1. Non-governmental Dispensary / Health Centre / Dispensary
2. Private commercial Dispensary / Hospital
3. Drug Shop (Baridi / Part 2)
4. General Shop
5. Kioski or Genge
6. Traditional healer
7. Other: _____

Was it possible to do the interview?

1. Yes 2. No

If yes, go to question # 2.

If no, why not?

1. You were asked to come back later
2. The outlet was closed today
3. The outlet had completely closed down
4. You were refused permission to interview because _____

If "1" or "2" come back later.

If "3" or "4" go to question #10.

If a second visit is made to the outlet:

Date of second visit:

/ / (day/month/year)

Was it possible to do the interview?

1. Yes 2. No

If yes, go to question # 2.

If no, why not?

1. You were asked to come back later
2. The outlet was closed today
3. The outlet had completely closed down
4. You were refused permission to interview because _____

If no, go to question #10.

2. Are there any drugs in stock today?

1. Yes 2. No

If Yes, go to #4.

If No, go to #3.

3. Have you sold any drugs in the last 2 months?

1. Yes 2. No

If Yes, go to #7.

If No, go to #9.

5. Next I would like to ask about antimalarials?

What drugs do you have in stock today for malaria?

1. In stock 2. Not in stock

and list any other antimalarials which are present and not included on the list.

Antimalarials:	List below any other antimalarials: (tablets / syrup / injectable)
Dawaquin tablets	
Elyquine tablets	
Elyquine syrup	
Homaquin tablets	
Malaraqin tablets	
Shelyquine tablets	
Shelyquine syrup	
Tanzanquine tablets	
Tanzanquine syrup	
Zenaquin tablets	
Chloroquine tablets (generic)	
Chloroquine syrup (generic)	
Fansidar tablets	
Orodar tablets	
Sulphadar tablets	
Sulfadoxine-pyrimethamine tablets (generic)	
Metakelfin tablets	
Sulfametopyramine and pyrimethamine tablets (generic)	
Amoquin tablets	
Camoquin tablets	
Emoquin tablets	
Malaridose tablets	
Amodiaquine tablets (generic)	
Fitoquin injection	
Chloroquine injection (generic)	
Quinine injection	
Quinine tablets	
Arsumax tablets	
Cotecxin tablets	

8. Where do you buy your drugs?

List the two places where they most frequently buy drugs.

<u>Type of outlet</u>	
1. General wholesaler	2. Drugs wholesaler
3. Registered pharmacy (Part 1)	4. Drug shop (Baridi /Part 2)
5. General shop	6. Distributor
7. Other (specify)	9. Don't know

(a) Type of outlet If 7, specify _____

Location (Town/Village):
 or location not known (mark "X")

Name of outlet:
 or name not known (mark "X")

(b) Type of outlet If 7, specify _____

Location (Town/Village):
 or location not known (mark "X")

Name of outlet:
 or name not known (mark "X")

9.

Name of interviewee

Is the interviewee the owner or in-charge of the outlet?

1. Yes 2. No

If yes, go to # 10.

If "No", name of owner or in-charge:

Guide for Qualitative Interviews at Facilities

Introduce the team, and explain where we are from. We are interested in learning more about the treatment of fever and malaria in this area.

Past studies have shown that malaria is a very important cause of illness in this area. We have also found out that many people visit non-governmental dispensaries and shops in this area when they are sick, including this health center/dispensary. We would like to find ways to improve the services that people receive. You may already have been visited by some of our colleagues from the DSS, who were completing a short questionnaire about the drugs you stock. We are now revisiting a small number of dispensaries, to discuss the treatment you provide in more detail. We'd therefore like to interview the person with main responsibility for managing this dispensary.

We would greatly appreciate your co-operation in this research. Participation in this activity is optional, and you do not need to answer any question that you do not want to. The interview will last one hour. The information that you provide us will be kept confidential, and is for research purposes only. Your name and the name of the dispensary will not appear in any report that comes out of this study. The information will be used for improving services only and will not be passed to any drug or health service regulatory authorities.

Do you have any questions? Do you agree to participate?

*Ask for permission to record
Switch on **tape recorder***

Ownership and Staff

1. Who **owns** this dispensary?
2. Please could you explain how this dispensary was **established**?
3. How many **people work** here?
 - What jobs do they do?
4. What is **your role** in the management of this dispensary?
5. Who makes **decisions** concerning the management of the dispensary?
For example:
 - Which drugs to buy
 - When and how much to purchase?
 - Prices to charge?
 - Hiring staff and salaries?
6. Does the owner own any **other dispensaries**?

Clients

7. What kind of **health problems** do people come here for?
8. What types of patients visit you for **fever and malaria**?
 - Place of residence (*probe*: which vitongoji; do any come from far away?)
 - Do your employees know many of the patients?

Services

11. What happens when a patient arrives here with fever or malaria?

12. Do you provide malaria **blood slides** here?

If yes:

- For what kind of patients?

13. What kind of **fees** do fever or malaria patients have to pay?

(Get fee list if available)

Drugs

14. Drugs stocked

- Which painkillers or antipyretics do you stock?

- Which antimalarials do you stock?

(Probe: SP, Quinine tablets, Quinine syrup, Quinine or CQ injections)

- Do you stock antibiotics?

(Probe: Cotrimoxazole or Septrin)

If they don't stock any kind of chloroquine:

15. Why do you not stock any kind of chloroquine?

If they don't stock any kind of SP?

16. Why do you not stock Fansidar or any other kind of SP?

17. Do you ever **run out of stocks** of panadol, aspirin, chloroquine, fansidar/SP *(if stocked)*

If yes:

- Why does this happen?

18. Choice of drug

- Who generally chooses the fever or malaria drug - does the health worker always advise the patient, or do you ever find that a fever or malaria patient asks for a specific drug?

19. Setting drug prices

- How do you decide what prices to charge for drugs?

- Do you give any fee exemptions?

If yes:

- What type of exemptions?
- Are these often given in practice?

20. Do patients ever receive **credit**?

If yes:

- What kind of patients?
- On what terms?

21. What do you **do with the fees**?

Probe:

- Are they retained here or passed onto a higher level?
- What are they used for?
- Do the staff get any share of the fees?
- Do you need to collect enough revenue to cover all your costs?

22. How are the **staff paid**?

Probe:

- Salary only, or also share of income, or other incentive payments.
- Do they get any other benefits? Do they get dispensary services at reduced prices or for free?

Competition

23. Which places do you consider your main **competitors**, or the main alternatives for customers for fever and malaria? **Why?**
- How long does it take to travel to these competitors?
 - *If there are facilities or other shops nearby not mentioned, why are they not considered as competitors?*
 - Do you compete with traditional healers for customers?
24. Which provider in this area has the **most customers** for fever or malaria?
- 25. Competitors' drug prices**
- Are your drug prices the same as the prices your competitors charge?
Probe for Aspirin, paracetamol, chloroquine and SP, if stocked.
 - *If yes, how does it happen that you all charge the same drug prices?*
 - Do you have any sort of agreements or understandings with these other providers about the prices you charge?
26. Why do your patients **prefer** to visit **this dispensary** for fever or malaria, rather than visiting **other health facilities**?
27. Why do other patients **prefer** to visit **shops** to buy drugs?
28. How do you try to **attract** more patients to this dispensary?
29. Do you ever **send patients to other providers**? Where do you send them and why?
Probe:
- If a patient with fever or malaria is severely ill?
 - Do you ever give patients prescriptions to go and buy drugs elsewhere?
- If yes:*
- Why?
 - Where do the patients go to get the drugs?

Regulation and Supervision

30. Do you ever receive visits for **supervision**?
If yes:
- Who comes to visit you?
 - How often do they come?
 - When was the most recent visit?
 - What was covered and what was the outcome?
 - Do you find these visits useful?
31. Are you required to pay **taxes** to the government?
- Who do you pay?
 - How are they collected?
 - How much do you pay per year?
32. Are you required to get any kind of **business licence or registration**?
If yes:
- What kind of licence/registration
 - What process did you have to go through to register it / get a licence?
 - How long did it take?
 - How much did you have to pay?
 - How often are you required to renew the licence / registration?
- If no:*
- Have you tried to get a licence / registration

If yes:

- Why did you not succeed?

33. Have you ever been visited by government inspectors?

If yes:

- How many times a year do they come?
- When was the most recent visit?
- Who visited you, what was covered and what was the outcome?
- Did they leave any kind of inspection certificate?

34. What are the regulations about what drugs can be provided sold in this dispensary?

- Officially what drugs is this dispensary allowed to provide?
- If there were no regulations concerning drugs, would you provide different drugs?

35. Would you like to see any changes in the regulatory system?

Change In Drug Policy

36. Have you heard that the Government is replacing chloroquine with SP/Fansidar as first line treatment for malaria in Tanzania?

- What are your views on that policy?
- How do you think it will change your activities?

37. Have your employees had any specific training on the policy change?

38. Have you received any guidelines or leaflets giving information about the policy change? (if yes, ask to see them)

Records

39. What type of records do you keep of:

- Drugs purchased wholesale?
 - Drugs dispensed?
 - Number of patients
 - Patient details (e.g. age, diagnosis, location of residence, drugs dispensed)
- (if yes, ask to see them)

Fill in the staff table for each person.

Fill in the drugs table for each painkiller or antimalarial stocked.

Observation: Record a description of:

1. Facility buildings

(type of structure, number of rooms, orderliness, cleanliness)

2. Facility location

(market center/vijijini/shamba, estimated travel time to main road, bus stop, shops, nearest market place, nearest town, train station)

3. Location of the interview

4. Interviewee

5. Services provided

Tick if they provide:

Inpatient net	Delivery Net insecticide	Outpatient Curative	MCH	Lab tests Mosquito
---------------	--------------------------	---------------------	-----	--------------------

- 6. Location and packaging of drugs stored**
(cleanliness, direct sunlight, temperature, orderliness, are drugs kept in their original package)
- 7. Check whether any drugs have passed their expiry date?**
- 8. Describe any adverts/promotional materials for drugs displayed?**
- 9. Is the facility license displayed?**
- 10. Are the qualifications of any of the staff displayed?**
- 11. Other observations e.g. customers visiting facility during interview**

Guide for Qualitative Interviews at Shops

Introduce the team, and explain where we are from.

We are interested in learning more about the treatment of fever and malaria in this area. Past studies have shown that malaria is a very important cause of illness in this area. We have also found out that many people buy drugs from shops when they are sick. (*Show pie chart from 2000 household survey*). We would like to find ways to improve the services that people receive, but up till now little attention has been paid to shops, although we can see that they are a very important sources of care. You may already have been visited by some of our colleagues from the DSS, who were completing a short questionnaire about the products you stock. We are now revisiting a small number of the shops, to discuss the business of drug selling in more detail. We'd therefore like to interview the person with main responsibility for managing this business.

We would greatly appreciate your co-operation in this research. Participation in this activity is optional, and you do not need to answer any question that you do not want to. The interview will last between one and two hours. The information that you provide us will be kept confidential, and is for research purposes only. Your name and the name of your business will not appear in any report that comes out of this study. The information will be used for improving services only and will not be passed to any drug regulatory authorities.

Do you have any questions? Do you agree to participate?

*Ask for permission to record
Switch on tape recorder*

Ownership & Staff

1. Who owns this shop?
2. When did this shop open?
3. How many staff work here?

Fill in the staffing table for each person, including the owner.

4. Who makes decisions about managing the business?

For example:

- Which drugs to stock?
- Prices to charge?

5. Who serves in the shop?
6. Does the owner own any other shops or businesses?

Customers

7. What kind of health problems do people visit this shop for?

Probe:

- First aid (huduma ya kwanza) or complete treatment (tiba kabisa)
8. What types of customers visit you for fever and/or malaria?
 - Well off or poor?
 - Location of residence (probe which vitongoji customers come from; do any come from far away?)
 - Do you know most of the customers?
 - All retail or any wholesale customers?

9. How many customers do you usually get per day?

- In total
- For drugs
- For fever or malaria

Drugs

11. Drugs stocked

- Which malaria drugs do you stock?
(Probe: Fansidar tablets, Quinine tablets, Quinine syrup, Quinine or chloroquine injections)
- Do you sell antibiotics?
(Probe: Cotrimoxazole e.g. Septrin)

If they don't stock any kind of chloroquine:

12. Why do you not stock any kind of chloroquine?

If they don't stock any kind of SP:

13. Why do you not stock Fansidar or any other kind of SP?

14. Choice of drug

- Who generally chooses the fever or malaria drug - does the customer usually request it themselves or do the sales staff advise?
- Do you try and influence the choice of product? Why?
- Do customers ever come with prescriptions from health care staff?

15. Do your sales of drugs for fever and malaria vary at different times? Why?

Probe:

- Different days of the week?
- Different times of the month?
- Different months of the year?

16. Do you ever run out of stocks of panadol, aspirini, klorokwini, fansidar/SP (*if stocked*)

If yes:

- Why does this happen?

17. Setting drug prices

- Explain how you decide what prices to charge for drugs.
- Do you bargain with customers over the prices?
- Do you vary your prices? Why?
 - for different quantities purchased?
 - for different customers? (e.g. cheaper or free for poor customers)

18. Do customers ever receive credit??

If yes:

- what type of customers?
- on what terms?

19. How are the staff paid?

Probe:

- salary only, or also share of income, or other incentive payments
- Do they get any other benefits? Do they get shop goods at reduced prices or for free?

20. Drug Policy Change

- Have you heard that the Government is replacing chloroquine with SP/Fansidar as first line treatment for malaria in Tanzania?
- What are your views on that policy?
- How do you think it will change your business?

Information & Training

21. How do you get information about drugs?

Probe:

- which drugs are best?
- new drugs?
- correct dosing
- side-effects?

22. Have you had any specific training on the use of fever and malaria drugs?

23. Have you received any guidelines or leaflets giving information about these drugs? *(if yes, ask to see them)*

Services (If Drug Store)

24. Do you provide consultations or diagnostic tests here?

Microscopy

If they provide malaria microscopy:

25. Why do you provide microscopy here?

26. How many slides do you usually read per week?

27. How much do customers pay per test?

Consultations

If they provide consultations:

28. Who sees the patients?

29. What happens during a consultation for fever or malaria?

30. What fees would a patient with fever/malaria have to pay?
(collect a fee list if available)

Break?

Wholesale Goods

31. Where do you buy your wholesale supplies of drugs?
(ask for name of outlet, type of outlet and location)

32. Why do you use these suppliers?

33. Do you buy other products from these suppliers?

34. How do you transport your stocks?

- How often do you receive new stocks?
- Do you have any problems with the availability of wholesale drugs?

35. Do you receive visits from representatives of drug companies or wholesalers?

If yes:

- How often do they come?
- What takes place during these visits?
- What information do they provide you with?

36. Do you get any free products with your drug purchases e.g promotional materials, training materials, gifts

37. Does the wholesaler or distributor have any rules about the products you purchase or the prices you can charge?

(e.g. recommended retail price, product tie-ins)

38. In places we have come from we have heard stories about drugs from health facilities getting into shops. Have you ever heard stories such as these?

Break?

Competition

39. Which places do you consider your main competitors for customers for fever and malaria? Why?

- How long does it take to travel to these competitors?
- *If there are facilities or other shops nearby not mentioned, why are they not considered as competitors?*
- Do you compete with traditional healers for customers?

40. Competitors' drug prices

- Are your drug prices the same as the prices your competitors charge?

Probe for Aspirin, Paracetamol, chloroquine and SP if stocked.

- *If yes, how does it happen that you all charge the same prices for drugs?*
- Do you have any sort of agreements or understandings with these other providers about the prices you charge?

41. Why do your customers prefer to buy drugs from your shop rather than visiting a health center or dispensary?

42. Why do your customers prefer your shop to other shops?

43. How do you try to attract more customers to your shop?

44. Why do you think some customers choose other shops instead of yours?

45. Do you ever send customers to other providers? Why?

Probe:

- If a patient with fever or malaria is seriously ill?

46. Are there other ways in which you cooperate with other providers?

47. Do you think other people will set up similar businesses in this area in the near future?

If no:

- Why not?

If yes?

- Do you think they will take away your customers?

48. Do shops like this often go out of business?

- *Probe: go bankrupt?*
- What sorts of factors cause this to happen?
- Do you think that this could happen to your shop?

Capital Costs

49. Are you planning to expand this shop or open other shops?
50. What problems do shopkeepers face in expanding or opening new shops?
51. If people need to raise capital, how do they do that?
52. How did you get the capital to start this shop?

Regulations

53. Is this shop registered (as large shop, small shop/kiosk, stall (genge)?)
54. Have you got a business licence?
If yes:
- What type of licence?
 - What process did you have to go through to get the licence?
 - How long did it take?
 - How much did you pay for the licence?
55. Has **Bwana Afya** (Health inspector? – not sure of title in English) visited you?
If yes:
- How many visits to you usually have in a year?
 - When was the most recent visit?
 - What was covered and what was the outcome?

If Drug shop:

56. Have you got a permit from the Pharmacy Board?

If yes:

- What process did you have to go through to register it?
- How long did it take?
- What registration payments did you make?

If no:

- Have you tried to register it?

If yes:

- Why did you not succeed?

57. What factors do you think influence whether applications for permits are successful?

58. Have you ever received a visit from a regulatory officer?

If yes:

- How many visits to you usually have in a year?
- When was the most recent visit?
- Who visited you, what was covered and what was the outcome ini?

59. Which drugs is this shop officially allowed to sell?
- Would you like to see any changes in the regulatory system?

Records

60. Do you keep any records of:
- Drugs purchased wholesale?
 - Drugs sold retail?
 - Details about customers e.g. age, diagnosis, location of residence, drugs dispensed
- If yes, *can we see the records?*

Suggestions

61. What strategies do you think could be used to improve the treatment for fever and malaria that people in this community receive

Fill in the drugs table for each painkiller or antimalarial stocked.

Observation: Record a description of:

1. Shop buildings

(type of structure, number of rooms, orderliness, cleanliness)

2. Shop location

(market center/vijijini/shamba, estimated travel time to main road, bus stop, shops, nearest market place, nearest town, train station)

3. Location of the interview

4. Interviewee

5. Products stocked

Tick if there:

Dry food	Packaged food	Fresh food	Sodas	Cigarettes
Soap powder	Toiletries	Household goods	Clothes	Bicycle spares
Drugs	Syringes	Mosquito net	Net insecticide	Mosq Coils

6. Location and packaging of drugs stored

(cleanliness, direct sunlight, temperature, orderliness, are drugs kept in their original package)

7. Check whether any drugs have passed their expiry date?

8. Describe any adverts/promotional materials for drugs displayed?

9. Is the shop license displayed?

10. Are the qualifications of any of the staff displayed?

11. Other observations e.g. customers visiting shop during interview



Code Number from Outlet Inventory |__|__|__|__|

Serial Number: |D|__|__|__|__|

Outlet Survey Drug Check List

District Code:	__ __ __
Village Code:	__ __ __
Name of Kitongoji:	_____
Type of outlet:	_____
Name of shop / facility:	_____
Name of owner:	_____
Household DSS number:	__ __ __ __ __
Name of household:	_____
or	
DSS number for nearest household:	__ __ __ __ __
Name of nearest household:	_____

I would like to ask about drugs for pain and fever that are sold here, then drugs for malaria, then cotrimoxazole drugs. I would like to know about the trade names of all oral and injectable drugs. I will read you a list of trade names to help us ensure that we cover all those we are required to check. Afterwards I will ask you to tell me if you have in stock are any other drugs in this category that are present and not included on the list.

8. I would like to know first whether the following drugs for pain relief and fever are in stock now:

1. In stock 2. Not in stock

Aspirin only: Tablets	<input type="checkbox"/> Asprin tablets <input type="checkbox"/> Junior Aspirin tablets	<input type="checkbox"/> Aspro tablets <input type="checkbox"/> Maxarin tablets	Aspirin tablets __
_____		_____	

Paracetamol only: Tablets	<input type="checkbox"/> Dawanol tablets <input type="checkbox"/> Maxadol tablets <input type="checkbox"/> Sheladol tablets <input type="checkbox"/> Paracetamol tablets (generic)	<input type="checkbox"/> Elydol tablets <input type="checkbox"/> Panado tablets <input type="checkbox"/> Totomol tablets	<input type="checkbox"/> Elymol tablets <input type="checkbox"/> Panadol tablets <input type="checkbox"/> Zenadol tablets	Paracetamol tablets __
_____		_____		

Other Painkillers:	<input type="checkbox"/> Action tablets <input type="checkbox"/> Dakika tatu tablets	<input type="checkbox"/> Cafemol tablets <input type="checkbox"/> Hedex tablets	<input type="checkbox"/> Cafenol tablets <input type="checkbox"/> Mara Moja tablets
_____		_____	
_____		_____	

Paracetamol only: Syrup	<input type="checkbox"/> Amidol syrup <input type="checkbox"/> Maxadol syrup <input type="checkbox"/> Panamol syrup <input type="checkbox"/> Paracetamol syrup (generic)	<input type="checkbox"/> Elydol syrup <input type="checkbox"/> Medmol syrup <input type="checkbox"/> Sheladol syrup	<input type="checkbox"/> Elymol syrup <input type="checkbox"/> Panadol syrup
_____		_____	

8a. Do you have any other painkillers/antipyretics in stock which have not yet been listed? |__|

1=yes 2=no 9=don't know
 If yes, list them in the appropriate box above.

9. I would now like to ask if the following antimalarials are in stock:
 1. in stock 2. not in stock

Chloroquine: Tablets	<input type="checkbox"/> Dawaquin tablets	<input type="checkbox"/> Homaquin tablets	<input type="checkbox"/> Malariaquin tablets
	<input type="checkbox"/> Mediquin tablets	<input type="checkbox"/> Shelyquine tablets	<input type="checkbox"/> Tanzaquine tablets
	<input type="checkbox"/> Zenaquin tablets	<input type="checkbox"/> Chloroquine tablets (generic)	
_____			Chloroquine tablets __

SP: Tablets	<input type="checkbox"/> Falcidin tablets	<input type="checkbox"/> Fansidar tablets	<input type="checkbox"/> Malaradox tablets
	<input type="checkbox"/> Metakelfin tablets	<input type="checkbox"/> Orodar tablets	<input type="checkbox"/> S-fin tablets
	<input type="checkbox"/> Sulphadar tablets	<input type="checkbox"/> SP (Sulfadoxine-pyrimethamine) tablets (generic)	
_____			SP tablets __

Amodiaquine: Tablets	<input type="checkbox"/> Amoquin tablets	<input type="checkbox"/> Emoquin tablets	<input type="checkbox"/> Malaratab tablets
	<input type="checkbox"/> Malaridose tablets	<input type="checkbox"/> Amodiaquine tablets (generic)	

Quinine: Tablets	<input type="checkbox"/> Kwinil tablets	<input type="checkbox"/> Quinitab tablets
	<input type="checkbox"/> Quinine tablets (generic)	
_____		_____
_____		_____

Other antimalarials	<input type="checkbox"/> Arsumax tablets	<input type="checkbox"/> Artemether tablets	<input type="checkbox"/> Cotecxin tablets
	<input type="checkbox"/> Halfan tablets		
_____		_____	
_____		_____	

Chloroquine: Syrup	<input type="checkbox"/> Elyquine syrup	<input type="checkbox"/> Shelyquine syrup	<input type="checkbox"/> Tanzaquine syrup
	<input type="checkbox"/> Mediquine syrup	<input type="checkbox"/> Chloroquine syrup (generic)	
_____			_____
_____			_____

SP: Syrup	<input type="checkbox"/> Falcidin syrup	<input type="checkbox"/> Sulphadar syrup
_____		_____
_____		_____

Amodiaquine: Syrup	<input type="checkbox"/> Amodar syrup	<input type="checkbox"/> Emoquin syrup
_____		_____
_____		_____

Quinine: Syrup	<input type="checkbox"/> Quinine syrup (generic)

Chloroquine:		
Injection	<input type="checkbox"/> Chloroquine injection (generic)	
_____	_____	_____
_____	_____	_____

Quinine:		
Injection	<input type="checkbox"/> Kwinil injection	<input type="checkbox"/> Quinine injection (generic)
_____	_____	_____
_____	_____	_____

9a. Do you have any other antimalarials in stock which have not yet been listed?
 1=yes 2=no 9=don't know
 If yes, list them in the appropriate box above.

10. Finally, I would now like to ask if the following cotrimoxazole drugs are in stock:
 1. in stock 2. not in stock

Cotrimoxazole (Sulphamethoxazole & Trimethoprim):			
Tablets	<input type="checkbox"/> Biotrim tablets	<input type="checkbox"/> Septrin tablets	<input type="checkbox"/> Shetrim tablets
	<input type="checkbox"/> Cotrimoxazole tablets (generic)		
_____	_____	_____	_____
_____	_____	_____	_____

Cotrimoxazole (Sulphamethoxazole & Trimethoprim):			
Syrup	<input type="checkbox"/> Biotrim syrup	<input type="checkbox"/> Gestrim syrup	<input type="checkbox"/> Shetrim syrup
	<input type="checkbox"/> Septrin syrup	<input type="checkbox"/> Cotrimoxazole syrup (generic)	
_____	_____	_____	_____
_____	_____	_____	_____

10a. Do you have any other cotrimoxazole drugs in stock which have not yet been listed?
 1=yes 2=no 9=don't know
 If yes, list them in the appropriate box above.

Go to question #11



Code Number |__|__|__|__|

Retail Audit - Questionnaire: 2002

When you arrive, check that this information is correct:

District Code:

Village Code:

Name of Kitongoji:

Type of outlet:

Name of shop / facility:

Name of owner:

Household DSS number:

--	--	--	--	--	--	--

Name of household:

or

DSS number for nearest household:

--	--	--	--	--	--	--

Name of nearest household:

First Interview**1. Is it possible to do the interview?**

1=yes

2=no

If no, why not?

1=closed today

2=closed down completely

8=not applicable (possible to do interview)

3=refused: Why? _____

4=Other _____

2. Date of first interview:/|/|2|0|0|2|
(day/month/year)

I would like to ask you about antimalarials and then cotrimoxazole. I would like to know about the trade names of oral and injectable drugs. I will read you a list of trade names to help us ensure that we cover all those that we are required to check. Afterwards I will ask you to tell me if you have any drugs in stock in this category that are not included on the list.

3. I would like to know first whether the following antimalarials are in stock:

1. In stock

2. Not in stock

Chloroquine Tablets:
 Dawaquin tablets
 Mediquin tablets
 Zenaquin tablets

 Homaquin tablets
 Shelyquine tablets
 Chloroquine tablets (generic)

 Malariaquin tablets
 Tanzaquine tablets
SP tablets:
 Combimal tablets
 Fansidar tablets
 Malostat tablets
 Novidar tablets
 Rimodar tablets
 SP (Sulfadoxine-pyrimethamine) tablets (generic)

 Falcidin tablets
 Laridox tablets
 Metakelfin tablets
 ONLI-3 tablets
 S-fin tablets

 Falcistat tablets
 Malaradox tablets
 Mitafin tablets
 Orodar tablets
 Sulphadar tablets
Amodiaquine tablets:
 Amobin tablets
 Emoquin tablets
 Malaridose tablets

 Amodar tablets
 Laeokin tablets
 Amodiaquine tablets (generic)

 Amoquin tablets
 Malaratab tablets
Quinine tablets:
 Kwinil tablets
 Quinine tablets (generic)
 Quine tablets Quinitab tablets**Other antimalarial tablets**
 Arsumax tablets
 Halfan tablets
 Artemether tablets Cotecxin tablets**Chloroquine syrup:**
 Elyquine syrup
 Mediquine syrup

 Shelyquine syrup
 Chloroquine syrup (generic)
 Tanzaquine syrup**SP syrup:**
 Falcidin syrup
 Sulphadar syrup
 Falcigo syrup Orodar syrup**Amodiaquine syrup:**
 Amodar syrup
 Emoquin syrup

 Amoquin syrup
 Malarabit syrup
 Chemoquine syrup**Quinine syrup:** Quinaquin syrup Quinix syrup Quinine syrup (generic)

Chloroquine Injection:
 C-quine injection Chloroquine injection (generic)

Quinine Injection:
 Kwinil Injection Quinine Injection (generic)

4a. Do you have any other antimalarials in stock which have not yet been listed?
 1=yes 2=no 9=don't know

If yes, list them here:

4a. Trade name	4b. Formulation 1=tablets, 2=syrup, 3=Injection, 4=powder	4c. Generic name

5. Now I would like to ask if the following cotrimoxazole drugs are in stock:

1. In stock 2. Not in stock

Cotrimoxazole (Sulphamethoxazole & Trimethoprim):
Tablets Alprim tablets Biotrim tablets Cotrikant tablets
 Septrin tablets Shetrim tablets
 Cotrimoxazole tablets (generic)

Cotrimoxazole (Sulphamethoxazole & Trimethoprim):
Syrup Alprim syrup Biotrim syrup Combact syrup
 Gestrim syrup Septrin syrup Shetrim syrup
 Zeptron syrup Cotrimoxazole syrup (generic)

6. Do you have any other cotrimoxazole drugs in stock which have not yet been listed?
 1=yes 2=no 9=don't know

If yes, list them here:

6a. Trade name	6b. Formulation 1=tablets, 2=syrup, 3=Injection, 4=powder

If they don't have any antimalarials or cotrimoxazole, go to Question #7.

If they have antimalarials or cotrimoxazole:

Fill in the stock table columns A, B, C and D for each antimalarial or cotrimoxazole stocked.

7. We would like to return after two weeks to ask you again about your drug stocks, in order to estimate the quantity of drugs that you have dispensed in this period.

7a. Did they agree to make an appointment? 1=yes 2=no

7b. If no, why not? _____

7c. We plan to return here:

_____, / / 2002 Time: _____
Day Date/Month

8. May I ask your name? _____

Many thanks for your cooperation. When we return, we would like to know the quantity of drugs you have bought within this two week period. Therefore it would help us a lot if you would keep a record or carefully keep receipts for drugs during this period.

Fill in the code number from the Outlet Census at the top of each page of the questionnaire and stock table.

Interviewer: Checked by: Coded by:

June 2002

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

July 2002

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

August 2002

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

Second interview9. Is it possible to do the interview?

1=yes

2=no

If no, why not?

1=closed today

2=closed down completely

8=not applicable (possible to do interview)

3=refused: Why? _____

4=Other _____

10. Date of second interview:

|__|__|/|__|__|/|2|0|0|2|
(day/month/year)**Complete the stock table columns E, F and G for each antimalarial and cotrimoxazole stocked during the second interview.**

Then ask:

11. Since I was last here, have you purchased any other antimalarials or cotrimoxazole drugs?

1=yes

2=no

9=don't know

If yes, list them here:

11a. Trade name	11b. Formulation 1=tablets, 2=syrup, 3=injection, 4=powder	11c. Generic name

If they have purchased another drug:

List them in the stock table and complete columns A, B, C and E, F, G.

12. May I ask your name? _____

Many thanks for your cooperation.

Interviewer: |__|__|

Checked by: |__|__|

Coded by: |__|__|



Code Number |__|__|__|__|

Serial Number: |_J_|__|__|__|

Retail Audit – Stock table: 2002

When you arrive, check that this information is correct:

District Code:

Village Code:

Name of Kitongoji:

Type of outlet:

Name of shop / facility:

Name of owner:

Household DSS number:

--	--	--	--	--	--	--	--

Name of household:

or

DSS number for nearest household:

--	--	--	--	--	--	--	--

Name of nearest household:

Stock Table(2)

		Second interview			
		E. Quantity in stock today: E1. Number of tablets/bottles/vials/packets If there is an opened tin: E2. Height of tin (cm) E3. Height of tablets E4. Number of tablets in full tin (9999=don't know)	F. Since we were last here, what quantity of this drug have you purchased? (Number of tablets/bottles/vials/packets) (9999=don't know)	G. Since we were last here, have you disposed of any drugs that were not for customers/patients? G1. Why? 1=they were returned (specify where) 2=they were taken to another shop/facility (specify where) 3=they were thrown away 4=they were taken by the inspectors 7=other reason (specify reason) G2. Number of tablets/bottles/vials/packets	
A. Trade name (Or generic name if no trade name) _____ □□□□□□	B. Packaging 1=Pot 2=Paper 3=Blister 4=Bottle (syrup) 5=Vial/Ampoule 6=Packet (powder)	C. Size (mg or ml) (of each tablet/bottle/vial/packet) (9999=don't know)	D. Quantity in stock today: D1. Number of tablets/bottles/vials/packets If there is an opened tin: D2. Height of tin (cm) D3. Height of tablets D4. Number of tablets in full tin (9999=don't know)	D1. and D2. D3. D4.	G1. G2.
				D1. and D2. D3. D4.	G1. G2.
				D1. and D2. D3. D4.	G1. G2.
				D1. and D2. D3. D4.	G1. G2.
				D1. and D2. D3. D4.	G1. G2.
				D1. and D2. D3. D4.	G1. G2.
				D1. and D2. D3. D4.	G1. G2.

Stock Table(3)

		Second Interview				
		First Interview				
A. Trade name (Or generic name if no trade name)	B. Packaging 1=Pot 2=Paper 3=Blister 4=Bottle (syrup) 5=Vial/ Ampoule 6=Packet (powder)	C. Size (mg or ml) (of each tablet/bottle/ vial/packet) (9999=don't know)	D. Quantity in stock today: D1. Number of tablets/ bottles/vials/packets <i>If there is an opened tin:</i> D2. Height of tin (cm) D3. Height of tablets D4. Number of tablets in full tin (9999=don't know)	E. Quantity in stock today: E1. Number of tablets/ bottles/vials/packets <i>If there is an opened tin:</i> E2. Height of tin (cm) E3. Height of tablets E4. Number of tablets in full tin (9999=don't know)	F. Since we were last here, what quantity of this drug have you purchased? (Number of tablets/ bottles/vials/packets) (9999=don't know)	G. Since we were last here, have you disposed of any drugs that were not for customers/patients? G1. Why? 1=they were returned (specify where) 2=they were taken to another shop/facility (specify where) 3=they were thrown away 4=they were taken by the inspectors 7=other reason (specify reason) G2. Number of tablets/bottles/vials/packets
_____	□□□□□□	□□□□□□	D1. □□□□□□ and D2. □□□□□□ D3. □□□□□□ D4. □□□□□□	E1. □□□□□□ and E2. □□□□□□ E3. □□□□□□ E4. □□□□□□	□□□□□□	G1. □□□□□□ G2. □□□□□□
_____	□□□□□□	□□□□□□	D1. □□□□□□ and D2. □□□□□□ D3. □□□□□□ D4. □□□□□□	E1. □□□□□□ and E2. □□□□□□ E3. □□□□□□ E4. □□□□□□	□□□□□□	G1. □□□□□□ G2. □□□□□□
_____	□□□□□□	□□□□□□	D1. □□□□□□ and D2. □□□□□□ D3. □□□□□□ D4. □□□□□□	E1. □□□□□□ and E2. □□□□□□ E3. □□□□□□ E4. □□□□□□	□□□□□□	G1. □□□□□□ G2. □□□□□□
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_____	□□□□□□	□□□□□□	D1. □□□□□□ and D2. □□□□□□ D3. □□□□□□ D4. □□□□□□	E1. □□□□□□ and E2. □□□□□□ E3. □□□□□□ E4. □□□□□□	□□□□□□	G1. □□□□□□ G2. □□□□□□
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Stock Table(4)

Stock Table(4)		First interview		Second interview			
A. Trade name (Or generic name if no trade name)		B. Packaging 1=Pot 2=Paper 3=Blister 4=Bottle (syrup) 5=Vial/ Ampoule 6=Packet (powder)	C. Size (mg or ml) (of each tablet/bottle/ vial/packet)	D. Quantity in stock today: D1. Number of tablets/ bottles/vials/packets <i>If there is an opened tin:</i> D2. Height of tin (cm) D3. Height of tablets D4. Number of tablets in full tin (9999=don't know)	E. Quantity in stock today: E1. Number of tablets/ bottles/vials/packets <i>If there is an opened tin:</i> E2. Height of tin (cm) E3. Height of tablets E4. Number of tablets in full tin (9999=don't know)	F. Since we were last here, what quantity of this drug have you purchased? (Number of tablets/ bottles/vials/packets) (9999=don't know)	G. Since we were last here, have you disposed of any drugs that were not for customers/patients? G1. Why? 1=they were returned (specify where) 2=they were taken to another shop/facility (specify where) 3=they were thrown away 4=they were taken by the inspectors 7=other reason (specify reason) G2. Number of tablets/bottles/vials/packets
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ANNEX 5

CONSTRUCTION OF AN INDEX OF HOUSEHOLD SOCIO-ECONOMIC STATUS

A relative index of household socio-economic status (SES) was derived based on 19 dichotomous variables. The variables included were a combination of household construction (walls, roof and floor), utilities (sources of water, light and cooking fuel, use of toilet), and ownership of assets (livestock, bed, clock/watch, mattress, iron, mosquito net, radio, clothing cupboard, bicycle, sofa, motorbike and car/tractor). The questionnaire allowed a wide range of responses for each question on household construction and utilities, many of which had very low frequencies. Responses were therefore collapsed into dichotomous categories in each case, to represent those hypothesised to be superior (i.e. positively associated with SES) and those hypothesised to be inferior. For example, type of roof was categorised as either manufactured (tiles, cement, corrugated iron) or local/second-hand (coconut leaves, bamboo, thatch, sticks, mud, grass, plastic sheets, oil tins). The weights for each variable in the index were derived using principal component analysis (PCA), based on the first principal component, which gives an index providing maximum discrimination between households (Filmer and Pritchett 2001; McKenzie 2003). Formerly, given an asset vector x , the first principal component of the observations, y , is the linear combination

$$y = a_1 \left(\frac{x_1 - \bar{x}_1}{s_1} \right) + a_2 \left(\frac{x_2 - \bar{x}_2}{s_2} \right) + \dots + a_p \left(\frac{x_p - \bar{x}_p}{s_p} \right)$$

whose sample variance is greatest among all such linear combinations, subject to the restriction $a'a = 1$, where a is the vector of coefficients, and x_k and s_k are the mean and standard deviation of variable x_k . The construction of such indices implies the assumption that households have homogenous preferences for assets, and that asset prices do not vary across households.

The index was calculated across both Group X and Group A households. Data were incomplete for 1 household in Ulanga and 87 households in Rufiji, which were therefore not assigned PCA scores. The first principal component explained 21% of the variability in the SES variables, giving greatest weight to floor and roof construction, ownership of a mattress, and light and cooking sources (Table A5.1). The Table also shows the difference that ownership of each asset made to the household PCA score, calculated by dividing the weight of each variable by its standard deviation (a_k/s_k). The assets for which ownership made the greatest change to PCA score were ownership of a sofa or clothing cupboard (1.39 and 1.29 respectively) and floor construction and cooking fuel (1.09 and 1.06). All variables had the expected positive

association with SES, with the exception of having a private water supply. It is possible that this may reflect a higher probability of sharing a water supply in areas of higher population density, where households may tend to be better off.

Table A5.1 Results of principal components analysis of household survey variables to construct an index of SES

Variable	Mean	Standard Deviation	Weight	Impact on PCA score ²	Definition ¹
floormanu	0.12	0.322	0.35	1.09	=1 if floor made of tiles or cement
wallsmanu	0.21	0.409	0.27	0.66	=1 if walls made of fired bricks or cement
roofmanu	0.26	0.437	0.31	0.71	=1 if roof made of tiles, cement or corrugated iron
cookmanu	0.09	0.284	0.30	1.06	=1 if cooking fuel is electricity, gas, kerosene or charcoal
waterprivate	0.18	0.383	-0.05	-0.13	=1 if water source is piped water inside household or private well or pump
toilet	0.97	0.169	0.03	0.18	=1 if household has use of toilet
lightmanu	0.14	0.351	0.31	0.88	=1 if light source is electricity or hurricane lamp
Bed	0.95	0.224	0.07	0.31	=1 if household owns one or more of each asset
Watch/clock	0.35	0.476	0.24	0.50	
Mattress	0.33	0.469	0.32	0.68	
Iron	0.11	0.314	0.28	0.89	
Mosquito net	0.54	0.499	0.16	0.32	
Radio	0.49	0.500	0.24	0.48	
Clothing cupboard	0.05	0.217	0.28	1.29	
Bicycle	0.44	0.496	0.17	0.34	
Livestock	0.58	0.494	0.05	0.10	
Sofa	0.04	0.201	0.28	1.39	
Motorbike	0.005	0.068	0.01	0.15	
Car	0.003	0.053	0.04	0.75	

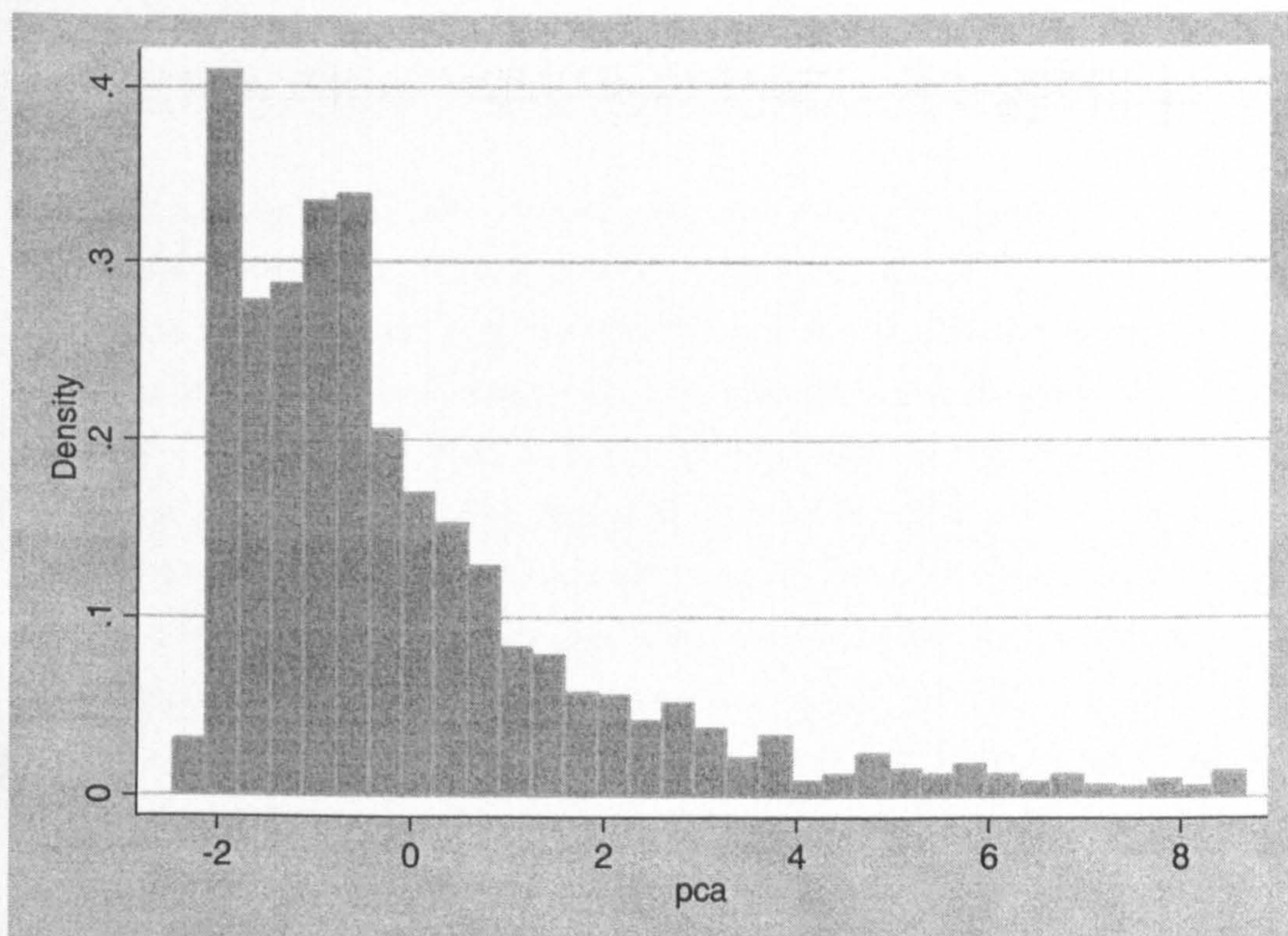
¹ Households were allocated 1 if at least some of construction materials or light/cooking fuel fell in these categories.

² Impact of a change from 0 to 1 for each variable (weight/standard deviation).

The PCA scores ranged from -2.46 to 8.67. Households were classified on the basis of their PCA scores into SES thirds of poorest, middle or better-off, with mean PCA scores of -1.6, -0.6 and 2.2 respectively, with a cut-off point of -1.11 between the poorest and middle thirds and 0.06 between the middle and better-off. Presentation of SES quintiles is more common, and has the advantage of giving a more sensitive indication of SES trends. SES thirds were used in this analysis because the distribution of PCA scores was highly skewed to the left (Figure A5.1), and there were some problems distinguishing between the poorest households (a phenomenon termed truncation (McKenzie 2003)). If quintiles were used the difference in mean score between the poorest and second poorest quintiles was only 0.55, meaning that a household

would shift from mid-quintile 5 to mid-quintile 4 by the ownership of just one additional asset, such as a mattress or watch, a difference which may not be economically meaningful. Dividing the data into asset thirds gives a difference in mean score between the poorest and middle thirds of 1.01, implying ownership of, for example, an additional mattress and watch, or a manufactured roof and bicycle, differences more likely to be indicative of true SES variation. In addition, use of quintiles would have led to small sample sizes in each SES group for the analysis of provider visits.

Figure A5.1 Histogram showing distribution of PCA scores used in calculation of asset index



Household head occupation and education were not included in the index but were used as an indication of its validity. Households where the head's main occupation was off-farm had significantly higher PCA scores than those who were mainly engaged in farming, with 72% of off-farm households in the better-off third, and only 8% in the poorest third. There was a significant correlation between the years of education of household head and PCA score ($r=0.4$, t test, $p<0.0001$), with 57% of households where the head had more than primary education in the top wealth third, compared with only 21% for those with no education.

PCA scores were not adjusted for household size, as the benefits of household construction, utilities and many durable assets were available at the household level (McKenzie 2003). Average household size was slightly higher among households of higher SES, meaning that,

although households were equally distributed between SES thirds by definition, 37% of individuals interviewed were in the better-off third, compared with 30% in the poorest third.

ANNEX 6

CALCULATION OF ANTIMALARIAL SALES VOLUMES AND VALUES

Data collected during the two retail audits were used to estimate total annual antimalarial sales volumes and values in the DSS areas, using the following steps:

1. For each audit, sales of each antimalarial between the 2 visits were calculated as:

$$\text{Sales} = (\text{Total at 1}^{\text{st}} \text{ visit}) + (\text{Deliveries between 1}^{\text{st}} \text{ and 2}^{\text{nd}} \text{ visit}) - (\text{Stocks thrown away or transferred to other shops/facilities}) - (\text{Total at 2}^{\text{nd}} \text{ visit})$$

2. To calculate fortnightly sales, sales volumes were scaled up or down pro rata, depending on the actual number of days between interviews for each outlet.
3. To sum across different drug types to measure total antimalarial sales, volumes were calculated in terms of purchases required for equivalent adult treatment doses, based on the adult doses shown in Table A1.6¹. For syrup and injectables, it was assumed that one whole bottle or vial would have to be purchased². The number of equivalent doses will be much lower than the actual number of customers, because 46% of provider visits were for patients under 14 years (household survey) who should receive a lower dose, and many people of all ages will have obtained less than the full treatment dose.
4. Sales data were missing for 7 products in retail audit 1, and 3 in retail audit 2, in most cases because the interviewee did not know the quantity delivered. Calculated sales were negative for 2 products in retail audit 1 and 1 in retail audit 2, clearly indicating an error so these observations were reclassified as missing. In order to calculate total sales for the survey sample, all missing values were replaced with the mean sales for each drug type by packaging and outlet type (e.g. mean sales of loose SP tablets in commercial drug stores).
5. To estimate total sales for all DSS areas it was necessary to approximate sales for outlets not interviewed. This comprised the private facility which refused in both audits, and the general shops stocking antimalarials not interviewed. The latter was estimated from the number not sampled or temporarily closed, multiplied by the estimated percent change in antimalarial stocking by these unobserved outlets. The percent change was calculated using turnover data from the outlet censuses in 2000 and 2001, which showed a 6.5% fall in the

¹ an alternative approach of measuring volumes in defined daily doses was inappropriate in this context because of the variation in the length of antimalarial regimens.

² in some cases more than one vial may be needed for a full dose with injectables, but our estimates were based on the quantity required to cover an initial pre-referral dose only, according to the Standard Treatment Guidelines.

number of general shops stocking antimalarials over the year³, leading to an estimated 3% fall between the outlet survey and retail audit 1 and a further 2% fall between retail audits 1 and 2. This gave an estimated 75 general stores stocking antimalarials not interviewed in retail audit 1, and 68 in retail audit 2. These outlets were assigned the mean sales for each drug type for their outlet type. As a result the true variation in sales across outlets will have been underestimated.

6. To estimate yearly sales it was necessary to extrapolate from the two 2-week periods. The two audits were undertaken at different times of year with the aim of capturing seasonal epidemiological and economic variation in total antimalarial sales and their distribution across outlet type. Table A6.1 shows the results for the two audits. The data did not show evidence of clear seasonal patterns. The total number of antimalarial doses was 12% higher during retail audit 2, but this concealed significant differences across DSS areas; an increase of 82% in Kilombero, 3% in Rufiji, and a fall of 35% in Ulanga. These patterns are difficult to interpret; the increase in Kilombero and fall in Ulanga were mainly due to changes in commercial drug shop sales, while in Rufiji a large fall in government facility doses was counterbalanced by a large increase for private facilities. Median sales per outlet were higher in retail audit 2 for facilities and drug shops, but the difference was only statistically significant for the latter (Wilcoxon Rank Sum test, $p=0.03$). There was little change in the overall proportion of doses sold through facilities (as opposed to shops), which was 63% in retail audit 1 and 61% in retail audit 2⁴. The number of doses sold by general stores fell by 13%. This was likely to reflect the intermittent nature of antimalarial stocking by general stores, and a longer term downward trend in the proportion stocking antimalarials, rather than a seasonal pattern (see Chapter 7 on Market Structure). It is possible that the timing of the two surveys did not capture seasonal variation at other times of year. During qualitative interviews drug store staff said that sales for fever/malaria increased during the wet season, with most specifying the period of heaviest rain ("*masika*") in March/April, although one mentioned the whole rainy season from October to May. Two drug stores and the commercial dispensary noted that there was also a smaller increase in drug sales post-harvest (July to October), associated with greater cash availability. General store interviewees were less consistent in their assessment of seasonal variation, but around half also perceived an increase in fever/malaria sales during the main rainy season. As a result of the inconclusive nature of the analysis of seasonal variation, annual sales were estimated simply by summing the sales figures for the two surveys and scaling up pro rata to yearly sales estimates. Some justification for this approach was provided by analysis of

³ composed of 42% stopped stocking antimalarials, 28% started stocking antimalarials, 19% closed down and 26% newly opened stockists (expressed as percentages of baseline antimalarial stockists).

⁴ We had anticipated that antimalarial volumes from Government outlets might be higher during retail audit 2 because it was contemporaneous with the 2002 IMPACT household survey, during which antimalarial availability at these facilities was ensured by the research team. However, their share was actually lower in retail audit 2, mainly due to a fall in Rufiji, while the share of private facilities rose.

government outpatient facility data which showed average monthly outpatients during the four months of the retail audit (February, March, June and July) to be only 3% higher than average monthly outpatients over the whole of 2002.

7. The value of antimalarial sales was approximated based on outlet survey data on the median price for each drug category by packaging and outlet type (e.g. median price of loose SP tablets in commercial drug stores). These prices do not necessarily reflect the actual prices paid for the drug sales recorded, as prices may have changed between the outlet survey and retail audit, and people may have been more likely to purchase brands with a lower than average price. For three items in village health stores and two in general stores there were no appropriate price observations, as they were not stocked during the outlet survey. Their prices were approximated with the median price from commercial drug stores. As government drugs were either heavily or completely subsidised, their value was approximated using 2002 international reference prices (IRP) from suppliers (Management Sciences for Health 2002), scaled up 15% for importation costs⁵, and 15% for internal transport, and using an exchange rate of US\$1=Tsh950.14⁶.

Table A6.1 Estimated 14 day antimalarial drug volumes in equivalent adult doses for retail audits 1 and 2

	Mean antimalarial doses per outlet		Median antimalarial doses per outlet		Total antimalarial doses for all outlets		% sales by outlet type	
	1	2	1	2	1	2	1	2
Retail Audit								
Government facilities	229	180	140	146	4122	3235	49%	34%
Private facilities	134	281	62	111	1206	2527	14%	27%
Commercial drug shops	87	98	22	43	2707	3334	32%	35%
Village-run drug shops	23	37	23	37	46	74	1%	1%
General stores ¹	3	3	0	0	387	335	5%	4%
Total					8,467	9,502	100%	100%

¹ General stores stocking antimalarials in 2001.

⁵ In fact 68% of antimalarial products in government facilities were domestically manufactured, and it would therefore have been more appropriate to exclude the 15% importation costs on this share of government medications.

⁶ From <http://www.oanda.com/> for the 1st Jan 2002.