# ACCESS TO PROMPT AND EFFECTIVE MALARIA TREATMENT IN THE KILOMBERO VALLEY, TANZANIA

**INAUGURALDISSERTATION**

zur

Erlangung der Würde eines Doktors der Philosophie

vorgelegt der

Philosophisch-Naturwissenschaftlichen Fakultät

der Universität Basel

von

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aus

Deutschland

Basel, 2007

Genehmigt von der Philosophisch-Naturwissenschaftlichen Fakultät auf Antrag von Herrn Prof. Dr. Marcel Tanner, Herrn Prof. Dr. Christian Lengeler und Frau Prof. Dr. Charlotte Braun-Fahrländer

Basel, den 16. Oktober 2007

Prof. Dr. Hans-Peter Hauri
Dekan

*Dedicated to the memory of my dad.*

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| | |
|---|---|
| ACT | Artemisinin-Based Combination Therapy |
| ADDO | Accredited Drug Dispensing Outlet |
| ALu | Artemether-Lumefantrine (trade name: Coartem) |
| CHF | Community Health Fund |
| CHMT | Council Health Management Team |
| CI | Confidence Interval |
| DDT | Dichlorodiphenyltrichloroethane |
| DFID | Department for International Development (U.K.) |
| DHS | Demographic and Health Survey |
| DMO | District Medical Officer |
| DNDi | Drugs for Neglected Diseases initiative |
| DSS | Demographic Surveillance System |
| EIR | Entomological Inoculation Rate |
| EMIC | Explanatory Model Interview Catalogue |
| FGD | Focus-Group Discussion |
| GAVI | Global Alliance for Vaccines and Immunization |
| GDP | Gross Domestic Product |
| GFATM | Global Fund to Fight AIDS, Tuberculosis and Malaria |
| GPS | Global Positioning System |
| HIV | Human Immunodeficiency Virus |
| HMIS | Health Management Information Systems |
| IEC | Information, Education, Communication |
| IHRDC | Ifakara Health Research and Development Centre |
| IMCI | Integrated Management of Childhood Illness |
| IMPACT-Tz | Interdisciplinary Monitoring Project for Antimalarial Combination Therapy in Tanzania |
| IPTi | Intermittent Preventive Treatment for Infants |
| IPTp | Intermittent Preventive Treatment for Pregnant Women |
| IQR | Interquartile Range |
| IRS | Indoor Residual Spraying |
| ITN | Insecticide Treated Net |
| KINET | Kilombero Insecticide-Treated Net Project |

| | |
|---|---|
| LLIN | Long-Lasting Insecticidal Net |
| MARA / ARMA | Mapping Malaria Risk in Africa / Atlas du Risque de la Malaria en Afrique |
| MCH | Mother and Child Health |
| MDG | Millennium Development Goals |
| MMV | Medicines for Malaria Venture |
| MOH(SW) | Ministry of Health (and Social Welfare) |
| MSD | Medical Stores Department |
| MSH | Management Sciences for Health |
| M&E | Monitoring and Evaluation |
| NGO | Non-Governmental Organization |
| NMCP | National Malaria Control Programme |
| OPD | Outpatients Department |
| OTC | Over-the-Counter |
| PIOP | Policies, Institutions, Organizations, and Processes |
| PMI | U.S. President's Malaria Initiative |
| RBM | Roll Back Malaria |
| PSI | Population Services International |
| PYO | People-Years Observed |
| QIRI | Quality Improvement and Recognition Initiative |
| RDT | Rapid Diagnostic Tests |
| SES | Socio-Economic Status |
| SFDDH | St. Francis Designated District Hospital |
| SP | Sulphadoxine (or Sulphametoxipyrazine)-Pyrimethamine |
| STI | Swiss Tropical Institute |
| TEHIP | Tanzania Essential Health Interventions Project |
| TFDA | Tanzania Food and Drugs Authority |
| TSh | Tanzanian Shilling |
| UN | United Nations |
| USD | US Dollar |
| VA | Verbal Autopsy |
| WHO | World Health Organization |

# ACKNOWLEDGEMENTS

I am greatly indebted to a number of people who all together contributed to the success of this work. First and foremost I would like to mention my main supervisor, Prof. Christian Lengeler. I am very grateful to him for all the time he invested to support me (scientifically and personally), for his constant encouragements, his good humour and his friendship that kept my spirits high throughout the period of this work. I would also like to thank Prof. Brigit Obrist with whom I enjoyed many fruitful and entertaining discussions. Her ideas shaped the way I think about the importance of social science research and also about myself. I am also indepted to Prof. Marcel Tanner, who was the one who sparked my interest in STI's work and who supported and believed in me from the moment he facilitated an exchange semester in Brazil in 2001 up until today. *Many thanks to the three of you!* My thanks are also directed to Dr. S. Patrick Kachur, whose opinion as an external expert provided valuable inputs to the work of our project. I enjoyed his hospitality when I visited Dar es Salaam and many entertaining evenings over a *Safari* in Ifakara or Dar es Salaam. *Thank you very much!*

During the time I was based in Ifakara I could enjoy the warmth and welcoming nature of many Tanzanian colleagues and friends. Before mentioning them, however, I would like to express by deep gratitude to the communities of the Kilombero and Ulanga Districts, their leaders, the health facility staff, the DMOs and CHMTs, for their time and collaboration throughout this work. *Asanteni sana!* I very much thank Dr. Hassan Mshinda for making it possible for me to conduct my work within the ACCESS team and for his critical revision and insightful inputs to the work we conducted. I am grateful to Mzee Makemba who made me feel welcome as part of the ACCESS team and who supported my first clumsy steps on unknown terrain. Without Iddy Mayumana, whom I admire for his commitment to our work and his loyalty to all his friends and colleagues, none of the studies we conducted would have been possible. Iddy, our field supervisor Goodluck John and our interviewers Irene Ngoja, Judith John, Hilda Mwabukusi and Sixbert Msagwa are a great team and I am thankful for all the efforts they made to collect the data in the field. I would not want to miss the unforgettable field trips I had, especially with Iddy and Goodluck, who were always there for me when I needed assistance of any kind. I also want to

express my thanks to Saidi King'eng'ena, our very committed shop survey supervisor, and to the fieldworker teams he led, for their contributions to the data collection. The shop studies drew on the work conducted by Dr. Catherine Goodman, to whom I would like to express my sincere thanks for sharing her experiences. *Asanteni sana wote!* Christopher Mshana, who is also incredibly committed and hard-working (*kazi kweli kweli!)*, contributed so much to the work of the whole team and I enjoyed the social marketing performances he organised together with Peter Ngwassi and the Social Marketing team. Angel Dillip, who joined the team in the last year, quickly became a very valued colleague and I enjoyed working with her and eating the *Makande* she prepared. Special thanks to her for the Swahili translation of the summary of this thesis. I would also like to thank the former team members June Msechu, with whom I worked on the development and the implementation of the first studies and Kusekwa Sono for their collaboration while they were part of the ACCESS team. I am also thankful for the good time I had with Mariette Fankhauser during her fieldwork in the frame of the *shamba* survey. With my successor in the field (and in my little *nyumba*), Sandra Alba, I have had fruitful exchanges, discussions and an exciting collaboration on the *shamba* survey. The exchanges with Dr. Nelly Iteba and Karin Gross, who only recently joined the team, were few but intensive and interesting. *I thank all of you!* I would also like to thank the staff of the DSS, Dr. Rose Nathan, Mathew Alexander, Jensen Charles, Chrisostom Mahutanga and all field interviewers for their valuable collaboration and interesting experiences from the villages that they shared with us. Many thanks to Amani and the data entry unit for the services they provided, and the IT unit who assisted with computer and internet problems. My sincere thanks are directed to Honoraty Urassa for his kind assistance in various situations. I would also like to say thanks to all other colleagues in Tanzania who contributed in one way or another to this work, especially Dr. Honorati Masanja, Oscar Mukasa, Pascal Mugasa, Dr. Abdulnoor Mulokozi, Fatuma Manzi, Dr. Salim Abdulla and the whole IMPACT team, Dr. Heather Ferguson, Dr. Gerry Killeen, Mama Eliza Yegella, Idda Ruzige, Joel Katana, Sikana and the ladies from the IHRDC guesthouse, Leka Tingitana, Wolfgang Schmied, Petronila Ngulukila and everybody else with whom I spent some time in Ifakara or Dar es Salaam. *Asanteni!*

While in Tanzania, I always enjoyed the friendship and hospitality of Yvonne Geissbühler in Dar es Salaam, who at any time had a spare bed for a stranded visitor from Ifakara and time for a relaxed dinner or night out. *Asante sana dada!* I also enjoyed the hospitality and fine cooking of Nicole and Marcel Stöckle in Ifakara, and the entertaining evenings over a *Tusker* or *Safari* with Stefan Dongus in Dar es Salaam – where I also had a good time with Beat, Beat and Juliana Pfister at the Swiss Garden Hotel. *Asanteni sana!*

While I spent most of the time in Ifakara, there are some more people from Basel and surroundings to whom I would like to express my gratitude. First, I would like to acknowledge the financial support from the Novartis Foundation for Sustainable Development which provided funding for the ACCESS Programme, including the work for my thesis. Special thanks go to Alexander Schulze for his collaboration and support throughout my work. At STI, I much appreciated the introductions of Prof. Mitchell Weiss into cultural epidemiology and the EMIC and his insightful comments on our work. Prof. Tom Smith and Laura Gosoniu were very helpful and assisting me when I had statistical queries and Prof. Don de Savigny could always provide illustrative graphs and new exciting insights into any topic in international health. *Thank you very much!* I also want to express my heartfelt thanks to Eliane Ghilardi, Margrith Slaoui and Christine Walliser for their help in so many occasions. Special thanks also to Dominique Forster and the IT team for rescuing my computer and to Andrew Lawrence for proof-reading parts of this thesis. My appreciation goes also to Stefanie Granado, Borna Müller, Bianca Plüss, Josh Yukich, Sonja Schöpflin, all other fellow students and all the remaining STI staff for the good time we had together at STI.

Last but not least, I wish to deeply thank my family who made my studies and this thesis possible. Thanks to the continuous support of my dear parents, my brother and my friends, and with the help of Serej in the final phase, I managed to happily complete this work. *Thank you so much!*

# SUMMARY

Malaria is the most important parasitic infection in humans, causing an estimated one million deaths annually. Most cases occur in young children in sub-Saharan Africa, supporting the vicious circle of disease and poverty.

Current control strategies have so far failed to reduce the disease in most parts of sub-Saharan Africa. Insecticide-treated mosquito nets (ITN) are effective in preventing malaria episodes and efficacious drugs (such as artemisinin-based combination therapies or ACTs) exist to cure malaria. However, a major problem is the delivery of quality health services, including life-saving drugs, to the ones in need. A variety of inter-linked factors influences patients' access to prompt and effective treatment. While growing resistance against commonly used antimalarials such as chloroquine or sulphadoxine-pyrimethamine (SP) is being addressed with the introduction of ACTs, obstacles to effective malaria treatment have been identified at the levels of the households (the demand side), the health system (the supply side), and in health policy.

The present thesis aimed at contributing to a better understanding of factors influencing access to malaria treatment in a positive or a negative way. The insights gained should inform the development of targeted interventions to improve access to malaria treatment and help to develop a general access framework.

The research was carried out as part of the ACCESS Programme, which aims to understand and improve access to effective malaria treatment in the districts of Kilombero and Ulanga, in south-eastern Tanzania. The ACCESS strategy is based on a set of integrated interventions, including (1) social marketing for improved care seeking at community level, (2) strengthening the quality of case-management in health facilities, and (3) strengthening the commercial drug retail sector. The interventions are accompanied by a comprehensive set of monitoring and evaluation activities.

Quantitative, semi-quantitative and qualitative methods were used for data collection in the area of the local Demographic Surveillance System (DSS) and the nearby

semi-urban centre of Ifakara. Between 2004 and 2006, community-based surveys were conducted to investigate treatment-seeking behaviour and estimate community-effectiveness of malaria treatment. A shop census and mystery shoppers (simulated clients) were used to monitor drug availability and the performance of shopkeepers in the retail sector. The DSS served as sampling frame for the community-based studies and provided demographic indicators, including morbidity and mortality data.

The investigation of treatment-seeking and illness perception revealed a better overlap of local and biomedical illness concepts than reported in earlier studies from the same area. This is likely to reflect the intensive social marketing and health education campaigns carried out during the past decade. Modern medicine was clearly preferred by most patients and 87.5% (95% CI 78.2-93.8) of the fever cases in children and 80.7% (68.1-90.0) in adults were treated with one of the recommended antimalarials (at the time SP, amodiaquine or quinine). However, an estimation of community-effectiveness revealed that only 22.5% (13.9-33.2) of the children and 10.5% (4.0-21.5) of the adults received prompt and appropriate antimalarial treatment, despite high health facility usage rates. Quality of case-management was not satisfactory and the exemption mechanism for under-fives was not functional. Consequently, the commercial drug retail sector played an important complementary role in the provision of malaria treatment. In order to increase treatment effectiveness and maintain the high efficacy of the recently introduced ACT, both treatment sources should be strengthened and their quality should be improved.

The seasonal movement of families to distant farming sites did not increase the risk of family members contracting malaria. In the fields, 97.9% (95.2-100) of all people were protected with mosquito nets but since few households stocked antimalarials at home, treatment had to be sought from distant health facilities or drug stores. Of the episodes that happened in the fields, 88.2% (72.6-96.7) were finally treated with an antimalarial, indicating that households made a considerable effort to obtain malaria treatment. It appeared that during the farming season, difficulties to mobilize resources coupled with the long distance to treatment sources led to delays in treatment-seeking. In this context, a comprehensive approach should be considered to improve access to treatment while at the same time assuring rational use of medicines and protecting fragile livelihoods.

Investigations in the retail sector found that antimalarial availability had decreased by almost 50% in commercial shops following the policy change from chloroquine to SP as first-line treatment in 2001. This decline was noted mainly in general shops, which were not tolerated any more to sell SP (while they could generally sell chloroquine prior to the policy-change). In 2004, five out of 25 studied villages with a total population of 13,506 (18%) had neither a health facility, nor a shop as source of malaria treatment. While there was no immediately apparent impact on overall antimalarial use, the decline may have disproportionately affected the poorest and most remote groups in the community. In the light of the policy change to ACT these issues need to be addressed urgently if the benefits of these efficacious drugs are to be extended to the whole population.

The assessment of shop keepers knowledge and behaviour revealed that drug store keepers had better knowledge of malaria and its treatment than their peers in general shops. In drug stores, mystery shoppers were more likely to receive an appropriate treatment (OR=9.6, 95% CI 1.5-60.5), even though at a higher price. As a distribution channel for ACTs, complementary to health facilities, upgraded drug stores may be the most realistic option. However, shopkeepers in drug stores need to be trained on the provision of correct malaria treatment. At the same time, the role of general shops as first contact points for malaria patients needs to be re-considered. Taking the importance of shops into account, interventions to increase the availability of ACTs in the retail sector are urgently required within the existing legal framework.

The insights gained in the ACCESS studies helped to design a generic access framework embedded into the context of livelihood insecurity. This framework links social science and public health research with broader approaches to poverty alleviation. Apart from offering an analytical frame for further scientific research, it suggests access policies and interventions that reach beyond health services.

In conclusion, the findings of this thesis underline the need for a comprehensive approach to analyze and improve access to treatment. In this setting, health systems factors appear to be major obstacles to treatment, while local disease perceptions did not appear to have a big influence on treatment access. There is an urgent need to improve quality of care at all levels and new avenues have to be explored to achieve

equitable coverage with essential health interventions. Health policies need to be formulated and implemented in a way that they effectively improve the quality of services for all population groups. Considering the close link of disease and poverty, any health intervention is unlikely to succeed without taking the demand side into consideration. A comprehensive approach should therefore not only include measures that enable patients to access providers of good quality care, but also contribute to the strengthening of household economies. In order to achieve a decline in malaria morbidity and mortality in Africa, a concerted effort of all stakeholders is required to translate efficacious tools into effective, equitable and sustainable interventions.

# ZUSAMMENFASSUNG

Malaria ist die bedeutendste parasitäre Erkrankung des Menschen, mit schätzungsweise einer Million Todesfällen pro Jahr. Die meisten dieser Fälle werden in jungen Kindern in Afrika südlich der Sahara verzeichnet, was zu dem Teufelskreis aus Krankheit und Armut beiträgt.

Die bisher angewandten Strategien zur Kontrolle der Malaria haben in den meisten Gebieten Afrikas südlich der Sahara noch nicht zu einer Reduktion der Malariafälle geführt. Zwar bieten mit Insektizid behandelte Mückennetze (ITN) einen wirksamen Schutz gegen eine Übertragung und die Krankheit kann mit neuen Medikamenten erfolgreich behandelt werden (z.B. mit Kombinationspräparaten auf der Basis von Artemisinin). Eine grosse Herausforderung ist aber weiterhin die Frage, auf welche Weise Patienten am besten mit Gesundheitsdienstleistungen (wie z. B. lebensrettenden Medikamenten) erreicht werden können. Verschiedene in gegenseitiger Beziehung stehende Faktoren beeinflussen ob Patienten rechtzeitig Zugang zu wirksamer Behandlung erhalten. Aufgrund zunehmender Resistenzen werden gegenwärtig gebräuchliche Malariamedikamente, wie z. B. Chloroquin oder Sulphadoxin-Pyrimethamin (SP), durch Artemsinin-Kombinationspräparate (ACT) ersetzt. Weitere Hindernisse sind jedoch auf der Ebene der Haushalte (Nachfrage-Seite), der Gesundheitssysteme (Angebots-Seite) und in der Gesundheitspolitik zu finden.

Das Ziel der vorliegenden Dissertation ist es, zum Verständnis der Faktoren beizutragen, welche den Zugang zur Malariabehandlung positiv oder negativ beeinflussen. Die dadurch gewonnen Einsichten sollten einerseits in die Entwicklung zielgerichteter Interventionen einfliessen, welche den Zugang zur Malariabehandlung verbessern, und andererseits zur Entwicklung eines umfassenderen Zugangs-Modells beitragen.

Die Forschungsarbeiten wurden im Rahmen des ACCESS Programms durchgeführt, welches zum Ziel hat, den Zugang zur Malariabehandlung in den Distrikten Kilombero und Ulanga im südöstlichen Tansania sowohl besser zu verstehen als auch zu verbessern. Die Strategie von ACCESS beruht auf einer Kombination

verschiedener Interventionen, einschliesslich (1) soziales Marketing für angemessenere Behandlung auf Gemeindeebene, (2) Qualitätsverbesserung der Behandlung in Gesundheitszentren und (3) Stärkung der Medikamentenbranche im Einzelhandel. Die Interventionen werden dabei von umfassenden Kontroll- und Evaluationsaktivitäten begleitet.

Daten für die vorliegenden Studien wurden mittels quantitativer, semi-quantitativer und qualitativer Methoden im Gebiet des lokalen demographischen Überwachungssystems (DÜS) und im angrenzenden semi-urbanen Ifakara erhoben. Zwischen 2004 und 2006 wurde mittels Befragungen auf der Ebene der Haushalte das Verhalten der Bevölkerung im Fall einer Fieberepisode untersucht, was eine Schätzung der Effektivität der Malariabehandlung ermöglichte. Durch eine Erhebung von Einkaufsläden und mittels Testkäufer wurde die Verfügbarkeit von Malariamedikamenten sowie die Leistung der Verkäufer im Einzelhandel überwacht. Das DÜS diente dabei zur Stichprobenplanung für Studien auf Gemeindeebene und lieferte demographische Daten, einschliesslich Daten zur Morbidität und Sterblichkeit.

Aufgrund der Studien zum Behandlungsverhalten bei Malariafällen konnte festgestellt werden, dass das lokale konzeptuelle Verständnis der Malaria dem biomedizinischen Konzept näher kommt als aus früheren Studien in der gleichen Gegend hervorgeht. Dies spiegelt höchst wahrscheinlich die intensiven Sozialmarketing und Gesundheitserziehungs-Kampagnen der letzten Jahrzehnte wider. Moderne medizinische Behandlung wurde von den meisten Patienten deutlich bevorzugt. 87.5% (95% CI 78.2-93.8) der Fieberfälle in Kindern und 80.7% (68.1-90.0) der Fälle in Erwachsenen wurden mit einem der empfohlenen Malariamedikamente (damals SP, Amodiaquine oder Chinin) behandelt. Eine Schätzung des Wirkungsgrades der Behandlung auf Gemeindeebene ergab jedoch, dass nur 22.5% (13.9-33.2) der Kinder und 10.5% (4.0-21.5) der Erwachsenen rechtzeitig mit einem geeigneten und richtig dosierten Malariamedikament behandelt wurden und dies obwohl zahlreiche Patienten ein Gesundheitszentrum aufgesucht hatten. Die Qualität der Malariabehandlung war nicht zufrieden stellend und die Mechanismen zur Kostenbefreiung für Kinder funktionierten nicht. Folglich spielte der kommerzielle Medikamenten-Einzelhandel eine wichtige Rolle in der Versorgung mit Malariamedikamenten. Um die Effektivität der Malariabehandlung zu erhöhen und die

hohe Wirksamkeit der eben eingeführten ACTs zu erhalten sollten beide Behandlungsquellen bestärkt und deren Qualität verbessert werden.

Saisonale Verschiebungen von Haushaltungen auf weit entfernte Anbauflächen erhöhten deren Risiko einer Malariaerkrankung nicht. Auf den Feldern waren 97.9% (95.2-100) der Haushaltsmitglieder durch Mückennetze geschützt. Da jedoch nur wenige Haushaltungen Malariamedikamente mit auf die Felder nahmen, mussten Patienten zur Behandlung zu weit entfernten Krankenstationen oder Medikamentenläden reisen. 88.2% (72.6-96.7) der Malariaerkrankungen auf den Feldern wurden letztendlich mit einem Malariamedikament behandelt, was darauf schliessen lässt, dass Haushaltungen einen grossen Aufwand betreiben um eine Behandlung zu bekommen. Es schien als ob Schwierigkeiten Ressourcen zu mobilisieren in Kombination mit langen Distanzen zur nächsten Behandlungsquelle während der Anbauzeit zu Verzögerungen in der Behandlung führten. In dieser Situation sollte daher ein umfassender Interventionsansatz in Erwägung gezogen werden, welcher den Zugang zur Behandlung verbessert, gleichzeitig aber den rationalen Gebrauch von Medikamenten sicherstellt und ebenso die fragilen Lebensgrundlagen der Menschen sichert.

Untersuchungen im Einzelhandel ergaben dass die Verfügbarkeit von Malariamedikamenten um fast 50% gesunken war, nachdem in 2001 Chloroquin durch SP als Erstbehandlung der Malaria ersetzt wurde. Diese Abnahme war überwiegend in normalen Läden zu verzeichnen, welchen es fortan nicht mehr gestattet war, SP zu verkaufen (im Gegensatz zu Chloroquin vor dem Kurswechsel). 2004 befand sich in 5 der 25 Studiendörfer mit einer Bevölkerung von 13'506 (18% der Gesamtbevölkerung) weder eine Krankenstation, noch ein Laden als Behandlungsort. Zwar konnte keine unmittelbare Wirkung auf den Gebrauch von Malariamedikamenten festgestellt werden, die Abnahme könnte jedoch die ärmsten und entlegensten Bevölkerungsgruppen am meisten getroffen haben. Im Zuge des derzeitigen Wechsels auf ACTs sollten diese Punkte dringend angegangen werden um den Nutzen dieser wirksamen Medikamente auf die ganze Bevölkerung auszudehnen.

Eine Beurteilung des Wissensstandes und Verhaltens von Verkäufern in Läden ergab, dass das Personal in Medikamentenläden besser über Malaria und Malariabehandlung bescheid wussten, als das Personal in normalen Läden. In Medikamentenläden erhielten Testkäufer eher ein geeignetes Malariamittel (OR=9.6), allerdings zu einem höheren Preis. Verbesserte Medikamentenläden wären wohl die realistischste Option für den Vertrieb von ACTs ausserhalb von Gesundheitszentren. Gleichzeitig sollte jedoch die Rolle, welche der normale Einzelhandel als erster Kontaktpunkt für Malariapatienten spielt, neu überdacht werden. Angesichts der Wichtigkeit des Einzelhandels, einschliesslich der Medikamentenläden, sind Interventionen dringend nötig, welche auf den gegebenen rechtlichen Grundlagen die Verfügbarkeit von ACTs im kommerziellen Sektor verbessern.

Die Einsichten, welche in diesen ACCESS-Studien gewonnen wurden, halfen mit, ein generisches Zugangs-Modell zu entwerfen, welches in den Rahmen unsicherer Lebensgrundlagen eingebettet ist. Unter den untersuchten Gegebenheiten waren Faktoren im Gesundheitssystem wichtige Hindernisse auf dem Weg zur Behandlung, lokale Auffassungen von Krankheit hingegen weniger. Die Qualität der Malariabehandlung muss darum dringend verbessert werden und neue Lösungen sind nötig um eine faire Abdeckung mit Gesundheitsdienstleistungen zu erreichen. Gesundheitspolitische Richtlinien müssen auf eine Art und Weise formuliert und implementiert werden, dass sie die Qualität der Behandlung für alle Bevölkerungsgruppen wirksam verbessern. Angesichts des engen Zusammenspiels von Krankheit und Armut können Gesundheitsinterventionen nur wirksam sein, wenn auch die Seite der Nachfrage berücksichtigt wird. Ein umfassender Ansatz sollte daher nicht nur dazu beitragen, dass Patienten gute Behandlungsorte erreichen, sondern sollte ebenfalls zur Stärkung der Haushalts-Ökonomien beitragen. Um eine Abnahe der Malariaerkrankungen und Todesfälle in Afrika zu erreichen braucht es eine gemeinsame Anstrengung aller Beteiligten, so dass wirksame Instrumente in effektive, faire und nachhaltige Interventionen umgesetzt werden können.

# MUHTASARI

Malaria ni ugonjwa muhimu wa vimelea unaomshambulia binadamu, unasababisha takribani vifo milioni moja kila mwaka. Mashambulizi mengi yanawapata watoto wadogo katika jangwa la Sahara, hali inayosababisha mzunguko mzima wa magonjwa na umasikini.

Mikakati ya kupambana na malaria kwa sasa inaonekana kushindwa kukabili ugonjwa huu katika sehemu nyingi za kusini mwa jangwa la sahara. Vyandarua vilivotiwa dawa vinafanya kazi ya kuzuia malaria pamoja na dawa zenye ubora (kama dawa mseto - ALu) zipo kwa ajili ya tiba ya malaria. Lakini kubwa limekuwa ni utoaji wa huduma bora za afya, pamoja na dawa za kuokoa maisha kwa wanaohitaji. Muungiliano wa sababu mbalimbali unasababisha mgonjwa kupata tiba sahihi ya malaria mapema. Wakati dawa za kutibu malaria kama chloroquine na SP zimethibika kushindwa kutibu malaria na badala yake dawa mseto (ALu) kuchukua nafasi, vikwazo katika kupata tiba sahihi ya malaria vimeelezwa kuwepo katika ngazi ya kaya (kwa wahitaji), na sekta ya afya (watoaji), na pia katika sera za afya.

Lengo la utafiti huu ni kuchangia katika uelewa bora wa sababu nzuri na mbaya zinazosababisha jamii kupata tiba ya malaria. Matokeo ya utafiti huu yatatoa mwanga kwa mikakati mbalimbali ya kimaendeleo kuimarisha upatikanaji wa tiba sahihi ya malaria na pia kutengeneza dira ya mradi wa ACCESS

Utafiti huu ulifanyika kama sehemu ya Mradi wa ACCESS, wenye lengo la kuongeza uelewa na kuimarisha upatikanaji wa tiba sahihi ya malaria katika wilaya za kilombero na ulanga, kusini-mashariki mwa Tanzania. Mikakati ya mradi wa ACCESS imelenga katika sehemu mbalimbali zikiwemo 1) Kuhamasisha jamii kuboresha huduma katika ngazi ya jamii 2) kuimarisha ubora wa huduma za afya katika vituo vya afya and 3) kuimarisha maduka yanatoa huduma za dawa. Mikakati hii imeambatana na shughuli mbalimbali za tathimini na ufuatiliaji.

Njia mbalimbali za kiutafiti zilitumika kukusanya maelezo ndani ya eneo linalotumika kukusanya takwimu za afya na pia katika tarafa ya Ifakara. Kati ya mwaka 2004 na 2006, utafiti katika jamii ulifanyika kuchunguza tabia za utafutaji matibabu na

makadirio ya uelewa wa tiba ya malaria. Sensa ya maduka na watafiti walitumika kufanya tathimini ya upatikanaji wa madawa na uwezo wa wauza maduka katika uuzaji dawa. Utafiti huu ulifanyika ndani ya eneo linalotumika kukusanya takwimu za afya ambapo maelezo binafsi ya wahojiwa yalikusanywa pamoja na maelezo ya magonjwa na vifo.

Utafiti huu wa utafutaji matibabu na uelewa wa magonjwa ulionyesha muungiliano mzuri wa maneno ya kisayansi na kijamii katika kuelezea ugonjwa zaidi ya ilivyoripotiwa kabla katika tafiti mbalimbali ndani ya eneo hilo. Hii inaweza kutokana na uhamasishaji jamii na kampeni za afya zilizofanyika hapo zamani. Dawa za kisasa ziliongoza kutumiwa na wagonjwa wengi na asilimia themanini na nane ya matatizo ya homa kwa watoto na asilimia themanini na moja ya watu wazima walitibiwa kwa dawa ya malaria iliyopendekezwa (kwa wakati huo SP, amodiaquine au quinine). Lakini makadirio ya utumikaji katika jamii yalionyesha kwamba ni asilimia ishirini na mbili nukta tano tu ya watoto and asilimia kumi nukta tano ya watu wazima walipata tiba sahihi ya malaria mapema, ukiachilia mbali matumizi makubwa ya huduma katika vituo vya afya. Ubora wa huduma za afya haukuwa wa kutosheleza na watoto chini ya miaka mitano ambao wanatakiwa kupata matibabu bure, hali haikuwa hivyo. Kwa hakika maduka yanayouza dawa, yalionekana kuwa mbadala kwa utoaji huduma kwa tiba ya malaria. Kwa ajili ya kuongeza mafanikio na kuimarisha ubora wa dawa mpya iliyopendekezwa, dawa mseto, vyanzo vyote vya utoaji huduma vinatakiwa vidumishwe na ubora wake uongezwe.

Uhamaji wa vipindi wa familia kwa ajili ya shughuli za kilimo mashambani haukuongeza uwezekano wa kushambuliwa na malaria kwa familia hizo. Katika mashamba asilimia tisini na saba nukta tisa ya watu wote walitumia vyandarua kwa ajili ya kinga lakini kwa sababu ni kaya chache tu zilizohifadhi dawa za malaria, matibabu yalitafutwa vituo vya afya vilivyokuwa mbali au katika maduka ya madawa. Kati ya matatizo yaliyojitokeza kipindi cha shamba, asilimia themanini na nane nukta mbili yalitibiwa kwa dawa za malaria, hii inaonyesha kwamba kaya zitumia jitihada za kutosha kutafuta tiba ya malaria. Ilitokea kwamba, kipindi cha shamba, matatizo katika kutafuta mali pamoja na umbali kufikia vituo vya tiba, vilisababisha ucheleweshaji wa utafutaji matibabu. Katika hili basi, njia sahihi inatakiwa ili

kuongeza upatikanaji wa huduma na wakati huo huo kuwezesha utumiaji mzuri wa madawa kusaidia wananchi wanaohama kwa ajili ya shughuli mbalimbali

Utafiti katika maduka ulionyesha kwamba upatikanaji wa dawa za malaria umepungua kwa asilimia hamsini katika maduka kutokana na mabadiliko ya sera ya afya kutoka chloroquine kwenda SP, kama dawa ya malaria iliyopendekezwa kwa tiba ya malaria mwaka 2001. upungufu huu ulionekana sana katika maduka ya kawaida, ambayo hayakuruhusiwa tena kuuza SP (kinyume na ilivyokuwa kwa chloroquine kabla ya mabadiliko ya sera). Mwaka 2004, vijiji vitano kati ya ishirini na tano vilivyofanyiwa utafiti na vilivyokuwa na jumla ya wakazi 13,506 (asilimia kumi na nane) hawakuwa na aidha kituo cha afya au duka lolote kama chanzo cha tiba ya malaria. Wakati kulikuwa hamna madhara ya papo kwa papo katika matumizi ya dawa za malaria, upungufu huu umeathiri wasiokukuwa na uwezo na wale wanaoishi maeneo ya mbali zaidi na huduma katika jamii. Katika mabadiliko ya sera mpya ya dawa mseto, mambo haya yanatakiwa kuangaliwa kwa kina kama faida ya hizi dawa bora zitapanuliwa kuifikia jamii yote.

Tathmini ya uwezo na uelewa wa wauza maduka ulionyesha kwamba wauza maduka ya dawa wana uelewa mzuri wa malaria na tiba zake kuliko wauzaji wa maduka ya kawaida. Katika maduka ya dawa, watafiti waliweza kupata tiba sahihi, ingawa kwa bei kubwa zaidi. Kwa ajili ya usambazaji wa dawa mseto, na mbadala wa vituo vya afya, maduka ya dawa muhimu yanaweza kuwa suluhisho sahihi. Lakini, wauzaji wa maduka ya dawa wanatakiwa kupata mafunzo ya jinsi ya kutoa dawa sahihi za malaria. Na pia, umuhimu wa maduka ya kawaida kama kimbilio ya kwanza yanatakiwa kufikiriwa tena. Ukichukulia umuhimu wa maduka, mikakati inatakiwa kuongeza upatikanaji wa dawa mseto za malaria kwenye maduka haya.

Matokeo ya tafiti hizi yaliyofanyika ndani ya mradi wa ACCESS yamesaidia kujenga mtazamo mpya ndani ya mradi, na kuibua mtazamo wa kuangalia jamii kwa jinsi inavyojishughulisha kutafuta tiba. Mtazamo huu unaunganisha utafiti wa sayansi ya jamii na afya ya jamii kuangalia janga zima la kuondoa umasikini. Pia unatoa mwangaza kwa tafiti nyingine za kisayansi, na unapendekeza uwepo wa sera na mikakati inayovuka mipaka na kuangalia zaidi ya huduma za afya tu.

Kwa kuhitimisha, matokeo ya utafiti huu yanalenga kuwepo kwa muingiliano wa kimitazano katika kuchambua na kuongeza upatikanaji wa matibabu. Katika hili, sekta ya afya imeonekana kuwa kikwazo katika matibabu, wakati mitazamo ya magonjwa katika jamii haikuwa na madhara katika utafutaji matibabu. Kuna umuhimu wa haraka wa kuongeza ubora wa huduma za afya katika ngazi zote na uchunguzi kuendelea ili kuwe na usawa katika uwepo wa mikakati muhimu ya afya. Sera za afya zinatakiwa kuundwa na kufanyiwa kazi kwa njia ambayo itawezesha kuboresha huduma za afya kwa wanajamii mbalimbali. Ukichukulia muingiliano wa karibu kati ya magonjwa na umasikini, mikakati yoyote ya kiafya haitafanikiwa kwa urahisi kama haitachukua mategemeo ya wanjamii na kuyafanyia kazi. Mitazamo na mikakati mbalimbali inatakiwa sio tu kusaidia wagonjwa kupata huduma bora za afya bali pia kudumisha uchumi wa kaya. Ili kuweza kufikia lengo la kupunguza magonjwa na vifo vinavyosababishwa na malaria barani Africa, wadau wote wanatakiwa kuunganisha nguvu na kubadilisha nyenzo kuwa zenye usawa, imara na kuwa na mikakati ya kudumu.

# PART 1

## BACKGROUND

Paddies in the Kilombero Valley

# 1 INTRODUCTION

## *1.1 Malaria*

Malaria is a parasitic infection caused by protozoa of the genus *Plasmodium. Plasmodia* are transmitted from humans to humans by several species of blood-feeding female *Anopheles* mosquitoes. The four human-pathogenic *Plasmodia* species *P. falciparum, P. vivax, P. malariae* and *P. ovale* differ in pathogenesis and global distribution. *P. falciparum* causes most of the severe and fatal cases of malaria. It is the predominant species throughout sub-Saharan Africa. Since *P. vivax* can develop in mosquitoes at a lower temperature than *P. falciparum*, its geographical distribution is wider. *P. vivax* and *P. ovale* can form resting stages in the liver (hypnozoites) which may cause clinical relapses many months after the first attack. In humans, malaria parasites are found in the liver and in the blood where they invade, grow and replicate in erythrocytes (schizogony). Once sexual forms (gametocytes) of the parasite have developed and circulate in the bloodstream, they may be taken up by a female *Anopheles*, and the parasite's sexual reproduction can take place in the gut of the mosquito. After extensive replication in the outer wall of the mosquito-gut (sporogony), the parasites can pass via the salivary glands into the next human host, usually 10-14 days after the initial blood-meal (Figure 1.1) (Warrell & Gilles 2002; Greenwood *et al.* 2005).

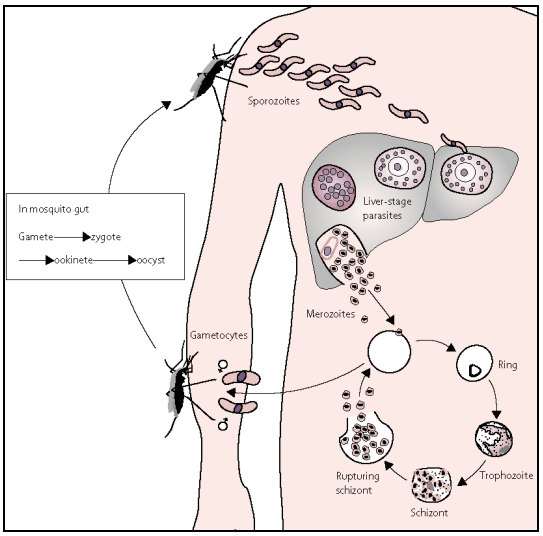


**Figure 1.1: Lifecycle of the malaria parasite in humans and mosquitoes**

Source: Greenwood *et al.* 2005

## *1.2 Clinical features of malaria*

The clinical features of uncomplicated malaria are well known. In semi-immune populations, malaria infections often results in asymptomatic parasitaemia. Clinical attacks manifest themselves as febrile paroxysms with accompanying symptoms such as headache, cough, body pains, chills, vomiting and diarrhoea (Warrell & Gilles 2002). Then, there is a continuum from mild to severe disease. Severe malaria is a complex multi-system disorder, characterized by one or more of the following clinical features: severe anaemia, prostration, impaired consciousness, respiratory distress (acidotic breathing), multiple convulsions, circulatory collapse, pulmonary oedema, abnormal bleeding, jaundice, and haemoglobinuria (WHO 2000b; Mackintosh *et al.* 2004). Impaired consciousness and respiratory distress were found to be the most dangerous clinical features (Marsh *et al.* 1995; Schellenberg *et al.* 1999).

Cerebral malaria and severe anaemia are the most common syndromes of severe malaria in semi-immune children and they are responsible for long-term developmental impairments and most of the deaths in children (Carter *et al.* 2005). Cerebral malaria is a heterogeneous syndrome with a high case-fatality rate, in which the sequestration of parasites in peripheral blood vessels plays a certain role. Apart from the direct fatal outcome, cerebral malaria can result in brain damage in surviving children and lead to behavioural disorders and impaired growth and development (Breman 2001; Greenwood *et al.* 2005). Severe anaemia results from the destruction of red blood cells, either directly by the malaria parasite or indirectly by immune mechanisms. It may have multiple aggravating causes and goes often unnoticed as it is not easily recognised by caretakers. Severe anaemia in children may lead to long-term neurological, cognitive, and developmental impairments (Breman 2001; Schellenberg *et al.* 2003b). A special risk group are pregnant women who are more likely to develop severe malaria than non-pregnant adults, especially during the second and third trimesters. During pregnancy, severe malaria endangers the life of both the pregnant woman and her foetus. Placental malaria is common and associated with low birth-weight and subsequent increased infant and child mortality (Marchant 2004). Maternal anaemia may result in impaired development of the foetus

and anaemic neonates. Cases of congenital malaria, however, are rare (WHO 2000b; Breman 2001; Schellenberg *et al.* 2003b).

## *1.3 Global malaria situation*

Malaria is the most important parasitic infection in humans. Most estimates of malaria-related mortality suggest that about 1 million deaths a year are directly due to malaria (Snow *et al.* 2005). However, it is difficult to obtain an accurate measurement of how many people die from this disease (de Savigny & Binka 2004). National health statistics of most developing countries are found to be an unreliable source of information and estimates are often based on different and sometimes contradictory sources. Furthermore, indirect effects of the disease on other infections, such as HIV (ter Kuile *et al.* 2004), or on nutrition and more broadly on poverty, may contribute to an even higher death toll. This impact is reflected in estimates of up to 3 million malaria-related deaths a year worldwide (Breman *et al.* 2004). Almost all of these deaths occur in children and are caused by *P. falciparum* (Phillips 2001).

The enormous impact of malaria on morbidity and mortality poses a challenge for achieving the Millennium Development Goals (MDG) (United Nations 2005). These goals for the development of the most deprived regions in the world were adopted by the United Nations General Assembly in September 2000 and range from halving extreme poverty to halting the spread of major diseases and providing universal education by the year 2015 (United Nations General Assembly 2000). Three out of the eight MDGs are directly linked to the successful reduction of the disease burden caused by malaria: to reduce the mortality rate among children under five by two thirds (MDG 4); to reduce the maternal mortality ratio by three quarters (MDG 5); to halt and begin to reverse the incidence of HIV/AIDS, malaria and other major diseases (MDG 6). In order to achieve the targets set by the health MDGs, several publications have recently called for a bigger effort in controlling disease in developing countries, as well as for the re-evaluation of currently applied strategies (Molyneux & Nantulya 2004; Travis *et al.* 2004; United Nations 2005; Evans *et al.* 2005; Bryce *et al.* 2006).

Historically, the distribution of endemic malaria ranged from temperate to tropical regions. In the temperate regions of the world, the elimination of malaria has been successful. In the 1930s to 1950s, countries such as the United States, Italy, Greece and Spain have become free of autochthonous malaria, as a result of socioeconomic development (i.e. improved housing) and intensive antimalarial interventions. The measures applied comprised environmental management such as draining of swamplands to eliminate *Anopheles* breeding sites, and the use of insecticides, including indoor house spraying using dichlorodiphenyltrichloroethane (DDT). Climatic conditions with cold winters facilitated these measures as they shorten mosquito life and prolong the time period required for the parasite to complete its life-cycle within the cold-blooded mosquito (Warrell & Gilles 2002).

Today, endemic malaria is spread throughout the tropical and sub-tropical regions of Africa, Asia and Latin-America (Figure 1.2). The tropical areas of the world have a combination of rainfall, temperature and humidity that maximizes survival of the *Anopheles* mosquito and speeds-up completion of the parasite life-cycle (Craig *et al.* 1999).

Recent progress has been made in controlling malaria in parts of Asia and Africa (Barat 2006; Barnes 2007). However, a literature review documents a dramatic increase in the global population at risk over the last century, mainly due to demographic changes in Africa and Asia. It estimates that by 2010, 3.4 billion people will live at risk of malaria, compared to 0.9 billion in 1900 and about 3 billion in 2002 (Hay *et al.* 2004). In recent years, not only the absolute number, but also the percentage of the global population at risk of malaria has increased again (Figure 1.3). Recent trends of urbanization in developing countries will also affect the change of the epidemiological pattern of malaria (Donnelly *et al.* 2005).

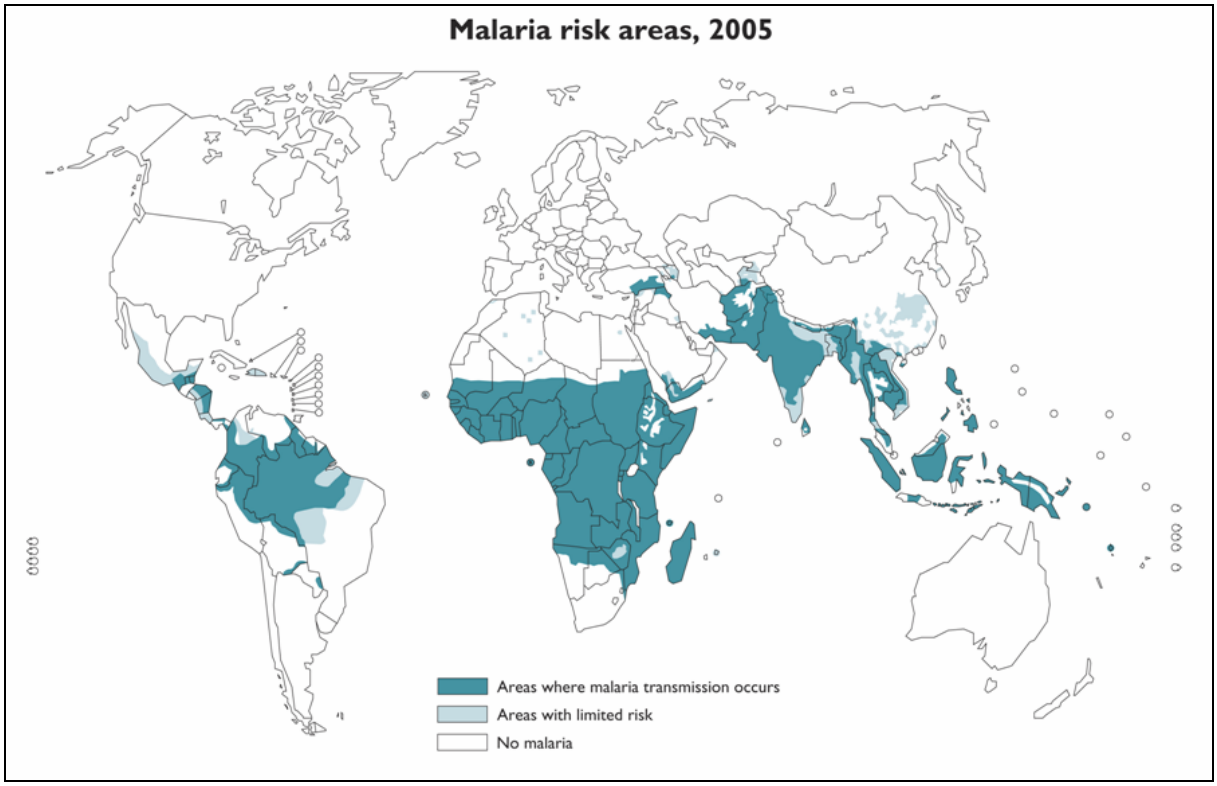


**Figure 1.2: Geographical distribution of malaria**

Source: World Health Organization 2005 (http://www.who.int/globalatlas)

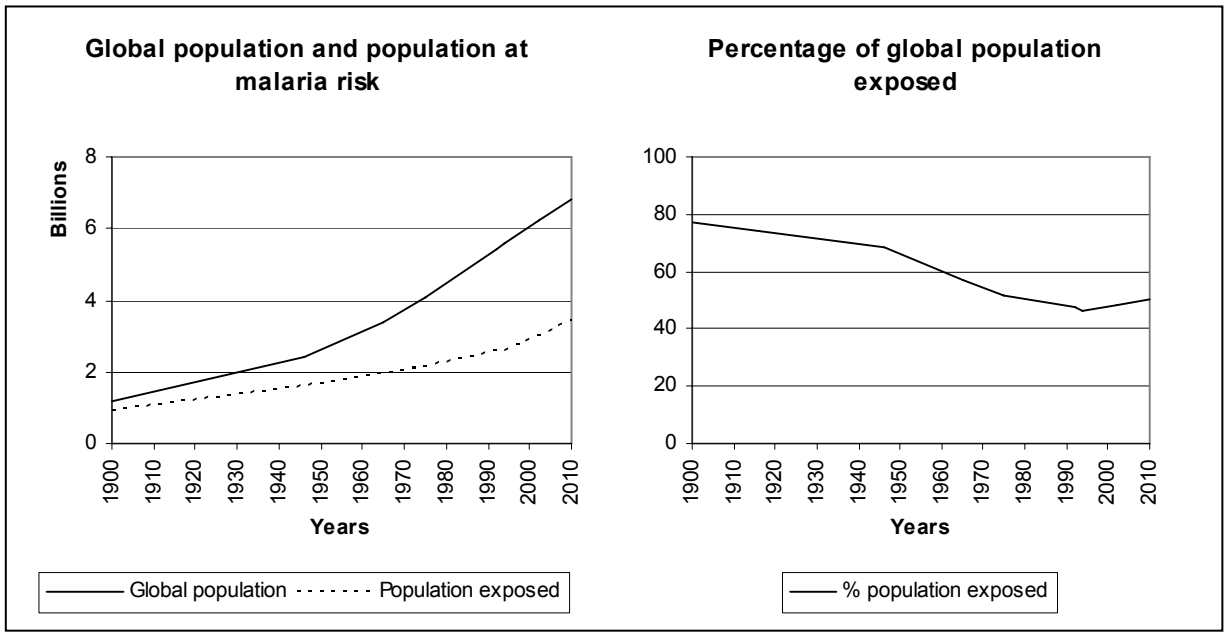


**Figure 1.3: Global population at risk of malaria**

Data source: Hay *et al.* 2004

The brunt of the malaria burden is born by the population of sub-Saharan Africa, where *P. falciparum* is the predominant species and the mosquito vectors are the most efficient. 60% of the global estimate of 0.5 billion clinical malaria episodes and 70-90% of the 1 to 3 million malaria deaths a year occur in Africa, mostly south of the Sahara (Breman *et al.* 2004; Snow *et al.* 2005; WHO & UNICEF 2005).

In areas of stable *P. falciparum* transmission, such as in large parts of sub-Saharan Africa, very young children and pregnant women are the groups at highest risk. Most malaria deaths in these areas occur in children under 5 years of age, who have not yet acquired partial immunity against infection. Pregnant women, whose immunity to malaria is temporarily impaired, are particularly at risk as their infections are often asymptomatic and may be overlooked because peripheral blood films may be negative (Snow *et al.* 1999; WHO 2000a).

Estimates suggest that out of the 0.5 billion clinical attacks that occur every year, 2-3 million are severe cases (Figure 1.4). The final outcome of an infection with *P. falciparum* parasites depends on a variety of factors, such as virulence of the parasite, genetic and immunological factors and the nutritional status of the human host. Malaria and other infectious diseases such as HIV/AIDS may adversely affect each other. Furthermore, sociological factors, including treatment seeking behaviour are also likely to play an important role (Greenwood *et al.* 1991; Greenwood *et al.* 2005).

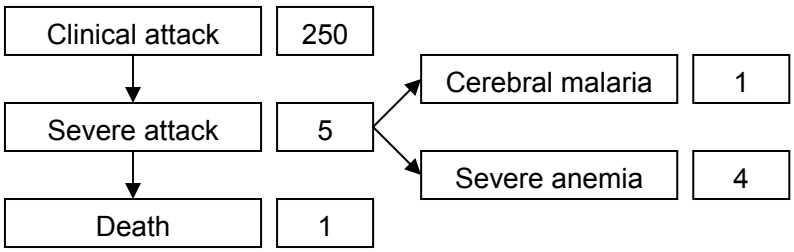


**Figure 1.4: Possible outcomes of infection with *Plasmodium* in children**
Numbers indicate estimated annual number of cases (in millions) of African children likely to fall into each category. Data source: Greenwood *et al.* 2005

## *1.4 Malaria and poverty*

The burden of malaria in endemic countries extends beyond the direct health impact. Malaria imposes economic costs on households and states. Repeated malaria attacks contribute to prolonged absence from school and work. Consequences are poorer school performances and the loss of workdays and income. Furthermore, evidence suggests that repeated disease episodes may impair intellectual development (Fernando *et al.* 2003). In addition to income loss, household economies can be overburdened by expenditures for the prevention and treatment of illness episodes, sometimes leading to cases of catastrophic household expenditures (Xu *et al.* 2003). Malaria increases government spending on vector control, health services, subsidies for treatments, research, and training. It has further been suggested that malaria has a major impact on local economies through changes in household behaviour, demography, schooling or migration. Additionally, on a macroeconomic level, malaria may impede tourism, trade and foreign investments (Sachs & Malaney 2002).

A mutual link between malaria and poverty is now widely accepted. While malaria can promote poverty, poverty also increases vulnerability to malaria. On a macro-level, malaria is most widespread in countries in development. Malaria endemic countries are poorer and have slower economic growth than non-malarious countries. A comparison of malarious and non-malarious countries found a more than five times lower average gross domestic product (GDP) in countries with intensive malaria transmission (US$ 1,526 vs. US$ 8,268). Further, countries with intensive transmission had a 1.3% lower annual economic growth rate between 1965 and 1990 than other countries (Gallup & Sachs 2001; Sachs & Malaney 2002). In addition to the differences between countries and regions, there are inequities within countries. People of all socio-economic groups in malaria-endemic countries fall ill from malaria. Yet, the children of the poorest people often bear the heaviest disease burden. They are more exposed to additional risk factors, less resistant to diseases, less likely to use preventive measures and less likely to get appropriate care when ill. They often live in areas under-served by health facilities (Victora *et al.* 2003; Worrall *et al.* 2005; Njau *et al.* 2006).

## 1.5 Burden of malaria in Tanzania

Tanzania has an estimated population of about 38 million people with an annual population growth rate of 2.2% in 2005 (WHO 2006c). The risk of malaria transmission along with the length of the transmission season varies over time and space, mainly due to climatic variations across the country. Of the total population, 87% live in regions suitable for stable perennial or seasonal malaria transmission (4 or more months per year) and therefore at risk of endemic malaria. 4% live in areas with highly seasonal or unstable transmission and 9% face no transmission in average years (Figure 1.5). This data was derived from a model of seasonality of transmission based on climatic suitability using MARA LITe software (Mapping Malaria Risk in Africa/Atlas du Risque de la Malaria en Afrique [MARA/ARMA] collaboration, South African Medical research Council) (MARA/ARMA 2004).

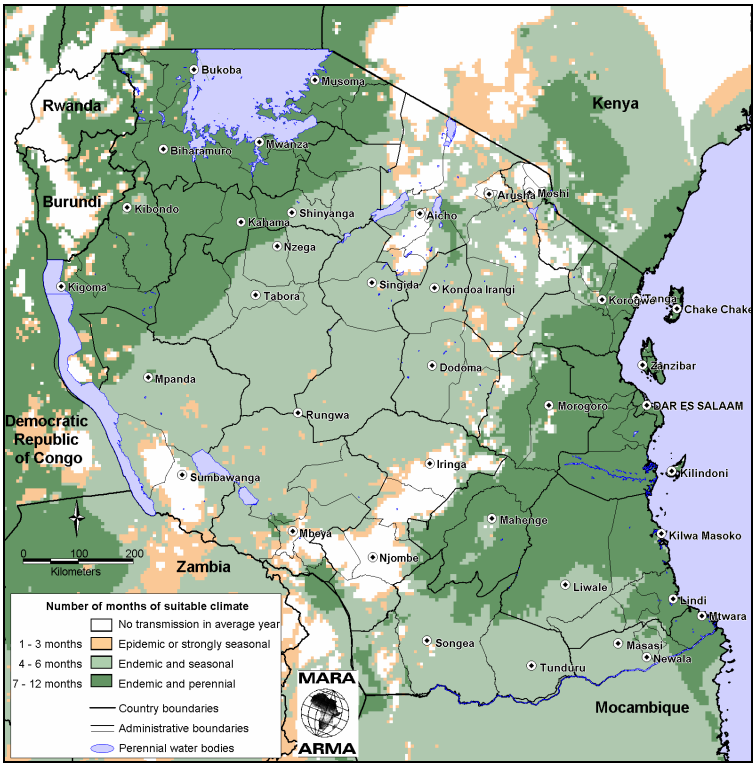


**Figure 1.5: Duration of the malaria transmission season in Tanzania**

Source: MARA/ARMA collaboration (http://www.mara.org.za)

Transmission intensity in Tanzania is characterized by high entomological inoculation rates (EIR), a measure for the number of infectious bites per person per year. EIR and multiplicity of infection were shown to be associated with increased malaria

morbidity. A tenfold increase in the EIR corresponded to a 1.6-fold (95% confidence interval [CI] = 1.4-2.0) increase in malaria incidence (Smith *et al.* 1998). A review of EIR values across Africa found that Tanzanian EIR estimates were among the highest with a mean of 367 infectious bites per person per year (ib/p/y, range 94-667). The overall mean of EIR for Africa was 146 ib/p/y (range 0-884) (Hay *et al.* 2000).

Reliable estimates of the morbidity and mortality burden of malaria in Tanzania are compromised by a lack of reliable data sources. In most developing countries, health management information systems (HMIS) are weak and data collection incomplete (de Savigny & Binka 2004). This is partly the reason for contradictory data from health statistics, facility-based and community-based studies, or demographic surveillance systems (DSS).

District-level statistics from health facilities reported 11.2 million outpatient (OPD) attendances, 2.1 million admissions and 18,000 deaths due to malaria in 2004 (MOHSW 2006a). Yet in reality, many malaria episodes are managed outside the formal health sector and many deaths occur at home, thus escaping official records (Breman 2001). In the Ifakara DSS, which has a good network of health facilities and a highly frequented district hospital nearby, still about 30% of all deaths occur outside a health facility (Ifakara DSS 2002). Facility-based data are therefore most likely to provide an underestimation of the real disease burden. More reliable data should be expected from DSS or cross-sectional community-surveys. On the other hand it should be noted that misdiagnosis of malaria in health facilities is common and that not all cases of febrile illness (often used as proxy indicator for malaria in community surveys) are really cases of malaria (Reyburn *et al.* 2004; Amexo *et al.* 2004).

During the 2004 Demographic and Health Survey (DHS) 24% of under-fives were reported to have had a fever (as proxy indicator for malaria) in the two weeks preceding the survey (National Bureau of Statistics 2005). A household survey carried out by the National Malaria Control Programme (NMCP) found 32% of under-fives with a recent fever in 2005 (MOHSW 2006b), representing a decline compared to 35% in 1999 (United Republic of Tanzania 2005). Data from the Ifakara DSS suggests a malaria-related mortality in under-fives of 3.7 per 1,000 person-years in 2003 (Ifakara DSS, unpublished, cited in United Republic of Tanzania 2005). Overall,

32% of total mortality is attributed to malaria (41% in under-fives) (USAID - CDC 2005). In absolute numbers, there are 100,000–125,000 deaths per year from malaria, up to 80,000 of which are in children under the age of five years. Most of the under five deaths occur during the rainy seasons between November and December (short rains), and between March and June (long rains), a seasonality that is most likely due to malaria. It is estimated that a Tanzanian child under five years has on average 0.7 episodes of malaria per year (USAID - CDC 2005).

This high number of clinical attacks, including many cases of severe disease, presents a challenge to the Tanzanian health system. Data from district-level health statistics for 2004 suggest that malaria, acute respiratory infections, pneumonia and diarrhoeal diseases were the major causes for outpatient attendance in health facilities. Malaria accounted for 39% of all outpatient attendances in under-fives and for 48% in the age-group of five years and above. In inpatients under five years, 34% of the primary diagnoses were uncomplicated malaria and 11% severe malaria. In the age group over five, malaria accounted for 42% and severe anaemia for 10%. In peripheral health facilities (i.e. excluding referral hospitals), 48% of deaths in under-fives and 26% of deaths in patients over five years were attributed to malaria (MOHSW 2006a).

It is estimated that US$ 121 million are spent annually on the prevention and control of malaria in Tanzania, amounting to 3.5% of the GDP. One-third of public health facilities' expenditures are devoted to malaria (USAID - CDC 2005). An economic analysis on data from 1998 concluded that 71% of total malaria expenditures came from private sources (e.g. households) (Jowett & Miller 2005). However, this is likely to have changed recently, considering the latest influx of money from malaria control initiatives and funding agencies such as the US President's Malaria Initiative (PMI) or the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM).

## *1.6 Malaria control*

In order to develop successful malaria control measures, a sound understanding of the local epidemiology, as well as of the socio-cultural and political context is

fundamental. Strategies for controlling malaria have changed over the past decades, differing from one setting to the other, depending to a large extent on priority-setting at global and national level, on the costs and effectiveness of available control tools, and on the local feasibility of their implementation. In 1956, the World Health Organization (WHO) launched the Malaria Eradication Campaign with the aim to completely stop malaria transmission in malarious countries. As a result, large parts of southern Europe, the USA, Latin America, the Middle East and parts of Asia were freed from malaria. This was achieved through the widespread and meticulously organized application of the insecticide DDT and through environmental management. In tropical regions, this approach was less successful and the global eradication strategy was abandoned after 1969 (Nájera 2001; Warrell & Gilles 2002).

Since 1992, the focus has been on malaria *control* (rather than eradication) with the aim to reduce morbidity and mortality to an extent that the disease is no longer a major public health problem (Nájera 2001). This approach is at the heart of a renewed effort to fight malaria, which started at the turn of the 21$^{st}$ century. At the African Summit on Roll Back Malaria, held in April 2000 in Abuja (Nigeria), African Heads of State agreed on a concerted effort to reduce the burden of malaria on the continent. They endorsed the ambitious goal of halving the number of malaria deaths by the year 2010 (Yamey 2000). They agreed to ensure, that by 2005:

- at least 60% of those suffering from malaria have prompt access to affordable and appropriate treatment within 24 hours of the onset of symptoms,
- at least 60% of those at risk of malaria, particularly children under five years of age and pregnant women, are protected by insecticide-treated mosquito nets (ITNs) and other interventions, and
- at least 60% of all pregnant women who are at risk of malaria have access to chemoprophylaxis or intermittent preventive treatment (IPT).

In 2005, these goals were changed from 60% to 80% to be reached by 2010, although most of the countries had not even managed to meet the 2005 targets (Yamey 2004; RBM Partnership 2005).

To achieve this, the WHO and the Roll Back Malaria (RBM) Partnership promote a control strategy for Africa that emphasises the importance of using the most effective

existing tools and resources to the fullest extent (WHO & UNICEF 2005; RBM Partnership 2005). The strategic components and the tools, which should be chosen in consideration of the local setting, have been identified as:

- **Effective malaria prevention through vector control**
  - ITNs, preferably long-lasting insecticidal nets (LLIN)
  - Indoor residual spraying (IRS) with DDT or other recommended insecticides
- **Intermittent preventive treatment (IPT)**
  - IPT during pregnancy (IPTp) with sulphadoxine-pyrimethamine (SP)
  - IPT in infants (IPTi) as soon as safety and effectiveness is proven
- **Prompt and effective treatment**
  - Artemisinin-based combination therapies (ACTs)
- **Reduction of the impact of emergencies and epidemics**
  - Early warning and rapid response systems

These updated guidelines now consider the re-emerging use of IRS (WHO 2006b), the proven efficacy of ACT (WHO 2001a) along with the potential benefits of IPTi (Schellenberg *et al.* 2005) and the well-known effectiveness of ITNs (Lengeler 2004). Importantly, the current strategy addresses the fact that most existing health systems do not have a sufficient capacity (human resources, management, infrastructure) to implement the increased interventions package. Hence, it stresses the need for strengthening health systems, building local capacity and ensuring sustained financing (RBM Partnership 2005).

The WHO recommendations have been adopted by most African countries and adapted to the local context. The NMCP of Tanzania formulated its four strategic approaches to malaria control in the 2002-2007 Medium Term Strategic Plan (Figure 1.6) (MOH 2002).

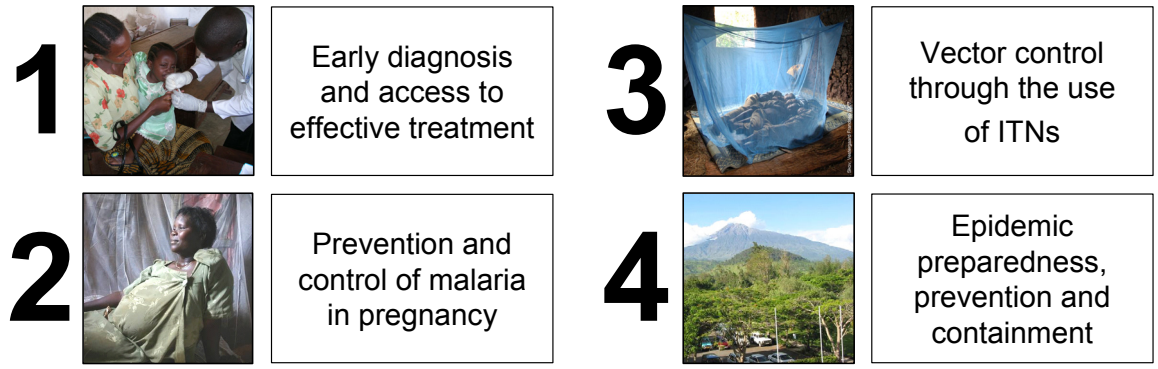


**Figure 1.6: Tanzanian malaria control strategy**

Combining different control approaches, together with a strong management, have led to some important initial successes. Recent progress in malaria control was reported from South Africa, namely KwaZulu-Natal (Barnes *et al.* 2004), Eritrea (Nyarango *et al.* 2006), Bioko (Kleinschmidt *et al.* 2006), Madagascar (Romi *et al.* 2002), southern Mozambique (Sharp *et al.* 2007), and Zambia (Singer 2005). These efforts all benefited from the renewed attention that has been devoted to malaria in recent years. It led to new initiatives and a ten-fold increase in financing for malaria control activities between 1998 and 2006 (Feachem & Sabot 2007).

With effective control tools and up-to-date implementation guidelines at hand, the challenge remains to deliver the interventions to those who are affected, particularly the most vulnerable young children and pregnant women living in underserved areas. Increased attention is therefore being devoted to the question of how to build health systems, delivery mechanisms and a political environment which improve people's access to malaria prevention and treatment (Barnes 2007).

# 2 ACCESS TO MALARIA TREATMENT

## *2.1 Access to health in the global discussion*

With growing prosperity, and technical and scientific advances, the availability of means to improve health has constantly increased. At the same time, the gap between rich and poor – between, as well as within countries and regions - has become wider. While for all major diseases (including malaria, HIV/AIDS and tuberculosis) effective treatments or preventive measures exist, large parts of the world's population are unable to gain access to these means (Victora *et al.* 2003). In a vicious circle, the poorest suffer from the greatest burden of disease while at the same time they often lack access to effective health care (Goddard & Smith 2001; Victora *et al.* 2003; WHO 2005b). According to WHO estimates, 1.7 billion people, i.e. 30% of the world's population (1999), have inadequate or no access to essential medicines. To a similar extent, they may lack access to diagnostics, preventive measures or general health infrastructure. 80% of these people live in low-income countries (WHO 2004c).

In recent years, access to health care has become an important topic in international health. The discussion arose partly as a consequence of growing drug resistance, an issue which is not only relevant for antimalarial medicines but also for other anti-infectious agents. Antimalarial drug resistance emerged in the 1960s and has steadily progressed and spread over the last decades. The main foci for resistance have been found in South-East Asia and South America, leading to more and more complex first-line drug regimens. Africa has seen the emergence of drug resistance against the widely used chloroquine since the 1980s, starting in East Africa and spreading rapidly over the whole continent. Nowadays, chloroquine is virtually useless as a first-line treatment and SP is following in its footsteps in much of sub-Saharan Africa. A resulting increase in malaria-specific mortality may therefore loom if alternative treatments are not rapidly implemented (Trape *et al.* 1998; White *et al.* 1999; White 2004). The increasing need for new efficacious treatment and prevention has driven the creation of international initiatives such as Medicines for Malaria Venture (MMV) (MMV 2007a), the Drugs for Neglected Diseases initiative (DNDi) (DNDi 2003), or the Global Alliance for Vaccines and Immunization (GAVI) (GAVI

Alliance 2007). The declared aim of these organizations is to develop and introduce new and efficacious drugs and vaccines for diseases of the developing world – a market which is largely beyond the economic interests of pharmaceutical companies. Similarly, the “Grand Challenges in Global Health” initiative also focuses on new technologies for better tools in order to achieve advances in prevention and treatment of diseases of the poor (GCGH 2006).

The development of efficacious drugs, especially for so-called neglected diseases, or diseases of the poor, is of paramount importance. However, it is essential to consider that in the most deprived regions of the world, developing a new intervention (drug, vaccine, etc.) and delivering it to country-level will not necessarily translate into effectiveness at community-level (Amin *et al.* 2004). The same can be observed in marginalised population-groups within otherwise well-off countries (Goddard & Smith 2001).

One central question is whether countries (i.e. their health budget) and patients can afford the medicines they require. This aspect of access is addressed by the campaigns of leading international non-governmental organizations, such as Oxfam (Oxfam 2007) and Médecins Sans Frontières (MSF 2007). They advocate access to essential drugs as a human right and criticize commercial pricing and patenting for drugs. Some of these advocacy campaigns are rooted in the HIV/AIDS activist movement and many are inspired by it (GAP 2007). Criticism of patents and prices also comes from the Commission on Intellectual Property, Innovation and Public Health which argues that international agreements, such as the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement impede poor countries from creating competitive medicine markets, resulting in unaffordable drug prices (t Hoen 2006). Unaffordable drug prices are often seen as the only major reason why people in developing countries do not receive effective treatment for curable diseases. This argument is especially popular among activist movements in industrialized countries. Sometimes, even health agencies assume that, once drug prices are lowered, access will be guaranteed. For example, in a recent newsletter on ACTs, the WHO lists, "how access to ACTs is being ensured". The list includes quality assurance, a call for tenders of ACTs, negotiating prices and financing of ACTs (WHO 2006a). Similarly, authors affiliated with the World Bank put a major

focus on macroeconomic aspects of drug purchasing and delivery mechanisms in order to improve access (Attridge & Preker 2005).

While efficacious drugs at affordable prices are essential for access to effective health care, they alone do not adequately reflect the complexity of the issue. Access to health is a multifaceted problem and factors limiting access are numerous, complex and often interrelated. Diverse solutions to overcome the problem of access have been proposed based on various different definitions of access, some of which will be further discussed in the following chapters (Penchansky & Thomas 1981; Waters 2000; Aye *et al.* 2002; Adamson *et al.* 2003).

The central prerequisite for patients to have access to health care is that they are reached by efficacious interventions. The question is therefore, how (and which) health systems can best respond to the health needs and deliver essential interventions to all parts of the society, explicitly including the poorest and most vulnerable (Travis *et al.* 2004; Singh 2006). Using the example of child health, Bryce *et al.* showed that the coverage with existing key interventions is critically low in most of the 60 countries that account for 94% of child deaths (Bryce *et al.* 2006). In most developing countries, weak or hardly functional health systems are preventing effective interventions from reaching the people in need (Travis *et al.* 2004). Vertical programmes such as campaigns for immunization or distribution of ITNs are likely to provide only short-term solutions which need to be complemented by improved routine delivery in order to be sustainable (Grabowsky *et al.* 2007; Lengeler & de Savigny 2007). However, little is known about which strategies are most suitable for scaling-up health interventions in resource-poor settings, and more research on this issue is urgently needed (Victora *et al.* 2003).

Several organisations have acknowledged the importance of an adequate supply, delivery and deployment to translate efficacy of new drugs or vaccines into health impact. As a result, some actors, such as MMV or GAVI have widened the scope of their activities and do not only work on the development of new tools, but also consider issues linked to their deployment (GAVI Alliance 2007; MMV 2007a). Similarly, the Global Health Program of the Bill and Melinda Gates Foundation is committed to not only encourage the development of lifesaving medical advances but

also help ensure they reach the people who are disproportionately affected (BMGF 2007). At the Ministerial Summit on Health Research organised in Mexico in 2004, Ministers of Health identified failing health systems as a central obstacle to achieving the MDGs by 2015 (Anonymous 2004). At the same time, the host country Mexico was an encouraging example of how improvements in the health system can lead to community-wide health impact (Sepulveda *et al.* 2006). The UN task force on the MDGs also acknowledged that the basis for any successful disease-control intervention would be functioning health systems. The specific health-related targets of the MDGs and the Abuja declaration can not be reached simply by the use of new and innovative control tools. Most importantly, existing interventions have to be implemented more effectively i.e. access needs to be optimized. Without increased investment in improving the performance of health systems in developing countries, neither malaria nor HIV/AIDS or tuberculosis can be effectively controlled (Ruxin *et al.* 2005).

Following the arguments of Penchansky and Thomas (1981) which are further discussed in the following chapter, access can be seen as the fit between the health providers (i.e. the health care system) and the patients. Hence what is needed is not only an optimal supply, but also a demand for the type of health-care which is offered by professional providers. Focusing only on the provider side may result in inequitable access if the demand side is not taken into account. While poorer people are more exposed to disease risks, they are also less likely to seek care from available appropriate providers, as shown in a study in Tanzania (Armstrong Schellenberg *et al.* 2003).

Demand-side barriers may hence be important factors deterring people from obtaining appropriate treatment (Ensor & Cooper 2004). One example is the differences between traditional and biomedical illness concepts. Febrile convulsions may be a sign of severe malaria and should, from a biomedical point-of-view, be treated promptly with an efficacious antimalarial drug and potentially an anticonvulsant. However, in parts of Tanzania, these symptoms are known as an illness called *degedege* which is often attributed to supernatural causes and preferably treated with traditional medicine (Makemba *et al.* 1996; Hausmann Muela 2000). Similar examples exist for other diseases, illustrating the importance of the

perspective of those affected. In a development-context this was taken up by the UK Department for International Development (DFID) in its Sustainable Livelihoods Framework (DFID 2001). This framework puts people at the centre of development. It considers their ability to mobilize resources within a given vulnerability context, influenced by their institutional and socio-cultural environment, in order to achieve sustainable livelihoods. In a similar way, this may be used for care-seeking models, as outlined in one of the following chapters. A recent paper by Ruger (2007) argues in a similar way, stressing the importance of individuals' ability to work towards health goals they value and the degree of support they receive from the society.

All these approaches cover fundamental, sometimes very specific aspects of access. Considering the complexity of the issue and taking into account the evident link of poverty, development, and health, a comprehensive analysis of access is essential in order to elucidate obstacles to effective health care. The following section reviews the evidence of obstacles to treatment for the concrete case of malaria. In chapter 10, we then propose an comprehensive access model which is based on several different analytical approaches and embedded in the context of rural livelihood insecurity.

## *2.2 Access to malaria treatment*

Previous research has identified several factors affecting access to appropriate malaria treatment and care beyond the point where drugs are available at the level of local providers. This section focuses specifically on malaria treatment and reviews studies on treatment-seeking behaviour, health services and health policy, rather than the development and production of efficacious medicines (Figure 2.1).

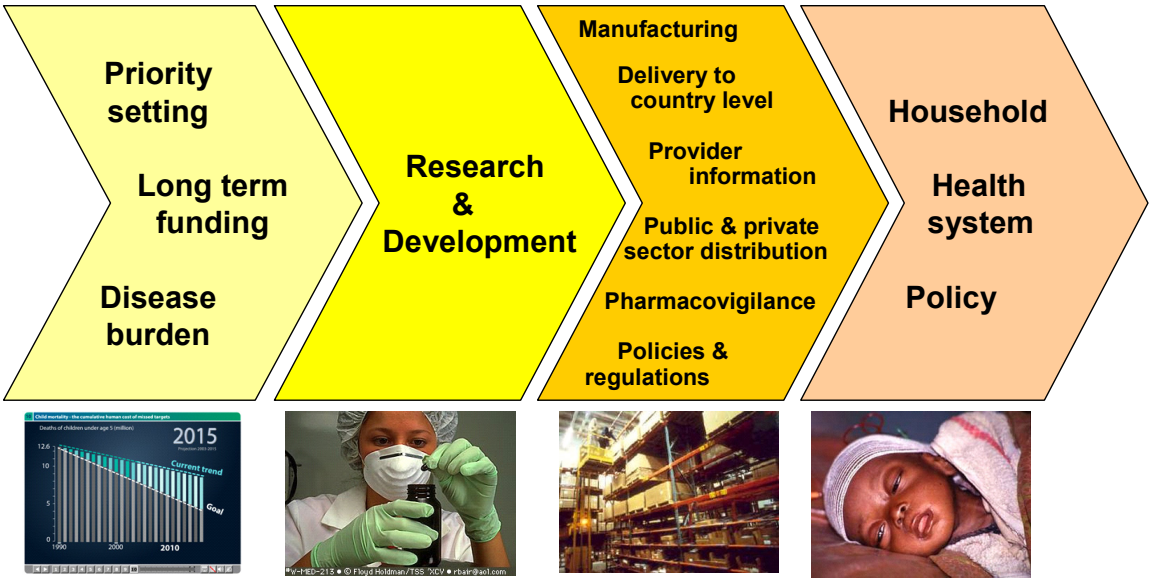


**Figure 2.1: All stages of drug development and deployment need to be considered in order to ensure equitable access by patients**

An unpublished literature review (Lengeler *et al.* 2002) identified a variety of barriers to prompt and effective malaria treatment, many of them inter-linked and interdependent. These barriers interfere with a successful treatment seeking process on several levels.

On the **demand-side**, i.e. at the level of the household, factors influencing access relate to the household's ability to initiate and successfully complete an appropriate treatment-seeking process. This includes the ability to mobilise and make use of available resources as described in more detail in chapter 10.

*Local illness experience and concepts* influence the recognition of a malaria episode and the initiation of treatment seeking. In Tanzania, there are different concepts of malaria in the population depending on the signs and symptoms of the disease. A clear distinction is often made between uncomplicated and severe forms of malaria. While uncomplicated cases with fever as main symptom are usually known as malaria (or *malaria*) and often associated with mosquitoes, there are different taxonomies for symptoms of severe malaria. As already briefly described in the previous section, *degedege* for example stands for febrile convulsions and is often linked with supernatural causes. Uncomplicated malaria is usually treated with

antimalarials or antipyretics, whereas the understanding of the causation of *degedege* leads to a more complex process of treatment seeking, often involving traditional medicine or healers at some stage (Makemba *et al.* 1996; Winch *et al.* 1996; Hausmann Muela 2000; Minja 2001; Mayombana 2004). However, this pattern appears to have changed in recent years, especially in areas where extensive health education campaigns were implemented (de Savigny *et al.* 2004b).

*The socio-economic situation* of a household determines its ability to pay for treatment of malaria episodes. Households have to cover direct costs, such as for diagnostics, drugs, or user fees but also indirect costs for the loss of working time, the travel to a care provider, or for alternative child care (Goodman *et al.* 2000). In the study area cash availability is low and seasonal, with shortages shortly after the beginning of the farming season when most cash was used to buy seeds and fertilizer, employ workers on the fields, etc. Availability of cash may influence the choice of treatment provider, as shown by Hausmann *et al.* (2000). The authors found evidence that people may be willing but not able to pay for biomedical health care, even when they can afford costly traditional medicine. They suggest that the ability to pay for traditional treatment can differ from the ability to pay for hospital attendance since many healers offer alternatives to cash payments (i.e. compensation in kind or in work, payment on a credit basis). Even more importantly, the activation of social networks for financial help is easier in the case of traditional healing, especially for poorer people. Overall, little is known about the willingness and ability-to-pay for malaria episodes. But there is substantial experience from the user fee literature that even modest amounts (a few USD) are enough to prevent at least the poorest households from accessing health care services (Armstrong Schellenberg *et al.* 2003; Manzi *et al.* 2005; Njau *et al.* 2006).

*Household circumstances*, such as the presence of a key decision-maker at the time of a medical emergency, are of importance for access to malaria treatment. Often it is the husband or an older woman who are in a position to allocate cash or other resources in the case of such an event. In absence of such a person a delay in care-seeking may happen. Molyneux *et al.* (2002) described how mothers received financial assistance or advice for 71% of the treatment-actions taken outside the home in Kenya. Reported disputes over perceived causes and appropriate therapy of

convulsions highlighted the importance of age, gender and relationship to the household head in treatment decision-making.

Another crucial element is the timing of a disease episode, both during the year and during the day. Disease episodes occurring during the farming season may bear a higher risk of not being addressed adequately compared to episodes taking place during other times of the year. This is in part related to the increased work burden at that time, but also to the lack of cash before the new harvest. Similarly, episodes taking place during the night or the week-end when health facilities are closed may lead to a delay in care-seeking (Lengeler *et al.* 2002).

On the **supply side**, access is determined by the degree to which the services and interventions reach those in need. While this comprises the availability of infrastructure as well as the supply of preventive and diagnostic tools and medicines, it also depends on how well the services offered by different providers fit the (perceived) needs of the patients.

*Geographic access* to health facilities is comparatively good in Tanzania, with 75% of the population living within 5 km of a health centre or dispensary. However, this proportion is lower in rural areas (68%) compared to urban centres (98%) and there are clear inequities in access (United Republic of Tanzania 2005). In Rufiji district, where the average travel time to the nearest facility was 20 minutes, the poorest households had 3 times longer travel times than the least poor (J. Armstrong Schellenberg and R. Nathan, personal communication).

*A variety of different providers* may be potential sources for antimalarial treatment. On the one hand, research in the study area revealed that most patients were using both the traditional and the formal health sector, often in parallel, depending on the perceived cause of their illness, the course of treatment and available financial means (Hausmann Muela *et al.* 2002). The services provided by traditional healers, which have been described elsewhere (Gessler 1995), will not be dealt with in detail in this thesis. On the other hand, there are several levels of providers in the formal sector, offering a range of different types of care. Health facilities may be run by the government, a non-governmental organization (NGO) or mission, or by a private

practitioner. NGO facilities in Tanzania were found to be more expensive than facilities run by the government, catering therefore rather to the better-off (Njau *et al.* 2006). Government health facilities should be more affordable and exemption systems should enable them to target also vulnerable population groups, such as young children and pregnant women. The private retail sector plays an important role in providing malaria treatment (Brugha *et al.* 1999; McCombie 2002; TDR/WHO 2006). In many settings over 50% of all fever episodes are treated primarily through retailers with minimal or no medical qualifications (Deming *et al.* 1989; Nydomugyenyi *et al.* 1998; Molyneux *et al.* 1999; Hamel *et al.* 2001). Depending on the country and the setting within a country (e.g. urban vs. rural), there may be several types of commercial retailers, such as pharmacies, drug stores, general shops, or mobile drug vendors (Molyneux *et al.* 1999; Marsh *et al.* 1999; Goodman *et al.* 2004; Granado 2007). In Tanzania, pharmacies and drug stores may sell antimalarial medicines, but general shops are not legally allowed to do so. Mobile drug vendors are virtually non-existent. Given the importance of the retail sector there are concerns over the lack of knowledge of correct treatment regimens by shop keepers, as well as a lack of quality control of drugs, leading to sub-standard drugs being found on the retail market (Braun 2005).

*Quality of care* is also a concern in the formal health sector (HERA 2006) and both technical and perceived quality of care need to be taken into consideration. Problems with *technical quality* relate to the appropriateness of a diagnosis or the prescribed treatment, but also to inter-personal care including proper advice. Studies on quality of services of health facilities in Tanzania found many shortcomings in the diagnoses and treatments provided (Eriksen *et al.* 2007). In another study, 30% of confirmed malaria cases were not prescribed any antimalarial drug (Font *et al.* 2001). While problems with supplies are frequent (Dillip *et al.* 2007), a further concern is inefficiencies in service delivery, such as irrational use of drugs, polypharmacy, and excessive use of injectables (Le Grand *et al.* 1999).

*Perceived quality* as assessed by patients does not necessarily correspond with the technical quality of care. Poor inter-personal skills of health workers, such as rude behaviour, long waiting times and concerns about a lack of diagnostics and drugs are

common reasons for a lack of trust in health services (Gilson *et al.* 1994; Gilson *et al.* 2005).

While there is general agreement about the problem, it seems less obvious which interventions can lead to improved health worker performance and better quality of care (Rowe *et al.* 2005; Gilson *et al.* 2005). In an effort to cope with the widespread lack of diagnostic tools, such as working microscopes, the Integrated Management of Childhood Illness (IMCI) strategy was developed (WHO 1997). The strategy is built on locally adaptable algorithms for the diagnosis and treatment of childhood illnesses based on clinical signs and symptoms. Its implementation was shown to result in a cost-effective improvement of quality of care (Bryce *et al.* 2005a). On the other hand, quality in the health sector is intrinsically linked to the adequate staffing of facilities and the motivation of health workers. Both are to some extent structural problems which need to be addressed not only at the level of health facilities but by the implementation of adequate policies.

On a **policy level**, decisions on the structure, staffing and financing of the health system are made and priorities for health interventions are defined. Interventions on the entire health system have been shown to result in improved health indicators (de Savigny *et al.* 2004a; Sepulveda *et al.* 2006). Health legislation on payment mechanisms or the selection and deployment of essential drugs can greatly determine equitable access to health care. Cost-sharing, user-fees, community health funds or other social protection schemes, as well as exemption mechanisms may enhance or obstruct access to prompt and appropriate treatment and care, depending on the local setting and complementary initiatives (Hutton 2004). Currently, the most controversial debate is on how and through which channels ACTs should be delivered to malaria patients. Limiting ACTs to the formal sector may result in less misuse of the drugs, while wider availability in drug stores might increase coverage. In addition, solutions have to be found to make the very expensive artemisinin-drugs affordable and accessible even to the poorest (Charlwood 2004; Pagnoni *et al.* 2005; D'Alessandro *et al.* 2005; Mutabingwa 2005).

The following chapter puts selected barriers to access in the context of an intervention programme aimed at improving access to malaria treatment. The

research for this thesis was carried out within the ACCESS Programme, in a rural Tanzanian setting. The research results are then presented in chapters 6-10 with a focus on the demand side (chapters 6 and 7), the supply side (chapters 8 and 9) and a general access framework which draws upon the evidence gathered so far in the frame of the ACCESS Programme.

# 3 UNDERSTANDING AND IMPROVING ACCESS TO PROMPT AND EFFECTIVE MALARIA TREATMENT AND CARE IN RURAL TANZANIA: THE ACCESS PROGRAMME

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This paper has been published in the
*Malaria Journal* 2007; 6:83

## *3.1 Abstract*


### 3.1.1 Background

Prompt access to effective treatment is central in the fight against malaria. However, a variety of interlinked factors at household and health system level influence access to timely and appropriate treatment and care. Furthermore, access may be influenced by global and national health policies. As a consequence, many malaria episodes in highly endemic countries are not treated appropriately.

### 3.1.2 Project

The ACCESS Programme aims at understanding and improving access to prompt and effective malaria treatment and care in a rural Tanzanian setting. The programme's strategy is based on a set of integrated interventions, including social marketing for improved care seeking at community level as well as strengthening of quality of care at health facilities. This is complemented by a project that aims to improve the performance of drug stores. The interventions are accompanied by a comprehensive set of monitoring and evaluation activities measuring the programme's performance and (health) impact. Baseline data demonstrated heterogeneity in the availability of malaria treatment, unavailability of medicines and treatment providers in certain areas as well as quality problems with regard to drugs and services.

### 3.1.3 Conclusions

The ACCESS Programme is a combination of multiple complementary interventions with a strong evaluation component. With this approach, ACCESS aims to contribute to the development of a more comprehensive access framework and to inform and support public health professionals and policy-makers in the delivery of improved health services.

## *3.2 Background*

The impact of malaria on health and local economies in sub-Saharan Africa is staggering. Between one and three million people die each year, mostly young children under five years of age. Deaths and illness contribute to a vicious circle of ill-health and poverty (Sachs & Malaney 2002; WHO & UNICEF 2005). In recent years, the fight against malaria has gained an increased level of attention from governments of affected African states as well as from international donor agencies. African heads of state agreed in the Abuja Declaration on a concerted effort to reduce the burden of malaria on the continent and endorsed the ambitious goal of the Roll Back Malaria Partnership of halving the number of malaria deaths by the year 2010 (Yamey 2000). Among the malaria control strategies promoted internationally and adopted by most endemic African countries, prompt access to effective treatment especially for young children and pregnant women features prominently (WHO & UNICEF 2005).

The need for prompt and effective treatment to prevent progression to severe disease and death essentially raises two important issues: first, the choice of a safe and efficacious drug and second, questions of how to optimize equitable access to rationally prescribed treatment.

In order to address the first point, artemisinin-based combination therapies (ACT) have been advocated as treatment of choice in Africa (White *et al.* 1999) in an effort to improve on drug efficacy following the increasing failure rate of a number of other drugs. Tanzania adopted this policy in 2004 and implemented it at the end of 2006 (MOHSW 2006c). However, the choice of an efficacious drug does not necessarily directly result in improved effectiveness, and issues related to safety, use in pregnancy, and cost are also still being discussed. Yet, it would go beyond the scope of this paper to thoroughly debate all issues related to a specific drug.

With regard to the second point, it is widely acknowledged that access to quality treatment is insufficient in many settings. The poorest people often have least access to effective treatment (Victora *et al.* 2003) and the underlying causes of this situation are increasingly debated. On a macro-level, the discussion on access to treatment often focuses around the development of new drugs (t Hoen 2006) and global

affordability issues, including pricing and patenting of drugs. International initiatives, such as Medicines for Malaria Venture (MMV) (MMV 2007b), are increasingly financing and speeding up the development and introduction of new efficacious antimalarials. At a local community level however, the situation is a lot more complex and availability and affordability of drugs are only few among a number of factors influencing prompt and effective treatment (McCombie 2002; Committee on the Economics of Antimalarial Drugs 2004). In many developing countries, weak health systems as well as lack of equipment and qualified staff lead to incorrect diagnosis and treatment (Font *et al.* 2001; Nsimba *et al.* 2002). Physical access may be impeded by long distances to the nearest point of care, inadequate logistics or inability to pay for secondary costs such as transport (Noor *et al.* 2003). Further, malaria is a common and socially well accepted illness in endemic countries and its potential severity is often underestimated. Insufficient knowledge of the appropriate treatment or an understanding of the illness that differs from the bio-medical explanation can lead to the use of alternative treatment sources and non-adherence to recommended regimens (Makemba *et al.* 1996; Tarimo *et al.* 2000).

Several initiatives have attempted to address access questions on a local level, either by strengthening home-based management (WHO 2005a), by improving the involvement of commercial drug providers (Marsh *et al.* 2004) or through a general improvement of health system performance. Information and education of caretakers and care providers has been useful in improving malaria case management and compliance at home and in drug selling shops (Kidane & Morrow 2000; Marsh *et al.* 2004; Afenyadu *et al.* 2005). Several models for improving case-management in health facilities have been tested and combined approaches were most likely to have a (sustainable) impact (Rowe *et al.* 2005). In any case, considering the complexity of the issues involved it seems obvious that there is no such thing as a single “magic bullet” approach to solve the problem. What is needed is a comprehensive concept addressing several of the access dimensions, ranging from availability and affordability to accessibility, acceptability and quality of care. This paper presents a programme that was developed to understand and improve comprehensively access to appropriate malaria treatment in a highly malaria-endemic rural area of south-eastern Tanzania.

The aim of the ACCESS Programme is to investigate factors influencing access to malaria treatment in rural Tanzania in order to develop a set of interventions addressing the main obstacles to access. These interventions are then thoroughly evaluated. The focus is on children below five years of age and pregnant women, who are the most vulnerable groups in this holo-endemic setting in terms of the detrimental consequences of malaria (WHO & UNICEF 2003; Breman *et al.* 2004). This paper presents a general overview of the ACCESS Programme, while future reports will provide detailed study results of the major evaluation and monitoring components.

## *3.3 Project description*

### 3.3.1 Study area

The programme's intervention area comprises the two districts of Kilombero and Ulanga in the south-east of Tanzania (Figure 3.1). The Kilombero River separates the two districts and forms the vast Kilombero Valley floodplain. Large parts of this valley are flooded during the rainy season which usually lasts from November to May. The valley is delimited by the Udzungwa Mountains in the north and the Mahenge Mountains in the south. Parts of Ulanga's southern and south-eastern areas, as well as Kilombero's extreme east are part of the Selous Game Reserve. The Kilombero district is connected to the Tanzania-Zambia highway through a mostly unpaved but well maintained road. For vehicles the only connection to the Ulanga district is made by a motorized ferry over the Kilombero River.

In 2002, there were 517,000 people living in the 109 villages of the two districts. Ifakara, the administrative capital of Kilombero, is the major settlement in the valley with a population of approximately 46,000. Ulanga's capital Mahenge is smaller with 7,300 inhabitants (United Republic of Tanzania 2003a). In the early 1970s, the national social engineering project to build communal villages ("vijiji vya ujamaa") brought the valley's scattered inhabitants to more organised village centres along the edges of the valley (Minja 2001). Most people there rely on subsistence farming for their livelihoods. Labour intensive rice farming on distant fields in the floodplain forces many families to move to their farming sites (*shamba* in Kiswahili) during the

cultivation period. In the fields people stay in improvised "*shamba* huts" for up to six or more months. Rice, maize and cassava are the main cash crops. The main agricultural exports from both districts are rice, timber, charcoal and some fish. Since the 1980s, an increasing number of nomadic Maasai and Sukuma pastoralists had moved to the valley with large cattle herds until a government directive ordered them in April 2006 to move to other parts of the country or to reduce their herds in order to preserve the Kilombero wetland ecosystem (Tanner *et al.* 1991; Liganga 2006).

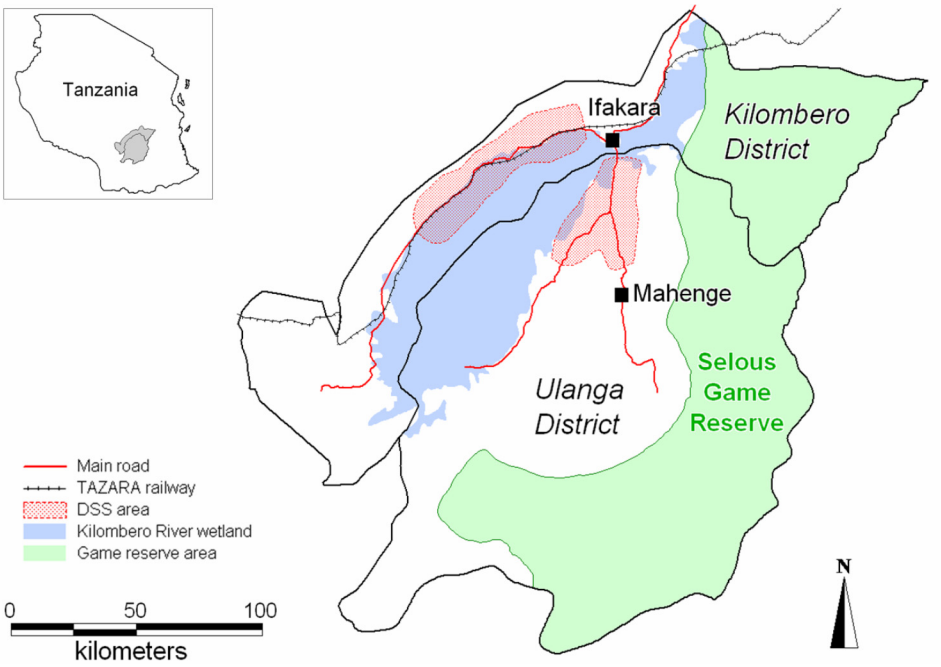


**Figure 3.1: Map of Kilombero and Ulanga districts with DSS area**

The climatic and ecological conditions in the floodplain are favourable for mosquito breeding. Malaria transmission in the valley is high and perennial. Recent work has confirmed entomological inoculation rates (EIR) of 350 infective bites per person per year, despite high mosquito net usage rates of 75% (G. Killeen, personal communication). At the level of health services, malaria is the most frequent diagnosis in outpatients in rural health facilities.

A number of malaria control interventions have been tested and/or implemented in the area by the Ifakara Health Research and Development Centre (IHRDC 2007) in collaboration with the Swiss Tropical Institute (STI 2007). The most extensive operation was the large-scale introduction of insecticide-treated nets (ITN) in the

frame of the KINET project (Armstrong Schellenberg *et al.* 1999). Today, promotion of ITN use through social marketing is ongoing in the frame of the national ITN programme.

Monitoring and evaluation (M&E) of the ACCESS Programme is carried out in the area of the local Demographic Surveillance System (DSS) (Armstrong Schellenberg *et al.* 2002). The DSS serves as a comprehensive epidemiological framework for studies on the project's impact. In the absence of a vital registration, DSS field workers routinely record births, deaths, migrations and socio-economic indicators for every household in a defined geographical area of 2400 $km^2$ (Figure 3.1). Each household is visited every four months. The area comprises 12 villages in Ulanga and 13 in Kilombero. In mid 2004, the total DSS population was 74,200 (Ulanga: 31,800; Kilombero: 42,400) in 17,050 households. The DSS does not include Ifakara town where ACCESS M&E activities are also implemented.

### 3.3.2 Main interventions

ACCESS interventions apply two main approaches:

1. Creating demand for appropriate malaria diagnosis and treatment in the community through a social marketing approach.

2. Strengthening the supply of quality malaria case-management at health facilities and drug shops through training, quality management, improved supportive supervision and new diagnostics.

The main areas of intervention are described below and summarized in Figure 3.2 (status at the end of 2006). Activities may change in the future as experience is gathered and analyzed by the programme's M&E activities.

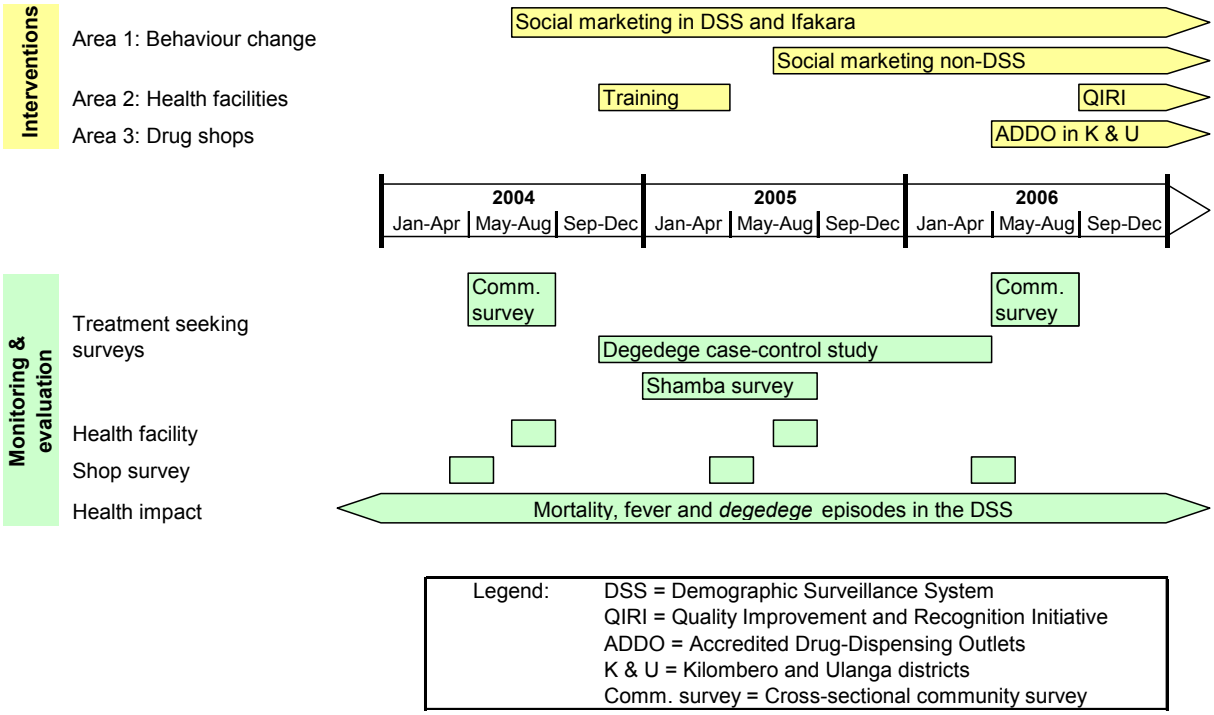


**Figure 3.2: Timeline with main interventions and M&E activities.**

### 3.3.3 Intervention area 1: Behaviour change campaigns for prompt and appropriate health care seeking

*Sensitization of community leaders*

As a first preparatory step in implementing community activities, local community leaders (political and religious leaders, leaders of social groups, non-governmental organizations and other key opinion leaders) were informed about ACCESS objectives and activities to gain their support and collaboration. The meetings also provided space for participants to share their views and concerns on programme-related issues.

*Social marketing*

A social marketing approach was chosen to increase knowledge and awareness of malaria and to promote prompt and appropriate treatment seeking from reliable sources. The design of the behaviour change communication campaign was based on experiences from projects such as KINET (Kilombero Net Project) (Armstrong Schellenberg *et al.* 1999; Minja *et al.* 2001), TEHIP (Tanzania Essential Health Interventions Project) (de Savigny *et al.* 2004a) and IMPACT-Tz (Interdisciplinary

Monitoring Project for Antimalarial Combination Therapy in Tanzania), as well as the national social marketing for ITNs and the results from exploratory focus-group discussions. In the first year, implementation was done in the DSS area and Ifakara only, followed by a step-wise scaling-up to the other villages of Kilombero and Ulanga.

The main *target audience* of the campaign are mothers and caretakers of children under five years of age and pregnant women. However, other household members and the general population are secondary audiences in order to achieve homogeneity of understanding in the population.

*Messages* stress the importance of prompt recognition of malaria symptoms and immediate correct treatment with the recommended first-line drug (sulphadoxine-pyrimethamine [SP] until end 2006). Health facilities and licensed drug stores (pharmacies, part II drug stores [*duka la dawa baridi*] and Accredited Drug Dispensing Outlets [ADDO; *duka la dawa muhimu*]) are promoted as sources of proper treatment and advice. Prevention methods, such as the use of ITNs and Intermittent Preventive Treatment in pregnancy (IPTp) are also advocated. Finally, one set of messages highlights high fever with convulsions (locally known as *"degedege"*) as a sign of severe malaria that can and should be treated at health facilities (rather than by traditional healers) (Makemba *et al.* 1996; Minja *et al.* 2001). ACCESS messages are in line with malaria-related messages on key family practices of the community-based Integrated Management of Childhood Illness (IMCI) (WHO 2004b).

*Communication channels* and materials to disseminate behaviour change messages were developed to reach a poor rural population in an efficient and cost-effective way. Road shows are the main vehicle for the campaign. The platform of a truck is used as a mobile stage for a health promotion team (Figure 3.3). The shows are divided in four parts:

1. Dancing competition to attract a large audience
2. Comedies and role plays portraying appropriate treatment seeking and consequences of delaying treatment

3. Public lecture on malaria transmission, signs and symptoms, dangers of malaria for young children and pregnant women, and prevention and correct treatment
4. Cinema show featuring stories on prompt and effective malaria treatment

Question-and-answer sessions at the end of each part allow interaction with the audience and distribution of promotion-materials (e.g. stickers, leaflets, T-shirts).

**Figure 3.3: ACCESS road show with social marketing truck**


**Figure 3.4: ACCESS billboard promoting prompt and correct treatment**

Permanent billboards were erected in major villages along the main road and posters affixed in public places (Figure 3.4). All materials carry campaign-related messages and the ACCESS logo (Figure 3.5). Materials were locally designed and pre-tested in the community.

Remote villages which are inaccessible with the truck are reached by a small 4WD vehicle branded with behaviour change slogans. It transports a mobile video unit and rooftop speakers to air behaviour change radio spots.

*Special campaigns in Mother and Child Health (MCH) clinics*

Special campaigns were implemented in MCH clinics. They were targeted especially at pregnant women and mothers of young children who may not attend road shows if they overlap with the women's duties in the household. During special sessions,

ACCESS health promoters and MCH clinic staff informed mothers on malaria, its prevention and its proper treatment. The benefits of malaria prevention using ITNs and IPTp were particularly emphasized.

**Figure 3.5: ACCESS Programme logo**

*Improved access for households spending the cultivation period away from home: The shamba component*

The main farming season, when many families stay in their field-huts, overlaps with the high malaria transmission season. Furthermore it represents a period of high vulnerability as it coincides with peak food insecurity, labour stress and difficult access to health services, family support and child care time. A study was undertaken within the programme to investigate the specific risks posed by staying in the fields. Results from this study may lead to the design of a “shamba intervention” if specific measures are deemed necessary.

### 3.3.4 Intervention area 2: Improved quality of care in health facilities

Trustworthy health care services of good quality are a core element for the delivery of effective diagnosis and treatment for malaria. As a result of the social marketing, the demand for quality services is expected to increase. In order to meet this demand, the health facility staff must be in the position and willing to deliver a good quality of care. The programme aims to improve quality of care with a focus on the following areas:

- Correct diagnosis through the proper use of the IMCI algorithm or with improved laboratory diagnosis
- Rational prescription of antimalarials, antipyretics and other drugs
- Appropriate advice on prescribed treatment and malaria prevention

Key activities of this component include initial refresher training for health facility staff on malaria treatment, followed by the strengthening of routine supportive supervision and the implementation of a quality management scheme in all health facilities. Training was based on IMCI algorithms for diagnosis and treatment which have proven (cost-)effective in improving quality and efficiency of child health care in rural Tanzania (Bryce *et al.* 2005a). A protocol for the refresher training was developed in close collaboration with the Council Health Management Teams (CHMT) of Kilombero and Ulanga. The training was targeted at clinical staff, lab technicians, and medical aids of public and private health facilities. It was carried out by the CHMT, appointed trainers and ACCESS staff with financial resources from the district and ACCESS.

The follow-up with routine supportive supervision will not focus on malaria only. It is planned to implement a comprehensive package of activities aiming at improving performance management for improvement of quality of services delivery: The Quality Improvement and Recognition Initiative (QIRI) was originally developed by USAID and adapted and implemented in Tanzania by the Ministry of Health (MOH) to improve the quality of reproductive and child health services within the 2001-2005 USAID-Tanzania programme support (MOH 2004). Between 2003 and 2006, the United Nations Population Fund (UNFPA) Tanzania through the European Union/UNFPA Sexual and Reproductive Health programme supported the MOH for further QIRI expansion in Tanzania (MOH 2003).

QIRI offers an integrated approach for the evaluation of quality of care combined with a strategy to establish the root causes of performance gaps and to develop implementable strategies to address them. A central element of this component is capacity building for joint supportive supervision and quality management, conducted by the regional and district health management teams together with community representatives. It is the aim of the programme to integrate quality management into the health supervision activities in the decentralized health system. Acknowledging the importance of patient-provider relationships and trust in health care (Gilson 2003; Gilson *et al.* 2005), QIRI is designed to pay particular attention to the patients' perception of the health services.

In most malaria endemic areas, diagnosis of malaria relies mainly on clinical signs and symptoms, especially in low level health facilities. In Tanzania, only hospitals and health centres are expected to have the possibility of performing microscopy for malaria diagnosis (MOH 2002), while dispensaries rely on a syndromic IMCI approach (WHO 1997). In the programme area, the malaria-attributable fraction estimated using the method of Smith *et al.* (Smith *et al.* 1994) showed that only 40% of all fever episodes were likely to be due to malaria (S. P. Kachur and S. Abdulla, personal communication). Absence of lab diagnosis may result in misdiagnoses and irrational drug-prescription (Font *et al.* 2001; Reyburn *et al.* 2004).

A promising alternative to microscopy are rapid diagnostic tests (RDT) based on the detection of *Plasmodium* antigens. However, there is little experience with RDTs in sub-Saharan Africa although they are widely used in Asia and Latin America (Bell *et al.* 2006). ACCESS plans to introduce RDTs in three dispensaries, so far lacking diagnostic tools for malaria. To compare the feasibility and value of RDTs versus conventional diagnostics, high quality microscopy will be assured in two health centres. The efficacy, effectiveness and cost-effectiveness of this intervention will be evaluated.

### 3.3.5 Intervention area 3: Improved malaria case management in drug selling shops

Self-treatment at home is often the first and quickest response to a malaria episode (McCombie 1996; Hamel *et al.* 2001; WHO 2005a). In many settings, the private drug retail sector plays an important role in providing drugs for home-based management of fever or malaria. On the other hand, drug shops often leave patients with sub-standard malaria drugs and poor prescribing practices (Marsh *et al.* 1999), leading to ineffective treatment and increasing drug resistance. Experience in Kenya showed that training private drug retailers can considerably improve the services they offer (Marsh *et al.* 2004). However, Tanzanian drug regulations do not allow general shops to sell the first-line antimalarial drugs (SP; or ACT since end 2006), even though the national malaria control strategy mentions explicitly the availability of antimalarials on household-level (MOH 2000; Hetzel *et al.* 2006; MOHSW 2006c).

As a result of this ambiguous policy, the initial plan to train general shop keepers had to be withdrawn and other avenues explored. As an alternative, the programme supports the introduction of Accredited Drug Dispensing Outlets (ADDO; *duka la dawa muhimu* in Kiswahili) in the two districts. The ADDO project is being implemented by the Tanzania Food and Drugs Authority (TFDA) and Management Sciences for Health (MSH). It aims to improve access to affordable, quality medicines and pharmaceutical services in drug retail outlets in rural and peri-urban areas where there are few or no registered pharmacies (Mbwasi 2005; MSH 2006). The main components of the ADDO project are activities to change the behaviour of shop owners and dispensing staff through the provision of education, incentives and regulatory coercion. It also entails efforts to positively affect client demand and expectation of quality products and services.

ADDOs are allowed to dispense a limited range of prescription-only medicines that are found on the national essential drugs list. Ideally at least one ACT should be available through this channel, most logically the one recommended as first-line treatment in the country (currently artemether/lumefantrine [ALu], brand name Coartem®). For the districts of Kilombero and Ulanga, ACCESS could successfully negotiate the introduction of highly subsidized ALu in ADDOs. The ACCESS social marketing campaign promotes ADDOs as source of quality malaria treatment.

### 3.3.6 Monitoring and evaluation

The M&E activities of ACCESS are based on three key components: (1) A semi-quantitative analysis aiming at a better understanding of factors influencing access to malaria treatment in order to develop an improved access framework, (2) process monitoring in order to understand how interventions operate, and (3) a thorough evaluation of the programme's impact on treatment seeking, quality of case-management and most importantly on the health of the population. An overview of the different evaluation activities in relation to key work areas is given in Table 3.1.

Overall and health impact evaluation is based on a plausibility assessment of the programme's impact within a before-after design, i.e. a historical control group (Habicht *et al.* 1999; Victora *et al.* 2004). In an attempt to control for possible

confounders, all other malaria control activities in both districts as well as other relevant parameters such as temperature and rainfall are closely monitored. Longitudinal data will also be compared to trends observed in Demographic and Health Surveys (DHS). A basic assumption is that the malaria transmission and other relevant epidemiological parameters remain largely unchanged during the period of observation with the exception of the factors that are monitored in the frame of the programme.

#### 3.3.6.1 Health impact assessment through the DSS

The health impact assessment will be based on data collected through the DSS. The main outcome indicators are: overall and malaria-specific mortality, reported fever incidence rates in children and adults, as well as reported *degedege* (convulsion) rates in children. Furthermore, the DSS will be used as a sampling frame for representative community-based epidemiological studies.

Cause-specific mortality is calculated on the basis of “verbal autopsies”. Since 2002, specially-trained DSS supervisors elicit information on causes of deaths by interviewing bereaved relatives about the circumstances of the death, the signs and symptoms observed during the illness leading to the death, and the action taken. This information is coded to give likely causes of death in broad categories.

The socio-economic status (SES) of households is assessed once a year on the basis of a list of household assets. This allows the results of DSS data and other community-based studies to be stratified by wealth quintiles, which is essential in order to consider equity dimensions in the analysis. The aim of the ACCESS Programme is to contribute to an equitable reduction of (malaria-related) mortality.

#### 3.3.6.2 Exploratory focus-group discussions

Initial exploratory focus-group discussions (FGD) with parents and caretakers of young children informed the programme on knowledge, attitudes and practices related to malaria treatment. A total of 88 people participated in the ten FGDs, four of

which were done with men, six with women. Main issues that came up during FGDs are listed in the results section.

#### 3.3.6.3 Community-based surveys on treatment-seeking for fever

Repeated cross-sectional community surveys are the programme's main tool to assess changes in care-seeking behaviour for fever episodes. Explanatory Model Interview Catalogues (EMIC) are used to simultaneously collect cultural epidemiological qualitative and quantitative data on patterns of distress, perceived causes and help seeking (Weiss 2001). A baseline survey was carried out in 2004 in the DSS villages and Ifakara town. Interviews were done with 80 caretakers of children and with 68 adults who experienced a fever episode in the preceding two weeks. Only people who had recovered from their illness the day of the interview were included while others were advised to consult a health professional. The same methodology will be applied in follow-up surveys every two years. It is expected that over the course of the programme, the number of appropriately treated fever episodes will increase with more people shifting to qualified care providers.

The EMIC was also used in a longitudinal study exploring treatment seeking during the cultivation period, when many people live in their *shamba* huts. About 100 household owning a temporary home in the fields were randomly sampled from DSS villages and followed up during one farming season. Each household was visited once a month by a team of field workers who recorded each family member's stay in the field, the occurrence of fever episodes and other indicators. In case of a fever episode in the preceding two weeks, an EMIC interview was conducted.

A household survey in a larger sample of 3'654 persons carried out in 2006 by a partner project (IMPACT-Tz) in the study area was used to assess uptake of social marketing messages by the population.

#### 3.3.6.4 Case-control study on degedege

A case-control study on *degedege* (convulsions) was nested in the DSS data collection. The study compares treatment seeking patterns and self-observed signs

and symptoms for fatal ("cases") and non-fatal ("controls") *degedege* episodes in children. *Degedege* has commonly been treated by traditional healers rather than with modern medicine (Makemba *et al.* 1996). However, this may have changed over time. EMIC questionnaires and extended verbal autopsies (VA) were used as data collection tools for non-fatal and fatal cases respectively. Non-fatal *degedege* cases were reported routinely by DSS field-workers. A random sample was then followed up every two weeks for an EMIC interview. This study is expected to provide information on observed "danger signs" and factors related to treatment seeking and leading to death or recovery. It will add an important aspect to the existing knowledge on management of fatal malaria including cases of convulsions as described by de Savigny *et al.* (2004b).

#### 3.3.6.5 Quality of care at health facilities

Initial assessment of quality of care is based on yearly surveys in a sample of public and private/mission health facilities. Tools were adapted from the multi-country evaluation of IMCI (Bryce *et al.* 2005b). Activities include patient-provider observations, as well as staff and patient exit interviews. Furthermore, laboratory equipment is checked for functionality and drug stocks are recorded. With the implementation of the QIRI tools for supportive supervision in 2007 (as outlined above), evaluation of quality of care will be done largely through QIRI which will assess quality of care twice annually in all health facilities. Results will then feed directly into activities aimed at improving quality of care. It is expected that the programme's interventions will lead to improved malaria case-management and more rational prescription of antimalarial drugs.

#### 3.3.6.6 Health facility attendance and availability of antimalarials

Health facility attendance data and frequency of specific diagnoses are routinely recorded by health facility staff for the health management information system (HMIS). This information is collected bi-monthly from all private and public health facilities in Ifakara (one public, one private) and the DSS area (10 public, five private) by ACCESS staff. Together with the DSS fever incidence data which provides a community estimate, this information will allow to calculate the proportion of fever

cases diagnosed as malaria and treated at health facilities. This proportion is expected to rise over the course of the project. In the frame of this activity, availability of antimalarial drugs is monitored in all health facilities in the DSS.

#### 3.3.6.7 Quality of antimalarial drugs

In 2005, a study was designed to get an overview of the quality of antimalarials available in the programme's study area. For this purpose, all antimalarial selling points in the 25 DSS villages as well as in Ifakara were visited, including general shops, drug stores, pharmacies and health facilities. Samples of SP, amodiaquine and quinine products were purchased and the amount of active ingredient quantified according to the United States Pharmacopoeia (USP 24) using previously set up high-performance liquid chromatography (HPLC) methods (Anonymous 2000; Braun 2005). In accordance with USP standards, products with less than 90% and more than 110% of the labelled amount of active ingredient were counted as failures.

#### 3.3.6.8 Quality of services at shops selling drugs

Based on the methodology developed by Goodman *et al.* (2004) for monitoring antimalarial drug availability, the DSS villages and Ifakara are searched annually for drug-selling shops and the shopkeepers are interviewed. A structured questionnaire is used to record current drug stock and shopkeeper's knowledge of malaria treatment. Simultaneously, the shop's locations are recorded with hand-held GPS devices. This approach allows monitoring the shopkeepers' knowledge of malaria treatment, the services and drugs offered, as well as the coverage of shops stocking drugs as a proxy for availability and accessibility.

In a second approach, "mystery shoppers" (simulated clients) buy drugs in local commercial outlets. For this purpose, local villagers are hired and instructed to go to a nearby shop and ask for treatment for fever/malaria on the basis of standard case scenarios.

#### 3.3.6.9 Costing of implementation activities

A financial analysis of the intervention costs will be performed after the interventions have been running for at least two years. A cost-effectiveness analysis will combine measures of effectiveness (see under health impact assessment) and financial costs. For this purpose, a clear distinction is maintained at the level of IHRDC administration between the cost related to interventions and the cost related to research, monitoring and evaluation.

#### 3.3.6.10 Assessing the impact of the introduction of Artemether-Lumefantrine

Tools developed by the ACCESS Programme will be used to monitor prospectively the health impact of the switch in first-line treatment for malaria from SP to Artemether-Lumefantrine. This assessment will be done in the frame of a related but separate project, called “Artemether-Lumefantrine in vulnerable patients - exploring health impact” (ALIVE). It will include monitoring changes in child mortality trends as well as annual community-based cross-sectional studies and an in-depth compliance study in 500 children.

## *3.4 Progress and results to date*

### 3.4.1 Community leaders’ sensitization and social marketing

Community activities started with the sensitization of community leaders followed by road shows in the 25 villages of the DSS area and in Ifakara town in 2004. The 2005 round covered an additional 56 non-DSS villages in both districts (59%) and by the end of 2006, a total of 114 (79%) villages were reached with both activities (Figure 3.6). On average 40 community leaders per village (90% of the invited) attended the sensitization meetings (total of over 5,000 in three years) and shared their views and concerns, such as:

*“We have seen different health care providers prescribing malaria treatment to patients differently. Some prescribe quinine alone, or SP alone and sometimes quinine and later on SP. We get confused! Which is the appropriate treatment for malaria?” (Participant, Idete village)*

*"Children, wives and sometimes relatives of the drug shop owners sell in some of the drug shops. We know these people; they have no formal training, only instructions. It is dangerous." (Participant, Igima village).*

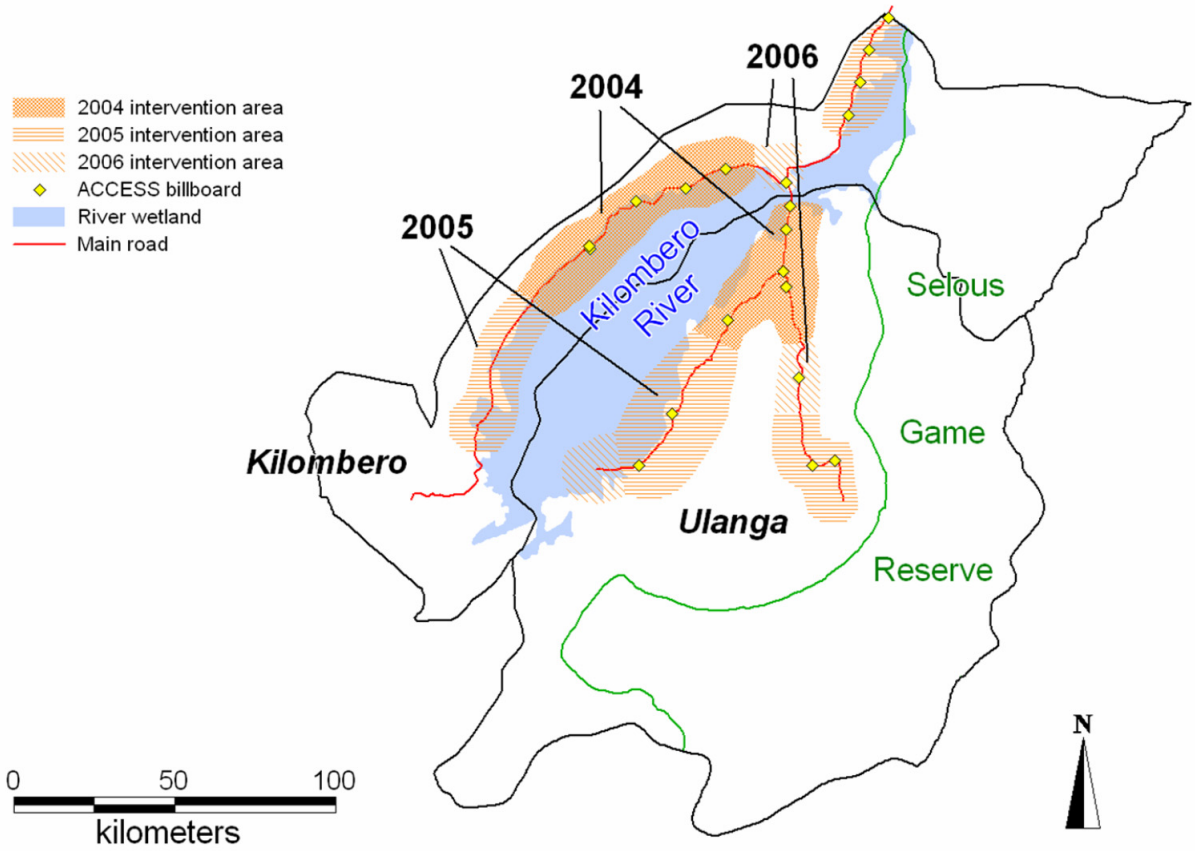


**Figure 3.6: Map of the study area showing intervention areas 2004 – 2006.**

Road shows were generally very well attended. Turn-up varied considerably depending on the size of the village, ranging from few hundred to a few thousand people during big shows such as in Ifakara. In a cross-sectional survey done in 2006 in the DSS area, 39% (95% CI 37.2 to 40.4) of the people mentioned that they had attended an ACCESS road show. Men were 2.2 (95% CI 1.9 to 2.5) times more likely to have attended such a show than women (P<0.001) and younger people were more often exposed than older (Figure 3.7). Further, many people had been in contact with or seen promotion materials such as t-shirts and caps (48%), a vehicle displaying ACCESS slogans (46%), or billboards (35%). Community leaders' sensitization meetings reached 16% of the interviewed.

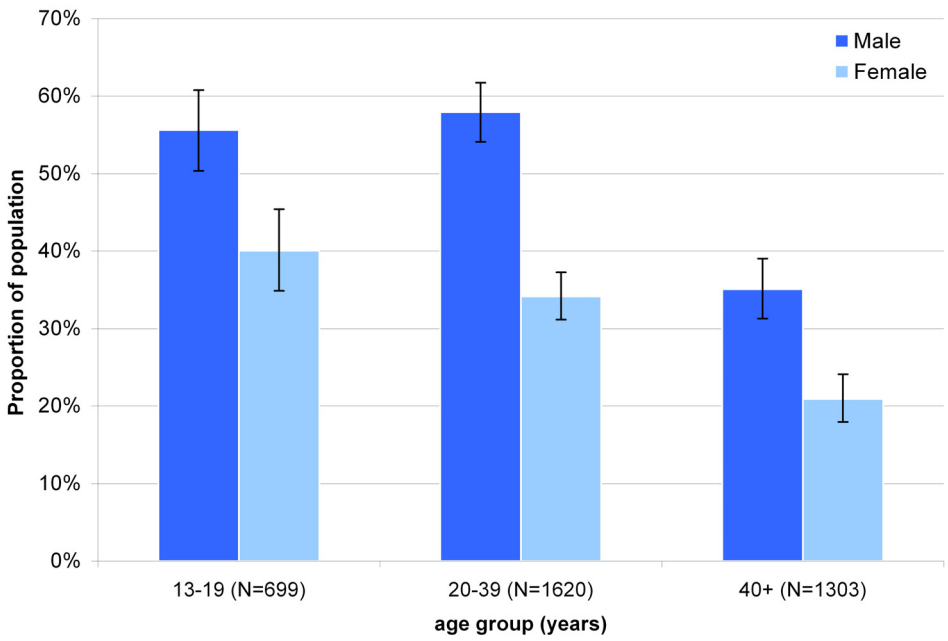


**Figure 3.7: Coverage of social marketing campaign in 25 DSS villages: proportion of the population that has attended an ACCESS road show by age group**

### 3.4.2 MCH campaigns

So far, 18 special sessions for pregnant women have been carried out in MCH clinics in the DSS area, one in Ifakara and 28 in non-DSS villages of both districts. In the DSS alone, about 4,700 mothers attended the sessions, representing approximately 28% of all women in reproductive age.

### 3.4.3 Health facility intervention

Between November 2004 and April 2005, several refresher training sessions were organised in collaboration with the CHMTs of Kilombero and Ulanga. In Ulanga, 100 (89% of total) clinicians, nurses, medical aids and technicians from rural dispensaries and health centres attended the trainings. In Kilombero, 39 (93% of total) clinicians were trained. The tools for supportive supervision and quality management are currently being developed.

### 3.4.4 Accredited Drug Dispensing Outlets

The ADDO programme was targeted at the 32 existing drug stores in Ulanga and 93 in Kilombero District (Mbwasi *et al.* 2005; Risha *et al.* 2005). After a preparatory phase of training shop owners and dispensers, setting up or renovating shop infrastructure and a licensing procedure, ADDOs were launched in Ulanga in May 2006 and in Kilombero in July 2006. By end 2006, there were 114 ADDOs operational in Kilombero district and 44 in Ulanga (R. Mbwasi, personal communication).

### 3.4.5 Monitoring & evaluation

2004 baseline population of the DSS area was 74,200 people, with a crude death rate of 11.6/1,000 people-years observed (PYO). The probability of dying before reaching the age of one year is 63.9/1,000 PYO and before the age of five 109.5/1,000 PYO. The risk of a fever episode (*"homa kali"*) in the two weeks preceding the interview was estimated at 144/1,000 people between May and August and 119/1,000 between September and December. The risk of a *degedege* episode in the previous two weeks was 12/1,000 people between September and December. Mosquito net coverage during the main cultivation period (and peak malaria transmission season) was high in the field huts, with 93-100% of households having a net in their huts and an average of over 97% of people in the huts sleeping under a net (treated or not) the night preceding the interview (Fankhauser 2006).

There were seven health facilities in the 13 Kilombero DSS villages and seven in the 12 Ulanga DSS villages in 2004 (one facility per 5,300 people). By 2006, one private dispensary had closed down in Kilombero and a new public dispensary had been opened in Ulanga. The St. Francis Designated District Hospital in Ifakara serves as main referral hospital for all villages in the DSS. On average per month, each of these facilities recorded 240 out-patient visits due to malaria, over 60% of which were children under five. Malaria accounted for 52% of all out-patient visits of children under five and for 37% of all patients over the age of five (Figure 3.8). In addition to health facilities, there were 30 shops in Kilombero DSS, 13 in Ulanga DSS and 14 in Ifakara offering antimalarial drugs (Hetzel *et al.* 2006).

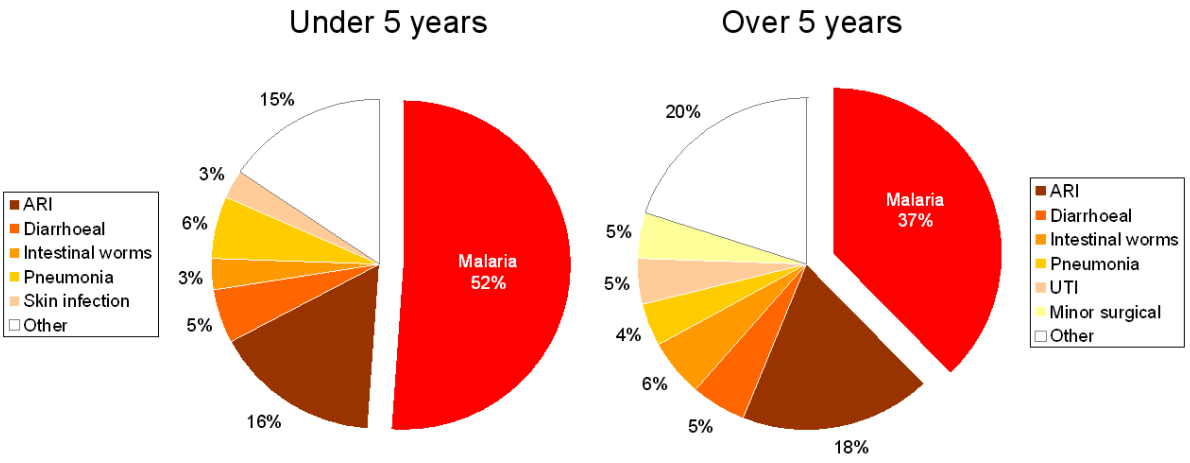


**Figure 3.8: Average monthly out-patients attendance at 16 health facilities in the DSS and Ifakara in 2004** (ARI=Acute Respiratory Infections)

Focus-group discussions revealed mainly the following malaria-related concerns:

- SP had a bad reputation in Tanzania following media coverage on severe side-effects (Stevens-Johnson syndrome) at the time of its introduction as first-line treatment in 2001(Nsimba 2006). Some people feared SP although they or their children had never experienced severe side-effects, which are known to be rare (Gimnig *et al.* 2006). People were confused about different SP brand names.
- Modern medical treatment was preferred over traditional medicine and children were treated more quickly than adults. Drug shops were often more conveniently reachable and adults would often buy paracetamol from a shop as first treatment for a fever episode.
- A majority of the people failed to resort to sources of treatment that they otherwise would prefer - such as a hospital. Factors such as cost, absence of trusted medical professionals, unavailability of diagnostic instruments, long waiting time, and distance were mentioned as important obstacles.

These findings, together with national treatment guidelines and information from other projects and surveys were used as basis for developing the behaviour change campaign.

Quality tests of antimalarials (SP, amodiaquine and quinine) purchased from health facilities and shops in 2005 confirmed the existence of sub-standard drugs in the

study area. In total 25% of the collected tablet samples did not meet the USP specifications for the amount of active ingredient and were mostly under-dosed. 12% of them contained only minimal amounts of active ingredient. Overall, 24% of the collected SP tablets and 40% of the quinine sulphate tablets were sub-standard. All amodiaquine tablets and quinine injections contained the labelled amount of active ingredient. Sub-standard drugs were found mainly at general and drug shop level and mostly originated from Tanzania and India (Braun 2005).

## *3.5 Discussion and conclusions*

In order to develop and validate a generic framework on issues related to access to treatment (Obrist *et al.* 2007), the ACCESS Programme took malaria as an empirical case study. Of course, access issues are also pressing with regard to most other high-burden or neglected diseases in developing countries. By focusing on malaria we chose a poverty-related disease that affects large parts of sub-Saharan Africa in terms of both, disease and economic development, at a time when funding for its control is more readily available than ever before (Nafo Traore 2005).

The Kilombero Valley is an area for which the malaria situation has been particularly well described thanks to numerous research activities (Smith *et al.* 1993; Smith *et al.* 1998; Drakeley *et al.* 2003; Schellenberg *et al.* 2003a). The preventive use of insecticide-treated mosquito nets has been advocated through the large social-marketing of the KINET project between 1997 and 1999. It resulted in high levels of ITN ownership and use (Armstrong Schellenberg *et al.* 1999; Armstrong Schellenberg *et al.* 2001). However, access to prompt and appropriate treatment is still poor. A baseline study in the frame of this programme found that only 14% of young children received an effective antimalarial in the correct dose on the day of illness onset (Hetzel *et al.* 2007b). The aim is, therefore, to expand the successful approach chosen for ITNs to the crucial issue of access to treatment. The main target groups of the interventions are those most at risk in holo-endemic areas such as the Kilombero Valley: young children and pregnant women (WHO & UNICEF 2003; Breman *et al.* 2004; WHO 2004a).

Interventions to improve the complex issue of access to malaria treatment are more likely to be successful if several working approaches are combined. Social marketing applies concepts and techniques used in commercial marketing to prompt behaviour change that benefits the target group (Andreasen 1995). In recent years, it has become increasingly popular in health promotion where it has been proven effective e.g. in promoting the use of ITNs and reducing child mortality (Armstrong Schellenberg *et al.* 2001). However, care has to be taken that men and women profit equally from the approach – a challenge that has to be tackled by the programme. In the frame of ACCESS, the marketed "product" is the knowledge and awareness of malaria and the concept of treating a malaria episode appropriately. The "price" to be paid by the community is the adoption of the desired care-seeking and preventive behaviour. However, inducement of behaviour change alone is not sufficient; health services which are acceptable and of good quality must be available. Hence, the behaviour change campaign is also a way of empowering the community to demand for good quality health care. Activities to improve quality of health services become central components of the programme.

The major providers of malaria treatment services remain health workers. Their practices are influenced by a variety of factors and environments (Rowe *et al.* 2005). The Integrated Management of Childhood Illness (IMCI) strategy adopted by Tanzania is an effective step to improve health worker performance leading to a reduction in child mortality (Armstrong Schellenberg *et al.* 2004) and out-of-pocket expenditures by patients (Manzi *et al.* 2005). However, health systems often fail to implement effective guidelines in a sustainable way (Haines *et al.* 2004). The challenge therefore remains to assure adherence to IMCI guidelines and to address factors not directly related to case-management (e.g. motivation or job satisfaction). Multi-faceted approaches including supervision and strengthening of district-level health management are more likely to improve performance (Rowe *et al.* 2005). The ACCESS Programme therefore combines training and information with the implementation of a quality-improvement process including strengthening the supportive supervision capacity of the district health management team.

As an alternative to formal health services, antimalarials can be obtained from the commercial sector. Drug shops and general stores are the most important alternative

treatment sources for malaria in the study area (Goodman *et al.* 2004; Goodman 2004). In an attempt to ensure quality of services, antimalarial drugs sales have recently been banned in general shops. With no alternative sources replacing general shops this policy resulted in a decreased availability of antimalarials in the study area (Hetzel *et al.* 2006). An alternative approach which has worked well in Kenya would be training of drug vendors (Marsh *et al.* 2004). However, current Tanzanian legislation does not allow the selling of antimalarials in general shops. Consequently, any national strategy has to focus on improving the performance of drug stores and their dissemination to underserved areas through the ADDO project.

For the impact evaluation of ACCESS, a plausibility design had to be adopted (Habicht *et al.* 1999). Identifying a comparable place as control area would not have been possible and randomization of different areas for intervention would not be feasible within the frame of this programme. Supporting evidence for causally linking an observed impact with the programme's interventions will be obtained through the collection of multiple indicators on intervention delivery, coverage and potential confounders. While the limits of such a design in establishing a causal link are obvious and well known, it needs to be recognized that any large-scale implementation goes through an iterative process of measuring progress and impact while continuously adapting and improving the process. Consequently, the interpretation of results has to take into account contextual changes and external influences. Data from other DSS sites and DHS in Tanzania will be of particular importance in interpreting mortality data and putting them into perspective.

Baseline data demonstrated heterogeneity in the availability of treatment sources, unavailability of medicines and providers and serious quality problems with regard to drugs and services. This supports the basic assumption that there are several inter-linked factors influencing access to effective malaria treatment.

The comparative advantage of the ACCESS Programme is its combination of multiple interventions on different levels of the health system, including a strong evaluation and research component. With this approach, the programme also aims to contribute to the wider debate on access to appropriate health care in developing countries. Based on Penchansky and Thomas' (1981) understanding of "access" as

the degree of "fit" between the health system and its users, the ACCESS Programme aims at developing a more comprehensive access framework (Obrist *et al.* 2007). This can then inform and support public health professionals and policy-makers in the delivery of improved health services, ideally leading to better health and well-being.

## *3.6 Authors' contributions*

MWH was responsible for the baseline surveys of the M&E component and wrote the manuscript in collaboration with the other authors. AS, BO, CL and HM conceived the programme and its components and provided technical support and supervision. AM, CM and NI were responsible for the development and implementation of the interventions. AD, SA and IM were responsible for data collection and analysis for M&E. RN is in charge of the DSS and NI of the overall project management. JDN and RAK were responsible for the IMPACT-Tz household-survey which provided social marketing coverage data. All authors read and approved the final manuscript.

## *3.7 Acknowledgements*

We thank the communities of Kilombero and Ulanga districts as well as their leaders for their interest and active participation in the programme. The ACCESS Programme greatly benefits from its collaboration with the district and regional health authorities, the National Malaria Control Programme (NMCP), the Tanzania Food and Drugs Authority (TFDA), IMPACT-Tz, Management Sciences for Health (MSH), Population Services International (PSI) and other local and international collaborators. We acknowledge the inputs of S. P. Kachur (IMPACT-Tz), S. Abdulla (IHRDC), R. Mbwasi (MSH), G. Killeen (IHRDC) and M. G. Weiss (STI). The ACCESS Programme is funded by the Novartis Foundation for Sustainable Development. This paper was published with permission of Dr. Andrew Kitua, Director-General, National Institute for Medical Research. Ethical clearance of the programme proposal was granted by the National Institute for Medical Research of the United Republic of Tanzania (NIMR/HQ/R.8a/Vol. IX/236, 16th September 2003).

**Table 3.1: ACCESS Programme components and corresponding indicators for evaluation** (refer to main text for details)

| Indicator | Sources of verification/study methods | Sample | Timing |
|---|---|---|---|
| **Intervention area 1: Behaviour change campaign**<br>(Expected results: Improved health care seeking behaviour for all fever/malaria episodes) | | | |
| Proportion of episodes treated according to national guidelines within 24h | Cross-sectional community surveys (fever and degedege) with EMIC tool | Random sample of households | Repeated (baseline, mid-term, end) |
| Treatment-shift to qualified providers | DSS (morbidity) and health facility attendance | DSS area, all health facilities | Continuous |
| Equitable access to appropriate treatment | DSS SES data | DSS area, all health facilities | Continuous |
| **Intervention area 2: Quality of care in health facilities**<br>(Expected results: Improved quality of care in health facilities, especially malaria case-management, incl. diagnosis, prescription, treatment, advice, compliance) | | | |
| Proportion of episodes receiving correct prescription and appropriate advice | Quality of care surveys in health facilities | Sample of health facilities | Repeated (baseline, mid-term, end) |
| Patient's satisfaction with services | QIRI | All health facilities | Continuous |
| **Intervention area 3: Malaria case-management in shops**<br>(Expected results: Improved quality of malaria case-management in drug selling shop, such as retailing practices, prescriptions, advice) | | | |
| Proportion of episodes receiving correct prescription and appropriate advice | Mystery shoppers | All drug stores and random sample of general shops | Annually |
| Shop-keepers' knowledge of malaria symptoms, correct treatment and advice<br><br>Availability of first- and second-line antimalarial drugs | Cross-sectional surveys in shops stocking drugs | All retailers stocking drugs | Annually |

**Table 3.1 (continued)**

| Indicator | Sources of verification/study methods | Sample | Timing |
|---|---|---|---|
| **Shamba component**<br>(Expected results: Coverage of appropriate malaria treatment and care services extended to underserved areas, incl. shamba households) | | | |
| Proportion of households within 5km range of qualified provider | DSS GPS data | All households, health facilities and shops stocking drugs | Repeated |
| Proportion of episodes in underserved areas / poor households /shamba houses receiving correct treatment | Cross-sectional community surveys (fever and degedege), DSS SES data | Random sample of households | Repeated (baseline, mid-term, end) |
| **Health impact**<br>(Expected results: Reduction of malaria related morbidity and mortality, especially in children under five and pregnant women) | | | |
| Proportion of malaria-related deaths | DSS mortality data: overall and cause-specific. | All households | Continuous |
| Number of fever episodes. | DSS fever incidence | All households | Continuous |
| **Additional studies** | | | |
| Understanding and perception of malaria, its treatment and prevention | Focus-group discussions | 10 groups of caretakers of children under five years in Ifakara and DSS | Once prior to interventions |
| Risk factors for fatal outcome of *degedege* | Case-control study | Cases: *degedege*-related child deaths in DSS<br>Controls: recovered *degedege* cases | Once |
| Vulnerability and coping strategies of households during the farming season; movement patterns and health seeking | Cohort study with *shamba* households | Random sample of households with field (*shamba*) house | Once |
| Antimalarial drug quality | Cross-sectional survey | All drug stocking retailers and health facilities | Once |

EMIC = Explanatory Model Interview Catalogue. DSS = Demographic Surveillance System. SES = Socio-economic Status. QIRI = Quality Improvement and Recognition Initiative. GPS = Geographic Positioning System.

# PART 2

# AIMS AND OBJECTIVES, STUDY AREA, METHODOLOGY

Goodluck John and Sixbert Msagwa during field work

# 4 AIMS AND OBJECTIVES

## *4.1 Aims and objectives*

The overall aim of the studies presented here was to contribute to a better understanding of the factors influencing access to malaria treatment in a rural Tanzanian setting. The insights gained should inform ACCESS Programme interventions and help to develop an improved general access framework.

The general and specific objectives of the studies were as follows:

1. **To investigate treatment-seeking behaviour for malaria related illness episodes**
   1.1. To investigate patterns of distress and perceived causes related to malaria
   1.2. To quantify treatment-seeking options
   1.3. To investigate factors related to prompt and effective case-management

2. **To enable a better understanding of the disease burden, access to health services, and responses to malaria related illness episodes of farming families during the cultivation period**
   2.1. To quantify risks of fever episodes during the farming season
   2.2. To investigate movement patterns of farming families
   2.3. To investigate preventive measures taken while in the fields
   2.4. To understand treatment-seeking actions taken while in the fields

3. **To assess the availability of antimalarials in the private retail sector following the change of first-line treatment from chloroquine to SP**
   3.1. To quantify the number of shops offering antimalarial treatment
   3.2. To assess the availability of different antimalarial products on the private market
   3.3. To map spatial coverage of shops selling antimalarials
   3.4. To investigate changes of private-sector availability of antimalarials following the policy change from chloroquine to SP in 2001

4. **To assess the knowledge and behaviour of private drug retailers in terms of case-management of febrile illness episodes**
   - 4.1. To validate data obtained on antimalarial availability through mystery shoppers (simulated clients)
   - 4.2. To assess shop keepers' understanding of malaria symptoms
   - 4.3. To assess treatment and advice offered in different types of shops selling drugs

As reflected in these objectives, this thesis focused on demand-side aspects of access and on the performance of the commercial retail sector on the supply-side. An assessment of the quality of care in health facilities was not part of this thesis since.

All studies were designed to contribute to the overall goal of the ACCESS Programme, which is to contribute to the reduction of overall and child mortality through improving access to prompt and effective malaria treatment in two rural districts in Tanzania.

# 5 STUDY AREA

All studies were carried out in the two districts of Kilombero and Ulanga, Morogoro Region, southern central Tanzania (Figure 5.1).

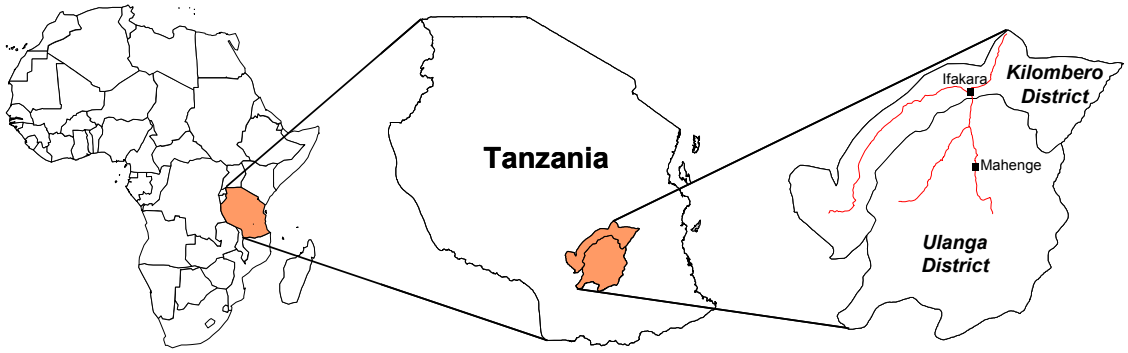


**Figure 5.1: Location of Kilombero and Ulanga Districts in Tanzania**

The Udzungwa Mountains in Kilombero and the Mahenge limestone plateau in Ulanga define the Kilombero valley which has been described as the largest seasonal freshwater lowland floodplain in East Africa (Wetlands International & Ramsar 2007). Basic demographic indicators for the area are summarised in Table 5.1.

**Table 5.1: Basic demographic indicators of the study districts**

| Indicator | Kilombero | Ulanga | Total |
|---|---|---|---|
| Population (2002)[1] | 322,779 | 194,209 | 516,988 |
| Percentage female[1] | 49.6 | 50.7 | 50.0 |
| Percentage <5 years[1] | 14.8 | 16.3 | 15.4 |
| Average household size[1] | 4.4 | 5.3 | 4.7 |
| Population growth rate 1988-2002[1,2] | | | 2.6 |

[1]Source: 2002 Population and Housing Census

[2]Morogoro Region

In 1996, prior to the implementation of a large-scale ITN intervention trial (Kilombero Insecticide-Treated Net Project [KINET] project), a DSS was established in the two districts (Armstrong Schellenberg *et al.* 1999; Armstrong Schellenberg *et al.* 2002). The DSS covers 12 villages in Ulanga District and 13 in Kilombero District in an area

of approximately 2400 km$^2$. In mid-2004, the population of the DSS was 31,800 in Ulanga and 42,400 in Kilombero.

Just outside the DSS area, Ifakara town is the Kilombero District headquarter and major trading centre in the valley. According to the national census in 2002, the town's population was 45,680 (United Republic of Tanzania 2003a). Ifakara has a long tradition of development cooperation and health research (Tanner *et al.* 1994). From here, the Ifakara Health Research and Development Centre (IHRDC) implemented several research and intervention projects on malaria, such as the successful social marketing for ITNs through the KINET project (Armstrong Schellenberg *et al.* 2001; Abdulla *et al.* 2001), the first trial of the SPf66 malaria vaccine in Africa (Alonso *et al.* 1994), studies on antimalarial drug resistance development (Mshinda *et al.* 1996; Mugittu *et al.* 2005; Mugittu *et al.* 2006), and the efficacy and safety of IPTi with SP (Schellenberg *et al.* 2001).

The studies presented here were carried out in the DSS villages and, partly, in the town of Ifakara. Additional and more detailed information on the study area can be found in the ACCESS Programme description in chapter 3.

## *5.1 Malaria situation in the study area*

In the Kilombero valley, *P. falciparum*-malaria is highly endemic and perennial with seasonal transmission patterns. Principal vectors are *Anopheles gambiae* sensu lato and *Anopheles funestus*. Historical EIR estimates reached over 300 ib/p/y for rural areas, including 2979 ib/p/y in one particular house (Smith *et al.* 1993). Recent studies confirmed a decline of EIR from a mean of 1481 to 244 following large-scale social marketing of ITNs (G. Killeen, personal communication). At the level of outpatient health services, malaria is the most frequent problem to which 40% (over five years of age) to 50% (under five years of age) of all visits are attributed (Hetzel *et al.* 2007c). The malaria-related mortality in under-fives in the area was 3.7 per 1,000 person-years in 2003 and total under-five mortality was 32.7 per 1,000 person-years in the same year (Ifakara DSS, unpublished and United Republic of Tanzania 2005).

## 5.2 Malaria control and other health interventions in the study area

Within the DSS area, there are a number of government and private (mostly missionary) dispensaries and health centres offering malaria treatment and care (Table 5.2). The St. Francis Designated District Hospital (SFDDH) in Ifakara is the largest hospital and primary referral point in the two districts, with approximately 400 beds. Apart from health facilities, malaria treatment can be obtained from a range of private retailers, including drug stores and general shops.

**Table 5.2: Health facilities in the DSS area and Ifakara town**

| Location | Level | Category |
|---|---|---|
| **Kilombero District, DSS villages** | | |
| Idete | Dispensary | Govt. |
| Lukolongo | Health centre | Govt. |
| Mbingu | Dispensary | Mission |
| Mbingu | Dispensary | Govt. |
| Mchombe | Dispensary | Mission |
| Mngeta | Dispensary (closed end 2004) | Private |
| Namwawala | Dispensary | Govt. |
| **Ulanga District, DSS villages** | | |
| Idunda | Dispensary (open since 2005) | Govt. |
| Igota | Dispensary | Mission |
| Iragua | Dispensary | Govt. |
| Iragua | Dispensary | Mission |
| Kichangani | Dispensary | Govt. |
| Kivukoni | Dispensary | Govt. |
| Lupiro | Health centre | Govt. |
| Milola | Dispensary | Govt. |
| **Ifakara, Kilombero District** | | |
| Ifakara (SFDDH) | Designated district hospital | Govt. / mission |
| Ifakara | Dispensary | Private |

Malaria control in the two districts follows the strategy of the National Malaria Control Programme (NMCP) (MOH 2002). However, due to IHRDC's research activities in the area, some control strategies may have been pursued with more emphasis than

in other districts. While the trials carried out in a clinical setting in few health facilities may not have had a large community-effect, ITN activities had a verifiable impact.

The KINET project introduced large scale social marketing for ITNs and treatment kits in the DSS villages in 1997 following formative research on people's perceptions of causes of child death, mosquito nets, net treatment, and malaria (Minja *et al.* 2001). In mid-1999, all villages in the two districts had been reached. Within three years, ITN coverage rose from 10% to over 50% and a 27% increase in child survival was associated with ITN use (Armstrong Schellenberg *et al.* 2001). Considerable beneficial effects on morbidity in children (Abdulla *et al.* 2001), anaemia in pregnant women (Marchant *et al.* 2002) and cost-effectiveness of social marketing were also demonstrated (Marchant *et al.* 2002; Hanson *et al.* 2003). A discount voucher for pregnant women was tested within KINET and later served as the model for the Tanzanian National Voucher Scheme (Mushi *et al.* 2003). From 2000 on, a national ITN strategy was implemented with countrywide social marketing through Population Services International (PSI) (Magesa *et al.* 2005). In Kilombero and Ulanga, marketing of the KINET-ITNs branded *Zuia Mbu* was abandoned in favour of the PSI-marketed ITNs and treatment kits in 2004. KINET had already demonstrated how continuous exposure to social marketing increased the use of ITNs. This is today reflected in an ITN coverage of over 75% following 10 years of continuous social marketing activities (Killeen *et al.* 2007).

With regard to malaria case-management, the introduction of IMCI in health facilities was an important step towards improved quality of child care. Kilombero and Ulanga Districts began IMCI implementation in 2002 after having been non-IMCI control districts for the evaluation of IMCI in Tanzania from 1997 to 2002 (Tanzania IMCI Multi-Country Evaluation Health Facility Survey Study Group 2004). In this evaluation, IMCI was associated with better observed quality of care at no additional costs for caretakers or the districts (Armstrong Schellenberg *et al.* 2004; Tanzania IMCI Multi-Country Evaluation Health Facility Survey Study Group 2004; Bryce *et al.* 2005a).

Children below the age of five years and pregnant women are generally exempted from expenditures at government facilities. This includes (at least in theory) free consultation and medicines. However, unofficial ("under the table") fees may be

charged occasionally or stock-outs of drugs may force people to pay for medicines elsewhere. For the remaining patients, different payment schemes exist in the two districts. Kilombero District government health facilities are running on a cost-sharing scheme, which has been described as significantly more expensive to users, than non-cost-sharing schemes (Manzi *et al.* 2005). No user fees are charged in Ulanga district and a Community Health Fund (CHF) constitutes a form of risk-protection for members of the fund. However, anecdotal evidence found that membership is not very popular due to the relatively large advance-payments. Different health financing schemes have a clear impact on out-of-pocket expenditures by patients and may positively or negatively influence access to health services, especially by the poorest. According to Manzi *et al.* (2005) the now prevailing payment scheme in government facilities in Ulanga (no user fees and IMCI implemented) seems to be more economic than the one in Kilombero.

# 6 METHODOLOGY

The studies described hereunder are part of the baseline assessment within a before-after design for the evaluation of the ACCESS Programme. Quantitative, semi-quantitative and qualitative methods were used for data collection in order to gain an in-depth understanding of behavioural and other factors related to treatment access.

Data collection for the several studies was done during a three-year field stay between 2004 and 2006, as outlined in Figure 6.1. Different sampling strategies, data collection tools and procedures were developed to investigate treatment seeking behaviour under varying circumstances (to achieve objectives 1-3) as well as availability and quality of case-management and advice in the retail sector (to achieve objectives 4-5). All data collection tools were developed in English and translated into Kiswahili for use in the field.

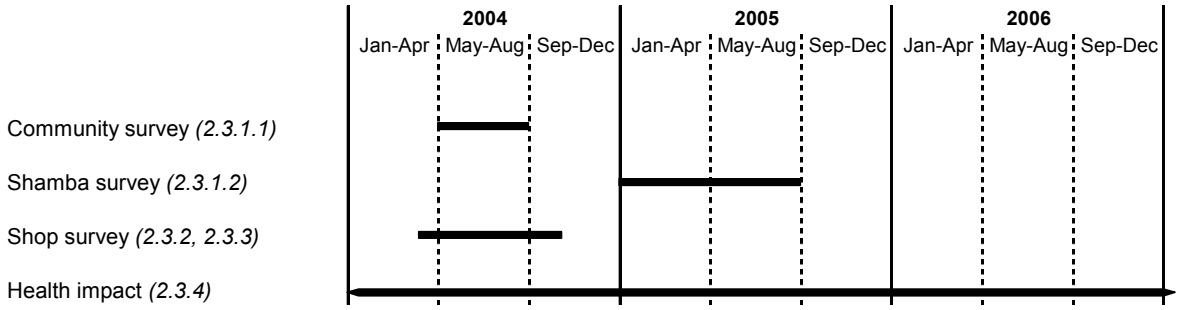


**Figure 6.1: Timeline of studies**

## *6.1 Treatment-seeking surveys*

Treatment-seeking behaviour for recent episodes of fever was investigated using Explanatory Model Interview Catalogues (EMIC) (Weiss 2001). EMIC are semi-structured questionnaires which allow the collection of qualitative and quantitative cultural epidemiological data on patterns of distress, perceived causes and help seeking. The development of the EMIC was based on qualitative research on people's understanding of malaria and prevailing and preferred treatment seeking options. Qualitative research included focus-group discussions carried out in the frame of the ACCESS Programme and previous more in-depth studies on malaria in

the Kilombero valley or other parts of Tanzania (Hausmann Muela 2000; Minja 2001; Mayombana 2004). The EMIC were administered to a caretaker (if the patient was younger than 12 years) or to the patient. A “fever episode” was defined as any febrile illness perceived as such by the patient or caretaker. Patients with an illness episode who had not recovered prior to the interviewer’s visit were not included in the studies but were advised to seek care from a reliable source.

The same EMIC was used in three different studies described hereunder. In each of these, a different form was used for patients under the age of five years and patients above five years. The original EMIC forms used in the field were in Swahili. An English version of the EMIC for children can be found in Appendix 1.

### 6.1.1 Cross-sectional community survey on treatment-seeking for a recent fever episode

This survey was done between May and August 2004 in the DSS villages and Ifakara. It included children and adults with a reported fever episode in the preceding two weeks. A random sample of households was drawn from the DSS database, relative to the size of each village. For Ifakara, no household database was available. We therefore used the local administrative structure and collected data on households through village, hamlet and ten-cell leaders (Figure 6.2) to perform a two-stage random sampling (ten-cell, household). Results of this survey are reported in chapter 7.

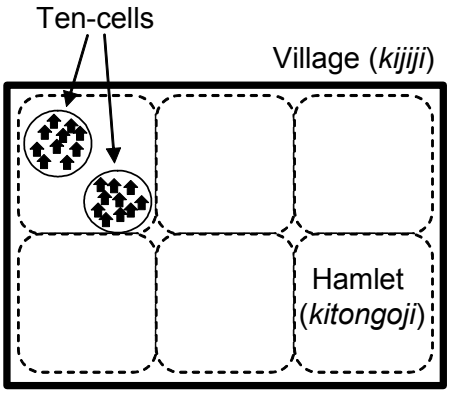


**Figure 6.2: Administrative structure used for random sampling**

### 6.1.2 "*Shamba* survey" on treatment-seeking for recent fever during the farming season

A longitudinal study of a cohort of farming households was conducted between mid-January and August 2005. A two-stage stratified sampling was performed to select households from four randomly sampled DSS villages in each of the two districts. Households were followed-up during their stay in the fields (*shamba*) and visited monthly over the study period. At each visit, a structured questionnaire was used to record each household member's whereabouts, activities, use of mosquito nets and recent fever episodes. In case a fever episode was reported, an EMIC interview was done with the patient or the caretaker. Families' main houses in the villages and their *shamba* locations were recorded with GPS units for distance-calculations. Results of this survey are reported in chapter 8.

## *6.2 Shop surveys*

Between May and June 2004, the DSS area and Ifakara were searched for any kind of shops stocking drugs. This included pharmacies, drug stores, general retailers, wholesalers, kiosks or *genge* (temporary stalls). The shops were found with the help of local leaders and with an outlet-list which had been established during earlier shop surveys in 2001 and 2002 (Goodman 2004). Each outlet's location was recorded using hand-held Global Positioning System (GPS) devices. A structured questionnaire was used in all shops to record the services and drugs offered (in particular the brands of antimalarials and antipyretics) and the shop keepers' knowledge of malaria and its treatment. Results of this survey are reported in chapters 9 and 10.

## *6.3 Mystery shoppers*

In a follow-up study to the shop survey in September and October 2004 the shop keepers' behaviour in selling drugs and giving advice was assessed. For this purpose, we used simulated clients ("mystery shoppers") in a sub-sample of approx. 10% of the outlets stocking drugs. Local villagers were hired and instructed to go to a nearby shop and ask for treatment for a fever/malaria episode. The mystery shoppers were identified by local DSS enumerators who lived in the villages and knew people who

could be trusted to do such a job. The shop visits were based on three standard case scenarios:

(A) a child, aged 2-4 months, with fever/hot body for one day and problems with drinking/breastfeeding,

(B) a child, aged 2-4 years, with recurring fever/hot body for 3 days (especially at night), problems with drinking and eating, diarrhoea and tiredness/not playing with friends as usual,

(C) an adult, with recurring fever/hot body for 2 days, headache, dizziness and loss of appetite.

Mystery shoppers were provided with money to buy the drugs in the outlets. After their visit to a shop, they were interviewed using a catalogue of questions on what they did and said during their visit and what advice and drugs they were given. Results of this study are reported in chapter 10.

## *6.4 Demographic Surveillance System*

The DSS was used as an epidemiological framework for all studies, except for those carried out in Ifakara town. In the absence of a vital registration, trained field workers routinely record births, deaths, in- and out-migrations and socio-economic indicators for every household in the 25 DSS villages. Each of the approximately 17,000 households (2004) is visited every four months.

The DSS database served as sampling frame for the community-based studies on treatment-seeking. Furthermore, it provided basic demographic data, household GPS locations and socio-economic household data. DSS field workers also participated in the shop survey and mystery shoppers study creating a link to the local community.

## *6.5 Data entry and analysis*

All quantitative data from treatment-seeking and shop surveys was double-entered and cleaned by the data unit of the IHRDC using Microsoft FoxPro or Access software. Qualitative data, such as narrative parts of the EMIC as well as mystery shoppers interviews were entered by ACCESS Programme staff using Microsoft Word.

Data analysis was performed with Intercooled Stata 8 and 9 (StataCorp, College Station, Texas, USA) for quantitative and MAXqda2 (VERBI GmbH, Marburg, Germany) for qualitative data. For spatial data, MapInfo Professional 7.0 (MapInfo Corporation, Troy, New York, USA) and ArcView GIS 3.3 Software (Environmental Systems Research Institute, Inc., Redlands, California, USA) was used.

## *6.6 Ethics*

All studies presented here were reviewed as part of the ACCESS Programme proposal. Ethical clearance was granted by the Institutional Review Board of the IHRDC and the National Institute for Medical Research of the United Republic of Tanzania (NIMR/HQ/R.8a/Vol. IX/236, 16th September 2003). The author of this thesis was granted Research Permits by the Tanzania Commission for Science and Technology (2004-189-CC-2001-40, 17 August 2004; 2005-314-ER-2001-40, 31 August 2005; 2006-265-ER-2001-40, 17 August 2006).

All study participants were asked for oral informed consent prior to conducting the surveys and all participants were free to reject an interview. For obvious practical reasons this was not the case for shop keepers during the mystery shoppers study. For those cases in which names were recorded (e.g. for linkage with the DSS database), participants were assured that their data would be kept in confidence. Final reports did not mention any names of study participants and shop keepers names only appeared in connection with their shops location but not with the services offered. Confidential data such as names of participants or participants' businesses were not revealed to authorities.

# PART 3

## RESULTS

Examining a child during an ACCESS event

# 7 OBSTACLES TO PROMPT AND EFFECTIVE MALARIA TREATMENT LEAD TO LOW COMMUNITY-EFFECTIVENESS IN TWO RURAL DISTRICTS OF TANZANIA

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This paper has been submitted to
*BMC Public Health*

## *7.1 Abstract*


### 7.1.1 Background

Malaria is still a leading killer in sub-Saharan Africa. Yet access to prompt and effective malaria treatment, a mainstay of the malaria control strategy, is insufficient in many settings. Little is known about obstacles to treatment and community-effectiveness of case-management strategies. This research quantified illness models, treatment seeking behaviour and access to treatment in a highly endemic rural Tanzanian community. The aim was to provide in-depth understanding of obstacles to treatment access in order to develop practical and cost-effective interventions.

### 7.1.2 Methods

We conducted community-based treatment-seeking surveys with 226 recent fever episodes in 2004 and 2005. The local Demographic Surveillance System provided additional household information. A census of drug retailers and health facilities provided data on availability and location of treatment sources.

### 7.1.3 Results

After years of health education, the biomedical concept of malaria has largely been adopted by the community. Traditional illness models of severe malaria were not anymore a significant barrier to modern treatment. 87.5% (78.2-93.8) of the fever cases in children and 80.7% (68.1-90.0) in adults were treated with one of the recommended antimalarials (at the time SP, amodiaquine or quinine). However, only 22.5% (13.9-33.2) of the children and 10.5% (4.0-21.5) of the adults received prompt and appropriate antimalarial treatment. Health facility attendance increased the odds of receiving an antimalarial (OR=8.1) but did not have an influence on correct dosage. The exemption system for under-fives in public health facilities was not functioning and drug expenditures for children were as high in health facilities as with private retailers. This information is highly relevant to improve access to malaria treatment in the community.

### 7.1.4 Conclusions

A clear preference for modern medicine was reflected in the frequent use of antimalarials. Yet, quality of case-management was far from satisfactory as was the functioning of the exemption mechanism for the main risk group. Poor drug efficacy and quality may have further decreased effectiveness. Private drug retailers played a central role in complementing existing formal health services. Such health system factors need to be tackled urgently in order to translate the high efficacy of newly introduced artemisinin-based combination therapy (ACT) into equitable community-effectiveness and health-impact.

## *7.2 Background*

Malaria is killing over one million people every year, mostly children under five years of age in sub-Saharan Africa (WHO & UNICEF 2005). After failed attempts to eradicate malaria in most parts of Africa, it was recognized that only integrated control programmes combining different approaches were likely to bring alleviation (Greenwood *et al.* 2005). One mainstay of the control strategy promoted by the World Health Organization is prompt access to effective treatment for episodes of malaria (WHO & UNICEF 2005). It is difficult to estimate how many people worldwide lack access to effective and affordable treatment. Yet, it can be safely assumed that of the 2.4 billion people (2005) living in low-income countries (World Bank 2007), only few have access to high quality health-care. In the case of malaria, it has been shown that access to and quality of treatment is unsatisfactory in many settings (McCombie 2002; Committee on the Economics of Antimalarial Drugs 2004), hence contributing significantly to the high death toll. Increased attention is currently being paid by donors and researchers to these issues. It is worth considering that lack of access is a complex issue that should be put into the context of poverty, vulnerability and livelihoods to be better understood (Obrist *et al.* 2007).

Several strategies have been proposed and tested to improve access to malaria treatment, including scaling-up of home-based management (WHO 2005a; Gyapong & Garshong 2007), stronger involvement of the private sector (Marsh *et al.* 2004; TDR/WHO 2006), improving case-management in health facilities (Rowe *et al.* 2005) as well as integrated approaches (Nyarango *et al.* 2006). In addition, it is now widely acknowledged that no malaria-control strategy can be successful and sustainable without an increased investment in the local health systems through which the interventions can be channelled (Travis *et al.* 2004; Singh 2006; Feachem & Sabot 2007).

The studies presented here assessed knowledge of malaria, treatment seeking behaviour and access to malaria treatment in a rural Tanzanian community. The research was carried out in the frame of a comprehensive intervention programme to improve access to malaria treatment in rural Tanzania (ACCESS Programme) (Hetzel *et al.* 2007c).

In this context, the studies provided in-depth understanding of obstacles to treatment access which are crucial to develop practical and cost-effective interventions to improve access at community-level. The development of a generic access framework fitted in the context of livelihood insecurities also benefited from the quantitative information gained in this research (Obrist *et al.* 2007).

Indicators to measure access and effectiveness have to be chosen carefully in order to provide relevant information. Commonly used measures such as “percentage of episodes treated with an antimalarial” may be convenient for monitoring purposes but might give a distorted picture of the reality. This research provided for the first time a quantified estimation of the community effectiveness of malaria treatment on the basis of different key access indicators.

## *7.3 Methods*

### 7.3.1 Study setting

Treatment seeking for fever episodes and availability of treatment services were studied in the districts of Kilombero and Ulanga, Morogoro Region, south-eastern Tanzania, in 2004 and 2005. The study area comprised the 25 villages of the local Demographic Surveillance System (DSS) (Armstrong Schellenberg *et al.* 2002) with a population of 74’200 in 2004, as well as the town of Ifakara (2001 population census: 45,726 (United Republic of Tanzania 2003a)), the district capital of Kilombero. The area is predominantly rural and the malaria transmission is high and perennial (Drakeley *et al.* 2003; Killeen *et al.* 2007). In 2004, there were 14 health facilities (9 public, 5 private/mission) in the DSS area, as well as one private clinic and one district hospital in Ifakara. Malaria accounted for roughly half of all outpatient visits in these health facilities. Government and private health facilities in Kilombero are running on a cost-sharing scheme. In Ulanga, no user fees are charged in government facilities and a Community Health Fund (CHF) offers a form of risk-protection for members of the fund. A more detailed description of the study area can be found elsewhere (Hetzel *et al.* 2007c). At the time of the study, the recommended first-line treatment for uncomplicated malaria was SP, the second line treatment

amodiaquine, and quinine was recommended as third-line treatment and for cases of severe malaria (MOH 2000).

### 7.3.2 Treatment seeking surveys

To investigate understanding of malaria and treatment seeking behaviour for recent fever cases, two surveys were carried out:

1. a cross-sectional cultural-epidemiological community survey in the DSS area and Ifakara town
2. a longitudinal study investigating treatment seeking during the farming season (*shamba* survey).

For the **cross-sectional community survey**, we took a village-stratified random sample with the number of households per village weighed by total village-size. A total of 318 households were drawn from the registered 16'220 households in the 25 DSS villages. Only households with at least one child under the age of five years were eligible.

Sampled households were visited by a DSS interviewer between May and August 2004, within the schedule of the routine DSS data collection. In all households which reported a fever episode in the previous 14 days, the patient or caretaker (if the episode was in a child younger than 12 years) was interviewed. Patients who had not yet recovered were not included but advised to seek care from a health facility.

For Ifakara town no up-to-date household list was available as sampling frame. The local administrative structure was used to establish a list of households and to perform a two-stage random sampling of 223 households. The ward Ifakara comprises five villages (vijiji) with 17 hamlets (vitongoji). In each hamlet, groups of originally ten households are represented by a ten-cell leader (balozi). Every household in Ifakara was assumed to belong to one ten-cell leader. Through visits to village and hamlet leaders, a comprehensive list of all 329 ten-cell leaders in Ifakara ward was established. A random sample of 35 ten-cell leaders was then drawn and visited in order to establish a complete household list for their ten-cells. From these lists, six households per ten-cell were then randomly sampled. A household may only

have been missed if it was not recorded by any ten-cell leader. We tried to avoid double-listing of households claimed by several ten-cell leaders by cross-checking the names of the household heads. Sampled households in Ifakara were visited by two trained interviewers in May 2004. The same inclusion and exclusion criteria as in the DSS villages applied.

Spatial data on household locations as well as socio-economic status calculations were obtained from the DSS database, which could provide such information for 70% of all interviewed cases.

The **longitudinal *shamba* survey** (in Swahili, *shamba* = farm) was carried out between December 2004 and August 2005 to investigate treatment seeking during the farming season. It included a random sample of approx. 100 farming households from 10 randomly selected DSS villages which were followed-up during the main cultivation period. Every month, interviews were done for recent fever episodes in these households, applying the same inclusion and exclusion criteria as in the cross-sectional community survey. However, as the sampling methodologies differed (cross-sectional vs. longitudinal, general population vs. farming households), the two surveys were not equally representative of the general population. For the analysis of people's understanding of malaria we assumed that there would be no difference between the two samples and included both data. However, the treatment seeking and risk factor analysis for the *shamba* survey was done separately and presented elsewhere (Hetzel *et al.* 2007a).

To interview patients and caretakers, field-workers used an **Explanatory Model Interview Catalogue (EMIC)** (Weiss 2001). The EMIC is a semi-structured questionnaire based on an explanatory illness model. It was developed on the basis of preceding focus-group discussions and further qualitative research on people's understanding and experience of malaria (Hausmann Muela 2000; Minja *et al.* 2001; Mayombana 2004). Data collected with the EMIC comprised quantitative variables as well as narratives on reported signs and symptoms ("patterns of distress"), perceived causes of the illness as well as help seeking. Its aim was to elicit comprehensively the experience of illness and resulting treatment-seeking behaviour from the point of view of those affected.

Selection of cases was based on self-reported fever. This took into account that in absence of diagnostic tools, most episodes of fever suggestive of malaria are treated presumptively based on the reports given by the patient or the caretaker. The Integrated Management of Childhood Illness (IMCI) algorithms, which are implemented in the study area, advocate an assessment based on clinical signs and symptoms. The data analysis took into consideration the reported signs and symptoms as well as the name given to the illness by the respondent.

Oral informed consent was obtained from all study participants prior to the interviews. Ethical clearance of was granted by the National Institute for Medical Research of the United Republic of Tanzania (NIMR/HQ/R.8a/Vol. IX/236, 16th September 2003).

### 7.3.3 Availability of treatment services

Access to treatment is, among other things, clearly a function of the availability of treatment sources. We geo-located 16 health facilities and 498 drug selling shops (DSS and Ifakara) in a cross-sectional survey in May – June 2004 (Hetzel *et al.* 2006).

### 7.3.4 Statistical analysis

Epi Info 6 was used for all random sampling procedures. Data were double entered using Microsoft FoxPro and Microsoft Access (Microsoft Corp.), and checked for coding errors and consistency. Statistical analysis was done with Intercooled Stata 9 (College Station, Texas, USA). For spatial analyses, MapInfo Professional 7.0 (MapInfo Corp., Troy, New York, USA) and ArcView GIS 3.3 (ESRI, Redlands, CA, USA) were used.

For cultural-epidemiological data on patterns of distress and perceived causes, answers were given values according to whether they were reported spontaneously (value of 2) or upon probing (value of 1) and out of these, mean prominence values were calculated. The Kruskal-Wallis test was used for testing differences of the ranked outcomes between sub-groups of the sample. $Chi^2$ and Fisher's exact tests were used for testing associations.

Univariate and multivariate logistic models were fitted to assess the effect of several predictors on prompt and effective treatment, as defined below. Univariate analysis was done on all possible predictors on which data had been collected within the frame of the programme. For the multivariate models, predictors were chosen on the grounds of evidence from scientific literature, plausibility, as well as significance in the univariate analysis. Models were compared using the likelihood ratio test.

For this paper, the analysis was limited to children under the age of five and adolescents and adults over 12 years.

## *7.4 Results*

### 7.4.1 Study sample

During the cross-sectional community survey, 154 recent fever cases were included in the study (approximately 28% of all sampled households). 80 (52%) cases were in children under 5 years of age and 57 (37%) in adolescents and adults over 12 years. The *shamba* survey added another 29 children under 5 years and 28 adults over 12 years to the sample. Basic sample characteristics are summarized in Table 7.1.

**Table 7.1: 2004 Community survey sample characteristics (N=154)**

| Characteristics | 2004 community survey (N=154) | | 2005 *shamba* survey (N=66) | |
|---|---|---|---|---|
| | Freq. | Percentage | Freq. | Percentage |
| ***Age (years)*** | | | | |
| 0-4 | 80 | 51.9 | 29 | 43.9 |
| 5-9 | 12 | 7.8 | 6 | 9.1 |
| 10-19 | 14 | 9.1 | 5 | 7.6 |
| 20-29 | 11 | 7.1 | 13 | 19.7 |
| 30-39 | 16 | 10.4 | 9 | 13.6 |
| 40-49 | 12 | 7.8 | 2 | 3.0 |
| 50+ | 8 | 5.2 | 2 | 3.0 |
| ***Sex*** | | | | |
| Female | 85 | 55.2 | 30 | 45.5 |
| Male | 69 | 44.8 | 36 | 54.5 |

**Table 7.1 (continued)**

| | | | | |
|---|---|---|---|---|
| ***Residence*** | | | | |
| Ulanga DSS villages | 61 | 39.6 | 37 | 56.1 |
| Kilombero DSS villages | 49 | 31.8 | 29 | 43.9 |
| Ifakara | 44 | 28.6 | NA | NA |
| ***Religion (of caretaker if patient <12 years)*** | | | | |
| Muslim | 63 | 40.9 | 24 | 36.4 |
| Christian | 91 | 59.1 | 42 | 63.6 |
| ***Years of formal education (of caretaker if patient <12 years)*** | | | | |
| Mean (years) | 5.5 (95% CI 4.98, 5.96) | | 6.5 (95% CI 6.09, 6.94) | |
| Median (years) | 7 | 53.9 | 7 | 78.8 |
| ***Household income regular and dependable*** | | | | |
| Yes | 75 | 48.7 | 40 | 60.6 |
| Possibly | 18 | 11.7 | 3 | 4.6 |
| Uncertain | 16 | 10.4 | 8 | 12.1 |
| No | 45 | 29.2 | 15 | 22.7 |

### 7.4.2 Local understanding of febrile illness

The subsequent analysis of patterns of distress and perceived causes, all children under the age of five years (80+29) and adults over 12 years (57+28) were considered (194 in total).

Based on the illness labels given by the interviewees, the fever cases were classified into three illness categories that roughly correspond with biomedical malaria (Table 7.2):

- *malaria*
- *homa* (fever), and
- *degedege* (convulsions, usually known as illness of young children)

This classification is common in the population as has been described in detail in earlier qualitative studies from Tanzania (Makemba *et al.* 1996; Hausmann Muela 2000; Mayombana 2004). *Degedege*-labelled cases were relatively rare and hence less significant for this analysis. The two cases in adults which were labelled *degedege* were not included in the analysis. Patterns of distress (PD) and perceived causes (PC) were ranked according to their prominence in the interviewee's accounts

as described above. Similar PD and PC were grouped for analysis. A detailed list of PD and PC variables with prominence values can be found in the Appendix 2.

**Table 7.2: Illness labels for children under 5 years and adults over 12 years**

| Illness label | Children | | Adults | |
|---|---|---|---|---|
| | Freq. | Percentage | Freq. | Percentage |
| Malaria | 68 | 62.4 | 54 | 63.5 |
| Homa | 24 | 22.0 | 26 | 30.6 |
| Degedege | 8 | 7.3 | 2 | 2.4 |
| *Missing* | 9 | 8.3 | 3 | 3.5 |
| **Total** | **109** | | **85** | |

#### 7.4.2.1 Patterns of distress (PD)

In **children**, fever symptoms (hot head, hot body, etc.) were the most prominently mentioned symptoms, reflecting the fever-based case-definition. Signs and symptoms related to body strength were the second most prominently reported PD, with having “no strength” being significantly more prominent in the *malaria* compared to the *homa* category (P=0.023). Vomiting was also more prominent in the *malaria* compared to the *homa* category (P=0.033). It was more prominently reported than diarrhoea in all categories. Symptoms of convulsions (such as twitching, stiff body, “eyes turn white”, kicking of leg/arm, froth in the mouth, mouth twisted sideways, but also delirium, falling down, and being easily startled or frightened) were most prominent in the *degedege* category. Twitching was significantly more prominent in the *degedege* compared to the *malaria* (P=0.029) and the *homa* categories (P=0.022). Respiratory symptoms were less prominent in all categories (Figure 7.1). 68 (62.4%) cases showed one or several of the aforementioned signs of convulsions. Of these, 44 (61.1%) were labelled *malaria*, 15 (20.8%) *homa*, and 7 (9.7%) *degedege*, showing clearly that many caretakers make a link between convulsions and malaria.

In **adults** the same fever case definition applied as in child cases. Nevertheless, symptoms related to body strength or pain were more than or as prominent as fever. Specifically headache was prominent in both, the *homa* and the *malaria* categories. In the *homa* category, headache was considerably more prominent than “hot body”.

Diarrhoea and vomiting were equally frequent in the two categories. In both, nausea and vomiting were more prominent than diarrhoea. Difficult breathing or cough were less prominent in adults than in children. Convulsion-symptoms, such as twitching, etc. which are common in *degedege* in children were not probed – but also not mentioned spontaneously (Figure 7.1). Overall there was no clear difference between adult cases labelled *homa* and *malaria* with regard to reported PD.

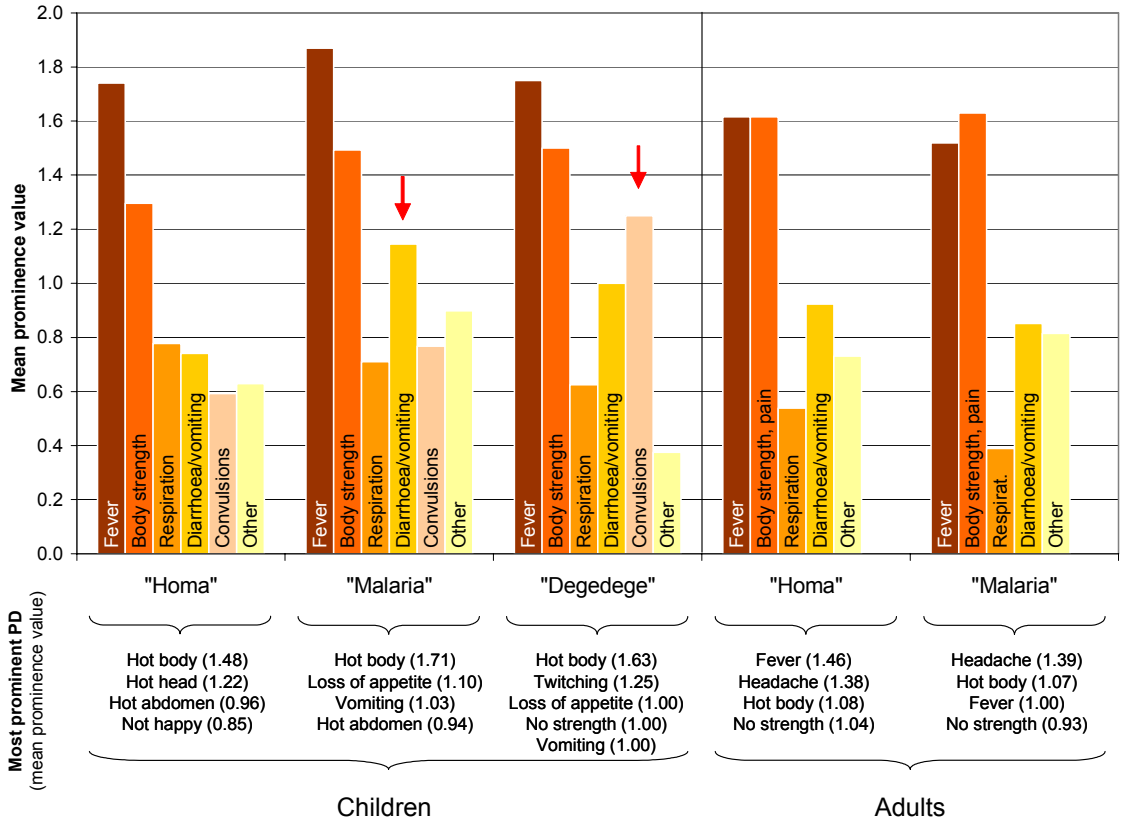


**Figure 7.1: Pattern of distress (PD) by illness category.**
Grouped (bars) and most prominent signs and symptoms.

### 7.4.2.2 Perceived causes (PC)

For cases in **children**, mosquito bites were the most prominent PC. Differences between *malaria, homa* and *degedege* categories were not statistically significant. Houseflies (*nzi*) were significantly more prominently mentioned in the *degedege* compared to the *malaria* category (P=0.027). A “bird or insect called *degedege*”, previously reported to be seen as a cause of *degedege* (Makemba *et al.* 1996) was not significantly associated with the *degedege* category or symptoms of convulsions.

PC related to fatigue, work, physical constitution were significantly more prominent in the *homa* than the *malaria* category (P=0.023), especially the illness being a "stage of child growth" (P=0.033). Cold weather as a cause was most prominent in the *homa*, and least prominent in the *malaria category* (P=0.044). Heat as well as cold weather, were the second most prominent PC in the *degedege* category, following mosquito bites. Supernatural causes (God, spirits, sorcery, etc.) were not mentioned very prominently altogether. However, in the *malaria* category, God was mentioned most prominently, just after “mosquito bites”. PC related to contamination, ingestion and diet were not very prominent in all categories (Figure 7.2).

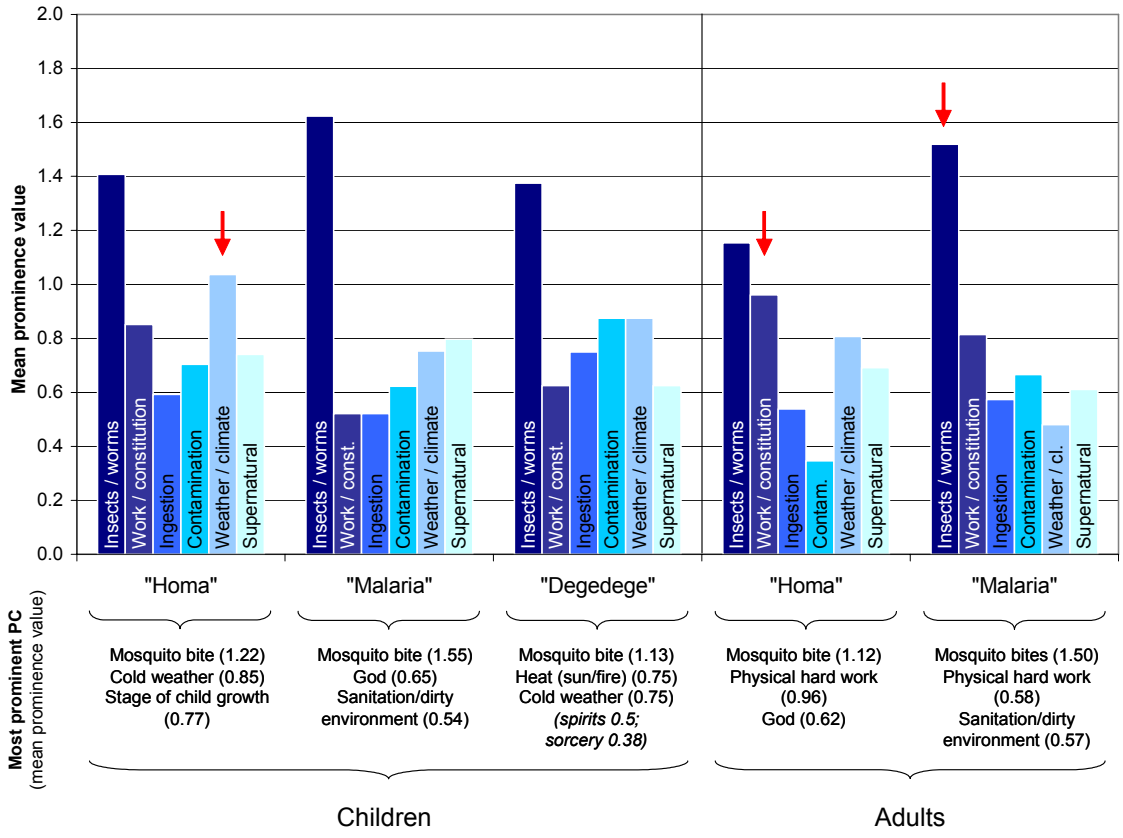


**Figure 7.2: Perceived causes (PC) by illness category.**
Grouped (bars) and most prominent PC.

Also in **adults**, mosquito bites were the most prominent PC in both, the *malaria* and the *homa* categories. In the *malaria* category, mosquito bites were mentioned more prominently although this was not quite statistically significant (P=0.062). Other insects were only rarely mentioned. Fatigue, work, physical constitution related PC were more prominent in the *homa* category. Physical hard work was more prominent

in the *homa* than the *malaria* category, with borderline significance (P=0.057). PC related to contamination, especially sanitation/dirty environment (P=0.030) were significantly more prominent in the *malaria* category (P=0.040). Weather/climate related PC were more prominent in the *homa* than the *malaria* category with borderline significance (P=0.057). Of all supernatural PC, God was mentioned most prominently with no significant difference between the categories. Ingestion/diet related causes were not prominently mentioned in either of the two categories (Figure 7.2).

### 7.4.3 Help seeking for fever episodes

The subsequent analysis of help seeking for a recent febrile illness episode was limited to the 2004 cross-sectional community survey data on 80 children under 5 and 57 adults over 12 years.

#### 7.4.3.1 First action and differences between illness labels

The most frequent first action taken by 79.0% (95% confidence interval [CI] 66.1-88.6) of adults and 80.0% (70.0-88.1) of caretakers of children was the administration of antipyretics (Figure 7.3). Antimalarials were clearly less often administered as first action, with no significant difference between children (42.5%, 31.5-54.1) and adults (52.6%, 39.0-66.0).

Even in child-cases labelled *malaria*, antipyretic administration (78.8%, 95% CI 65.3 to 88.9) was more frequent as first action than administration of antimalarials (48.1%, 34.0-62.4). Antimalarial administration was not significantly different between the illness labels or between cases with (44.7%, 29.9-59.4) or without convulsions (39.4%, 21.8-57.0). There was a significant difference between the areas of residence (P=0.007) with antimalarial being administered most frequently in Ulanga DSS (60%) and less frequently in Kilombero DSS (39%) and Ifakara (18%).

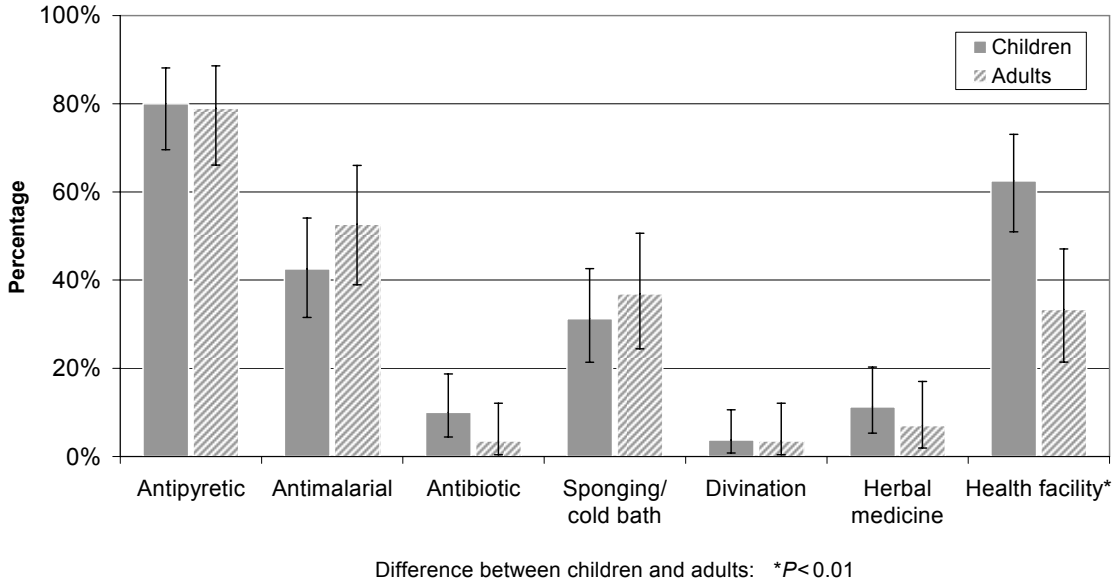


**Figure 7.3: First help-seeking action.**
Error bars represent 95% confidence intervals.

While also in adult cases, antipyretics were administered most frequently in both *homa* and *malaria* labelled cases, antimalarials were taken more frequently for *malaria* than for *homa* (P=0.028). The opposite was the case for antipyretics (P=0.039).

Health facility attendance was the second most frequently mentioned first action for children (62.5%, 51.0-73.1), and this was significantly different from adult cases (33.3%, 21.4-47.1; P=0.001). Adults visited clearly less frequently a health facility than they used antipyretics or antimalarials. While health facility visits of children did not differ between the two districts or Ifakara, significantly more adults went to a health facility in Ifakara than in the DSS villages of Kilombero (P=0.041). In terms of health facility attendance rates, no significant difference was seen between the illness labels.

Cooling one's body through sponging or a cold bath was mentioned for over 30% of children and adults. For adults, a cold bath or shower was significantly more frequent in the *malaria* (51.4%, 34.0-68.6) than the *homa* (10.5%, 1.3-33.1) category (P=0.003).

Traditional medicine or divination was not common in children (11.3%, 5.3-20.3) and adults (7.0%, 2.0-17.0), but in children herbal medicine was significantly more often given to cases of *degedege* than to *homa* or *malaria* (P=0.02).

#### 7.4.3.2 Expenditures for antimalarials

Information on expenditures for antimalarial drugs was available for 70 children and 46 adults who had received an antimalarial. Expenditures for patients exclusively attending either a health facility or a drug store are presented in Table 7.3. Children and adults paid similar prices in health facilities and in drug stores. Although children should be treated free of charge in government health facilities, they paid on average 540 Tanzanian Shilling (Tsh) (median price, interquartile range [IQR] 0-1100 Tsh) for antimalarial medicine obtained in health facilities. It was not possible to distinguish between private and public health facilities in this analysis. However, in households from villages without a private health facility, child treatments from health facilities were not significantly cheaper, suggesting that exemption mechanisms were indeed not properly implemented. Quinine (median price Tsh 570, IQR 0-1100) was sold frequently and was on average more expensive than SP (Tsh 300, IQR 0-500), contributing substantially to total drug expenditures.

**Table 7.3: Expenditures for antimalarials in health facilities and general shops (in TSh). US $1 = Tsh. 1,117 (July 2004)***

| | Children | | | Adults | | |
|---|---|---|---|---|---|---|
| | **n** | **Median expenditure (IQR)** | **Range** | **n** | **Median expenditure (IQR)** | **Range** |
| Health facility | 35 | 540 (0-1100) | 0 to 3000 | 15 | 500 (200-700) | 0 to 2700 |
| Drug store | 16 | 600 (400-900) | 0 to 3600 | 21 | 540 (400-800) | 60 to 2000 |

* OANDA currency website (www.oanda.com)

IQR = Interquartile range

### 7.4.4 Access to treatment and community effectiveness

In order to estimate community effectiveness, a range of key indicators of access to malaria treatment were assessed (Table 7.4).

Overall, an almost 100% usage of biomedical treatment was noted in adults and children. Antimalarial administration to children was common (88.8%) with the majority receiving quinine (53.8%). 34.9% of the children who received quinine, were given an injection or infusion. Less than half of the children and adults received the first-line drug SP. 28.8% (95% CI 19.2-40.0) of the children and 12.3% (5.1-23.7) of the adults were treated with more than one product, usually with two (P=0.022).

Few episodes were treated with an antipyretic only, or with an antibiotic. Overall, children (76.3%, 65.4-85.1) were significantly more often brought to a health facility than adults (56.1%, 42.4-69.3; P=0.013). Children (53.8%, 42.2-65.0) were also more likely to receive their antimalarial from a health facility than adults(29.8%, 18.4-43.4; P=0.005). Adults on the other hand opted significantly more frequently for non-exclusive (P=0.04) or exclusive (P=0.055) home-management with antimalarials than children. Generally, drug stores were the most important source for home-treatment and adults were more likely to get their antimalarials from drug stores than children (P=0.007). However, of the 57 children who were brought to a health facility and received an antimalarial, 24.6% obtained the drugs from a source other than the facility.

**Table 7.4: Key indicators for help seeking and access to malaria treatment in individuals with fever in the preceding two weeks**

| Indicator | Children | | | | Adults | | | P |
|---|---|---|---|---|---|---|---|---|
| | n | % | 95% CI | TDHS[2] | n | % | 95% CI | |
| N | 80 | | | | 57 | | | |
| Episodes treated | 80 | 100 | 95.5-100 | | 57 | 100 | 93.7-100 | |
| ***Medications:*** [1] | | | | | | | | |
| Modern medicine | 80 | 100 | 95.5-100 | | 56 | 98.3 | 90.6-100 | 0.416* |
| Antimalarial drug (AM) | 71 | 88.8 | 79.7-94.7 | 58.2 (88.6) | 47 | 82.5 | 70.1-91.3 | 0.293§ |
| - SP | 38 | 47.5 | 36.2-59.0 | 23.7 (33.8) | 25 | 43.9 | 30.7-57.6 | 0.673§ |
| - amodiaquine | 10 | 12.5 | 6.2-21.8 | 22.1 (29.3) | 5 | 8.8 | 2.9-19.3 | 0.491§ |
| - quinine | 43 | 53.8 | 42.2-65.0 | 11.9 (23.5) | 23 | 40.4 | 27.6-54.2 | 0.122§ |
| - other AM | 2 | 2.5 | 0.3-8.7 | | 1 | 1.8 | 0.0-9.4 | 1.000* |
| Antipyretic only | 9 | 11.3 | 5.3-20.3 | | 9 | 15.8 | 7.5-27.9 | 0.438§ |
| Antibiotic | 8 | 10.0 | 4.4-18.8 | | 2 | 3.5 | 0.4-12.1 | 0.194* |
| ***Treatment sources:*** [1] | | | | | | | | |
| Health facility visit | 61 | 76.3 | 65.4-85.1 | | 32 | 56.1 | 42.4-69.3 | **0.013**§ |
| AM from health facility | 43 | 53.8 | 42.2-65.0 | | 17 | 29.8 | 18.4-43.4 | **0.005**§ |
| AM not from health facility | 28 | 35.0 | 24.7-46.5 | | 30 | 52.6 | 39.0-66.0 | **0.040**§ |
| AM from drug store | 19 | 23.8 | 15.0-34.6 | | 26 | 45.6 | 32.4-59.3 | **0.007**§ |
| AM from general shop | 8 | 10.0 | 4.4-18.8 | | 4 | 7.0 | 2.0-17.0 | 0.761* |
| AM from home stock (or relative/neighbour) | 10 | 12.5 | 6.2-21.8 | | 6 | 10.5 | 4.0-21.5 | 0.723§ |
| Exclusive home-management with AM[3] | 14 | 17.5 | 9.9-27.6 | | 18 | 31.6 | 19.9-45.2 | 0.055§ |
| ***Delay in first (immediate) help-seeking:*** | | | | | | | | |
| Antipyretic on day 1 | 51 | 79.7 | 67.8-88.7 | | 32 | 71.1 | 55.7-83.6 | 0.301§ |
| AM on day 1 | 16 | 47.1 | 29.8-64.9 | | 15 | 50.0 | 31.3-68.7 | 0.814§ |
| Health facility on day 1 | 24 | 48.0 | 33.7-62.6 | | 5 | 26.3 | 9.2-51.2 | 0.103§ |

[1]One episode may be treated with several drugs from various sources; [2]Tanzania Demographic and Health Survey 2004-05 (data for Morogoro Region in brackets); [3]Episodes never brought to a health facility; *Fisher's exact test; §Chi-square test

Generally, antipyretics were used more promptly than antimalarials in children and adult cases. Antipyretic use was also quicker than visits to a health facility. For the first actions taken, there was no significant difference between the delay observed in children and adult cases. However, for overall antimalarial use, 76.3% (65.4-85.1) of the children received an antimalarial on the day the fever started or the day after, while only 56.1% (42.4-69.3) of adults took the medication within that period (P=0.013). If adjusted for age class (adult/child), those who had their antimalarial from a health facility were more likely to receive it on the day the illness started (P=0.004).

#### 7.4.4.1 Community effectiveness

Effectiveness of malaria treatment does not only depend on drug efficacy, but to a large extend on wide coverage and timely access to the drugs, provider compliance with treatment guidelines and adherence to the correct dosage by the patient.

The access indicators measured in this research allowed an estimation of community effectiveness of malaria treatment which is shown in Figure 7.4. The main indicators shown in the figure (and explained below), illustrate clearly how dramatically community effectiveness is reduced because of weaknesses in the treatment chain..

1. **Use of a recommended antimalarial (SP, amodiaquine or quinine) ④**
   87.5% (78.2-93.8) of children and 80.7% (68.1-90.0) of adults received one of the antimalarials recommended by the national guidelines (MOH 2000).
2. **Use of a recommended antimalarial on the same or next day ⑤**
   72.5% (61.4-81.9) of children and 56.1% (42.4-69.3) of adults received the recommended antimalarial on the day of onset of the symptoms or the day after.
3. **Use of a correctly dosed recommended antimalarial on the same or next day ⑥**
   42.5% (31.5-54.1) of children and 36.8% (24.4-50.7) of adults received the timely administered antimalarial in the recommended dose. Dosage was assessed based on what people reported to have taken or administered to the

child. Due to a lack of detailed information, it was assumed that all injections were correctly dosed. Most wrong dosages were under-dosages.

4. **Use of a correctly dosed antimalarial, appropriate considering the reported symptoms, on the same or next day ⑦**

   22.5% (13.9-33.2) of children and 10.5% (4.0-21.5) of adults received timely treatment with correctly dosed SP or amodiaquine for reported symptoms of uncomplicated malaria and quinine if severe symptoms (incl. difficult breathing, yellow eyes, convulsions, delirium (MOH 2000; Mackintosh *et al.* 2004)) were reported.

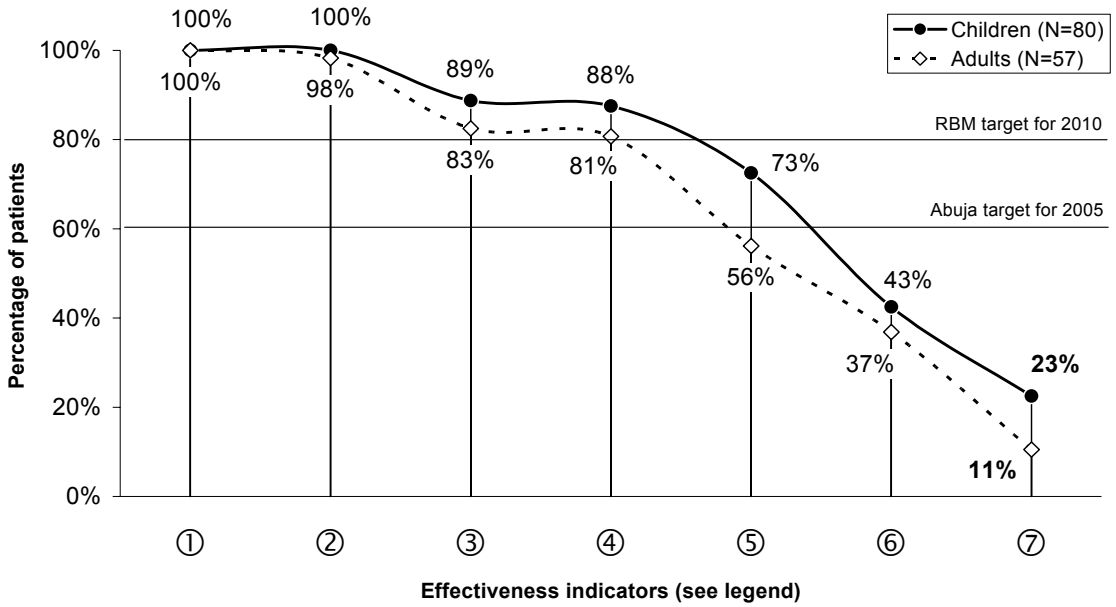


**Figure 7.4: Estimated effectiveness of fever treatment modelled based on patients' or caretakers' accounts.**

**Legend:**

① Episode treated
② Drug administered
③ Antimalarial administered
④ Recommended antimalarial
⑤ Recommended antimalarial on same or next day
⑥ Recommended antimalarial on same/next day, in correct dose
⑦ Recommended antimalarial on same/next day, correct dosage, considering reported symptoms

In this study, antimalarial usage rates reached a satisfactory level of over 80%. However, mere usage rates are misleading. If drug dosage, delay, and reported signs and symptoms were taken into account, treatment effectiveness reached only 11% and 23% for adults and children, respectively.

#### 7.4.4.2 Factors related to prompt and effective treatment

Three multivariate logistic models were fitted to assess predictors for the administration of a recommended antimalarial, as well as for timely and correctly dosed treatment (Figure 7.5). Models were fitted once for the DSS only and once for both the DSS and Ifakara households. Spatial information and SES were only available for the DSS households.

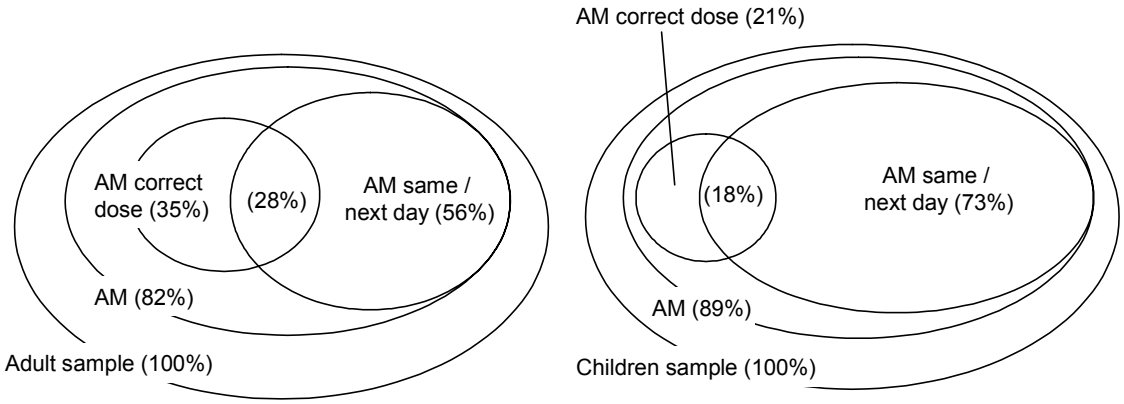


**Figure 7.5: Graphical illustration of treatment indicators assessed in the multivariate models***

* Circles are roughly proportional to the percentage of patients. AM = antimalarial

The model assessing predictors for a recommended antimalarial in DSS households revealed that labelling the illness as a *homa* (fever) (OR=0.08, 95% CI 0.02-0.32), administration of traditional herbal medicine as first action (OR=0.08, 0.01-0.58) and the total number of people in the household (OR=0.78, 0.63-0.96) decreased the odds of receiving a recommended antimalarial. On the other hand, attending a health facility during the course of the illness (OR=8.09, 1.92-34.12) increased the odds of receiving a recommended antimalarial (Table 7.5). If this model was fitted with DSS and Ifakara households, only the effects of the *homa*-label and the number of people in the household were retained. In the univariate analysis, recognising the illness in

the fields (*shamba*) and increased distance to the nearest antimalarial provider were also significantly correlated with less antimalarial administration, while reported diarrhoea or vomiting significantly increased the odds. Episodes in DSS households were less likely to receive a recommended antimalarial than those in Ifakara.

The second model assessed predictors for timely treatment (i.e. on the day of illness onset or the day after) among all those receiving an antimalarial. None of the plausible predictors was significantly correlated with the outcome, with the exception of number of people in the household, which decreased the odds of receiving an antimalarial promptly (OR=0.81, 0.66-0.98). Neither the age of the patient, nor the distance to the nearest provider, nor prior treatment with other medicine was found to significantly predict the outcome (Table 7.6).

The third model assessed predictors for correct dosage among those receiving SP or amodiaquine. This analysis did not consider quinine, as it was not possible to establish the accuracy of the dosage of quinine injections. It resulted that compared to adults, children's odds of receiving the correct dose was significantly decreased (OR=0.26, 0.09-0.81). Cases from DSS households were more likely to receive a correctly dosed drug than those from Ifakara (OR=4.69, 1.26-17.43) (Table 7.7).

**Table 7.5: Univariate and multivariate analyses of predictors for administration of a recommended antimalarial (SP, amodiaquine or quinine)**

| | Univariate model* | | | Multivariate model** | | |
|---|---|---|---|---|---|---|
| **Exposure variable** | **Crude OR** | **95% CI** | **P** | **Adjusted OR** | **95% CI** | **P** |
| **Age group** | | | | | | |
| Adult | 1 | | | 1 | | |
| Child | 1.67 | 0.66-4.26 | 0.280 | 0.65 | 0.12-3.57 | 0.619 |
| **Total number of people in household** | 0.85 | 0.73-0.99 | 0.041 | **0.78** | **0.63-0.96** | **0.022** |
| **Place of illness recognition** | | | | | | |
| Home | 1 | | | 1 | | |
| Shamba | 0.19 | 0.07-0.51 | 0.001 | 0.29 | 0.07-1.25 | 0.096 |
| **Diarrhoea or vomiting reported** | | | | | | |
| No | 1 | | | 1 | | |
| Yes | 5.05 | 1.73-14.74 | 0.003 | 4.03 | 0.90-18.03 | 0.069 |
| **Signs of severe malaria** | | | | | | |
| No | | | | | | |
| Yes | 2.48 | 0.78-7.88 | 0.125 | 2.84 | 0.44-18.28 | 0.272 |
| **Illness label (self-defined)** | | | | | | |
| Malaria/ degedege | 1 | | | 1 | | |
| Homa | 0.10 | 0.04-0.29 | 0.000 | **0.08** | **0.02-0.32** | **<0.001** |
| **First action: Antipyretic** | | | | | | |
| No | 1 | | | 1 | | |
| Yes | 0.61 | 0.17-2.23 | 0.451 | 1.43 | 0.22-9.34 | 0.706 |
| **First action: Traditional medicine** | | | | | | |
| No | 1 | | | 1 | | |
| Yes | 0.24 | 0.07-0.81 | 0.022 | **0.08** | **0.01-0.58** | **0.012** |
| **Health facility attendance** | | | | | | |
| No | 1 | | | 1 | | |
| Yes | 4.46 | 1.69-11.78 | 0.003 | **8.09** | **1.92-34.12** | **0.004** |
| **Antimalarial provider in village[1]** | | | | | | |
| No | 1 | | | 1 | | |
| Yes | 2.10 | 0.67-6.59 | 0.201 | 1.02 | 0.14-7.34 | 0.981 |
| **Distance to nearest AM provider (km)***[/1]** | 0.01 | 0.00-0.43 | 0.017 | | | |
| **Study area** | | | | | | |
| Ifakara | 1 | | | | | |
| DSS | 0.22 | 0.05-0.98 | 0.046 | | | |

* 137 observations; ** 136 observations; *** 76 observations; [1] Incl. health facilities, drug stores and general shops stocking antimalarials in mid-2004; AM = antimalarial

**Table 7.6: Univariate and multivariate analyses of predictors for timely administration of a recommended antimalarial (on the day of illness onset or the day after)**

| Exposure variable | Univariate model* | | | Multivariate model** | | |
|---|---|---|---|---|---|---|
| | Crude OR | 95% CI | P | Adjusted OR | 95% CI | P |
| **Age group** | | | | | | |
| Adult | 1 | | | 1 | | |
| Child | 2.11 | 0.87-5.12 | 0.097 | 1.91 | 0.69-5.31 | 0.215 |
| **Total number of people in household** | 0.81 | 0.68-0.96 | 0.014 | **0.81** | **0.66-0.98** | **0.032** |
| **Place of illness recognition** | | | | | | |
| Home | 1 | | | 1 | | |
| Shamba | 0.62 | 0.21-1.83 | 0.387 | 0.88 | 0.26-2.98 | 0.835 |
| **Diarrhoea or vomiting reported** | | | | | | |
| No | 1 | | | | | |
| Yes | 1.21 | 0.50-2.93 | 0.677 | 1.19 | 0.43-3.29 | 0.742 |
| **Illness label (self-defined)** | | | | | | |
| Malaria/degedege | 1 | | | 1 | | |
| Homa | 1.79 | 0.48-6.64 | 0.387 | 2.16 | 0.53-8.79 | 0.283 |
| **First action: Antipyretic** | | | | | | |
| No | 1 | | | 1 | | |
| Yes | 0.83 | 0.28-2.49 | 0.744 | 0.81 | 0.24-2.71 | 0.736 |
| **First action: Traditional medicine** | | | | | | |
| No | 1 | | | 1 | | |
| Yes | 0.45 | 0.10-2.03 | 0.299 | 0.36 | 0.07-1.87 | 0.225 |
| **Health facility attendance** | | | | | | |
| No | 1 | | | 1 | | |
| Yes | 1.29 | 0.50-3.37 | 0.597 | 1.61 | 0.55-4.77 | 0.386 |
| **Antimalarial provider in village**[1] | | | | | | |
| No | 1 | | | 1 | | |
| Yes | 0.85 | 0.22-3.26 | 0.810 | 0.66 | 0.15-2.91 | 0.587 |
| **Distance to nearest AM provider (km)*****/1** | 0.10 | 0-18.57 | 0.382 | | | |
| **Type of nearest provider*** ** | | | | | | |
| Shop | 1 | | | | | |
| Health facility | 1.66 | 0.44-6.20 | 0.453 | | | |
| **Antimalarial source: Health facility** | | | | | | |
| No | 1 | | | | | |
| Yes | 1.33 | 0.56-3.20 | 0.520 | | | |
| **Antimalarial source: Shop or home** | | | | | | |
| No | 1 | | | | | |
| Yes | 0.75 | 0.31-1.80 | 0.519 | | | |

* 116 observations; ** 115 observations; ***616 observations; [1] Incl. health facilities, drug stores and general shops stocking antimalarials in mid-2004; AM = antimalarial

**Table 7.7: Univariate and multivariate analyses of predictors for correct dosage of SP or amodiaquine**

| | Univariate model* | | | Multivariate model* | | |
|---|---|---|---|---|---|---|
| **Exposure variable** | **Crude OR** | **95% CI** | **P** | **Adjusted OR** | **95% CI** | **P** |
| **Age group** | | | | | | |
| Adult | 1 | | | 1 | | |
| Child | 0.26 | 0.10-0.71 | 0.008 | 0.26 | 0.09-0.81 | 0.019 |
| **Sex of patient** | | | | | | |
| Female | 1 | | | 1 | | |
| Male | 0.77 | 0.31-1.90 | 0.563 | 0.86 | 0.29-2.54 | 0.787 |
| **Total number of people in household** | 1.07 | 0.90-1.27 | 0.444 | | | |
| **Education of patient/caretaker (years)** | 1.06 | 0.92-1.22 | 0.392 | 1.06 | 0.91-1.23 | 0.483 |
| **Place of illness recognition** | | | | | | |
| Home | 1 | | | | | |
| Shamba | 1.39 | 0.48-4.03 | 0.546 | | | |
| **Diarrhoea or vomiting reported** | | | | | | |
| No | 1 | | | | | |
| Yes | 0.69 | 0.27-1.73 | 0.424 | | | |
| **Illness label (self-defined)** | | | | | | |
| Malaria/ degedege | 1 | | | | | |
| Homa | 0.88 | 0.28-2.72 | 0.817 | | | |
| **Health facility attendance** | | | | | | |
| No | 1 | | | 1 | | |
| Yes | 0.49 | 0.18-1.38 | 0.178 | 1.13 | 0.22-5.73 | 0.886 |
| **Antimalarial source: Health facility** | | | | | | |
| No | 1 | | | | | |
| Yes | 0.55 | 0.22-1.39 | 0.207 | 0.46 | 0.11-2.01 | 0.305 |
| **Study area** | | | | | | |
| Ifakara | 1 | | | 1 | | |
| DSS | 3.01 | 1.01-9.01 | 0.048 | 4.69 | 1.26-17.43 | 0.021 |

* 75 observations

## *7.5 Discussion*

Access to prompt and effective malaria treatment can be investigated using different approaches. Depending on the perspective, the focus may be laid on the patient's behaviour, the health system performance or the livelihood context; or, the three approaches may be combined, as elaborated by Obrist *et al.* (2007). This paper assessed treatment effectiveness mainly from the perspective of the patients. It considered only patients who recovered from their febrile illness. The results are from studies with a limited sample size, carried out in two districts with a long history of malaria-control and research activities. This needs to be considered when making inferences to other areas. However, the analysis revealed some important issues for the development of future malaria control strategies.

The reliance on patients' or caretakers' accounts can result in misdiagnosis and misreporting. However, many illness episodes brought to rural health facilities are diagnosed based on the patient's or caretaker's reported symptoms rather than by proper clinical assessment and laboratory test (Font *et al.* 2001; Eriksen *et al.* 2007). Even the Integrated Management of Childhood Illness (IMCI) strategy which is implemented in the study districts advocates exclusive clinical assessment of patients in rural dispensaries in the absence of reliable diagnostic tools (WHO 1997). And more importantly, it is the patient's perceived ill-health that triggers help-seeking, rather than a parasitological test or clinical diagnosis (McCombie 2002).

It has been recognised fro a long time that understanding of malaria by the community as an illness which can be treated with modern medicine will determine successful implementation of effective case-management (WHO 1993). This research tried for a first time to quantify the distribution of reported signs and symptoms as well as perceived causes in relation to local illness labels. Different illness concepts that relate to malaria in Tanzania have been described in detail and special attention has been paid to *degedege*, a febrile convulsive illness often related to severe malaria. The concept of *degedege* was traditionally linked to spirits in the form of a bird or a moth and mainly herbal treatment would be administered by traditional healers (Makemba *et al.* 1996; Oberländer & Elverdan 2000). In our studies, fevers with convulsions were in most cases labelled *malaria* rather than

*degedege*. Studies done between 1995 and 1997 in the same area found that concepts of *degedege* and *malaria* were fuzzy; while *degedege* may have been seen as a cause of severe malaria, only mild malaria would be related to mosquito bites (Minja *et al.* 2001; Hausmann Muela *et al.* 2002). In 2004 a clear change could be noticed with mosquito bites being the most prominently mentioned perceived cause, also in cases with convulsions or those labelled *degedege*. A more comprehensive analysis of *degedege* in particular is currently in preparation (citation?).

In contrast to *degedege* which would be considered a severe and dangerous illness (Hausmann Muela *et al.* 2002), *homa* (usually translated as "fever") was often regarded as a normal stage in child growth or was attributed to weather conditions. *Homa* was a febrile illness without vomiting or other more severe symptoms. Very similar findings have been reported from different areas in Tanzania (Mayombana 2004). While for *homa* and *malaria* different symptoms were reported in children, this was not the case in adults where headache was predominant for both labels. Adult *malaria* was attributed to mosquito bites or a dirty environment while *homa* was rather seen as caused by weather conditions or hard work. Overall it appeared that *malaria* was most prominently associated with mosquitoes whereas *homa* was more often attributed to other causes as well. In earlier studies, *homa* has been described as a label for general malaise and aches, sometimes even in absence of fever (Winch *et al.* 1996; Hausmann Muela *et al.* 1998), which may to some extent explain why fever as a symptom was not most prominent in all *homa* cases. The implications local illness labels may have were uncovered by the risk-factor analysis: Those cases labelled *homa* were more than 12 times (OR=0.08, 0.02-0.32) less likely to receive an antimalarial than cases labelled malaria or degedege.

A large overlap of the popular and biomedical concepts of malaria can be seen in part as a consequence and success of regular and intensive health education campaigns in the area, from the national "Mtu ni Afya" (Man is Health) campaign in the late 1970s (Hausmann Muela 2000) to the intensive KINET social marketing in the 1990s (Armstrong Schellenberg *et al.* 1999; Minja *et al.* 2001). Nevertheless, factual knowledge does not necessarily translate directly into improved behaviour, as

described by Hausmann *et al.* (2002). This is particularly true, since appropriate care-seeking depends on several factors other than illness understanding.

In contrast to what has been reported from earlier studies and other areas (von Seidlein *et al.* 2002; Amin *et al.* 2003; Nsungwa-Sabiiti *et al.* 2005), no fever episode remained untreated and antimalarial administration was very common. Even cases with convulsions (labelled *degedege* or *malaria*) were frequently treated with antimalarials (44.7% first action, overall 91.5%) and more rarely with traditional herbal medicine (17% first action). This is a major improvement in treatment seeking compared to the reported 35% herbal medicine and 2% antimalarial for *degedege* in 1995-97 (Hausmann Muela 2000). It confirms from a different angle what has been found by de Savigny *et al.* (2004b) who reported 78.7% first use of biomedical care for cases of fatal malaria in Tanzania. Considering that first treatment with herbal medicine was correlated with less antimalarial use (OR 0.08, 0.01-0.58), discouraging herbal treatment may help to increase treatment with antimalarials.

The first action taken was most frequently the use of an antipyretic and episodes considered to be *homa* were more likely to be treated with antipyretics only. Home-management with antimalarials was not very common, especially for children. This reflects the fact that antimalarials are nowadays less readily available in shops (Hetzel *et al.* 2006) and that Tanzania is not actively promoting home-based management of malaria. Adult episodes were more frequently treated with antimalarials from the private sector while 76% of the cases in children were brought to a health facility. Under the given circumstances, health facility attendance is desirable, especially for young children. Severe diseases other than malaria, e.g. pneumonia or meningitis, may anyway be detected and treated only in health facilities.

Attending a health facility during the course of the illness was associated with more use of a recommended antimalarial (OR=8.09, 1.92-34.12). However, the proportion of people receiving an appropriate antimalarial timely and correctly dosed (11% and 23% for adults and children, respectively) as an approximation for community effectiveness was too low and too far from the 80% target set by the RBM Partnership for 2010 (RBM Partnership 2005). It also puts into perspective the

indicator used in the 2004/5 demographic and health survey which reported 51.1% use of a recommended antimalarial on the same or next day for Tanzania and 82.7% for Morogoro Region (National Bureau of Statistics 2005)

Attending a health facility or obtaining the antimalarial from there was not associated with more appropriate drug dosage. More than half of the SP dosages from health facilities were incorrect considering the reported age of the patient. Children were almost four times less likely to receive an appropriate dose of SP or amodiaquine (OR=0.26, 0.09-0.81). Although this may in part be attributed to lack of provider compliance, poor patient adherence or reporting errors, quality of care seems to need considerable improvement. Limiting antimalarial sales largely to health facilities and drug stores (Hetzel *et al.* 2006) did apparently not result in an acceptable quality of case-management. The effect of the number of people in a household on (timely) antimalarial treatment may be a chance finding or related to intra-household relations (Molyneux *et al.* 2002). Yet it may also reflect that in larger families, child care is often delegated from parents to older siblings who may not well know how to handle an illness episode. In families with more children (or in addition old people), caretakers may be more busy and have less time devote to each one.

In this context it is worth considering that all estimates presented here did explicitly exclude the issue of drug efficacy, while actual efficacy of SP in children in nearby Mlimba village was reported to be only 65.7% (adequate clinical and parasitological response at day 28) (Mugittu *et al.* 2005). Furthermore, 24 % of SP tablets and 40 % of quinine sulphate tablets collected in the study area did not meet USP specifications for the amount of active ingredient and were mostly under-dosed (Braun 2005; Hetzel *et al.* 2007c). Adding this into an effectiveness-model would result in even lower levels of community effectiveness than reported here.

25% of child episodes seen at a health facility were treated with a shop-bought antimalarial. Since children under the age of 5 years are formally exempted from any charges at public health facilities (including for drugs), it would be desirable that they obtain their antimalarial from there. It might have been expected that resorting to the commercial sector for cases of childhood fevers would pose an additional and unnecessary burden on poor households since in the private sector no exemption

policy applies. Njau *et al.* reported significantly higher spending in drug stores (but not general shops) compared to government health facilities (Njau *et al.* 2006). However, data from this study suggests that in reality the exemption system was not functioning and that expenditures for drugs did not significantly differ between health facilities and drug stores. Treating a child in the private retail sector may even have been cheaper, since shops were closer to people's homes, resulting in lower secondary costs for time and transport. This may result in higher facility usage and possibly more use of antimalarials by richer households, as has been reported elsewhere (Armstrong Schellenberg *et al.* 2003). This link could however not be proven in our study. An additional problem were stock-outs of SP, amodiaquine, and quinine which were repeatedly observed in the study area (Dillip *et al.* 2007). Patients may therefore be forced to purchase medicines in the commercial sector which consequently plays a pivotal role in providing life-saving drugs in the case of delivery-failure of formal health facilities.

In the ongoing process of rolling out highly efficacious Artemisinin-based combination therapy (ACT), special attention will have to be paid to the quality of prescription in formal health facilities, the ability and willingness of patients to comply with the treatment regimen, as well as to the channels through which these drugs are brought to the patients. It needs to be closely monitored whether restricting ACT to the formal health sector will result in increased community effectiveness (timely administration of correctly dosed ACT to all those in need) or in a decrease in treatment rates without an improvement in the administered drug regimens.

## *7.6 Conclusion*

The local understanding of the biomedical concept of (mild and severe) malaria has improved after decades of continuous health education. Further education may have to focus on clear messages on how, when and where to treat a febrile illness instead of merely reiterating illness models. Availability of antimalarials has been largely limited to certified providers and health facility usage was very popular. Nevertheless, the quality of case-management was far from satisfactory. Decreased drug efficacy and sub-standard drug quality may have further decreased effectiveness at community level. Exemption mechanisms aim to facilitate treatment access for poor

and vulnerable groups but in our setting they did not seem to be properly implemented. Private drug retailers play a central role in the provision of timely malaria treatment, complementing the existing formal health services. All these issues can be attributed to a health system which is still too weak to deliver a growing number of increasingly complex health interventions. Such systems constraints need to be tackled urgently with an increased investment in the local health system in order to translate the high efficacy of newly introduced ACT into equitable community-effectiveness and health-impact.

## *7.7 Competing interests*

We, the authors, declare that we have no competing interests.

## *7.8 Authors' contributions*

MWH was involved in the design and implementation of the studies, analysed and interpreted the data and wrote the manuscript. BO and CL conceived the studies and contributed to the interpretation and discussion of the manuscript. JJM developed the EMIC together with BO and MWH, and was responsible for its implementation. RN was in charge of all DSS-related activities. AD contributed to the analysis of the data. AM and CM provided support in the field and contributed to the discussion of the findings. AS and HM contributed to the design of the study and to the discussion of the manuscript.

## *7.9 Acknowledgements*

Our sincere thanks go to the interviewees in the community and to the field interviewers of the DSS and ACCESS who did the EMIC interviews - *asanteni sana!* We much appreciated the help and collaboration of community leaders who facilitated our field-work. Special thanks to our research assistant Iddy Mayumana and to Goodluck John who supervised the field-work. Many thanks to the IHRDC data unit, and to Hilda Mwabukusi, who entered the questionnaires. We greatly acknowledge the inputs of Mitchell Weiss on the design and analysis of the EMIC. We also thank Tom Smith and Laura Gosoniu for statistical advice and the provision

of household GPS and SES data and Sandra Alba for general comments on the manuscript. This paper was published with the permission of Dr. Andrew Kitua, Director-General, National Institute for Medical Research. Funding for this research was provided by the Novartis Foundation for Sustainable Development.

# 8 MALARIA RISK AND ACCESS TO PREVENTION AND TREATMENT IN THE PADDIES OF THE KILOMBERO VALLEY, TANZANIA

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This paper has been accepted for publication in the
*Malaria Journal*

## *8.1 Abstract*


### 8.1.1 Background

The Kilombero Valley is a highly malaria-endemic agricultural area in south-eastern Tanzania. Seasonal flooding of the valley is favourable to malaria transmission. During the farming season, many households move to distant field sites (*shamba* in Swahili) in the fertile river floodplain for the cultivation of rice. In the *shamba*, people live for several months in temporary shelters, far from the nearest health services. This study assessed the impact of seasonal movements to remote fields on malaria risk and treatment seeking behaviour.

### 8.1.2 Methods

A longitudinal study followed approximately 100 randomly selected farming households over six months. Every household was visited monthly and whereabouts of household members, activities in the fields, fever cases and treatment seeking for recent fever episodes were recorded.

### 8.1.3 Results

Fever incidence rates were lower in the *shamba* compared to the villages and moving to the *shamba* did not increase the risk of having a fever episode. Children aged 1-4 years, who usually spend a considerable amount of time in the *shamba* with their caretakers, were more likely to have a fever than adults (OR=4.47, 95% CI 2.35-8.51). Protection with mosquito nets in the fields was extremely good (98% usage) but home-stocking of antimalarials was uncommon. Despite the long distances to health services, 55.8% (37.9-72.8) of the fever episodes were treated at a health facility, while home-management was less common (37%, 17.4-50.5).

### 8.1.4 Conclusions

Living in the *shamba* does not appear to result in a higher fever-risk. Mosquito nets usage and treatment of fever in health facilities reflect awareness of malaria. Inability to obtain drugs in the fields may contribute to less irrational use of drugs but may pose an additional burden on poor farming households. A comprehensive approach is needed to improve access to treatment while at the same time assuring rational use of medicines and protecting fragile livelihoods.

## 8.2 Background

Malaria continues to be a major public health problem, particularly for young children in sub-Saharan Africa (Lopez *et al.* 2006). Malaria has often been linked with agricultural practices, especially irrigation. Environmental management, such as well-designed irrigation schemes have been proposed as one of the means for reducing the burden of malaria in agricultural settings (van der Hoek 2004; Keiser *et al.* 2005).

Research on malaria risk related to farming activities has so far mainly focused on vector abundance and malaria transmission in areas with artificial irrigation (Ijumba *et al.* 2002a; Sissoko *et al.* 2004; Diuk-Wasser *et al.* 2007). Linkages between malaria and agriculture were found to be complex and specific to the local setting. Cultivation of rice may encourage the proliferation of malaria-transmitting *Anopheles* mosquitoes (Sogoba *et al.* 2007; Diuk-Wasser *et al.* 2007). Yet, due to lower density of human hosts in the fields in some areas, or zoophilic feeding behaviour of some vector species in others (Mutero *et al.* 2004), an increase in the number of mosquitoes does not necessarily translate into higher parasite prevalence in the human population. Research done in northern Tanzania reported lower malaria transmission in villages with irrigated crop production compared to adjacent savannah villages without irrigation. This was attributed to a higher standard of living and better health care in the studied irrigation schemes and has been referred to as the “paddies paradox” (Ijumba *et al.* 2002a).

By contrast, an analysis of the spatiotemporal patterns of malaria transmission in Thailand provided some evidence that the farming season and the movement of people to the location of their crops were associated with higher risk of malaria (Childs *et al.* 2006). Socio-cultural aspects were investigated in a study in Côte d’Ivoire which indicated that socio-economic transformations and changes in gender-specific tasks and responsibilities induced by the intensification of inland valley rice cultivation lead to a reduction of the capacity of women to manage disease episodes (De Plaen *et al.* 2003). Overall, no simple and clear association has so far been found between irrigated rice cultivation and malaria transmission (Ijumba & Lindsay 2001).

The Kilombero Valley in south-eastern Tanzania is a well-described highly malaria-endemic tropical wetland dominated by subsistence agriculture (Zehnder *et al.* 1987; Smith *et al.* 1993; Drakeley *et al.* 2003; Killeen *et al.* 2007). The valley's climatic and ecological characteristics are favourable for high and perennial malaria transmission. During the rainy season, large parts of the valley are flooded by the Kilombero River. The majority of the valley's farming residents take advantage of this natural flood irrigation to cultivate rice, which is the main staple food and the most important cash crop in the area. Only very few artificial irrigation schemes are in place. While artificial schemes may be established based on knowledge of water management and mosquito ecology (Keiser *et al.* 2005), there is little opportunity to influence the natural flooding of a vast floodplain such as the Kilombero Valley.

The geographical and ecological patterns of the Kilombero Valley lead to distinct seasonal movements of the local farming population. The valley's villages with their entire infrastructure are situated along the main roads on the edges of the flood plain. All health care providers, such as health facilities, drug stores or general shops selling drugs are located in the villages. Farming sites (*shamba* in Swahili) are often located at a considerable distance from people's homes in the fertile lower wetland. Due to the standing water, farms can often be accessed only by walking long distances and wading through water. During the main cultivation period, families therefore often move from the villages to the farms where they stay in temporary shelters, usually fabricated with branches and straw and often built on stilts to protect them from water and wild animals (Figure 8.1 a and b).


**Figure 8.1: *Shamba* houses (A & B) and main house in a village (C)**

The rainy season and hence main cultivation period occurs between February and June. It is considered a period of high vulnerability for the farming population because of recurring food insecurity (empty stocks before the harvest), labour stress (intensive work on the farm), poor access to preventive and curative health services

as well as family support due to the remoteness of the farms, little time for child care and poor access to clean water and adequate sanitation in the fields. Malaria transmission, fever incidence and mortality in the community show seasonal variations with a peak during the same season. It has therefore been speculated that the seasonal movement of parts of the population to their distant fields results in an increased risk of and vulnerability to malaria. Long distances from the farming sites to the next village and health facility can furthermore contribute to delayed and inappropriate care-seeking which may in part be compensated by more frequent use of home-stocked drugs. Eventually, disease episodes during the cultivation period may result in lower crop yield and consequently lower income with considerable impact on household economies, as was shown in a study conducted in Côte d'Ivoire (Girardin *et al.* 2004).

Hardly any of the literature published so far has focused on the impact of these seasonal movements on malaria incidence or the ability of people to cope with disease episodes, and it is unclear, how common such movement patters are on the African continent. We provide a qualitative and quantitative assessment of risks, access to health services and treatment-seeking related to fever episodes that occurred in farming households during the main cultivation period.

## *8.3 Methods*

This longitudinal study was carried out between January and August 2005 within the frame of a research and intervention project to understand and improve access to effective malaria treatment (ACCESS Programme), which is described in detail elsewhere (Hetzel *et al.* 2007c).

### 8.3.1 Study area and study population

The study was conducted in the area of a Demographic Surveillance System (DSS), in the districts of Kilombero and Ulanga, Tanzania. In mid-2005, the DSS had a population of 75,120. There is a short rainy season from October to December and a long one from February to June. Annual rainfall ranges from 1200 to 1800 mm and

annual mean temperature is around 26° C (Armstrong Schellenberg *et al.* 2002). The details of the study area have been described elsewhere (Hetzel *et al.* 2007c).

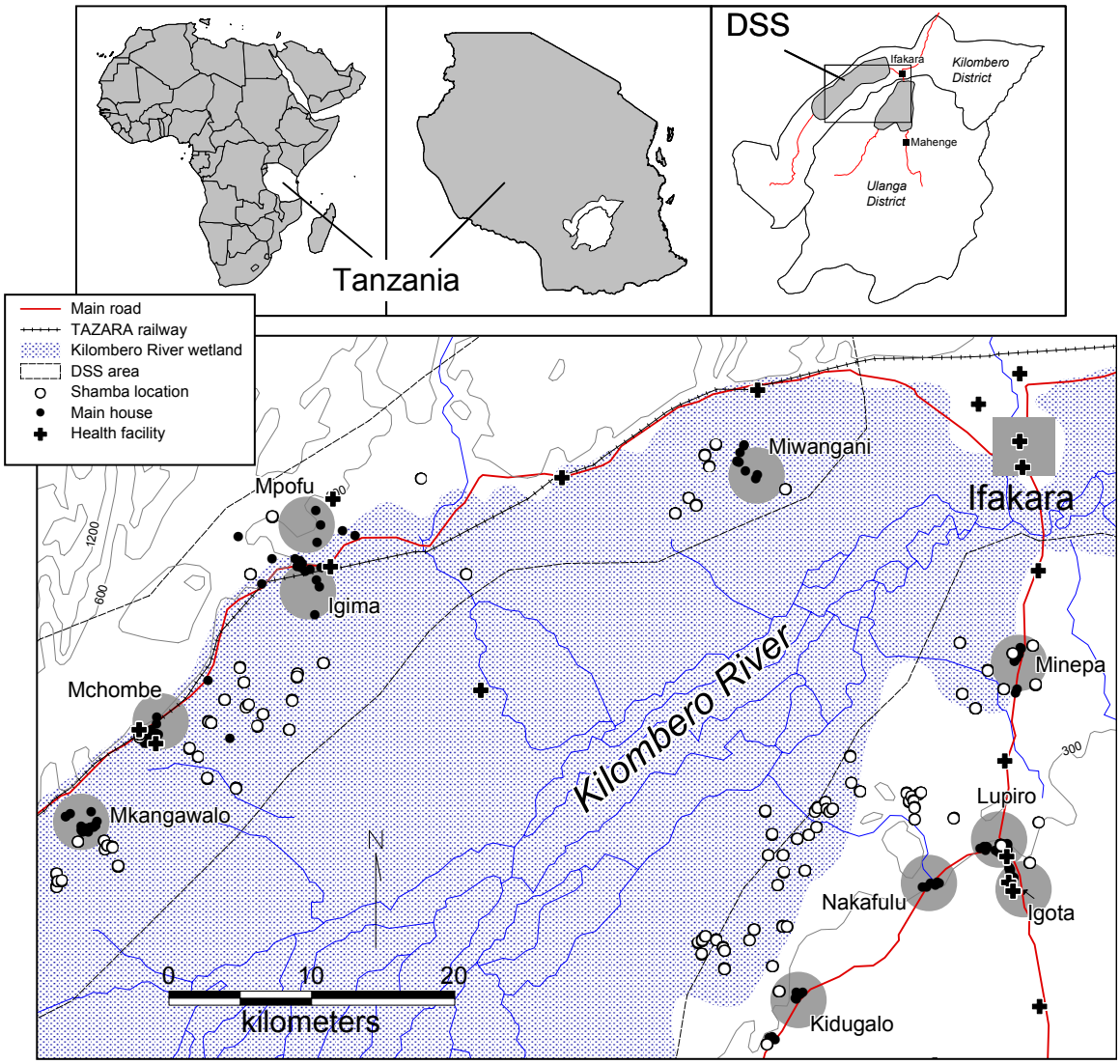


**Figure 8.2: Study area with Demographic Surveillance System (DSS), ten sampled villages (villages centres shaded grey), main houses and *shamba* locations**

For the initial visit in January 2005, ten out of a total of 25 DSS villages were chosen at random (Figure 8.2). Out of 5912 households that had previously reported to have a farming plot (*shamba*), a two-stage random sample of 159 households was drawn, proportional to the relative size of the villages. To compensate for 77 (54.7%) households which reported not to have a *shamba* anymore in 2005, an additional sample of 80 households was added to the study in March using the same sampling

strategy. Of these, another 40 (50%) households did not have a *shamba* anymore or did not cultivate it that year. The total number of households visited per round is reported in Table 8.1.

**Table 8.1: Number of households (main residencies and *shamba* houses) visited in each round**

| Round | Time | Main houses | Shamba | Total** |
|---|---|---|---|---|
| 1 | 15-29 Jan | 72 | N/A | 72 |
| 2 | 2-20 March | 25 | 47 | 72 |
| 2b* | 29 Mar-4 Apr | 40 | N/A | 40 |
| 3 | 6-27 Apr | 35 | 67 | 102 |
| 4 | 12-23 May | 32 | 69 | 104 |
| 5 | 11-27 Jun | 28 | 69 | 98 |
| 6 | 23 Jul-1 Aug | 61 | 26 | 87 |

* additional sample to compensate for losses to follow-up, as explained in the text

** in round 4 and 5, the differences between the sum of the two locations and the total value are due to missing information on the interview location

N/A = Not applicable

### 8.3.2 Data collection

Data was collected monthly from all households included in the study. Baseline data collection started in January 2005 in the main residences in the villages. The subsequent visits (rounds) took place in the *shamba* unless all family members were in the main residence at the time of the monthly visit. The sixth and last visit was done in July 2005 or earlier if the family had completely moved back from the fields to their main house. At every visit, two data collection tools were used:

*A) Household-level questionnaire*

During each round, the same structured questionnaire was applied to record each household member's whereabouts in the four preceding calendar weeks (day-time and night-time), activities performed on the farms, use of mosquito nets and number of recent fever episodes. The location of the main house and the *shamba* were recorded using hand-held GPS devices (Garmin® e-Trex®, Garmin Ltd.).

*B) Treatment-seeking questionnaire (EMIC)*

For those fever episodes which had occurred in the preceding two weeks, an in-depth interview was carried out to elicit detailed information on treatment seeking. Interviews were done with patients of 12 years and above and with caretakers of children under the age of 5 years. Cases that had not recovered the day of the interview were not interviewed and advised to seek care from a qualified provider. An Explanatory Model Interview Catalogue (EMIC) was used for data collection. EMICs are semi-structured questionnaires designed to collect quantitative and qualitative information (narratives) on the experience of illness and resulting treatment-seeking behaviour from the point of view of those affected (Weiss 2001). The EMIC was developed based on preceding focus-group discussions (Hetzel *et al.* 2007c) and further qualitative research on people's understanding of malaria (Hausmann Muela 2000; Minja *et al.* 2001; Mayombana 2004). The same forms had already been used in a previous treatment-seeking survey in the same area (Hetzel *et al.* 2007d).

In addition, information on the socioeconomic ranking of the households in the study was obtained from the DSS database. Each year, information is collected on proxy markers of socioeconomic status such as main sources of income, household ownership of assets, housing characteristics and water and sanitation facilities for all of the households in the DSS area. The 2005 survey collected information on 15,396 households.

### 8.3.3 Data entry and analysis

Data was double-entered at the Ifakara Health Research and Development Centre (IHRDC) data unit using Microsoft Access or FoxPro software (Microsoft Corp., Seattle, USA). Statistical analysis was done in Intercooled Stata 9 (StataCorp, College Station, Texas, USA) and mapping using MapInfo Professional 7.0 (MapInfo Corp., Troy, New York, USA) and ArcView GIS 3.3 (ESRI, Redlands, CA, USA).

An individual level and a household level model were fitted to quantify the effect of risk factors for a fever episode.

A logistic model was fitted at the individual level to quantify the effect of age and proportion of weeks spent in the *shamba* overnight on fever incidence. The outcome

variable at individual level was derived from the EMIC interviews. As EMICs were only done for recovered episodes (excluding acute cases), the outcome indicator represented only a proportion of the overall fever incidence. In the five cases in which more than one episode was recorded on the same person, one episode was chosen at random. At the household level, a logistic model with outcome variable "reported fever episode in the household in the past two weeks" was fitted to quantify the effect of household mosquito net ownership and use. In the final individual and household models, no account was taken of the clustering within individuals and households. Comparing the models with and without clustering using the likelihood ratio test revealed no evidence of significant between-individual or between-household variance (results not shown).

A descriptive analysis of household data on net ownership and drug home stocking was carried out. Averages were calculated over all rounds with no weighting since in each round approximately the same number of households was interviewed. Net usage average was weighed by number of observations (persons) per round.

Treatment seeking indicators were assessed at an individual level using EMIC data. All estimates derived from this retrospective study relied on self-reported help-seeking behaviour. Logistic models were fitted to assess the effect of likely predictors on several treatment seeking indicators.

Principal components analysis (PCA) was used to define the weights of a relative index of socioeconomic status (SES). The first principal component was chosen, since it summarises the largest amount of information common to the asset (Armstrong Schellenberg *et al.* 2003; Vyas & Kumaranayake 2006). The index was constructed for 14,603 out of 15,396 (94.8%) households in the DSS area from the following dichotomous variables: living in a rented accommodation (10% of the households), having income from any sort of business (11%), ownership of bike (49%), radio (57%), chicken (59%), and other animals (4%); presence of iron roof (30%), concrete/brick wall (44%), cemented floor (12%), toilet (91%) and toilet wall (12%) in the house. In addition, the following variables were measured on an ordinal scale: hectares of land owned (5% had no land, 30% up to one hectare, 31% more than one and up to two hectares, 17% had more than two and up to three hectares

and 17% had more than three hectares), number of rooms in the house (30% had one bedroom, 42% had two, and 28% had three or more) and number of mosquito nets owned (6% had none, 32% had one, 34% had two and 28% had three or more).

The first principal component accounted for 22% of the variability. Greatest weight was given to ownership of tin roof (0.39), the presence of concrete/brick walls (0.35), cemented floor (0.33), ownership of bikes (0.30), lighting by candles or petrol lamp (0.30), ownership of nets (0.29), number of bedrooms (0.28), wall around the toilet (0.27), and ownership of a radio (0.26). Households were classified into wealth-quintiles with mean indices of -2.25, -1.23, -0.32, 0.83, and 2.97. Households from the study were assigned their SES index and category from the analysis performed on the entire DSS database.

### 8.3.4 Ethical considerations

Study participants were informed about the study framework, aim and purpose and oral informed consent was obtained. Village authorities were informed about the activities prior to their onset. The study was granted ethical clearance as part of the ACCESS Programme by the institutional review board of the IHRDC and the Tanzanian National Medical Research Coordinating Committee (NIMR/HQ/R.8a/Vol.IX/236).

## *8.4 Results*

### 8.4.1 Sample characteristics

In each round, between 72 and 104 households were visited (Table 8.1). Over the six rounds 575 household visits were carried out and information was collected on 703 individuals. On average there were 5.92 (SD 2.46) members in each household. The sample comprised 24 infants (age <1 year), 82 children aged 1 to <5 years, 150 children aged 5 to <12 years, 66 adolescents aged 12 to <16 years and 354 adults (age 16 years and above). For 27 individuals no age was recorded. The age structure corresponded closely with the national age structure as reported in the 2002 population census (United Republic of Tanzania 2003a). The distribution of the

study-households in SES quintiles was as follows: 16% poorest, 21% second poorest, 26% middle, 23% second richest, 14% richest.

### 8.4.2 Exposure in the *shamba*

The field sites were on average located at a median linear distance of 7.3 km (interquartile range [IQR] 3.7-12.1) from the main houses. Main houses were closer to the nearest health facility (median distance 2.2 km; IQR 0.8-5.6) than *shamba* locations (7.9 km; IQR 6.0-10.1) (Wilcoxon rank-sum test W=-9.28, P<0.001). Actual travel distances and times between main house and *shamba* or to the next health facility did not only depend on the distance but also on the condition of the trails, the available means of transport (such as motorbike, bicycle, or canoe), and water levels. This was reflected in a parallel study in the same area in which distances to the next health facility of up to 19 km along people's walking paths were measured (Mayumana 2007).

Analysis of the reported whereabouts of people each week showed that depending on the activities performed in the fields, large parts of the households moved to the *shamba* for overnight stays. During the weeding (mid-February to mid-March) and harvesting seasons (May), the proportion of household members who spent days and nights in the fields peaked. Throughout the study period, going to the *shamba* only for the day was less frequent than staying overnight, which reflects the long distances and difficult accessibility of the field sites. However, at the beginning of the farming season when the crops were planted (January – mid February) a higher percentage of household members only spent the day in the fields and moved back to their main residence overnight (Figure 8.3). This proportion decreased in the following months. Over the whole study period, adults (over 16 years) and children below five years were most frequently found to spend the nights in the *shamba*, while children between 5-16 years (i.e. about school age) were most frequently permanently in the main house (Figure 8.4). Over the whole study, people spent, on average, 40.0% of the weeks in the *shamba* overnight.

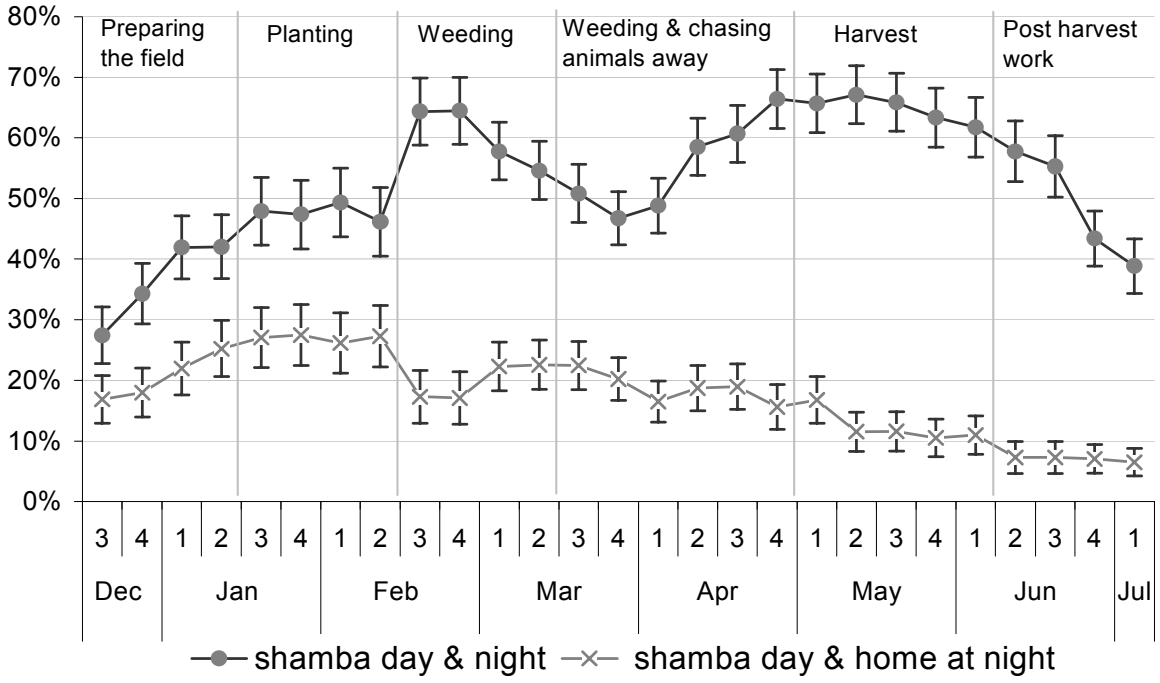


**Figure 8.3: Percentage of members of visited households in the *shamba* each week**

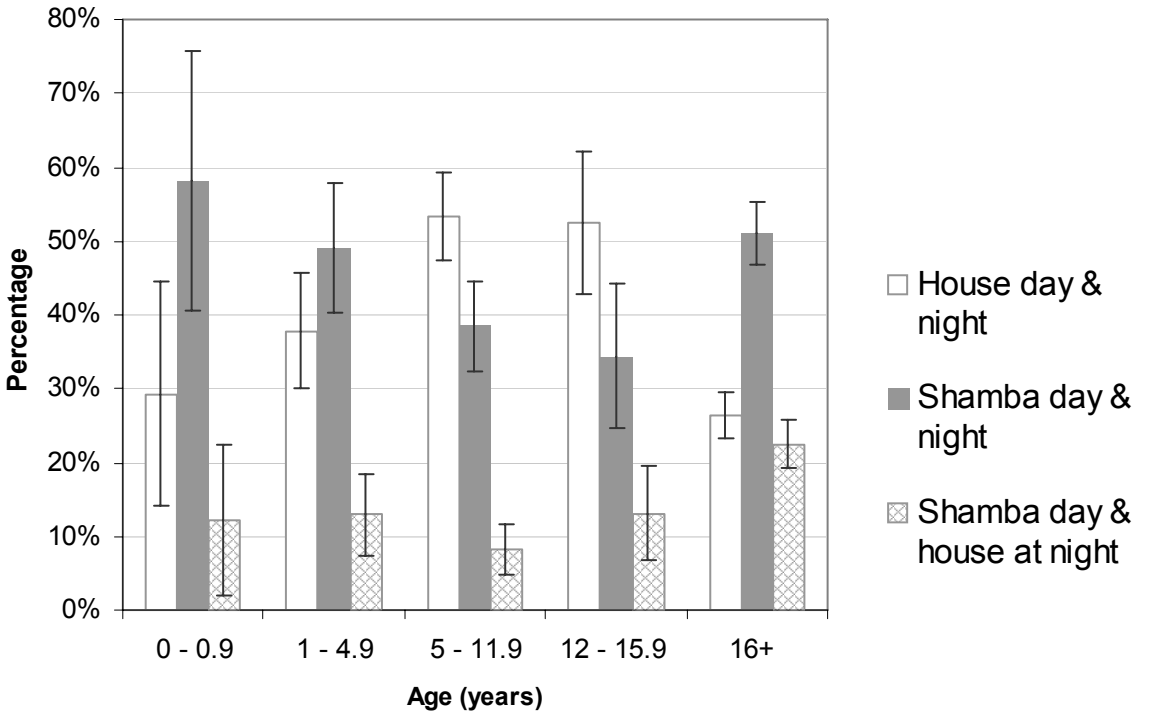


**Figure 8.4: Percentage of time (weeks) spent in the *shamba* or at home over entire study period. Error bars are 95% confidence intervals.**

### 8.4.3 Preventive measures

Overall, coverage and usage rates of mosquito nets were extremely high. On average, there was a mosquito-net in 93.6% of the main houses (95% confidence interval [CI] 89.9-96.2) and in 96.8% (93.9-98.5) of the *shamba* huts. Household ownership of nets treated with insecticide (ITN) was lower with 58.9% (52.7-64.9) and 59.2% (43.2-65.0) in the main house and the *shamba*, respectively. Averaged over the study period, 97.9% (95.2-100) of the people sleeping in the *shamba* reported to have used a mosquito net (treated or not) the preceding night

Over the whole study period, 50.5% (40.2-60.8) of the households reported to stock drugs in their *shamba* hut, varying from 21.2% to 34.0% between the rounds. Antipyretics were found most frequently (43.3% of all households; 33.3-53.7), while only few households stocked antimalarial drugs (6.2%; 2.3-13.0) (Figure 8.5).

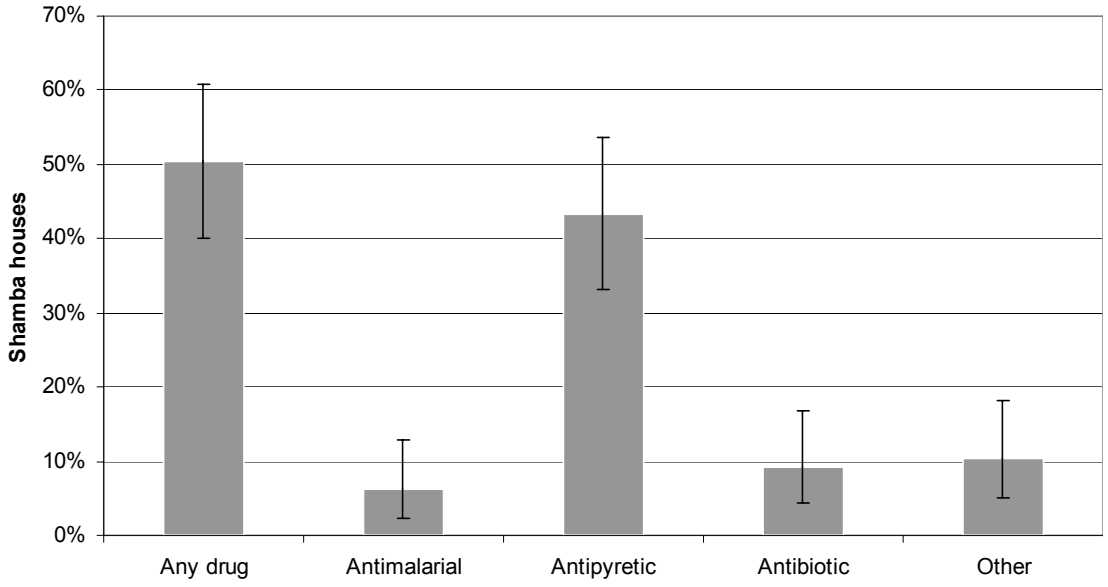


**Figure 8.5: Drug home stocking in the *shamba* huts. Error bars are 95% confidence intervals.**

### 8.4.4 Fever incidence

Over the study period 29% of households visited reported fever cases in the preceding two weeks. Some households (n=27 over all rounds) reported more than one fever episode. At an individual level, averaged over the whole study period, this

accounts for a two-week incidence rate of 6.1% which is lower than the 13% (7,102/55,514) reported routinely from the DSS for that period (Table 8.2)

In total 58 of these fever cases were followed up with an **EMIC interview**. However, one person was followed up on three consecutive occasions and three individuals on two consecutive occasions, leaving 52 independent EMIC interviews for the analysis at individual level (27 persons of 12 years and above, and 25 children under 5 years).

**Table 8.2: Number of individuals and households visited in each round and reported two-week fever incidence**

| Round | HH level | | | Individual level | | |
|---|---|---|---|---|---|---|
| | N | Fever | | N | Fever | |
| | | % | n** | | % | n** |
| 1 | 72 | 59 | 30 (/51) | 390 | 13.9 | 41 (/293) |
| 2 | 72 | 28 | 20 | 409 | 6.4 | 26 |
| 2b* | 40 | 42 | 14 (/33) | 209 | 8.7 | 17 (/195) |
| 3 | 102 | 24 | 24 (/101) | 584 | 4.7 | 32 (/596) |
| 4 | 104 | 26 | 27 | 596 | 5.4 | 32 |
| 5 | 98 | 19 | 18 | 547 | 3.5 | 19 (/541) |
| 6 | 87 | 29 | 26 | 489 | 5.5 | 27 |
| Overall | 575 | 29 | 158 (/545) | 3224 | 6.1 | 189 (/3103) |

* additional sample to compensate for losses to follow-up, as explained in the text

** numbers in brackets denote the denominator excluding missing values

### 8.4.5 Risk factor analysis at individual level

Results from the univariate model (Table 8.3) fitted at individual level showed evidence of a very slight increase in the odds of fever for every 10% increase in weeks spent overnight in the shamba (OR=1.09; 1.02-1.17). However, the effect was confounded by age and once this was accounted for in the multivariate model the effect of time spent in the *shamba* lost its significance. Age was a very strong independent predictor of fever incidence (likelihood ratio test [LRT] of inclusion chi-square=34.62, P<0.001). The odds of children aged 1 to under 5 years having a fever were 4.47 times the odds of adults (2.35-8.51). No evidence could be found of an increased risk for infants, although this may have been due to lower sample size

in this age group. There was no evidence of an interaction between the effect of age and time spent at the *shamba* overnight (LRT of inclusion chi-square=6.13, P=0.101).

**Table 8.3: Univariate and multivariate analyses of the relationship between fever incidence and risk factors (logistic regression)**

| Risk factors | Univariate | | | Multivariate | | |
|---|---|---|---|---|---|---|
| | n | OR (95% CI) | P* | n | Adjusted OR (95%CI) | P* |
| % weeks at *shamba* overnight (10% increase) | 688 | **1.09 (1.02 to 1.17)** | **0.013** | 667 | 1.06 (0.98 to 1.14) | 0.142 |
| Age (years) | 676 | | | | | <0.001 |
| 0-0.9 | | 2.63 | | | 2.51 | |
| | 24 | (0.83 to 8.27) | 0.098 | 23 | (0.79 to 8.01) | 0.119 |
| 1-4.9 | 82 | **4.53** | **<0.001** | 82 | **4.47** | **<0.001** |
| | | **(2.38 to 8.58)** | | | **(2.35 to 8.51)** | |
| 5-11.9 | 150 | 0.64 | 0.317 | 150 | 0.71 | 0.448 |
| | | (0.27 to 1.51) | | | (0.30 to 1.71) | |
| 12-15.9 | 66 | 0 | 0.026 | 65 | 0 | n/a |
| 16+ | 354 | 1 | - | 347 | 1 | - |

***** Wald test of significance of effect, LLR test of significance of variable in the model

### 8.4.6 Risk factor analysis at household level

Analysis of the crude effect of location of the interview showed a significant decrease in the odds of fever in households for which the interview was carried out at the shamba rather than in the main house (OR=0.53, 0.36-0.77). However, once corrected for the number of households in each round this effect was longer significant. The analysis at the household level showed no association of reported fever cases and net ownership (treated or untreated) or use. Given the consistently high level of net use, this was not surprising. No association was found between number of household members and fever incidence. However, households with a higher SES score were found to be more likely to report a fever case (OR=1.16, 1.01-1.32) (Table 8.4). This slight positive association may be attributed to a reporting bias. However, a chance finding cannot be ruled out as no association could be found when the same analysis was repeated for the entire DSS population (OR=1.02, 0.76-1.36).

**Table 8.4. Univariate analysis of the relationship between reported fever case in a household and household factors (logistic regression)***

| Household risk factors | n | Odds ratio (95% CI) | P |
|---|---|---|---|
| Interview at the shamba | 542 | 0.79 (0.50 to 1.23) | 0.300 |
| Net ownership in the household | 542 | 0.78 (0.34 to 1.79) | 0.564 |
| Number of nets owned | 543 | 1.08 (0.89 to 1.30) | 0.439 |
| Number of treated nets | 541 | 1.01 (0.86 to 1.19) | 0.873 |
| Number of people sleeping under a net | 545 | 1.00 (0.94 to 1.06) | 0.963 |
| SES index | 479 | **1.16 (1.01 to 1.32)** | **0.032** |
| Number of household members | 545 | 0.99 (0.91 to 1.06) | 0.820 |

* adjusted for number of households in each round

### 8.4.7 Treatment seeking

In total, 90.4% (79.0-96.8) of the followed-up fever cases were treated with one or more of the recommended antimalarials (55.8% sulphadoxine-pyrimethamine [SP], 28.9% amodiaquine, 13.5% quinine). 25.0% (14.0-38.9) of these antimalarials were administered on the same day, 71.2% (56.9-82.9) on the same or the next day. 53.8% (39.5-67.8) attended a health facility during the course of their illness, while 36.5% (23.6-51.0) practised exclusive home-management with shop-bought or leftover drugs from home stocks.

There was no statistically significant difference in these indicators between children and adults or between socio-economic groups. Treatment with a recommended antimalarial within two days was found to be slightly more frequent in under-fives (84.0%, 63.9-95.5) than in adolescents and adults above five years of age (59.3%, 38.8-77.6), with borderline significance (P=0.056). Whether the episode was first recognised in the *shamba* or the main house had no effect on whether it was treated with an antimalarial, treated within one or two days, or brought to a health facility (Table 8.5).

**Table 8.5: Treatment indicators for fever episodes recognised at home and in the *shamba***

| Indicator | Home | Shamba | P |
|---|---|---|---|
| | Percentage (95% CI) | Percentage (95% CI) | |
| N | 22 | 30 | |
| Treated with any drug | 95.8% (78.9 to 99.9) | 97.1% (84.7 to 99.9) | 0.803 |
| Antimalarial (AM)* | 95.8% (78.9 to 99.9) | 88.2% (72.6 to 96.7) | 0.290 |
| AM on day 1 or 2* | 62.5% (40.6 to 81.2) | 76.5% (58.8 to 89.3) | 0.252 |
| AM on day 1* | 16.7% (4.7 to 37.4) | 32.4% (17.4 to 50.5) | 0.171 |
| Health facility visit | 58.3% (36.6 to 77.9) | 55.8% (37.9 to 72.8) | 0.853 |
| Exclusive HMM‡ | 37.5% 18.8 to 59.4) | 32.4% (17.4 to 50.5) | 0.685 |

* Recommended antimalarial (AM): SP, amodiaquine or quinine
‡ Home-management

In the multivariate analysis, longer distance to the nearest health facility seemed to be associated with less exclusive home management (OR=0.79, 0.63-1.00) i.e. paradoxically, households whose *shamba* was far from a facility were less likely to administer an antimalarial without ever attending a health facility. No other significant predictors were found (Table 8.6). In reverse, visiting a health facility was slightly more likely if households were located further away from a facility (OR=1.40, 1.03-1.89).

The same analysis for non-exclusive home management (i.e. treatment with an antimalarial not obtained from a health facility, irrespective of whether a health facility was attended or not) as outcome did not reveal a significant effect of distance to the nearest health facility. However, non-exclusive home-management was more likely if the nearest provider was a drug store rather than a health facility or general shop (OR 8.95, 1.23-65.19). Hence, it appeared as if antimalarials would rather be obtained from outside a health facility if a drug store was close - but without preventing people from visiting a facility at some stage.

No significant predictors for administration of an effective antimalarial within one or two days were found in this analysis.

**Table 6: Multivariate analysis of factors related to exclusive home management (logistic regression)**

| Risk factors | Univariate | | | Multivariate | | |
|---|---|---|---|---|---|---|
| | n | OR (95% CI) | P | n | Adjusted OR (95% CI) | P |
| Age group | | | | | | |
| 12+ years | 27 | 1 | | 19 | 1 | |
| <5 years | 25 | 0.68 (0.22-2.14) | 0.514 | 24 | 0.49 (0.10-2.49) | 0.391 |
| Illness recognised | | | | | | |
| Home | 22 | 1 | | 18 | 1 | |
| *Shamba* | 30 | 0.72 (0.23-2.26) | 0.576 | 25 | 2.09 (0.36-12.04) | 0.409 |
| Type of closest provider | | | | | | |
| Health facility | 15 | 0.82 (0.23-2.90) | 0.760 | 16 | 1 | |
| General shop | 18 | 0.36 (0.10-1.33) | 0.126 | 15 | 0.33 (0.05-2.45) | 0.281 |
| Drug store | 12 | 1.32 (0.35-4.96) | 0.675 | 12 | 1.25 (0.18-8.79) | 0.821 |
| Distance to health facility (km) | 42 | **0.83 (0.68-1.00)** | **0.050** | **43** | **0.79 (0.63 to 1.00)** | **0.046** |
| Distance to nearest provider (km) | 42 | 0.82 (0.69-0.98) | 0.029 | 43 | - | - |
| Location | | | | | | |
| Kilombero | 24 | 1 | | 18 | - | - |
| Ulanga | 28 | 0.33 (0.10-1.08) | 0.066 | 25 | | |
| SES score | 47 | 0.93 (0.64-1.35) | 0.694 | 43 | 0.79 (0.46-1.36) | 0.395 |

***** Wald test of significance of effect

## *8.5 Discussion*

The seasonal movement of people to distant field sites is a prevailing pattern in the Kilombero Valley of Tanzania, and a major determinant of the lives of entire households. To which extent this pattern is common in the rest of sub-Saharan Africa is unclear, given the scarcity of data on this issue. Household members spend a considerable part of the farming season living in very basic shelters under difficult conditions. During the harvesting period, over 60% of the members of the farming households moved to the fields from where access to health services and other infrastructure is more difficult. Walking distances of up to 19 km are a reality in some areas (Mayumana 2007). Conversely, this also means that during the farming season a large part of the local population is difficult to reach with health services, messages and campaigns. Adults who bear the heaviest burden are those most frequently

spending the nights in the *shamba* houses. Young children who are most at risk of contracting malaria and generally more vulnerable are often accompanying their parents and therefore exposed to the same adverse conditions. Only school-aged children were spending most of the time in the villages, since school-attendance is compulsory for 7 years.

Adverse conditions in the *shamba* are clearly recognised by the local population. Extremely high (98%) mosquito-net usage rates reflect the immense nuisance posed by mosquitoes as well as the success of health education and social marketing in promoting the use of ITNs (Armstrong Schellenberg *et al.* 1999). However, many mosquito nets are not treated with insecticide calling for interventions to increase re-treatment rates or the implementation of long-lasting insecticidal nets (LLIN). Preparedness for malaria illness episodes is rather poor with only 6% of the households stocking antimalarials in the *shamba*, which may to some extent reflect the lower availability of the first-line treatment SP in shops in the study area (Hetzel *et al.* 2006). Better availability of appropriate antimalarial drugs close to people's homes could potentially promote prompt treatment of malaria episodes (WHO 2005a; Gyapong & Garshong 2007). Currently, registered drug stores and health facilities do not reach the *shamba* locations and this is unlikely to rapidly. Alternative approaches to provide people in the *shamba* with appropriate treatment should therefore be explored.

While accessibility to treatment services is clearly more difficult from the *shamba*, spending time there did not increase the odds of having a fever overall. Fever rates observed in the *shamba* were even lower than those in the main houses or rates derived from routine DSS reports. Similar findings have been reported from other places in Tanzania (Ijumba *et al.* 2002b). Estimates of entomological inoculation rates (EIR) in the Kilombero Valley did not reveal elevated malaria transmission in the *shamba* compared to village locations (Killeen *et al.* 2007). Lower malaria transmission fever incidence in the *shamba* could be attributed to lower population density in the fields and different feeding behaviour and transmission capacity of vectors, potentially leading to less transmission (Ijumba *et al.* 2002a). Yet, it may also be influenced by human behaviour. As *shamba* houses are very scattered, there is little opportunity for social life after dusk. People would therefore retreat to their huts

and go to bed earlier than in the villages and with the high mosquito net usage rates, most people would be effectively protected against *Anopheles* bites. Other explanation for the lower fever incidence in the *shamba* could not be found.

The analysis of treatment-seeking behaviour showed that most fever episodes were treated with an antimalarial and 56.9% of the episodes reached a health facility at some stage. Despite the long distance to the nearest facilities, few episodes were exclusively managed at home. This is supported by the findings of a related study which found that episodes from even the most distant *shamba* were eventually treated at a health facility (Mayumana 2007). No significant differences could be seen between episodes which were first recognised at the *shamba* or at the main house. This may on one hand be due to the small sample size. On the other hand, it was often observed that in case of an illness episode, household moved back to their main house from where treatment-seeking action would then be started.

From this study, the considerable distance between farming sites and health services did not appear to lead to a delay in treatment-seeking. However, the use of quantitative methods - a semi-structured questionnaire - may also have influenced this result. Mayumana (2007) investigated treatment delay in more detail in a qualitative study on livelihoods and health care. It appeared from his study that most cases occurring in the families' main houses were treated within 24 hours while episodes in the *shamba* only after three to five days.

Surprisingly, home management was less common the further away the nearest health facility was. This may be related to the fact that few households stocked antimalarial drugs in the *shamba* and households far from health facilities were also far away from drug stores or general shops stocking drugs. Hence, there was little opportunity to purchase antimalarials from alternative providers. Nevertheless, home management was still more frequent in this *shamba* survey (37.5%) than in a cross-sectional community survey done in 2004 in the same area. In that study, 23.4% of fever episodes were exclusively treated at home. At the same time, health facility attendance was higher with 76% children under 5 years of age and 56% adults being brought to a health facility (Hetzel *et al.* 2007d). This supports the assumption that access to health facilities is in fact more difficult for families staying in the fields

compared to the population in general. Episodes which occur in the *shamba* would therefore demand greater efforts (in terms of money and time) for families to obtain the preferred treatment and care at health facilities. Home-management with drugs provided to the households in or close to the *shamba* would most likely facilitate timely access to appropriate treatment but would need to be coupled with education of care-takers and training of drug-providers (Gyapong & Garshong 2007). However, any implementation strategy would have to take into account the draw-backs of low population densities and widely dispersed households in the fields.

## *8.6 Conclusions*

Seasonal movements of households to farming sites located at a considerable distance from their main residences are very common in the Kilombero Valley. Despite high malaria endemicity in this area, no increased fever incidence could be detected in people who spend days and nights in temporary shelters on their rice fields. Individual protection with mosquito nets was very high but preparedness for malaria episodes rather poor. Inability to obtain antimalarials easily from nearby drugs stores forced people to seek help from distant health facilities. On the one hand, this may facilitate the implementation of good quality case-management and rational prescription of drugs. However, each episode occurring in the *shamba* may well become a heavier social and economic burden than under normal circumstances. In such a situation, a comprehensive approach is needed to improve timely access to affordable treatment and care, while at the same time assuring rational use of medicines.

## *8.7 Authors' contributions*

MWH designed the study, developed the survey tools, participated in the data analysis and co-wrote the manuscript. SA participated in the data analysis and co-wrote the manuscript. MF supervised the data collection and participated in data analysis. IM coordinated the data collection, data cleaning and contributed to the manuscript. CL, BO, AS and HM conceived the study, provided technical support and contributed to the manuscript. RN provided the DSS data. AM, CM and NI contributed to the discussion on the manuscript and facilitated the field work.

## *8.8 Acknowledgements*

We thank all study participants for their readiness to actively participate in this survey. Special thanks go to our field interviewers Hilda Mwabukusi, Irene Ngoja, Judith John, Goodluck John, and Sixbert Msagwa who did the strenuous job of travelling from *shamba* to *shamba* during six months. We appreciated the services provided by our two motorbikes which carried us as far as two wheels can go and by our mechanics who repeatedly fixed them. Many thanks to Jürg Utzinger who gave valuable inputs on the manuscript and to Wolfgang Schmied who provided Figure 1C. This paper was published with permission of Dr. Andrew Kitua, Director-General, National Institute for Medical Research. The study was conducted within the frame of the ACCESS Programme, which is funded by the Novartis Foundation for Sustainable Development, Switzerland.

# 9 DECREASED AVAILABILITY OF ANTIMALARIALS IN THE PRIVATE SECTOR FOLLOWING THE POLICY CHANGE FROM CHLOROQUINE TO SULPHADOXINE-PYRIMETHAMINE IN THE KILOMBERO VALLEY, TANZANIA

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This paper has been published in the
*Malaria Journal* 2006; 5:109

## *9.1 Abstract*


### 9.1.1 Background

Malaria control strategies emphasize the need for prompt and effective treatment of malaria episodes. To increase treatment efficacy, Tanzania changed its first-line treatment from chloroquine to sulphadoxine-pyrimethamine (SP) in 2001. The effect of this policy change on the availability of antimalarials was studied in rural south-eastern Tanzania.

### 9.1.2 Methods

In 2001 and 2004, the study area was searched for commercial outlets selling drugs and their stocks were recorded. Household information was obtained from the local Demographic Surveillance System.

### 9.1.3 Results

From 2001 to 2004, the number of general shops stocking drugs increased by 15% and the number of drug stores nearly doubled. However, the proportion of general shops stocking antimalarials dropped markedly, resulting in an almost 50% decrease of antimalarial selling outlets. This led to more households being located farther from a treatment source. In 2004, five out of 25 studied villages with a total population of 13,506 (18%) had neither a health facility, nor a shop as source of malaria treatment.

### 9.1.4 Conclusions

While the change to SP resulted in a higher treatment efficacy, it also led to a decreased antimalarial availability in the study area. Although there was no apparent impact on overall antimalarial use, the decline in access may have disproportionately affected the poorest and most remote groups. In view of the imminent policy change to artemisinin-based combination therapy these issues need to be addressed urgently if the benefits of this new class of antimalarials are to be extended to the whole population.

## *9.2 Background*

The first and foremost malaria control strategy promoted by the World Health Organization (WHO) and adopted by most African countries emphasizes the need for treatment of malaria episodes with an efficacious drug within 24 hours after onset of symptoms (MOH 2002; WHO & UNICEF 2005). African heads of state agreed at the Abuja summit in April 2000 to ensure that by 2005 at least 60% of those suffering from malaria have access to affordable, appropriate and timely treatment (Roll Back Malaria/World Health Organization 2000).

However, in most areas of sub-Saharan Africa, this target is still far from being reached. Many malaria patients do not receive prompt and effective treatment for malaria, even if efficacious drugs are available on the local market (von Seidlein *et al.* 2002; Committee on the Economics of Antimalarial Drugs & Board on Global Health 2004; Nsungwa-Sabiiti *et al.* 2005) or at health facilities (Zurovac *et al.* 2005). A fever episode, especially in a child, often prompts action and very high treatment rates (over 90%) have been reported (McCombie 2002). On the other hand, household surveys in 28 African countries have shown that on average only 42% of children under five years of age with fever were treated with an antimalarial. In 80% of these cases chloroquine was used, which can not be considered any more an efficacious treatment in most areas (WHO & UNICEF 2003). While in case of a malaria attack many factors influence care seeking behaviour (McCombie 2002), one of the prerequisites for successful treatment of a malaria episode is the availability of effective antimalarial drugs close to where the episode occurs.

Self-treatment at home is often the first response to a malaria episode. In many of the studies reviewed by McCombie (1996) self-treatment was frequent in response to an episode of fever or malaria (44% of the self-treatment rates in published studies were reported to be above 50%). The same review found that almost half of all malaria episodes were exclusively treated outside the formal health care sector. Hamel (2001) reported from a study in Kenya that 32% of caretakers treated their children's fever exclusively at home, with an antimalarial. Data recently collected in our field site in southern Tanzania suggest that exclusive home treatment is less common, with 76% of recently feverish children attending a health facility during their illness.

However, not all of those children receive an antimalarial when visiting the health facility.

Reliance on home management and self-treatment raises crucially the issue of availability of antimalarials. In this context, the private retail sector has been shown to play an important role in the provision of drugs close to people's homes (McCombie 1996; Goodman *et al.* 2004). Shops are often preferred as first treatment choice because of better accessibility, shorter waiting times, more reliable drug stocks and lower costs (Brugha & Zwi 1998). The role of the retail sector in improving access to prompt malaria treatment has been recognized by WHO through its home-management of malaria (HMM) strategy (WHO 2005a).

The national drug policy in Tanzania was strengthened in 2003 when the Tanzania Food, Drugs and Cosmetics Act established the Tanzania Food and Drugs Authority (TFDA) as executive agency (United Republic of Tanzania 2003b). Since then the TFDA has been responsible for all regulatory aspects of drugs and other medical products in the country. The private retail sector for drugs includes two types of licensed drug shops as well as general stores. Mobile drug sellers are not common in most parts of Tanzania. Fully-fledged Part I pharmacies are headed by a pharmacist and are allowed to sell all registered prescription-only (Part I) and over-the-counter (Part II) drugs. In 2003, there were 344 Part I pharmacies in Tanzania, 60% of which were located in Dar es Salaam, and the rest scattered over other major towns (Battersby *et al.* 2003). Part II drug stores (known as *Duka la Dawa Baridi*) need to be staffed with a medically trained vendor and are allowed to sell over-the-counter drugs such as analgesics/antipyretics. However, in practice they sell a much wider variety of drugs. 5,666 Part II drug stores had been registered in 2003 (Battersby *et al.* 2003). According to Goodman (2004), general shops were formally not allowed to stock any drugs in 2003 but were in practice permitted to sell common OTC drugs, such as painkillers. However, the legal position of drugs in these outlets has been unclear.

Until 2001, chloroquine was the first line antimalarial and it was designated a Part II drug, available over-the-counter at Part II drug stores. In practice, chloroquine was also tolerated in general stores, where it was widely available (Goodman *et al.* 2004).

Since the 2001 policy change to sulphadoxine-pyrimethamine (SP) as first-line treatment and amodiaquine as second-line treatment, the first line antimalarial (but not the second-line) is prescription-only. Hence, SP can only be purchased legally in Part I pharmacies, besides being available in health facilities. In many parts of the country, SP has also been tolerated in Part II drug stores but not in general shops. These inconsistencies in applying legal regulations to the use and availability of SP have resulted in some level of confusion between government departments and in the development of malaria control strategies.

The change to SP aimed at increasing the effectiveness of malaria treatment and hence to decrease the malaria burden. However, little is known so far about the impact of this policy change in terms of availability of antimalarial drugs through different providers. Treatment effectiveness at community level is a function of many interlinked factors, not just the efficacy of the first line drug. In particular treatment must be available and accessible to the target population. This analysis assessed the change in availability and accessibility of antimalarial drugs in the private sector following the change of first-line treatment in Tanzania. The surveys were carried out in a rural Tanzanian setting in the frame of two projects on (1) access to malaria treatment (ACCESS Programme) and (2) deployment of antimalarial combination therapy (Interdisciplinary Monitoring Project for Antimalarial Combination Therapy in Tanzania – IMPACT-Tz).

## *9.3 Methods*

### 9.3.1 Study area

In 2001 and 2004, we conducted studies on antimalarial drug availability in the area of a Demographic Surveillance System (DSS) in the Kilombero and Ulanga Districts in south-eastern Tanzania (Figure 9.1). The DSS area covers 25 villages (13 in Kilombero and 12 in Ulanga) with almost 74,000 people (2004) in a highly malaria endemic floodplain, the Kilombero Valley (INDEPTH Network 2002). Malaria transmission in the area is intense and perennial with over 300 and in some areas up to 1,000 infective bites per person per year but with seasonal fluctuations depending on rainfall patterns (Smith *et al.* 1993) (Killeen, personal communication). Malaria is

the predominant cause of morbidity and mortality, accounting for about 50% of outpatient diagnoses at rural health facilities (INDEPTH Network 2002). There were seven health facilities in the DSS area of Ulanga and another seven in the DSS area of Kilombero District in 2001 and 2004.

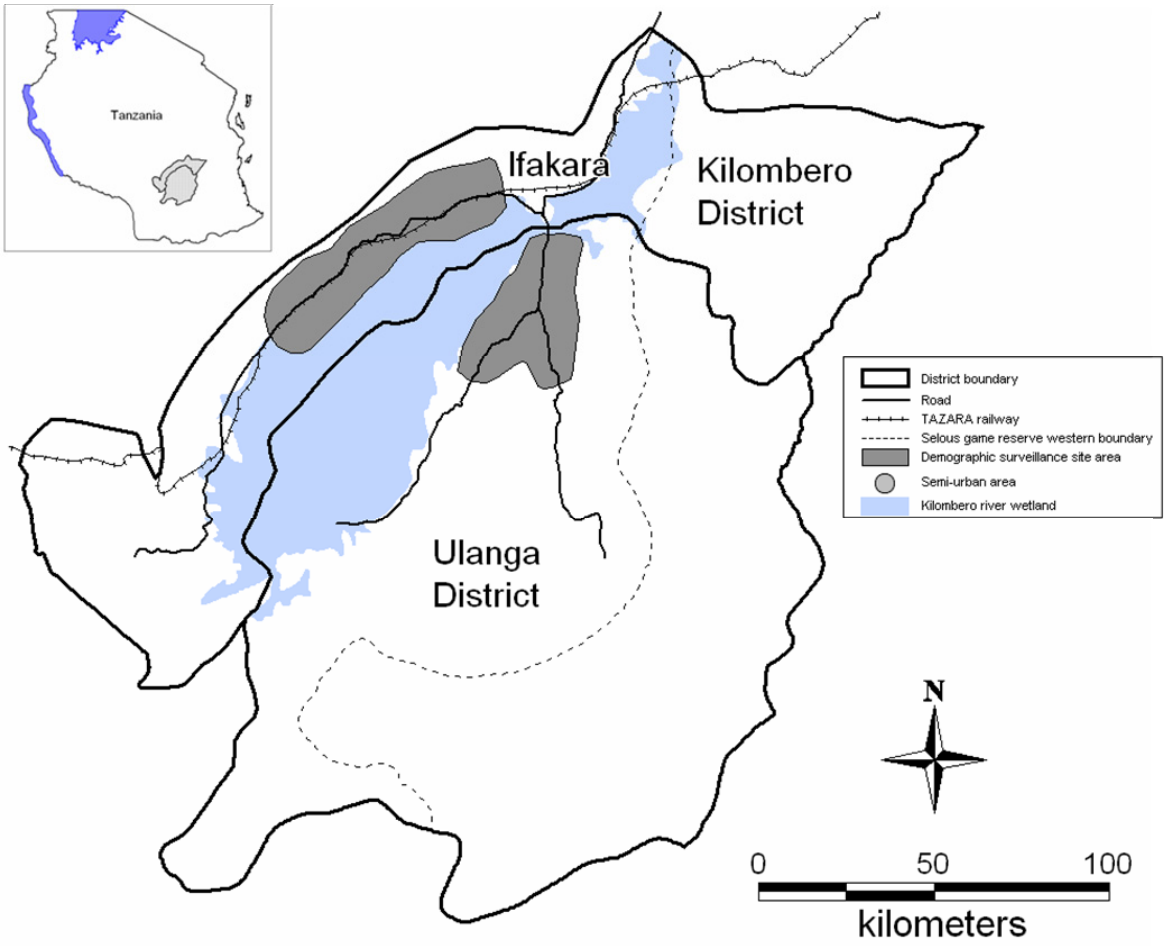


**Figure 9.1: Map of Kilombero and Ulanga districts showing Ifakara town and the Demographic Surveillance System (DSS).**

In 2004, the area of Ifakara town was also included in our studies. This semi-urban headquarters of the Kilombero District lies in the midst of the floodplain outside the DSS area. The population included in our studies was 45,700 in 2002 (United Republic of Tanzania 2003a). Malaria transmission is lower here, with a reported average of 29 infective bites per year (Drakeley *et al.* 2003) and a decrease in clinical incidence in recent years observed at the Designated District Hospital (Schellenberg *et al.* 2004). The study area is described in detail elsewhere (Tanner *et al.* 1991; Armstrong Schellenberg *et al.* 1999).

### 9.3.2 Shop surveys

From May to September 2001, the DSS area was searched for commercial outlets selling drugs, with the help of DSS field staff familiar with the study area and an outlet inventory from a previous study (Goodman *et al.* 2004). All outlets were then visited by interviewers who recorded the outlets' locations and their drug stocks. Survey methods are described in detail elsewhere (Goodman 2004). Data collection was completed before the new antimalarial drug policy with SP as first line drug was implemented in the area.

A further survey was done 3 years after the policy change, in May – June 2004. The outlet list was updated after consulting village leaders and DSS field staff. All outlets were visited again by interviewers who geo-located them using a hand-held GPS unit (Garmin® e-Trex®, Garmin Ltd.) and administered a questionnaire on drugs stocked, and other parameters not presented in this paper. In each survey, the questionnaires contained a checklist for common drug brand names obtained during pilot studies in local shops. Drugs were recorded as "in stock" only if the interviewer was shown the stock. Field supervisors checked the completed questionnaires and helped to resolve any queries. In 2004, the survey was extended to Ifakara town, where the outlets were identified with the help of local community leaders.

### 9.3.3 Follow-up on SP availability

A follow-up study was done in November 2004 to find the reasons for the low availability of the first-line antimalarial SP. For this purpose, 50 general shops were randomly sampled from all general shops that had stocked drugs or had sold drugs previously (n=474), weighted by the total number of shops in each of the three sampling units: Kilombero DSS, Ulanga DSS and Ifakara town. A second set of 50 shops was sampled as backup for shops temporarily or completely closed down. The shops were visited and a semi-structured questionnaire was administered to record stock of SP drugs, customer demand and wholesale sources for antimalarial drugs; if no SP was stocked, the reasons for this were elicited.

### 9.3.4 Household and health facility information

Demographic data as well as household GPS coordinates were derived from the core DSS database. Since 1997 DSS field workers have collected basic household information (births, deaths, migrations) three times per year, i.e. every household is visited every four months. Locations of DSS households and health facilities were recorded during routine DSS data collection and ACCESS Programme activities. While precise population data were available for all years, GPS locations of households had been recorded only once in 2001 and not updated since. GPS data were available for 12,005 households (total of all households in 2004: 16,220).

### 9.3.5 Ethical approval and informed consent

Ethical approval for the studies done within the ACCESS Programme and IMPACT-Tz was received from the institutional review board of the Ifakara Health Research and Development Centre and the Tanzanian National Medical Research Coordinating Committee (NIMR/HQ/R.8a/Vol.IX/236). In addition, IMPACT-Tz was approved by the review board of the U.S. Centers for Disease Control and Prevention. Participation was voluntary and interviewees were informed about the purpose and nature of the research. Oral informed consent was obtained prior to the interviews. Village authorities of the study area were informed about all research activities before their onset.

### 9.3.6 Data entry and analysis

Data were double entered using Microsoft FoxPro and Microsoft Access (Microsoft Corp. Seattle, USA) and checked for coding errors and consistency. Intercooled Stata 8.0 (Stata Corp., College Station, TX, USA) was used for analysis. Mapping of shops and households was done using MapInfo Professional 7.0 (MapInfo Corporation).

## *9.4 Results*

### 9.4.1 Drug stocking outlets

In 2001, 350 shops from an initial list of 439 outlets (80%) were interviewed, of which 287 stocked drugs on the day of the visit; these comprised 10 Part II drug stores and 277 general shops, but no Part I pharmacy. Of those not interviewed, 86 had closed permanently, 1 was temporarily closed, 1 refused, and for 1 no reason was recorded.

In 2004, 758 commercial outlets were visited, which were either listed in 2001 or reported by the community to have opened since then. In 625 (82%) of them, the shop-keeper was interviewed. 123 shops had closed down completely, another eight temporarily. Two shop keepers refused the interview. A total of 195 interviewed shops were in Ifakara and 430 in the DSS area. The interviewed shops ranged from little shacks with a grass-thatched roof to nicely furnished shops with brick walls and display cabinets made of glass.

In the DSS area in 2004 we recorded 19 Part II drug stores and 318 general shops stocking any type of drugs on the day of the visit (78% of interviewed shops). A further 16 outlets reported having sold drugs during the last month but were out of stock the day of the interview. As in 2001, there was no Part I pharmacy in these villages.

In Ifakara town, there were 10 Part II drug stores and 142 general shops stocking drugs in 2004. One Part I pharmacy and the hospital pharmacy of St. Francis Designated District Hospital were not included in the survey. An additional 7 general shops had sold drugs during the last month but were out of stock on the day of the interview.

Between 2001 and 2004, the total number of drug-selling shops increased in the DSS area. There were 15% more general shops stocking drugs (277 vs. 318) and the number of drug stores nearly doubled, from 10 to 19. In both years the absolute number of shops was higher in Kilombero than in Ulanga District, and the increase varied also considerably between the two districts: The number of general shops stocking drugs increased 4% in Ulanga and 23% in Kilombero. The number of drug

shops doubled in Kilombero but remained almost unchanged and low in Ulanga (Table 9.1). An analysis of these data in relation to population numbers is shown below.

**Table 9.1: Number of shops selling drugs and antimalarials**

| Location | Population | | General shops stocking drugs | | | Drug Stores | | | General shops stocking AM | | | Total of AM stocking shops | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 2001 | 2004 | 2001 | 2004 | Δ (%) | 2001 | 2004 | Δ (%) | 2001 | 2004 | Δ (%) | 2001 | 2004 | Δ (%) |
| **Ulanga DSS** | | | | | | | | | | | | | | |
| Idunda | 1736 | 1837 | 6 | 5 | -17 | 0 | 0 | | 1 | 0 | -100 | 1 | 0 | -100 |
| Igota | 1419 | 1533 | 6 | 6 | 0 | 0 | 0 | | 2 | 0 | -100 | 2 | 0 | -100 |
| Igumbiro | 2056 | 2311 | 9 | 10 | 11 | 0 | 0 | | 1 | 2 | 100 | 1 | 2 | 100 |
| Iragua | 3547 | 3704 | 6 | 8 | 33 | 0 | 1 | | 1 | 1 | 0 | 1 | 2 | 100 |
| Kichangani | 3119 | 3103 | 13 | 13 | 0 | 0 | 0 | | 1 | 0 | -100 | 1 | 0 | -100 |
| Kidugalo | 1695 | 2539 | 7 | 3 | -57 | 0 | 0 | | 4 | 0 | -100 | 4 | 0 | -100 |
| Kivukoni | 5634 | 5612 | 22 | 25 | 14 | 1 | 0 | -100 | 4 | 3 | -25 | 5 | 3 | -40 |
| Lupiro | 3591 | 4009 | 24 | 23 | -4 | 1 | 1 | 0 | 0 | 2 | | 1 | 3 | 200 |
| Mavimba | 2268 | 2417 | 11 | 15 | 36 | 0 | 0 | | 1 | 1 | 0 | 1 | 1 | 0 |
| Milola | 1277 | 1282 | 3 | 5 | 67 | 0 | 1 | | 1 | 0 | -100 | 1 | 1 | 0 |
| Minepa | 1955 | 1964 | 9 | 7 | -22 | 0 | 0 | | 2 | 1 | -50 | 2 | 1 | -50 |
| Nakafulu | 1079 | 919 | 6 | 7 | 17 | 0 | 0 | | 0 | 0 | | 0 | 0 | |
| **Sub-total** | **29376** | **31230** | **122** | **127** | **4** | **2** | **3** | **50** | **18** | **10** | **-44** | **20** | **13** | **-35** |
| **Kilombero DSS** | | | | | | | | | | | | | | |
| Idete | 4657 | 4661 | 9 | 18 | 100 | 1 | 1 | 0 | 1 | 0 | -100 | 2 | 1 | -50 |
| Igima | 3210 | 3793 | 17 | 21 | 24 | 1 | 4 | 300 | 12 | 3 | -75 | 13 | 7 | -46 |
| Ikule | 1571 | 2244 | 10 | 12 | 20 | 1 | 3 | 200 | 4 | 0 | -100 | 5 | 3 | -40 |
| Kisegese | 1113 | 1370 | 5 | 9 | 80 | 0 | 0 | | 3 | 2 | -33 | 3 | 2 | -33 |
| Lukolongo | 3526 | 3821 | 9 | 6 | -33 | 0 | 0 | | 1 | 1 | 0 | 1 | 1 | 0 |
| Mbingu | 4928 | 5380 | 14 | 24 | 71 | 1 | 1 | 0 | 7 | 5 | -29 | 8 | 6 | -25 |
| Mchombe | 4006 | 4452 | 30 | 37 | 23 | 2 | 3 | 50 | 9 | 0 | -100 | 11 | 3 | -73 |
| Miwangani | 1446 | 1702 | 7 | 9 | 29 | 0 | 0 | | 2 | 2 | 0 | 2 | 2 | 0 |
| Mkangawalo | 4426 | 4675 | 15 | 16 | 7 | 1 | 1 | 0 | 9 | 0 | -100 | 10 | 1 | -90 |
| Mngeta | 3218 | 3399 | 14 | 13 | -7 | 0 | 2 | | 2 | 1 | -50 | 2 | 3 | 50 |
| Mpofu | 1673 | 1897 | 1 | 1 | 0 | 0 | 0 | | 0 | 0 | | 0 | 0 | |
| Namawala | 2799 | 3675 | 19 | 19 | 0 | 1 | 1 | 0 | 5 | 0 | -100 | 6 | 1 | -83 |
| Njagi | 1597 | 1678 | 5 | 6 | 20 | 0 | 0 | | 2 | 0 | -100 | 2 | 0 | -100 |
| **Sub-total** | **38170** | **42747** | **155** | **191** | **23** | **8** | **16** | **100** | **57** | **14** | **-75** | **65** | **30** | **-54** |
| **Total DSS** | **67546** | **73977** | **277** | **318** | **15** | **10** | **19** | **90** | **75** | **24** | **-68** | **85** | **43** | **-49** |
| **Ifakara*** | | **45726** | | **142** | | | **10** | | | **5** | | | **15** | |

Δ (%) = Change in number of shops 2001-2004 in percent

Data for the DSS villages of Kilombero and Ulanga Districts and Ifakara town. Ifakara population: National census 2002.

### 9.4.2 Availability of antipyretics and antimalarials in general shops

In 2001 and 2004, 99% of general shops stocking drugs in the DSS had antipyretics/analgesics in stock. In 2004, the main products stocked in these outlets were paracetamol generics (93%), aspirin (79%) or co-formulations of paracetamol and another antipyretic/analgesic compound (25%). One particular paracetamol generic made in Tanzania (Sheladol™, Shelys Pharmaceuticals Ltd.) was found in 205 (64%) general shops.

In 2001, of the 277 general shops stocking drugs, 75 (27%) had an antimalarial in stock. All of these stocked chloroquine, while only 1% of all general shops stocked SP and less than 1% amodiaquine or quinine. None stocked injectable antimalarials.

In 2004, of the 318 general shops stocking drugs only 24 (8%) had an antimalarial in stock. 5% stocked amodiaquine, 3% SP and 1% quinine. One general shop had injectable quinine in stock.

In Ifakara in 2004, all except one of the 142 general shops stocking drugs had antipyretics/analgesics in stock. Paracetamol generics (89%) and co-formulations of paracetamol and another antipyretic/analgesic compound (49%) were more frequently stocked than aspirin (13%). Only five (4%) general shops stocking drugs had an antimalarial in stock, all of them amodiaquine.

Hence, within 3 years of the policy change from chloroquine to SP, the number of general shops that stocked antimalarials decreased by 68%, despite an increase in the number of general shops stocking drugs. The decrease was more marked in Kilombero (75%) than in Ulanga DSS area (44%). The proportion of shops stocking drugs that had antipyretics/analgesics remained unchanged. This resulted in a considerable increase in the number of general shops offering treatment for fever – but no cure for malaria.

### 9.4.3 Availability of antipyretics and antimalarials in drug stores

All Part II drug stores in the DSS area stocked antipyretics/analgesics as well as antimalarial drugs in 2001 and 2004. In 2004, they all stocked paracetamol generics and 84% stocked aspirin and diclofenac, a non-steroidal anti-inflammatory drug.

In 2001, the antimalarials stocked by the 10 drug stores in the DSS area were chloroquine (80%), SP (70%), quinine (70%) and amodiaquine (60%). 80% stocked also an injectable antimalarial.

In 2004, the 19 drug stores stocked mainly amodiaquine (95%), SP (90%), and quinine (74%). 68% stocked an injectable antimalarial, usually quinine.

In Ifakara in 2004, all of the 10 drug stores stocked paracetamol, 70% diclofenac generics and 40% aspirin. All drug stores had SP and amodiaquine and 80% had quinine in stock. 30% stocked an injectable antimalarial. Other antimalarial drugs, such as mefloquine or artesunate were only rarely found (Table 9.2).

In 2001, the then first-line drug chloroquine was the most frequently stocked antimalarial in both drug stores and general shops in the DSS area. In 2004, however, the second-line drug amodiaquine was more readily available than the first-line drug SP. The percentage of drug stores with the first-line drug in stock was nevertheless higher in 2004 (90% SP) than in 2001 (80% Chloroquine). In 2004, antimalarial injections were less frequently stocked than in 2001.

**Table 9.2: Products stocked by drug stores and general shops in the study area in 2004**

| **(a) Drug stores** | **Number of drug stores with product in stock (percentage)** | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Location** | **SP** | **AQ** | **QU** | **ART** | **Other** | **INJ** | **Any AM** | **Any AP** |
| Ulanga DSS (*N*=3) | 3 (100) | 3 (100) | 3 (100) | 0 (0) | 0 (0) | 3 (100) | 3 (100) | 3 (100) |
| Kilombero DSS (*N*=16) | 14 (88) | 15 (94) | 11 (69) | 0 (0) | 1* (6) | 10 (63) | 16 (100) | 16 (100) |
| Total DSS villages (*N*=19) | 17 (89) | 18 (95) | 14 (74) | 0 (0) | 1 (5) | 13 (68) | 19 (100) | 19 (100) |
| Ifakara (*N*=10) | 10 (100) | 10 (100) | 8 (80) | 2 (20) | 1** (10) | 3 (30) | 10 (100) | 10 (100) |
| **Total** (*N*=29) | **27 (93)** | **28 (97)** | **22 (76)** | **2 (7)** | **2 (7)** | **16 (55)** | **29 (100)** | **29** (100) |

**Table 9.2 (continued)**

| (b) General shops | Number of general shops with product in stock (percentage) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Location** | **SP** | | **AQ** | | **QU** | | **ART** | | **Other** | | **INJ** | | **Any AM** | | **Any AP** | |
| Ulanga DSS (*N*=127) | 5 | (4) | 5 | (4) | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) | 10 | (8) | 125 | (98) |
| Kilombero DSS (*N*=191) | 5 | (3) | 10 | (5) | 3 | (2) | 0 | (0) | 0 | (0) | 1 | (1) | 14 | (7) | 188 | (98) |
| Total DSS villages (*N*=318) | 10 | (3) | 15 | (5) | 3 | (1) | 0 | (0) | 0 | (0) | 1 | (0) | 24 | (8) | 313 | (98) |
| Ifakara (*N*=142) | 0 | (0) | 5 | (4) | 0 | (0) | 0 | (0) | 0 | (0) | 0 | (0) | 5 | (4) | 141 | (99) |
| **Total** (*N*=460) | **10** | **(2)** | **20** | **(4)** | **3** | **(1)** | **0** | **(0)** | **0** | **(0)** | **1** | **(0)** | **29** | **(6)** | **454** | **(99)** |

SP = Sulphadoxine-pyrimethamine or sulphalene-pyrimethamine; AQ = Amodiaquine; QU = Quinine; ART = Artesunate; CQ = Chloroquine; INJ = Antimalarial injection; AM = Antimalarial; AP = Antipyretics/analgesics. *Chloroquine; **Includes mefloquine and dihydroartemisinin tablets

### 9.4.4 Overall access to antimalarials

From 2001 to 2004, the total number of shops with antimalarials in stock (including drug stores and general shops) decreased in the DSS area by almost 50%, from 85 to 43. In 2004, more drug shops than general shops stocked antimalarials in the Kilombero DSS area and in Ifakara. By contrast, in the Ulanga DSS area, general shops stocking antimalarials outnumbered the few drug shops. The geographical distribution of antimalarial selling shops in 2001 and 2004 is displayed in Figure 9.2.

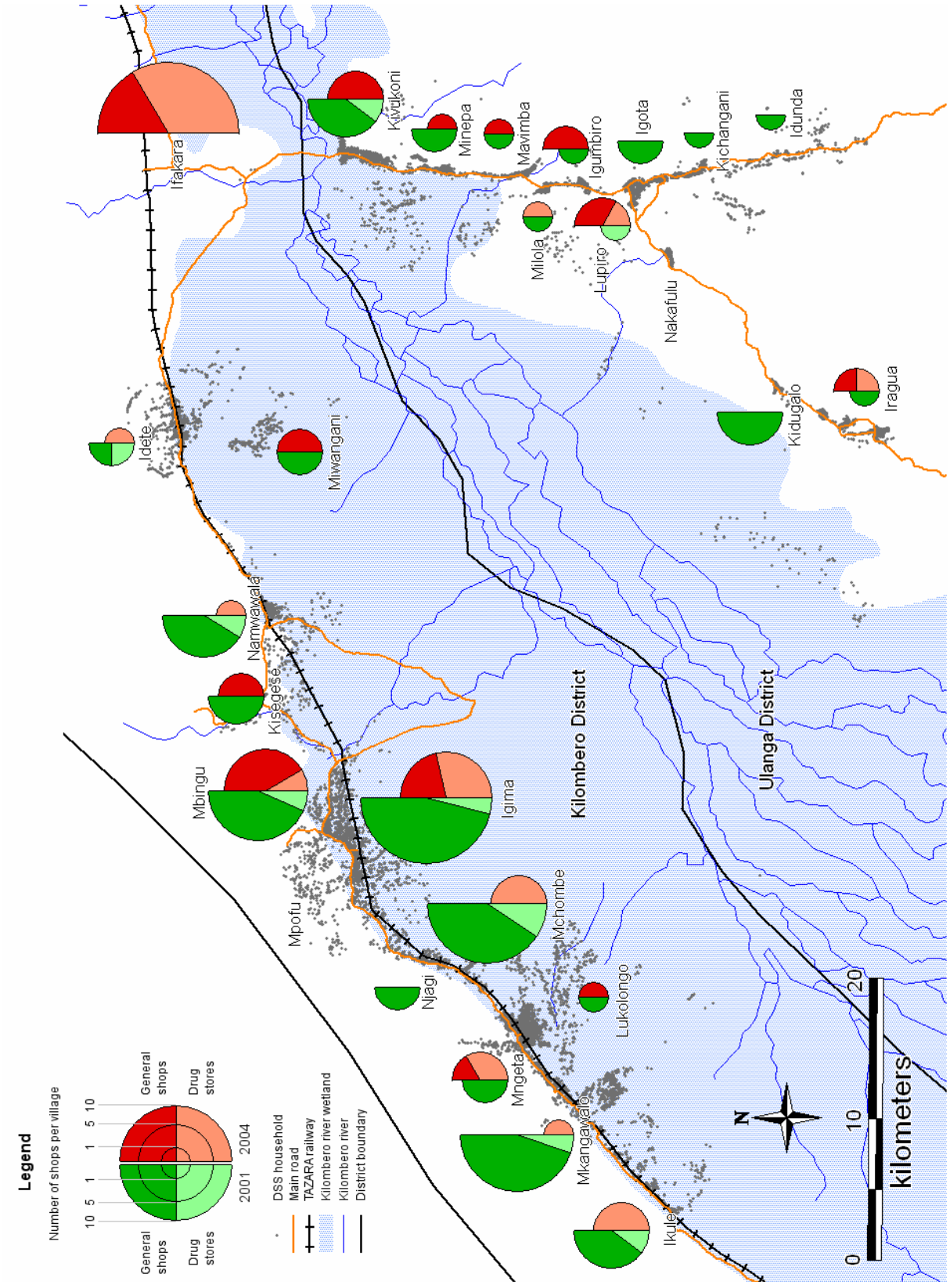


**Figure 9.2: Study area with households (small dots) and number of shops stocking antimalarials, per village, in 2001 and 2004.**

Data for Ifakara town only available for 2004

### 9.4.5 Reasons for not stocking SP

Of the 50 general shops stocking drugs that were re-visited in the follow-up study, one had SP and amodiaquine, and one only amodiaquine in stock the day of the re-visit. Shops without SP stated no permission to sell (65%), lack of demand (39%), or inability to buy the drugs (23%) as reasons for not stocking SP. In total 92% of the shop-keepers were aware that they were not allowed to sell SP and 31% of shops without SP had actually tried to buy SP but could not, usually because they did not have an appropriate drug store license. These findings suggest that the respective legislation was implemented quite effectively.

Only after specific probing did 5 shop keepers (10%) mention the bad reputation or perceived side effects of SP as reasons for not stocking it. Given that shop-keepers did report customer demand for antimalarials (51% for SP, 31% for amodiaquine, 24% for quinine and 16% for chloroquine) it is obvious that there are other determinants for stocking antimalarials than only customer demand.

### 9.4.6 Location of antimalarial selling points

While small general shops were found everywhere in the study area, shops stocking drugs were clustered in larger centres along with other resources such as permanent markets and health facilities. Linear regression analysis of the DSS data showed a significant correlation between the population of the villages and the number of shops stocking drugs (2001: $R^2 = 0.46$, $P < 0.001$; 2004: $R^2 = 0.55$, $P < 0.001$) as well as shops stocking antimalarials (2001: $R^2 = 0.21$, $P = 0.02$; 2004: $R^2 = 0.28$, $P = 0.006$). Whether or not there was a drug store in a village was significantly correlated with the size of the village in 2001 (likelihood ratio $\chi^2 = 13.14$, $P < 0.001$) and 2004 (likelihood ratio $\chi^2 = 7.62$, $P = 0.006$). In both years, there was no such correlation for general shops stocking antimalarials, even though the number of general shops varied with the size of the village.

The distance of households to outlets stocking antimalarials was influenced by the change in the number of outlets from 2001 to 2004. The increase in number of drug stores resulted in slightly more households living within a 2 km range of a drug store (43 vs. 46%) (Figure 9.3). However, the number of households within 2 km of any

shop selling antimalarials decreased (Figure 9.4) as well as the number of households living near any source of antimalarials - shops or health facilities (Figure 9.5). This resulted in more households being located at a farther distance from a treatment source (Table 9.3).

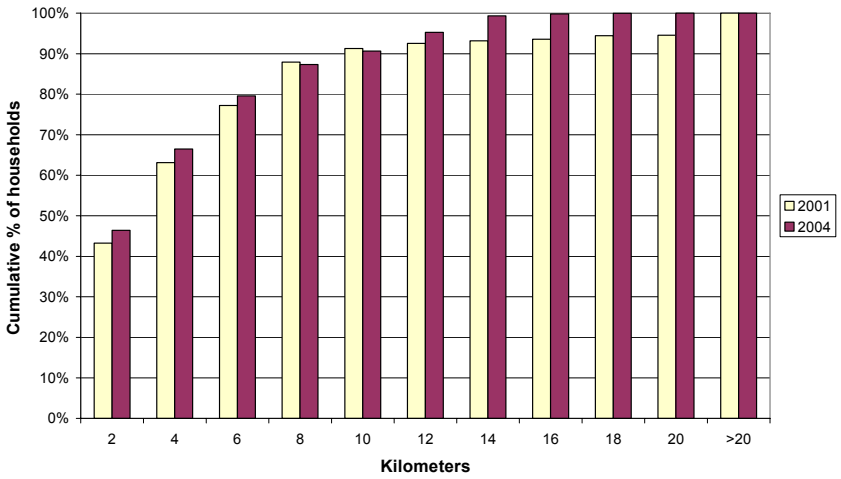


**Figure 7.3: Cumulative percentage of households within given distance to nearest drug store**

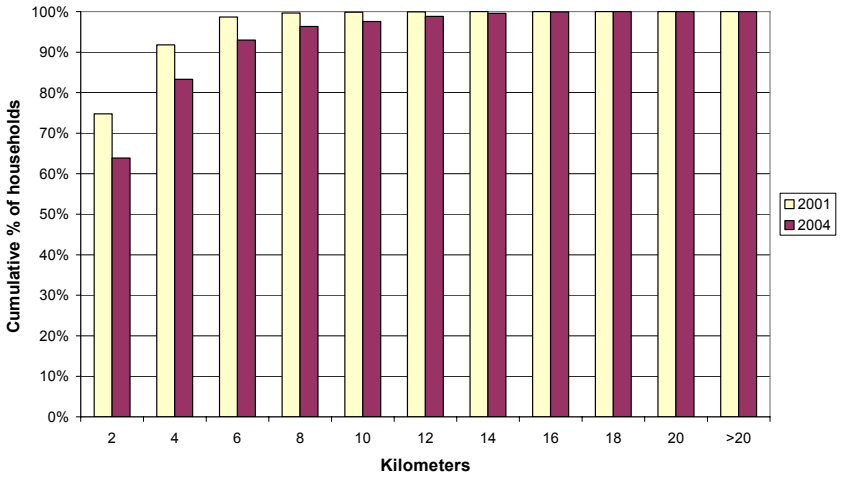


**Figure 7.4: Cumulative percentage of households within given distance to nearest shop stocking antimalarials (general shops and drug stores)**

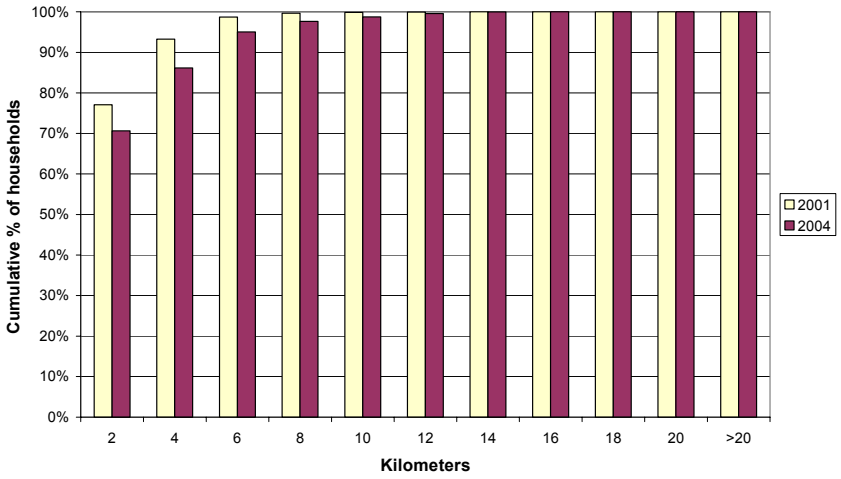


**Figure 9.5: Cumulative percentage of households within given distance to any source of antimalarials (general shops / drug stores / health facilities)**

**Table 9.3: Household distance to source of antimalarials**

| | Number of households (percentage) | | | | | |
|---|---|---|---|---|---|---|
| | Drug Store | | Drug store and general shop stocking AM | | Health facility and shops stocking AM | |
| Distance (km) | 2001 | 2004 | 2001 | 2004 | 2001 | 2004 |
| 0-2 | 5191 (43) | 5571 (46) | 8976 (75) | 7671 (64) | 9254 (77) | 8479 (71) |
| >2-10 | 5766 (48) | 5309 (44) | 3013 (25) | 4044 (32) | 2735 (23) | 3379 (28) |
| >10 | 1048 (9) | 1125 (9) | 16 (0) | 290 (2) | 16 (0) | 147 (1) |

In the DSS area the average population per shop stocking drugs decreased slightly from 235 in 2001 to 220 in 2004 due to the increase in number of shops. Similarly, the population per drug store decreased from 6'755 to 3'894, although it remained very high in Ulanga DSS (10,410 in 2004). The average for Kilombero DSS and Ifakara in 2004 was under the national average of about 6'060 persons per shop selling drugs (calculated on the basis of (Battersby *et al.* 2003; United Republic of Tanzania 2003a)). The population per shop stocking antimalarials increased considerably from 795 to 1,720 in the Kilombero DSS where the numbers of general shops stocking antimalarials had dropped most markedly. Adding health facilities to this calculation on the assumption that they have antimalarial drugs in stock does not change these ratios significantly (Table 9.4).

**Table 9.4: Population per shop**

| | Kilombero DSS | | Ulanga DSS | | Total DSS | | Ifakara |
|---|---|---|---|---|---|---|---|
| | 2001 | 2004 | 2001 | 2004 | 2001 | 2004 | 2004 |
| Population | 38170 | 42747 | 29376 | 31230 | 67546 | 73977 | 45726 |
| Population per shop stocking drugs (GS & DS) | 234 | 207 | 237 | 240 | 235 | 220 | 301 |
| Population per drug store | 4771 | 2671 | 14688 | 10410 | 6755 | 3894 | 4573 |
| Population per shop stocking AM (GS & DS) | 587 | 1425 | 1469 | 2402 | 795 | 1720 | 3048 |
| Population per source of AM, including shops and HF | 530 | 1155 | 1088 | 1562 | 682 | 1298 | 2690 |

GS = General shop; DS = Drug store; AM = Antimalarial; HF = Health facility

In 2001, of the 25 DSS villages, 12 had a health facility and a shop stocking antimalarials, 11 villages had only a shop. In 2 villages with a total population of 2,752 (4% of DSS) there was no antimalarial selling point at all. In 2004, 10 of the DSS villages had a health facility and a shop stocking antimalarials, eight had only a shop and two only a health facility. The number of villages without either of the two increased to five, with a total population of 13,506 (18% of total DSS population).

## *9.5 Discussion & conclusion*

In 2001, Tanzania embarked on a malaria treatment policy change from chloroquine to SP to increase the efficacy of malaria treatment. Four years later, the number of retail outlets stocking antimalarials had dropped to almost half the number in 2001. Furthermore, these outlets did not primarily stock the first-line antimalarial (SP) but rather the second-line drug amodiaquine. On the basis of access measures such as population per antimalarial outlet, number of villages with at least one antimalarial stockist, and distance to antimalarial stockists, availability of treatment has declined in 2004 compared to 2001.

This decrease did not affect all outlets equally. The number of Part II drug stores actually increased and in these outlets the first line drug SP was more often stocked in 2004 than chloroquine in 2001. Anecdotal evidence that some Part II drug stores opened after 2003 were running on the margins of legality was not investigated in the frame of this research, although we noticed that all except one drug seller we interviewed reported to have undergone some form of medical training. Most of them were nurse assistants with one year or less of medical training. From a regulatory point of view, the restriction to drug stores must be seen as a positive development, considering the risks of distributing antimalarials through general shops (Goodman *et al.* 2004). From a public health point of view, this development means that the overall number of antimalarial stocking outlets fell substantially and this bears its own risk.

Changes in availability did not equally affect the two Districts. While the relative decrease was larger in the Kilombero DSS area, the Ulanga DSS area had a lower number of shops stocking antimalarials, leaving as many as five out of 12 villages (42%; 32% of the population) without a single antimalarial retailer in 2004. Smaller villages in both districts were more at risk of losing their antimalarial retailer, as they were more likely to be served only by a general shop. However, the unit “village” may not always be absolutely adequate for such calculations, as some villages are clustered and distances between villages vary (unpublished observations). A household on the edge of one village may for example have a shop relatively close in the neighbouring village.

In Ulanga DSS in 2004, general shops stocking antimalarials outnumbered the few drug stores. The opposite was the case for the Kilombero DSS area and Ifakara, which might result in better rates of appropriate treatment in these areas - under the hypothesis that drug stores provide better services than general shops. This assumption, however, does not take into account people’s perception of the different types of shops and their services, and its impact on utilisation.

The high percentage of general shops stocking antipyretic drugs (74%) suggests a considerable consumer demand for drugs against pain or fever. In addition, over 50% of general shops not stocking antimalarials reported customer demand for SP drugs. This unmet demand may be related to temporary non-availability of services and

drugs at health facilities and/or longer distances to the closest facility or drug store. However, a generally good availability of SP in health facilities has been reported since the policy change (NMCP 2005), but stock-outs occurred recently in health facilities in the both Kilombero and Ulanga Districts.

Interestingly, chloroquine was still requested by patients who may appreciate its antipyretic effect (lacking in the case of SP). However, in 2004 only one shop was found to stock chloroquine, which was officially banned after the introduction of SP. Recent data on treatment seeking collected by the ACCESS Programme does support the observation that chloroquine has been effectively banned.

Lack of availability of antimalarials, particularly SP in general shops is clearly a result of the new drug regulations. The negative perceptions of SP because of the fear of severe side-effects, as described for Tanzania by Nsimba (Nsimba 2006), could not be found in our studies. Interestingly, shops without antimalarials reported more demand for SP than for amodiaquine, although other shops stocked more of the latter. This may reflect the prescription-free (OTC) status of amodiaquine. Amodiaquine has never been put on the list of prescription-only drugs, so it may still be available through non-pharmacy distribution channels.

Other antimalarial drugs than the ones recommended as first-, second- or third-line treatment were basically not available at retailer level. Undoubtedly, the much higher prices of these drugs limits their availability in rural areas. In contrast to Dar es Salaam (Kachur *et al.* 2006a), artemisinin-containing monotherapies are not (yet) frequently sold in our rather remote rural study area. This is encouraging in view of the introduction of artemisinin-based combination therapy (ACT), as widespread use of monotherapies could foster resistance development (WHO 2001b).

As with every cross-sectional study, our surveys have the limitation of capturing a certain situation of one point in the year, ignoring seasonal changes. However, data from the follow-up survey on reasons for not stocking SP, done in November 2004, suggest that the survey data are quite representative. And since the 2001 and 2004 surveys were done in the same season, the data are at least comparable over time.

As a result of decreased availability of antimalarials, the National Malarial Control Programme's goal of improving prompt access to effective treatment may be difficult to achieve, considering the importance of the private sector in providing drugs (McCombie 1996; Hamel *et al.* 2001; WHO 2005a). Home-treatment of malaria with a (mostly) shop bought antimalarial was shown to be done more rapidly than bringing a child to a health facility in an area with good availability of antimalarials in shops (Hamel *et al.* 2001). With antipyretic drugs being available far closer to people's homes than antimalarials, the initial treatment is more likely to be done with antipyretics, potentially delaying the administration of an effective drug against malaria. This is supported by community survey data from the DSS villages and Ifakara, where on the day of illness onset, 64% of recent fever cases in children were treated with an antipyretic but only 53% with an antimalarial.

However, the interpretation of our data is complicated by the fact that data from household surveys conducted in the same areas and time periods did not show a fall in antimalarial use between 2004 and 2001 (IMPACT-Tz collaboration, unpublished data, personal communication S. Patrick Kachur). There was a (non-significant) fall in the proportion of general store users obtaining an antimalarial for febrile illness (27% to 13%), but the overall probability of obtaining an antimalarial showed a (non-significant) increase (46% to 54%). This reflected mainly an improvement in antimalarial utilisation for government facility users, and the relatively small role of general stores in antimalarial provision in 2001. The relatively unimportant role of general stores was documented by data on antimalarial volumes in 2002, which showed that general stores accounted for only 7% of all antimalarials dispensed in the DSS areas (Goodman 2004). Although poorer people in these areas are no more likely to use general stores (Njau *et al.* 2006), it is possible that poorer groups were more affected by the change in antimalarial availability, as they were more likely to live in the most remote locations. Njau et al. (Njau *et al.* 2006) showed that it is the better-off who get better treatment for fever episodes. However, they spend significantly more money for the treatment they obtain from the more expensive non-governmental organisation facilities and from drug stores. Changing to better quality but also more expensive treatment sources may consequently not be an option for the poorest, unless exemption mechanisms (theoretically in place in public health facilities) increase affordability of treatment and care.

The regulatory environment that was created after the introduction of SP as first-line treatment does not support well the promotion of home-based management of malaria. This problem is likely to be further exacerbated by the imminent policy change in Tanzania with the introduction of a highly efficacious artemisinin-based combination therapy (ACT). The potential advantages of supplying ACT as prescription-only drugs through skilled providers, such as prevention of fast development of resistance and limiting irrational drug-use (D'Alessandro *et al.* 2005), need to be carefully weighed against the disadvantages of limiting ACT distribution to few suppliers, which may not easily be accessed by a considerable part of the population.

The Accredited Drug Dispensing Outlets (ADDO) Project which is currently being piloted in a few Tanzanian districts by TFDA and Management Sciences for Health may contribute to the solution to this problem (Mbwasi 2005). Its goal is to improve access to affordable quality drugs and services in drug retail outlets in rural or peri-urban areas. Activities include promoting and assisting in the establishment of new drug stores even in remote areas, and in training drug sellers and shop owners to dispense a limited range of prescription-only drugs. This initiative could increase the number of shops licensed to sell antimalarials and/or ACT in the frame of a quality service provision. A big question at this time is the high price of ACTs and hence the need for subsidies to make them affordable in poor rural areas.

To assure prompt and appropriate malaria treatment, availability of effective drugs close to people's homes is essential, combined with appropriate prescription practices and improved compliance on the patient's side. In case of the imminent policy change to ACT, these issues need to be taken into consideration. A pre-requisite for this is a good coordination of the efforts of the drug regulatory and the malaria control authorities. The aim must be to guarantee that the new drugs reach all those who need them in time. A precious chance would be missed if regulatory mechanisms prevented people from having prompt access to life-saving malaria treatment with ACT.

## 9.6 Authors' contributions

MWH designed and coordinated the 2004 surveys, analysed the 2004 data and drafted and finalized the manuscript. JJM and AM participated in the design and coordination of the 2004 surveys. CG was responsible for the 2001 shop survey, analysed the 2001 data and contributed to the manuscript. CL and BO contributed to the 2004 study design, data analysis and to the manuscript. SPK supervised the 2001 shop survey and contributed to data analysis, interpretation and the manuscript. AS participated in the design of the 2004 surveys and contributed to the discussion on the manuscript. RN provided the DSS household data. HM provided overall supervision and contributed to the discussion on the manuscript. The final manuscript was approved by all authors.

## 9.7 Acknowledgements

We thank the shop-keepers who participated in the surveys and our interviewers who carried out the field work. We appreciate the comments of Beatus Leon and Iddy Mayumana on an early draft of this paper. This paper is published with permission of Dr. Andrew Kitua, Director-General, National Institute for Medical Research. The ACCESS Programme is funded by the Novartis Foundation for Sustainable Development. IMPACT-Tz is primarily supported by funding from the United States Agency for International Development, the Centers for Disease Control and Prevention, and the Wellcome Trust. Catherine Goodman was supported by a Research Training Fellowship from The Wellcome Trust from 2001-2004 (ref 060184), and by a Postdoctoral Fellowship from the Economic and Social Research Council from 2004-2005 (ref PTA-026-27-0179).

# 10 MALARIA TREATMENT IN THE RETAIL SECTOR: DRUG SELLERS' KNOWLEDGE AND PRACTICES IN RURAL TANZANIA

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This paper has been submitted to
*PLoS ONE*

## *10.1 Abstract*


### 10.1.1 Background

Throughout Africa, the private retail sector has been recognised as an important source of antimalarial treatment, complementing formal health services. However, the quality of advice and treatment at private outlets is a widespread concern, especially with the introduction of artemisinin-based combination therapies (ACTs). As a result, ACTs are often deployed exclusively through public health facilities, potentially leading to poorer access among parts of the population. Documenting the performance of the retail sector is urgently required to improve and broaden delivery channels for life-saving drugs.

### 10.1.2 Methodology/Principal Findings

Using data from a shop census and an innovative mystery shoppers approach, we assessed knowledge and practice of shop keepers in private retail outlets in two rural Tanzanian districts. Shop keepers in drug store knew more about malaria and its treatment than their peers in general shops. In drug stores, 52% mentioned the correct child-dosage of sulphadoxine-pyrimethamine (SP) compared to only 3% in general shops. In drug stores, mystery shoppers were more likely to receive an appropriate treatment (OR=9.6), but at a higher price. Overall, adults were more often sold an antimalarial than children (OR=11.3). On the other hand, general shop keepers were often ready to refer especially children to a higher level if they felt unable to manage the case.

### 10.1.3 Conclusions/Significance

The quality of malaria case-management in the retail sector is not satisfactory. Drug stores should be supported and empowered to provide correct malaria-treatment with drugs they are allowed to dispense. At the same time, the role of general shops as first contact points for malaria patients needs to be re-considered. Interventions to improve availability of ACTs in the retail sector are urgently required within the given legal framework.

## *10.2 Background*

Treatment-seeking behaviour for malaria in sub-Saharan Africa is complex, often involving several steps and actors, depending on the local health system, society and culture (McCombie 1996; Obrist *et al.* 2007). As a result of poor access to and often poor performance of formal health services, presumptive treatment of malaria episodes at home has become a widespread option (McCombie 2002; Gyapong & Garshong 2007). The home-management of malaria (HMM) strategy of the WHO is promoting interventions to improve antimalarial drug use outside the formal health services as a complementary option to improve access to prompt and effective treatment at community level (WHO 2005a).

In most places, the private retail sector has been identified as an important source of drugs close to people's homes (Foster 1991; Snow 1992; Goodman *et al.* 2004). However, patients obtaining drugs from private retailers may not receive an antimalarial drug, even if it would be appropriate (Kachur *et al.* 2006b). If antimalarials are dispensed, dosages are often inappropriate, especially for more complex dosage regimens (Slutsker *et al.* 1994; Abuya *et al.* 2007). In order to improve community-wide effectiveness of antimalarial treatment, the popularity of home-management and the quality of treatment obtained from commercial shops need to be better addressed. Considerable improvement in case-management has been shown to be possible as a result of training private retailers in general shops (Marsh *et al.* 2004) and in drug stores (Mbwasi 2005).

The retail sector for drugs in Tanzania includes two types of licensed drug stores as well as general shops. Fully-fledged pharmacies are allowed to sell all prescription medicines and need to be headed by a pharmacist. Yet in 2003, 60% of the 344 existing pharmacies were located in Dar es Salaam and the rest in other larger towns (Battersby *et al.* 2003). Part II drug stores (*Duka la Dawa Baridi)* need to be headed by a person with basic medical or health-related training and can be found also in larger villages. These shops are allowed to sell all over-the-counter (OTC) drugs (e.g. analgesics/antipyretics). In practice however, they dispense a much wider variety of medicines, including prescription-only antimalarials. In 2003, 5666 registered part II drug stores were operating in Tanzania (Battersby *et al.* 2003). General shops are

not legally allowed to sell prescription drugs. However, they often sell common OTC medicines, such as painkillers (Figure 10.1).


**Figure 10.1: Part II drug store (left) and general shop (right) selling antimalarial treatment in rural Tanzania**

The studies presented here applied a mixed methods approach to compare factual knowledge with every-day practices of private drug retailers in treating cases of malaria in two Tanzanian districts. We included retailers in drug stores as well as general shops in order to get a comprehensive picture of the quality of treatment and advice that can be obtained from the private retail sector.

This research provides valuable information in the light of ongoing discussions on the distribution channels for highly efficacious antimalarial drugs, such as artemisinin-based combination therapies (ACT). The work was carried out within the frame of a project to improve access to prompt and effective malaria treatment in rural Tanzania (ACCESS Programme) (Hetzel *et al.* 2007c).

## *10.3 Methods*

### 10.3.1 Study setting

A systematic shop census and a complementary qualitative study using mystery shoppers were conducted in the districts of Kilombero and Ulanga, Morogoro Region, south-eastern Tanzania. The study area comprised the 25 villages of the local

Demographic Surveillance System (DSS) (Armstrong Schellenberg *et al.* 2002) and the town of Ifakara, 20 km to the east of the DSS. The mid-2004 population of the DSS was 74,200 and Ifakara had a population of 45,726 in the 2001 population census (United Republic of Tanzania 2003a).

Malaria is highly endemic in the area, accounting for roughly half of all outpatient visits in rural health facilities. The study area is described in more detail elsewhere (Hetzel *et al.* 2007c). Previous studies in the same setting found a range of easily accessible commercial outlets frequently selling drugs for fever episodes (Goodman *et al.* 2004). In 2004, 29 part 2 drug stores and 460 general shops stocking drugs were counted and chloroquine was found to be completely replaced on the market by sulphadoxine-pyrimethamine (SP) and amodiaquine (Hetzel *et al.* 2006).

At the time of the surveys, SP was the recommended first-line treatment for uncomplicated malaria; amodiaquine and quinine were second-line and third-line treatment, respectively. Quinine was the drug of choice for severe malaria (MOH 2000). All antimalarials were prescription-only medicines and could therefore legally be sold only in the one registered pharmacy located in Ifakara town. However, part II drug stores which were found in some villages were generally tolerated to stock and sell antimalarials. General shops were not allowed to stock any prescription drugs, which was reflected in the low availability of antimalarials reported elsewhere (Hetzel *et al.* 2006).

### 10.3.2 Shop census

Between May and June 2004, all commercial outlets in the DSS area and Ifakara town were visited in order to investigate the availability of antimalarial drugs in the retail sector. The detailed methodology of this census, as well as the results on drug availability have been published elsewhere (Hetzel *et al.* 2006). This paper makes use of additional information on shopkeepers' knowledge of malaria and its treatment, collected during the same survey. During the shop-visits, the shop keepers were asked to mention signs and symptoms of malaria. Then, they were asked what the recommended treatment was for uncomplicated malaria in a two-year-old child and

an adult. In addition, the interviewers recorded information on the estimated number of customers per day.

### 10.3.3 Mystery shoppers

The results of the census were complemented in September and October 2004 by "mystery shoppers", simulated clients who purchased drugs for predefined malaria case-scenarios.

From a preliminary list of outlets stocking drugs in 2004 (n=510), a sample of 111 general shops (approx. 20%) was chosen at random. The sample was drawn per village and weighed by village size. A back-up sample was drawn to compensate for shops that would be closed or could not be visited for other reasons. In addition, all 19 drug stores from the DSS area and 10 from Ifakara town were added to the sample.

Three case scenarios were randomly assigned to each shop:
(A) child aged 2-4 months, with fever/hot body for one day and problems with drinking/breastfeeding
(B) child aged 2-4 years, with recurring fever/hot body for 3 days (especially at night), problems with drinking and eating, diarrhoea and tiredness/not playing as usual
(C) adult, with recurring fever/hot body for 2 days, headache, dizziness and loss of appetite.
Symptoms for all scenarios did explicitly exclude signs of convulsions or unconsciousness. For the child-scenarios, the mystery shoppers would carry their children when visiting the shops, if at all possible.

Local DSS field staff identified suitable mystery shoppers from the villages in which the respective shops were located. On the day of the study, the mystery shoppers were explained the aim of the exercise and instructed by project staff. Mystery shoppers were asked to visit one selected shop and ask for treatment based on the aforementioned case-scenario. Each mystery shopper received 2,000 Tanzanian shilling (TSh) (US $1.80) to buy drugs. After completing their assignment, they were interviewed by project staff about what exactly happened when they visited the shops,

what they had told the shop keeper, and what advice and drugs they were given. Interviews were tape-recorded and later transcribed. Drugs and remaining money were collected, types and amount of drugs recorded, and the mystery shoppers were paid a small fee for their collaboration.

### 10.3.4 Data entry and analysis

Generic and brand names (if possible), as well as amount and price of the drugs obtained by the mystery shoppers were entered in a Microsoft Access database (Microsoft Corp., Seattle, USA). Interviews with the mystery shoppers were entered with word processing software in an RTF file and imported into MAXqda software (VERBI GmbH, Marburg, Germany) for analysis. Statistical analysis was done with Intercooled Stata 9 (StataCorp, College Station, Texas, USA).

### 10.3.5 Ethics

While mystery shoppers were fully informed and asked for informed consent, the nature of this study did not allow informing the shopkeepers in advance and asking them for consent to participate. To protect shopkeepers' privacy, no names of staff were recorded and names of shops were never mentioned in connection with the study's results. For the shop census, informed consent was obtained from shopkeepers as described in detail in the aforementioned publication.

The shop survey and mystery shopper study were granted ethical clearance as part of the ACCESS Programme proposal by the institutional review board of the Ifakara Health Research and Development Centre and the Tanzanian National Medical Research Coordinating Committee (NIMR/HQ/R.8a/Vol.IX/236).

## *10.4 Results*

### 10.4.1 Shop census

The sample for this analysis included interviews with shopkeepers of 29 Part 2 drug stores (*Duka la Dawa Baridi*) and 460 general shops, all of which stocked drugs the

day of the interview. General shopkeepers had on average a lower education than their peers in drug stores (7 vs.10 years, P<0.001). A shop keeper with medical or health-related qualifications was found in 93% of the drug stores and 1.5% of the general shops (P<0.001). Shopkeepers reported the number of customers buying drugs per day to be on average 19 (95% CI 14 to 24) in drug stores and 10 (9 to 11) in general shops (P<0.001).

#### 10.4.1.1 Knowledge of malaria symptoms and treatment

Shopkeepers of drug stores most frequently mentioned fever, headache and vomiting (86.2% each) as symptoms of malaria (not specified whether in children or adults). In general shops, fever (60.4%), headache (40.2%) and joint pains (38.9%) were most frequently mentioned (Table 10.1). Generally, shopkeepers of general shops seemed to be significantly less aware of malaria symptoms. They mentioned all of the recorded symptoms less frequently than shopkeepers of drug stores. Out of 15 symptoms associated with malaria, shopkeepers in drug stores mentioned on average 4.8 (95% CI 4.1 to 5.5), while in general shops they mentioned only 2.4 (2.3 to 2.5) (P=0.005). If asked for “severe malaria” (*malaria kali*), a similar picture arose. The symptoms most often mentioned by general shop keepers were high fever (43.7%) and weakness (17.9%), while in drug stores, shop keepers most often mentioned high fever (79.3%) and convulsions (*degedege*) (51.7%) (Table 10.1).

In drug stores, most shopkeepers knew that an antimalarial drug was the recommended treatment for malaria in a two year-old child (89.7%) and in an adult (93.1%). In general shops, shopkeepers most frequently said that the child should be referred to a health facility (34.3%) while adults should take an antimalarial drug (53.7%). Shopkeepers of drugs stores had significantly better knowledge of malaria treatment, as shown in Table 10.2. In drug stores, 65.5% mentioned SP as the recommended treatment for a child aged 2 years and 79.3% for an adult. In general shops this percentage was significantly lower. Of those who mentioned SP, 78.9% knew the correct child dose in drug stores and 26.8% in general shops (P<0.001). No shopkeeper mentioned traditional treatment, or that the episode should not be treated at all.

**Table 10.1: Malaria symptoms mentioned most frequently by shopkeepers (N=489)**

| | Drug store | General shop | |
|---|---|---|---|
| **symptom** | **% (95% CI)** | **% (95% CI)** | **P*** |
| N | 29 | 460 | |
| **What are symptoms of malaria?** | | | |
| Fever | 86.2 (68.3-96.1) | 60.4 (55.8-64.9) | **0.006** |
| Headache | 86.2 (68.3-96.1) | 40.2 (35.7-44.9) | **0.000** |
| Joint pains | 62.1 (42.3-79.3) | 38.9 (34.4-43.5) | **0.014** |
| Vomiting | 86.2 (68.3-96.1) | 32.5 (28.2-37.0) | **<0.001** |
| Malaise | 31.0 (15.3-50.8 | 19.6 (16.1-23.5) | 0.138 |
| Feeling cold | 17.2 (5.8-35.8) | 16.3 13.0-20.0) | 0.895 |
| Poor appetite | 20.7 (8.0-39.7) | 9.8 (7.2-12.9) | 0.063 |
| Weakness | 27.6 (12.7-47.2) | 7.2 (5.0-10.0) | **<0.001** |
| Diarrhoea | 27.6 (12.7-47.2) | 5.9 (3.9-8.4) | **<0.001** |
| Dizziness | 13.8 (3.9-31.7) | 3.9 (2.3-6.1) | **0.013** |
| Don’t know | 0.0 (0.1-11.9) | 11.5 (8.7-14.8) | 0.053 |
| **What are symptoms of severe malaria?** | | | |
| Changed behaviour | 24.1 (10.3-43.5) | 17.0 (13.7-20.7) | 0.326 |
| Unconsciousness / coma | 17.2 (5.8-35.8) | 7.4 (5.2-10.2) | 0.059 |
| Weakness | 34.5 (17.9-54.3) | 17.9 (14.5-21.7) | **0.027** |
| Anaemia | 10.3 (2.2-27.4) | 0.7 (0.1-1.9) | **<0.001** |
| Convulsions (*degedege*) | 51.7 (32.5-70.6) | 10.0 (7.4-13.1) | **<0.001** |
| Splenomegaly (*bandama*) | 3.4 (0.1-17.8) | 0.2 (0.0-1.2) | **0.008** |
| High fever | 79.3 (60.3-92.0) | 43.7 (39.1-38.4) | **<0.001** |
| Don't know | 3.4 (0.1-17.8) | 27.1 (23.1-31.5) | **0.005** |

* Wilcoxon rank sign test

**Table 10.2: Shopkeepers' understanding of the recommended treatment of uncomplicated malaria (N=489)**

| Treatment‡ | Drug store % (95% CI) | General shop % (95% CI) | P* |
|---|---|---|---|
| N | 29 | 460 | |
| **Child aged two years with uncomplicated malaria** | | | |
| Referral to health facility | 3.4 (0.1-17.8) | 34.3 (30.0-38.9) | **0.001** |
| Antipyretic | 55.2 (35.7-73.6) | 30.9 (26.7-35.3) | **0.007** |
| Antimalarial | 89.7 (72.6-97.8) | 31.7 (27.5-36.2) | **<0.001** |
| - SP | 65.5 (45.7-82.1) | 12.2 (9.3-15.5) | **<0.001** |
| - SP + PCM | 34.5 (17.9-54.3) | 4.6 (2.8-6.9) | **<0.001** |
| - SP correct dose | 51.7 (32.5-70.6) | 3.3 (1.8-5.3) | **<0.001** |
| - SP correct dose + PCM | 31.0 (15.3-50.8) | 0.9 (0.2-2.2) | **<0.001** |
| **Adult with uncomplicated malaria** | | | |
| Referral to HF† | 0 (0-11.9) | 23.7 (19.9-27.9) | **0.003** |
| Antipyretic | 55.2 (35.7-73.6) | 43.9 (39.3-48.6) | 0.237 |
| Antimalarial | 93.1 (77.2-99.2) | 53.7 (49.0-58.3) | **<0.001** |
| - SP | 79.3 (60.3-92.0) | 35.0 (30.6-39.6) | **<0.001** |
| - SP + PCM | 48.3 (29.4-67.5) | 15.7 (12.5-19.3) | **<0.001** |
| - SP correct dose | 75.9 (56.5-89.7) | 28.9 (24.8-33.3) | **<0.001** |
| - SP correct dose + PCM | 44.8 (26.4-64.3) | 14.3 (11.3-17.9) | **<0.001** |

SP = Sulphadoxine-pyrimethamine; PCM = Paracetamol

* Wilcoxon rank sign test

‡ Double-mentioning possible

† one-sided, 97.5% confidence interval

In a multivariate logistic regression analysis adjusted for shop type, number of customers and shop location, higher general education was a significant predictor of knowing SP as recommended treatment for adults (OR=1.15, 95% CI 1.02-1.30; P=0.020). A health-related qualification was a strong predictor of knowing SP as a child treatment (OR=12.36, 2.45-62.20; P=0.002). Correctly dosed SP for adults - but not for children - was correlated with higher education (OR=1.15, 1.01-1.30; P=0.032) and a health-related qualification (OR=4.80, 1.08-21.34; P=0.039). Generally, there seemed to be better knowledge of the appropriate treatment among shopkeepers in Ulanga DSS villages, compared to Kilombero DSS and Ifakara town.

#### 10.4.1.2 Referral

Shop keepers were asked for situations in which they would refer a customer to another outlet or a health facility. In drug stores, 19 or 65.5% of the shop keepers said they would refer customers if they showed signs of severe malaria, in general shops this was indicated by 259 or 56.3%. Of the general shop keepers, 56 or 12.6% said they would never refer somebody to another outlet or a health facility, while this was never mentioned by shop keepers of drug stores.

### 10.4.2 Mystery shoppers

A total of 20 Part 2 drug stores and 98 general shops were visited by mystery shoppers. General shops comprised all sorts of outlets, from permanent modern shops to temporary stalls. Case-scenarios were distributed as shown in Figure 10.2.

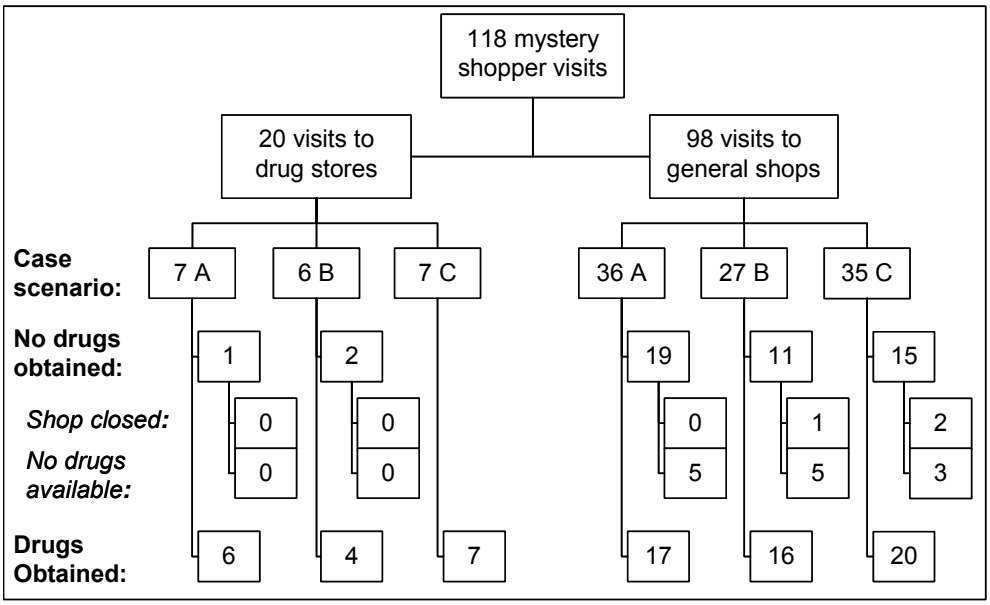


**Figure 10.2: Flow-chart of mystery shoppers study**

Case scenarios: A = child, aged 2-4 months; B = child, aged 2-4 years; C = adult. (Refer to main text for details.)

#### 10.4.2.1 Drug sale

Mystery shoppers obtained drugs in 53 (54.1%, 95% CI 62.1-96.8) general shops and 17 (85.0%, 43.7-64.2) drug stores (P=0.01) (Table 10.3).

**Table 10.3: Number of shops that dispensed drugs to mystery shoppers**

| | Drug store | General shop | Total |
|---|---|---|---|
| **Area** | **n (%)** | **n (%)** | **n (%)** |
| Ulanga DSS | 2/2 (100) | 23/30 (76.7) | 25/32 (78.1) |
| Kilombero DSS | 10/10 (100) | 20/44 (45.5) | 30/54 (55.6) |
| Ifakara | 5/8 (62.5) | 10/24 (41.7) | 15/32 (46.9) |
| **Total** | **17/20 (85.0)** | **53/98 (54.1)** | **70/118 (59.3)** |

Out of the 17 **drug stores** that sold drugs, 88.2% (63.6 to 98.5) dispensed an antipyretic and the same percentage of 88.2% (63.6 to 98.5) an antimalarial (Table 10.4). SP, amodiaquine and quinine were sold six times each. Once, SP and quinine were sold together. All drug stores sold SP together with paracetamol, as recommended in the national guidelines (MOH 2000). Quinine was always, and amodiaquine in most cases sold together with paracetamol.

No antimalarials other than SP, amodiaquine or quinine were dispensed. Two drug stores sold an antibiotic, together with amodiaquine or quinine + paracetamol. In the Kilombero DSS villages, Vitamin B was sometimes dispensed together with antimalarials.

Of the 53 **general shops**, 84.9% (72.4 to 93.3) sold an antipyretic, usually paracetamol and 18.9% (9.4 to 32.0) sold an antimalarial, either SP or amodiaquine. 3 out of 5 times, SP was dispensed together with paracetamol. 2 out of 4 times, amodiaquine and paracetamol were dispensed together. Twice, general shop sold an antibiotic (Table 10.4).

On average, drug shops sold more products per client than general shops, which often had only paracetamol on offer. Drug stores most frequently sold two products (to 44% of the mystery shoppers) (mean 2.9 products, 95% CI 2.0 to 3.8). General shops most often sold only one product (66% of the mystery shoppers) (mean 1.5 products, 1.2 to 1.8).

**Table 10.4: Types of medicines sold to mystery shoppers**

| | Drug stores (N=17) | General shops (N=53) |
|---|---|---|
| **Type of drugs** | **n (%)** | **n (%)** |
| **Antimalarials** | | |
| SP | 6 (35.3) | 5 (9.4) |
| Amodiaquine | 6 (35.3) | 4 (7.6) |
| Quinine | 4 (23.5) | 0 |
| Any antimalarial | 15 (88.2) | 10 (18.9) |
| **Antipyretics** | | |
| Paracetamol | 14 (82.4) | 39 (73.6) |
| Any antipyretic | 15 (88.2) | 45 (84.9) |
| **Other drugs** | | |
| Antibiotic | 2 (11.7) | 2 (3.8) |
| Vitamin B complex | 5 (29.4) | 0 |
| **Combinations** | | |
| SP & paracetamol | 6 (35.3) | 3 (5.7) |
| Amodiaquine & paracetamol | 4 (23.5) | 2 (3.8) |
| Quinine & paracetamol | 4 (23.5) | 0 |
| SP & quinine | 1 (5.9) | 0 |
| Antimalarial & antibiotic | 2 (11.7) | 0 |

#### 10.4.2.2 Predictors of drug sale

Univariate and multivariate models were fitted to assess factors related to obtaining an antimalarial and obtaining an antimalarial treatment according to Tanzanian guidelines.

Adjusted for the confounding effect of age group (i.e. case scenarios A, B, C, as described above), visits to a drug store resulted significantly more often in obtaining a drug than visits to a general shop (OR=6.02, 95% CI 1.57 to 23.10) and shopkeepers in the DSS were more likely to sell a drug than their counterparts in Ifakara (OR=2.53, 1.04 to 6.18).

In drug stores, mystery shoppers were significantly more likely to receive an antimalarial (OR=76.47, 13.07 to 447.50) (Table 10.5). Adults were more likely to be sold an antimalarial compared with infants (OR=9.30, 1.70 to 50.92) and compared

with the two child scenarios (OR=11.27, 2.36 to 53.81) (not in table). There was no significant difference in this outcome between shops located in the villages or in Ifakara town.

In order to assess whether the observed difference in antimalarial dispensing was due to a lower availability of drugs in general shops, the same analysis was carried out only with shops that had dispensed any drugs at all. It resulted that drug stores were again more likely to dispense an antimalarial than general shops (OR=70.71, 9.38 to 533.10). If a drug was sold, mystery shoppers were in both types of shops equally likely to receive an antipyretic drug.

**Table 10.5: Univariate and multivariate logistic regression analysis of the relationship between (any) antimalarial drug obtained and selected predictors (all visited shops)**

| Predictor | n | Univariate model | | Multivariate model | |
|---|---|---|---|---|---|
| | | Odds Ratio (95% CI) | P* | Odds Ratio (95% CI) | P* |
| **Case scenario** | | | | | |
| - Child 2-4 months | 43 | 1 | | 1 | |
| - Child 1-4 years | 33 | 0.85 (0.22-3.30) | 0.815 | 0.62 (0.09-4.00) | 0.612 |
| - Adult | 42 | 3.43 (1.18-9.98) | 0.024 | 9.30 (1.70-50.92) | **0.010** |
| **Shop type** | | | | | |
| - General shop | 98 | 1 | | 1 | |
| - Drug store | 20 | 26.40 (7.91-88.10) | <0.001 | 76.47 (13.07-447.50) | **<0.001** |
| **Location** | | | | | |
| - Ifakara | 32 | 1 | | 1 | |
| - DSS | 86 | 0.95 (0.35-2.53) | 0.911 | 1.65 (0.41-6.66) | 0.480 |

* Wald test of significance of effect

Adjusted for the same confounders as listed in Table 10.5, mystery shoppers visiting a drug store were more likely to receive the recommended first-line antimalarial SP

(OR=9.62; 1.53 to 60.53) or even SP together with paracetamol (OR=16.40; 2.28 to 117.99) than those who went to a general shop.

Again, the same analysis was carried out only for those shops that had dispensed an antimalarial. In this case, drug stores did not dispense SP (or SP with paracetamol) more often than general shops.

#### 10.4.2.3 Price

In drug stores, mystery shoppers paid a median price of TSh 1000 or US $0.90 (interquartile range [IQR] 0.50-1.53) for drugs, while in general shops they spent only TSh 140 or US $0.13 (IQR 0.09-0.29, equality-of-medians test P<0.001).

**Table 10.6: Linear regression model of predictors of higher expenditures for antimalarial drugs**

| Risk factors | n | Univariate model | | Multivariate model | |
|---|---|---|---|---|---|
| | | Estimated effect (95% CI) | P* | Estimated effect (95% CI) | P* |
| **Case scenario** | | | | | |
| - Child 2-4 months | 20 | 1 | | 1 | |
| - Child 1-4 years | 22 | -0.12 (-0.42 to 0.18) | 0.423 | -0.16 (-0.37 to 0.05) | 0.124 |
| - Adult | 26 | -0.15 (-0.44 to 0.13) | 0.285 | -0.25 (-0.45 to -0.06) | **0.012** |
| **Number of products** | 68 | 0.19 (0.11 to 0.27) | <0.001 | 0.12 (0.05 to 0.19) | **0.001** |
| **Shop type** | | | | | |
| - General shop | 50 | 1 | | 1 | |
| - Drug store | 18 | 0.75 (0.56 to 0.95) | <0.001 | 0.59 (0.38 to 0.80) | **<0.001** |
| **Location** | | | | | |
| - Ifakara | 15 | 1 | | 1 | |
| - DSS | 53 | -0.11 (-0.39 to 0.17) | 0.434 | -0.06 (-0.24 to 0.13) | 0.548 |

*Wald test of significance of effect

In a multivariate linear regression model we assessed the effect of the age group (case scenario A, B, C), the number of products sold, the shop type and the location (Ifakara vs. DSS) on the price charged to the mystery shoppers. Significantly less (-25%) money was spent for adult cases (case scenario C) compared to children aged 2-4 months (case scenario A) (P=0.012) and 59% more in drug stores than in general shops (P<0.001). Obviously, more money was spent if more drugs were sold (12% more per additional product; P=0.001) (Table 10.6).

#### 10.4.2.4 Dosage and advice

The accuracy of the dosages was judged from the amount of drugs the mystery shoppers obtained and from their accounts of the advice they were given by the shopkeepers.

10/11 (90.9%) SP doses were tablets, one was a suspension. 4/10 (40.0%) amodiaquine doses were tablets and 6 were suspensions. Quinine was sold 2/4 (50%) times as tablets, and twice as syrup.

10/11 (90.9%) SP dosages (incl. the suspension) and 4/10 (40%) amodiaquine dosages (2 tablets, 2 suspensions) were correct, considering the amount sold and the advice given. For two amodiaquine doses, no dosage information was available. Quinine tablets and syrup doses were all wrongly dosed. With the low number of samples no relevant comparison could be made between the appropriateness of the dosages and the shop types. Yet it should be noted that in general stores, all SP dosages tablet were correct, while in the drug stores, 1/6 was under-dosed (adult case). On the other hand, all amodiaquine dosages which were sold in drug stores (and for which the dosage information was available) were correct while those sold in general shops were under-dosed.

3 (15.0%) drug stores and 29 (29.6%) general shops did not sell any drugs to the mystery shoppers although they would have had drugs in stock (Figure 10.1). In all of these drug stores the mystery shoppers were advised to seek treatment or advice from a health facility. In the general shops, 86.2% (25/29) of the shopkeepers

referred the mystery shoppers to a higher level: 62.1% (18/29) to a health facility and 31.0% (9/29) to a drug store (some of them to both).

## *10.5 Discussion*

The private retail sector plays a central role in the provision of malaria treatment in Tanzania. In rural areas, 68% of the population live within 5km of a health centre or a dispensary (98% in urban areas) (United Republic of Tanzania 2005). Yet, poor quality of care, shortage of skilled providers, stock-outs of essential drugs, and long waiting times (Mamdani & Bangser 2004; Dillip *et al.* 2007) are challenges which may drive patients to seek care (or at least buy drugs) from more expensive private or mission facilities, or from drug stores. The private retail sector can complement health facility services where the facilities are unable to deliver (Hetzel *et al.* 2007d).

In the studies presented here, drug stores reported to have significantly more customers for drugs than general shops, reflecting the relative importance of these types of outlets in the provision of antimalarial medicines. In an earlier study, general shops have been described as being important treatment sources for fever/malaria, with 29% of fever cases using this source of treatment. Yet, in terms of drug volumes, general shops accounted for only 6-7% of all antimalarial doses dispensed in the two study districts (Goodman 2004).

General shops are important first contact points of patients with a network of treatment providers. They are numerous even in small villages and often more easily accessible than drug stores or health facilities (Hetzel *et al.* 2006). While general shops are not legally allowed to dispense antimalarial drugs, they are recognised in the national policy as one component of the health care delivery structure (MOH 2000; MOH 2002). Providers in general shops are generally less knowledgeable about malaria and its appropriate treatment, supporting the ban of antimalarial drugs from these outlets. Surprisingly, only 60% of general shopkeepers mentioned *homa* (fever) as a symptom of malaria. In part, this may be explained by the parallel use of *homa* as a term to describe a less severe febrile illness or general malaise (Winch *et al.* 1996; Hausmann Muela 2000). Knowing the correct treatment was clearly a function of the shopkeeper's education, which in general shops was lower than in

drug stores. Only 3.3% of the shop keepers in general shops were able to mention the correct SP dosage for children and 28.9% for adults. However, they did not seem to be completely unaware of their limitations, as 34.3% of the general shop keepers mentioned referral to a health facility as the correct action for a 2 year-old child with malaria.

Drug stores on the other hand are the lowest level of providers which is generally tolerated to dispense prescription-only antimalarial drugs. Unfortunately, they often do not reach out into small villages or remote areas (Hetzel *et al.* 2006). Shop keepers in drug stores were more knowledgeable about malaria-related symptoms and malaria treatment than their counterparts in general shops. Knowledge of antimalarial treatment was strongly correlated with basic medical or health-related training, a prerequisite for shop keepers of licensed part II drug stores (United Republic of Tanzania 2003b). Yet, their performance was still not very satisfactory, with only 51.7% mentioning SP in the correct dosage as recommended treatment for children.

*Knowledge vs. practice*

In order to get a realistic picture of drug-sellers' performance, we used mystery shoppers; an approach which is innovative and has been used in only few occasions in African private sector settings (Tavrow *et al.* 2003; Nyazema *et al.* 2007). The main challenge of applying this methodology in a rural setting, which is to find un-suspicious and capable mystery shoppers within a certain village, was tackled with the help of knowledgeable village-based DSS field staff.

Daily shopkeepers' practices clearly reflected their level of understanding of appropriate treatment, the current drug regulations, as well as the low antimalarial availability in general shops (Hetzel *et al.* 2006). Antipyretics were frequently sold in drug stores and general shops. Most drug stores (88.2%) also sold antimalarials to the mystery shoppers, usually in combination with paracetamol. In contrast, during a study conducted elsewhere in Tanzania in which shop keepers were under observation, only 17.1% of febrile patients had received an antimalarial (Kachur *et al.* 2006b). In general shops, 18.9% of the mystery shoppers were sold an antimalarial. This was slightly more than would have been expected based on the shop census in

which 8% of all general shops that had drugs in stock also stocked an antimalarial (Hetzel *et al.* 2006).

While many shop keepers in drug stores knew that SP was the recommended treatment for children and adults, in practise, amodiaquine and quinine were sold as often as SP. This may to some extent reflect that amodiaquine was slightly more readily available in drug stores and, according to anecdotal evidence, quinine was popular as it was often regarded a strong and powerful medicine (Hetzel *et al.* 2006). Overall, it was more likely that a mystery shopper received an antimalarial or even SP in a drug store. However, drug stores did not adhere better to the guidelines than general shops. This may in part be attributed to the fact that in general shops there were fewer different antimalarial products available and therefore less opportunity to diverge from the first-line regimen. Mere non-availability may also be a reason why no other antimalarials than SP, amodiaquine and quinine were sold, along with the fact that with the cash provided by the researchers, the mystery shoppers would not have been able to purchase expensive drugs such as artemisinin mono therapies or ACT (Kachur *et al.* 2006a).

Altogether, adults would more readily be dispensed an antimalarial than children. This is interesting in the light of findings from a cross-sectional community-survey in which adults would be treated more frequently with shop bought drugs while children were more often brought to a health facility (Hetzel *et al.* 2007d). This may give some indications of provider-side influences on treatment-seeking behaviour.

Treatments for adults were 25% cheaper than treatments obtained for very young children and drug stores were more expensive than general shops. The latter was also found in another study in the same area, where more expensive treatments were obtained from non-governmental organisation (NGO) facilities and drug stores, usually by people from the better-off socio-economic stratum (Njau *et al.* 2006).

Private retailers may commonly be perceived as being mainly business-driven in their behaviour. In this study we found that in theory, more than half of all shop keepers said they would refer severely ill patients and general shopkeepers commonly regarded referral as best option for young children. In practice, 15% (3/20) of drug

stores and 30.5% (25/82) of general shops did not sell any medicines but referred the simulated patients to a higher level of care – although they would have had drugs in their shops. The awareness of shopkeepers that certain cases need to be dealt with at a higher level may be a good entry point for interventions targeted at the retailer level. Several projects targeting private drug retailers, have already counted on the ability and willingness of shopkeepers to refer severe or complicated cases to an appropriate facility (Marsh *et al.* 1999; Mbwasi 2005).

*Implications for policy and interventions*

The importance of the retail sector as a source of malaria treatment and care complementary to health facility has been recognised internationally (TDR/WHO 2006) and within Tanzania (MOH 2002). However, the major concern regarding the private sector has been inadequacy of the treatments offered by often untrained (or not sufficiently trained) shopkeepers (Marsh *et al.* 1999; Brugha *et al.* 1999; McCombie 2002). This issue has re-emerged in the discussions about appropriate delivery channels for ACTs. Defining the role of each type of retailer present in a health system within the frame of their capabilities and the given legal context is an important first step in improving quality and access.

Fully-fledged pharmacies only reach 17% of the Tanzanian population and are hence not sufficient to meet the demand for essential drugs (Ndomondo-Sigonda *et al.* 2005). Part II drug stores which are the largest network of licensed drug-retailers in Tanzania (Battersby *et al.* 2003) are licensed to sell only OTC drugs, to which none of the recommended antimalarials belongs. Kachur *et al.* showed that patients at drug stores are as likely to be infected with malaria as patients seeking care at health facilities (Kachur *et al.* 2006b). Considering this demand for antimalarial treatments, there is a need to make efficacious antimalarial drugs available in drug stores. In reality this is usually tolerated by the authorities who recognise the lack of alternatives. In order to improve the quality of services in drug stores, specialised training for drug vendors may be a valid option for improving management of malaria-cases, as has been shown in other areas (Marsh *et al.* 2004). The mere definition of educational prerequisites as currently the case for Part II shops may only lure health workers away from health facilities to a more profitable business in the retail sector. Yet, training alone is unlikely to improve performance if not coupled with appropriate

means of rewarding the shopkeepers for good practices (Brugha & Zwi 1998; Brugha *et al.* 1999). These approaches are combined in a project that upgrades Part II shops to Accredited Drug Dispensing Outlets (ADDO) and that is currently being implemented in selected districts in Tanzania (Mbwasi 2005; Ndomondo-Sigonda *et al.* 2005).

The role of general shops should not be the dispensing of prescription medicines. Yet, due to their importance as easily accessible first contact point for malaria patients, they should not be completely left aside when targeting the private sector. There are several options to strengthen their role in the health sector. Firstly, they could be upgraded to drug retailers (e.g. ADDOs) if appropriately trained, thereby increasing the population coverage with antimalarial providers. Secondly, general shop keepers could be trained on the appropriate first aid for malaria cases with OTC medicines and subsequent referral to a higher level. Considering that general shops may manage malaria cases only with antipyretics, particularly in places where they are the nearest provider, targeted information or training may decrease the number of inappropriately managed cases at the lowest level. The social pressure exerted on shopkeepers by communities' expectations on their performance should not be under-estimated. In our study, a considerable number of shopkeepers did without business in favour of referring the patient to a drug store or a health facility.

Including all levels of formal and informal health care providers is feasible within the existing legal framework and guided by the national malaria control policy. Alternative approaches including lowest level shops may be a step forward in improving access for people living in remote areas or deprived villages which so far lack any provider of antimalarial medicines (Hetzel *et al.* 2006).

## *10.6 Conclusion*

Private retailers play an important role in the provision of prompt and effective malaria treatment, complementing the services of formal health facilities. Yet, the quality of case-management in the retail sector leaves much room for improvement. Drug stores should be empowered and encouraged to provide correct malaria-treatment with drugs they are legally allowed to dispense. At the same time, the role

of general shops as important first contact points for malaria patients needs to be re-considered within the given legal framework.

Interventions on shop-level should consider all types of private retailers. While antimalarial medicines, such as ACTs ought to be dispensed only by qualified personnel, general shop keepers may acquire sufficient knowledge to properly recognise malaria cases and refer them to a trained provider.

## *10.7 Authors' contributions*

MWH was responsible for all aspects of the shop census, contributed to the development of the mystery shoppers study, selected the sample, analysed the data together with AD and wrote the manuscript in collaboration with the other authors. JJM prepared the mystery shoppers research plan and data collection activities, and supervised the field-work. CL and BO conceived the research questions and contributed to the design of both studies and the discussion of the manuscript. AM and CM provided support during field-work and contributed to the discussion of the findings. AS and HM contributed to the research questions and the study design. All authors read and approved the final manuscript.

## *10.8 Acknowledgements*

We thank all the shopkeepers for (in part unknowingly) participating in our surveys. We appreciated the support from local leaders and DSS staff in tracing the sampled outlets and finding mystery shoppers in the field. Many thanks go to our shop survey team and to all mystery shoppers. We very much acknowledge the commitment of our shop survey supervisor Saidi King’eng’ena who did an excellent job in coordinating the field work and coding and checking the questionnaires. The studies were conducted within the frame of the ACCESS Programme, which is funded by the Novartis Foundation for Sustainable Development, Switzerland.

# 11 ACCESS TO HEALTH CARE IN CONTEXTS OF LIVELIHOOD INSECURITY: A FRAMEWORK FOR ANALYSIS AND ACTION

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This paper has been published in
*PLoS Medicine* 4(10): e308

## *11.1 Abstract*

Universal and equitable access to quality health care is not only a health but also a development issue. To improve access, novel community approaches have to better align health care services with the resources of the poor. This article suggests a framework linking social science and public health research with broader livelihood approaches to poverty alleviation and exemplifies the approach with research findings and interventions of the ACCESS Programme in Tanzania. Such an approach examines access as a critical factor in a double sense: people 1) need access to household and community assets in order 2) to be able to access health care services. It thus illuminates a neglected aspect of the illness-poverty trap: While it is true that illness reduces people's productive capability and medical costs deplete their livelihood resources, people may in fact not even gain access to health services because they lack access to the required household and community assets. This insight not only opens up new lines of scientific inquiry, it also calls for access policies and interventions that reach beyond health services.

## 11.2 Introduction

Access to health care is a major health and development issue. Most governments declare that their citizens should enjoy universal and equitable access to good quality care. However, even within the developed world, this goal is difficult to achieve, and there are no internationally recognized standards on how to define and measure "equitable access" (Oliver & Mossialos 2004). Evidently, big disparities exist between the poor and the better off with respect to access to health care services and health status (Gwatkin 2001; Victora *et al.* 2003; Gwatkin 2005). Gaps in child mortality between rich and poor countries are wide, as well as between the wealthy and the poor within most countries. Poor children are not only more likely than their better off peers to be exposed to health risks and have less resistance to disease, they also have less access to preventive and curative interventions. Even public subsidies for health frequently benefit rich people more than poor people. Clearly, more of the same is not enough (Victora *et al.* 2003): To improve equitable access, innovative and community-based approaches are needed to better align health care services with poor people's needs, expectations, and resources.

This article presents a framework for analysis and action to explore and improve access to health care in resource-poor countries, especially in Africa. The framework links social science and public health research with broader development approaches to poverty alleviation. It was developed in the frame of the ACCESS Programme, which focuses on understanding and improving access to prompt and effective malaria treatment and care in rural Tanzania as an empirical case study (Hetzel *et al.* 2006; Hetzel *et al.* 2007c). The article first provides a brief outline of three approaches to investigating health care access, focusing either on health seeking, health services, or livelihoods. It then presents a framework that combines the three approaches, exemplified with research findings and interventions of the ACCESS Programme.

## 11.3 Access to health care from three perspectives

Health-seeking studies focus on people (Suchman 1965; Chrisman 1977; Kleinman 1980; Mackian *et al.* 2004). They apply pathway models and follow sick persons step

by step from the recognition of symptoms through different types of help seeking until they feel healed or capable of living with their condition. Health-seeking studies provide a deeper understanding of why, when, and how individuals, social groups, and communities seek access to health care services, and investigate interactions between lay persons and professionals (Montgomery *et al.* 2006). In this perspective, social actors are the potential driving force for improving access to effective and affordable health care, but they are often constrained by politics and the economy on national and international levels (Singer & Baer 1995; Baer *et al.* 1997; Farmer 1999).

Health service studies concentrate on factors influencing access to health care, which they commonly define as utilization rates (Penchansky & Thomas 1981; Fiedler 1981; Andersen 1995). They apply determinants' models and consider access as a general concept summarizing a set of more specific dimensions, such as availability, affordability, accessibility, adequacy, and acceptability. Although they take into account demographic characteristics of health service users, their knowledge about the disease, and, more recently, wealth as measured by household assets, health services studies tend to pay more attention to the supply than the demand side (Gulliford *et al.* 2002; Ensor & Cooper 2004). They search for policy interventions to reduce supply barriers and improve the delivery of services, including availability of health facilities, equipment, and qualified staff, staff skills, protocols of diagnosis, treatment, and quality of care. Moreover, they are less oriented towards health-seeking processes. Interventions on the demand side are commonly limited to information, education, and communication (IEC) campaigns.

Livelihood approaches—as the name implies—emphasize assets (including material and social resources) and activities needed to gain and sustain a living under conditions of economic hardship (Chambers 1989; Chambers & Conway 1991; Chambers 1995; Carney *et al.* 1999; DFID 2001; Hussein 2002). Access is a key issue for sustainable livelihoods (De Haan & Zoomers 2005). Recent studies applying the Sustainable Livelihood framework of the United Kingdom Department for International Development to study HIV/AIDS (Seeley & Pringle 2002) and malaria (J. Chuma, unpublished PhD thesis) demonstrate the many difficulties people face in gaining access to household and community assets and how this constrains their strategies to cope with the disease. In other words, not only possession, but

mobilization of household and community assets is a critical factor influencing people's access to health care and other health-related services. Interventions target communities and social groups, emphasize solidarity and empowerment, and try to improve livelihood conditions.

## *11.4 Access to health care with a livelihood focus*

The Health Access Livelihood Framework combines health service and health-seeking approaches and situates access to health care in the broader context of livelihood insecurity (Figure 11.1).

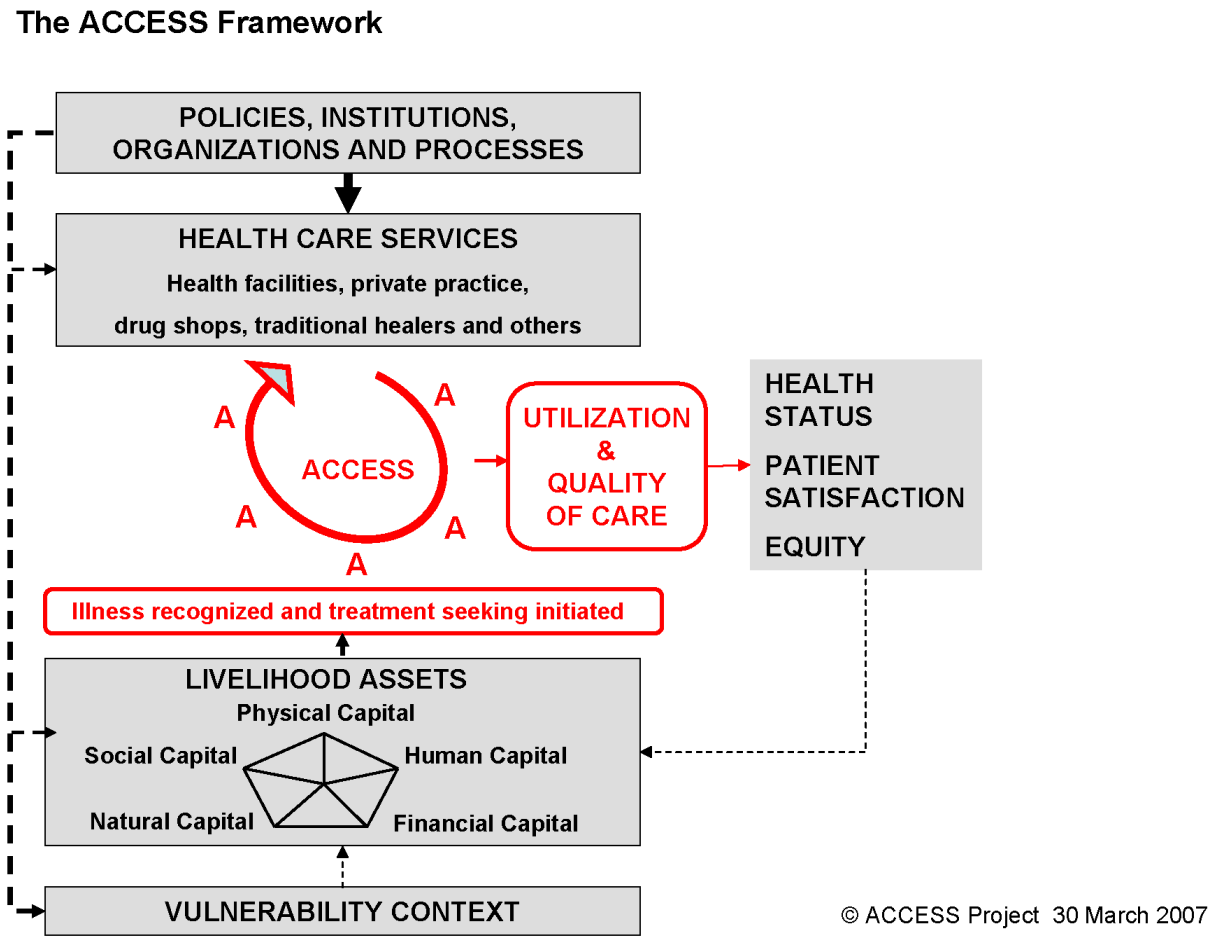


**Figure 11.1: The Health Access Livelihood Framework**

Once people recognize an illness and decide to initiate treatment, access becomes a critical issue. Five dimensions of access influence the course of the health-seeking process: Availability, Accessibility, Affordability, Adequacy, and Acceptability. What degree of access is reached along the five dimensions depends on the interplay between (a) the health care services and the broader policies, institutions, organizations, and processes that govern the

services, and (b) the livelihood assets people can mobilize in particular vulnerability contexts. However, improved access and health care utilization have to be combined with high quality of care to reach positive outcomes. The outcomes can be measured in terms of health status (as evaluated by patients or by experts), patient satisfaction, and equity.

### 11.4.1 Five dimensions of access

Access becomes an issue once illness is recognized and treatment seeking is initiated. Five dimensions of access influence the course of the health-seeking process: Availability, Accessibility, Affordability, Adequacy, and Acceptability (see Table 11.1).

**Table 11.1: Five dimensions of access to health care services**

| Dimension | Questions |
|---|---|
| **Availability:** The existing health services and goods meet clients' needs. | What types of services exist? Which organizations offer these services? Is there enough skilled personnel? Do the offered products and services correspond with the needs of poor people? Do the supplies suffice to cover the demand? |
| **Accessibility:** The location of supply is in line with the location of clients. | What is the geographical distance between the services and the homes of the intended users? By what means of transport can they be reached? How much time does it take? |
| **Affordability:** The prices of services fit the clients' income and ability to pay. | What are the direct costs of the services and the products delivered through the services? What are the indirect costs in terms of transportation, lost time and income, bribes, and other "unofficial" charges? |
| **Adequacy:** The organization of health care meets the clients' expectations. | How are the services organized? Does the organizational set up meet the patients' expectations? Do the opening hours match with schedules of the clients, for instance the daily work schedule of small-scale farmers? Are the facilities clean and well kept? |
| **Acceptability:** The characteristics of providers match with those of the clients. | Does the information, explanation, and treatment provided take local illness concepts and social values into account? Do the patients feel welcome and cared for? Do the patients trust in the competence and personality of the health care providers? |

A review of literature from Tanzania found, for instance, that people considered the availability of essential drugs a prerequisite to the credibility of health services (Mamdani & Bangser 2004). Problems of accessibility, including long distances to nearest dispensary or health center, scarce public transport, and lack of bicycles and other private means continued to be major access barriers. Issues related to affordability were also major obstacles: complaints about fees were frequent, and even if official fees were exempted (e.g., for children under fives) or waived (e.g., for persons temporarily unable to pay), people often ended up paying for drugs, small charges, kerosene, and even ambulance transport. Poor people had to resort to short-term coping strategies like selling critical assets such as crops to pay for health care, especially in times of emergencies. Adequacy and acceptability in terms of people's judgment of quality of care also played an important role.

What degree of access is reached along the five dimensions depends on the interplay between (a) the health care services and the broader policies, institutions, organizations, and processes (PIOP) (SDC/NADEL 2006) that govern the services, and (b) the livelihood assets people can mobilize and combine in particular vulnerability contexts. Hence, access improves as health care services become better aligned with clients' needs and resources.

### 11.4.2 The health care services and the PIOP

Sick persons and caregivers seek help not only in health facilities or private practice, but also in drug shops and pharmacies as well as from healers representing a wide array of medical traditions. Access to these health care service providers is governed by cultural norms, policies, laws and regulations, which themselves are influenced by broader trends in society, global health policy, research, and development.

In malaria control, for instance, the World Health Organization has increasingly recognized the role of the private retail sector in improving access to prompt malaria treatment, since self-treatment at home is often the first response to a malaria episode (WHO 2005a). The National Malaria Control Programme of Tanzania also acknowledges the importance of shops for home management of malaria (MOH 2002). A shop survey of the ACCESS Programme showed, however, that the

proportion of general shops with antimalarials in stock had dropped from 27% in 2001 (Goodman *et al.* 2004) to 8% in 2004 (Hetzel *et al.* 2006). The reduced availability of antimalarials in general shops was largely due to a change in the policy of the Ministry of Health. Until 2001, chloroquine was the first-line antimalarial and was treated as an over-the-counter drug; Part II drug stores—a category of shops below pharmacies—were allowed to sell chloroquine and, in practice, chloroquine was also tolerated in general shops, where it was widely available (Goodman *et al.* 2004). After the policy change from chloroquine to sulphadoxine-pyrimethamine (SP) as the first-line antimalarial in 2001, SP remained classified as prescription-only. The Tanzania Food and Drugs Authority (TFDA), which is responsible for all regulatory aspects of drugs and other medical products in the country, did not reclassify SP as an over-the-counter drug. Hence, SP could only be legally sold in pharmacies (Part I drug shops). In many parts of the country, SP was also tolerated in Part II drug stores, though not in general shops. In the study area, the TFDA regulations were enforced, and while the change in malaria policy resulted in a higher treatment efficacy, it also led to an almost 50% decrease in the availability of antimalarials. To improve the availability of antimalarials for home management of malaria, the ACCESS Programme decided to collaborate with a TFDA-supported program that upgrades Part II shops and enables them to sell antimalarials and other essential drugs (Mbwasi 2005; MSH 2006).

### 11.4.3 Livelihood assets and the vulnerability context

Whether people actually recognize an illness and seek treatment in drug shops or through other health care services depends to a large extent on their access to livelihood assets of the household, the community, and the wider society. These livelihood assets comprise human capital (local knowledge, education, skills), social capital (social networks and affiliations), natural capital (land, water, and livestock), physical capital (infrastructure, equipment, and means of transport) and financial capital (cash and credit) (DFID 2001). The availability of these assets is influenced by forces over which people have little control, for instance economy, politics or technology, climatic variability or shocks like floods, draughts, armed conflicts or epidemics. Such factors may be referred to as their vulnerability context.

In the study area of the ACCESS Programme, the Kilombero Valley in southeastern Tanzania, the natural environment increases people's vulnerability to health risks (Hetzel *et al.* 2006). Malaria is highly endemic, transmission is intense and perennial, and malaria is the predominant cause of morbidity and mortality. Large parts of the valley are flooded during the rain season from November to May. Most of the 517,000 people living in the 109 villages (2002) rely on subsistence agriculture. Labor-intensive rice farming on distant fields in the floodplain forces many families to move to their farming sites during the cultivation period (Hetzel *et al.* 2007a). Already in the village, families face many difficulties in gaining access to the resources necessary for malaria prevention and case management, but even more so in the farming sites (Mayumana *et al.* 2007).

For nearly all members of the study communities, land is the backbone of their livelihood (natural capital) (Mayumana 2007). To raise cash for renting bicycles, buying drugs, or paying treatment expenses (financial capital), farmers have to tap household savings, sell food stock, borrow from local money lenders, and work as causal laborers. Family members and relatives take sick children to health care services, buy drugs, and provide practical and moral support (social capital). Bicycles feature prominently as an asset enabling treatment seeking (physical capital). Popular and biomedical concepts of malaria nowadays overlap (human capital), probably as a consequence of regular and intensive IEC and social marketing campaigns. During its first phase (2003–2007), the ACCESS Programme invested in social marketing to increase knowledge and awareness of malaria and to promote prompt and appropriate treatment seeking from reliable sources (Hetzel *et al.* 2007c). For the second phase starting in 2008, additional initiatives to facilitate access to livelihood assets are planned, such as support to community health funds and provision of microcredits.

### 11.4.4 Health care utilization and quality of care

Depending on access to health care services and to livelihood assets, people develop multiple and changing health care utilization strategies. They may take no action at all or use different service providers simultaneously or in sequence. However, even if they gain access and health care utilization takes its course, the

outcome in terms of health status (as evaluated by experts or by patients), patient satisfaction, and equity (defined as equal access to health care by those in equal need (Oliver & Mossialos 2004)) is subject to the technical quality of care. In a broad sense, technical quality of care includes provider compliance and diagnostic accuracy, safety of the product, and patient compliance (or adherence; see Figure 11.1).

An ACCESS Programme study to determine the effectiveness and promptness of fever treatment based on caregivers' accounts highlights the impact of quality of care (Hetzel *et al.* 2007d). A community survey of a random sample of 318 household identified 80 children under five years of age who had a fever (considered as a proxy for malaria) during the 14 days preceding the interview. The results show that 100% of the sick children were treated with a pharmaceutical drug (an antipyretic or antimalarial), 88% were treated with the recommended antimalarial, 76% received the recommended antimalarial on the same day or the day after the fever started, 43% got the recommended antimalarial on the same day or the day after the fever started in the correct dosage, and only 23% were given the recommended antimalarial on the same day or the day after the fever started, in the right dosage, considering also age and the reported symptoms. The multivariate analysis showed that access to and use of a health facility during the course of the fever increased the chance of receiving one of the recommended antimalarials (SP, amodiaquine, or quinine, according to national guidelines) ($p$ = 0.004). On the other hand, antimalarials from health facilities were not more accurately dosed than those obtained from shops. To improve quality of care in health facilities, the ACCESS Programme supported the Council Health Management Teams of the two districts in carrying out refresher training in malaria case-management for health facility staff, followed by strengthening of routine supportive supervision and the implementation of a quality management scheme in all health facilities (Hetzel *et al.* 2007c).

## *11.5 Conclusion*

Even the most powerful diagnostic tests, drugs, and vaccines have little public health impact if they do not reach the poor. Providing the goods, as well as the services to

deliver them, and ensuring that goods and services are of high quality, are major challenges by themselves, especially in a resource-poor setting. But unless additional efforts are made to enable poor people to gain access to these goods and services, as well as to more basic livelihood assets required to initiate treatment seeking, equitable access remains an empty formula of politicians and experts. This is an aspect of the illness–poverty trap that is often overlooked. While it has been increasingly acknowledged that ill-health contributes to poverty because health costs deplete people's meager resources, it is hardly recognized that people often cannot even gain access to health services because they cannot mobilize critical livelihood resources. This article presents an innovative framework that pulls together the strength of social sciences, public health research, and development studies. Through this combination of perspectives and expertise, a more comprehensive, but structured analysis of access to health care in resource-poor settings can be achieved, which will lead to the identification of key entry points and targeted action for health and poverty alleviation in horizontal community-based approaches.

## *11.6 Acknowledgments*

We acknowledge the inputs of M. Tanner, M. Weiss, and other colleagues at the Swiss Tropical Institute. Our understanding of the links between access and livelihood draws on discussions within the program of the National Center for Competences in Research "North-South: Research Partnerships for Mitigating Syndromes of Global Change," supported by the Swiss National Science Foundation and the Swiss Agency for Development and Cooperation. This paper was published with the permission of Dr. Andrew Kitua, Director-General, National Institute for Medical Research, Tanzania. Ethical clearance of the ACCESS Programme proposal was granted by the National Institute of Medical Research of the United Republic of Tanzania (NIMR/HQ/R.8a/Vol. IX/236, September16, 2003).

## *11.7 Author contributions*

BO and AS wrote the manuscript in collaboration with the other authors. BO, CL, and HM designed the ACCESS Programme. NI, AM, and CM were responsible for the development and implementation of the interventions. SA, AD, MWH, and IM were

responsible for data collection and analysis. RN is in charge of the Demographic Surveillance Site and NI of the overall project management. All authors contributed to and approved the final manuscript. **Funding:** The ACCESS Programme is funded by the Novartis Foundation for Sustainable Development. The Health Project Manager (AS) of the Novartis Foundation contributed to the project design and the development of this generic access framework. **Competing Interests:** The authors have declared that no competing interests exist. The corresponding author, Brigit Obrist, has supplied the information regarding the contribution of Hassan Mshinda to the manuscript and his competing interest and it is correct to the best of her knowledge. The co-author works for the Novartis Foundation for Sustainable Development which is fully funded by the pharmaceutical company Novartis. The Foundation works independently from the company's business and supports non-for profit health programs in developing countries.

# PART 4

# DISCUSSION AND RECOMMENDATIONS

On a *shamba* in Ulanga District

# 12 DISCUSSION

The present thesis investigated factors influencing access to prompt and effective malaria treatment in a highly malaria-endemic area of rural Tanzania. The aim of this research was to contribute to a better understanding of access to treatment in order to inform the development of targeted interventions. In addition, the findings should feed into a more general model of access which could be used for conceptual and analytical purposes. This chapter starts with a review of the methodological approaches, followed by a discussion of the main research findings with reference to the original objectives described in chapter 4 and the frameworks developed within the ACCESS Programme. Finally, the implications for malaria control interventions and health policy are discussed and recommendations for further research on access are made.

## *12.1 Methodological issues*

The research for this thesis was carried out within a rural DSS area and the nearby semi-urban centre of Ifakara. The local DSS offered a unique opportunity to integrate community-based studies into a well-established data-collection routine. At the same time, the DSS provided demographic data which could be used as sampling frame and as denominator for community-level indicators. Last but not least, the DSS which has been operational since 1996 (Armstrong Schellenberg *et al.* 2002), has built a solid bridge between the researchers at IHRDC and the community, via village-based DSS field-interviewers. Most of the studies were also conducted in Ifakara town, which is situated outside the DSS. Sampling of households was more challenging there and demographic data was only available from the 2002 national population census (United Republic of Tanzania 2003a).

Operationally, carrying out the research in the DSS was a big advantage and some information could not have been collected without this system. Thanks to the DSS, research results could be compared to data from earlier studies conducted in the same area. And other projects, such as IMPACT-Tz, which were simultaneously taking place within the DSS, provided valuable additional information which was not collected directly through ACCESS activities (e.g. chapter 9). Nevertheless, certain

trade-offs need to be considered when interpreting the research results. The long-standing presence of researchers in the area may have influenced the way people answered to survey questions. Every household in the DSS is visited three times a year by a field-interviewer and it is possible that people become tired of repeatedly answering the same or similar questions. On the other hand, villagers may appreciate the visits of DSS staff as courtesy and opportunity to share their problems and concerns. In fact, both situations have been reported from the field. The understandable request of the community for some kind of return for their continuous collaboration should be met by an investment into activities that improve health and welfare in the area on the basis of the acquired knowledge.

The possibility of a “Hawthorne effect” also needs to be considered (Roethlisberger & Dickson 1939; Last 2001). Respondents may adapt their responses (or their behaviour) as a consequence of the increased attention paid to them by the DSS staff. In concrete terms this could mean that somebody either reports a more adequate care-seeking behaviour or even takes more appropriate actions as a result of knowing that he or she is being studied. Consequently, observations made by researchers may not accurately reflect the situation in the community (as it would be without the researchers’ attention). Yet, the actual behaviour of the residents of the study area is likely to be influenced not only by the DSS but to a larger extent by previous intensive malaria control activities that had been going on in the area, particularly the KINET social marketing for ITNs (Armstrong Schellenberg *et al.* 1999; Armstrong Schellenberg *et al.* 2001).

Whether and how the findings can be extrapolated to the rest of Tanzania or even further may be different for each component of the present research. It is likely that awareness of malaria and its appropriate prevention and treatment is higher in the study area than in the rest of Tanzania. For example, in 2004-05, the DHS-reported household ownership of mosquito nets was 46% for Tanzania mainland, while Morogoro Region, in which the study area is located, reported 65% - the highest rates outside Dar es Salaam (National Bureau of Statistics 2005). In the DSS, a mean net usage of 75% was reported (Killeen *et al.* 2007), while the Tanzanian average was 31% (National Bureau of Statistics 2005). Similarly, the reported antimalarial usage by under-fives with a recent fever in Morogoro Region (89%) was

higher than the Tanzanian average (58%). IPTp on the other hand, a more recent intervention, was not better implemented in the study area (51% of women received SP during their last pregnancy) than in the rest of the country (54%) (National Bureau of Statistics 2005). It may be concluded that the results related to malaria prevention and treatment presented in this thesis display a more optimistic situation than what is the reality in other parts of the country.

The high use of mosquito nets may to a certain extent also be the result of the enormous nuisance posed by the many mosquitoes (not only *Anopheles*) which proliferate in the humid environment of the Kilombero Valley (Killeen *et al.* 2007). The seasonal movement of families to their farming sites within the valley (see chapter 8) is another special feature of the study area. It is unclear how widespread such movements patterns are in other regions and hence how results which are related to this particularity can be projected to other places.

Generally, in extrapolating the research findings, the health system context, including for example the way health services are financed, should also be taken into consideration. Concretely, the Kilombero District operates on a cost-sharing scheme, while Ulanga District has a community health fund. In both districts, a pull-system for drug delivery to health facilities is in place, i.e. facilities order drugs according to their estimated needs. In certain other Tanzanian districts, health facilities are still supplied with a standard drug-kit. Across Africa, treatment-seeking patterns may vary considerably, as a comparison with the findings of Granado (2007) reveals. She found high use of traditional medicine by adults in Abidjan, while in rural Kilombero Valley, traditional medicine use was the exception (Granado *et al.* 2006).

These examples just highlight a few issues that need to be considered when projecting the results of this thesis to other settings.

Most ACCESS studies presented in the previous chapters used a mixed methods approach, combining qualitative and quantitative methods of data collection in different ways. This thesis put the main emphasis on the analysis of the quantitative aspects, but without loosing sight of the contributions and results of the qualitative data.

The main instrument used in the treatment-seeking surveys (chapters 6 and 7) was the Explanatory Model Interview Catalogue, or EMIC (Weiss 1997). Though rooted in the study of stigma and disease in India (Weiss 2001), the EMIC has subsequently been used in several occasions as an interview-tool in cultural epidemiological research of malaria (Ahorlu *et al.* 2005; Granado 2007). The EMIC differs from classical epidemiological questionnaires by the way it is developed and structured: qualitative studies (in our case mainly focus-group discussions) provide the basis for the development of an illness model as defined by those affected by the condition. The importance of high-quality exploratory qualitative research needs to be stressed at this point. Open-ended questions and screening queries on pre-defined categories of answers allow an in-depth assessment of the representation and aetiology of this illness model, its frequency and associated actions taken by the affected. While criticized by some as too superficial (Waldram 2006), the EMIC provides an opportunity to study the distribution of a perceived illness model without (1) the disadvantages of small-scale ethnographic studies, or (2) the application of a purely biomedical definition which is not necessarily shared by the community. Thanks to this approach, a quantitative estimation of the distribution of signs and symptoms as well as perceived causes of fever cases was possible. However, due to the comprehensiveness of the EMIC, interviews may become rather long and field-workers need sufficient training and practice to be able to satisfactorily complete the form. In the community survey (chapter 6) this was challenging since the forms were filled by DSS field-interviewers, each of whom had only few fever-cases to interview. As they were working on their own, the recommended setup with one interviewer and one recorder could not be implemented. Several times, recorded narratives were kept very short and provided only limited additional information. Occasionally, the lengthiness of the interview might even have discouraged interviewers to complete a form when they were short of time. A better approach was applied in Ifakara where a permanent team of interviewers collected the data. They always worked in pairs and did not have any other tasks alongside. Unfortunately, applying the same approach in the DSS area would have interfered with DSS routine data collection activities. For our purpose, it would seem advisable to shorten the EMIC to the most important questions without loosing its main cultural epidemiological characteristics, while at the same time refining the sections on help-seeking actions.

The shop survey or shop census (chapters 8 and 9) used existing questionnaires that had previously been applied in the same area (Goodman *et al.* 2004; Goodman 2004). The questionnaire was adapted to the specific research questions of this study and harmonised with the new drug policy (e.g. new recommended antimalarial treatment after 2001). In an attempt to find proxy-indicators for the size and structure of retail outlets, a pilot study recorded information on products sold, building structure, staffing and measures of the shop size. Unfortunately, no indicators could be found that were significantly correlated with the size, type, or building structure of the shop (M. Hetzel and C. Lengeler, unpublished data). Several field-interviewers who had been involved in the previous shop surveys carried out by Goodman and colleagues (Goodman *et al.* 2000) could be recruited again, including an experienced field supervisor. An experienced and well trained field team was important in order to establish good relations with the shopkeepers who would be asked rather private questions on their businesses. In some occasions, it was a challenge to convince shopkeepers that the interviewers had not been commissioned by the revenue authorities.

The mystery shoppers study (chapter 9) applied a more innovative approach. So far, mystery shoppers (simulated clients) have only rarely been used to assess the performance of retail outlets in Africa. Two studies, one in Kenya and one in Zimbabwe, assessed drug shop keepers' performance using mystery shoppers (Tavrow *et al.* 2003; Nyazema *et al.* 2007) and in few occasions, the approach was applied to assess reproductive health services (Harrison *et al.* 1998; Stanback & Janowitz 2003). In research conducted in industrialised countries mystery shoppers are more widely used (Sykes & O'Sullivan 2006; Gosselt *et al.* 2007; Alte *et al.* 2007). Compared to classical observational studies on performance of treatment providers, there are several advantages in the mystery shoppers approach. Firstly and most important, the shopkeepers are not aware that they are being studied. While this may be criticised from an ethical point-of-view, it is expected to increase the validity of the results and decrease the chance of a "Hawthorne effect". In our case, all shopkeepers had consented to being interviewed during the preceding shop survey and the central ethical aspects were addresses in that shop names or shop keepers' names were never mentioned in connection with the results. Secondly, this approach is based on standard case scenarios. The situations are therefore more comparable

than observational data when customers present with a wide range of complaints. It is also likely that the mystery shoppers remember better the advice they were given compared to a randomly interviewed patient or caretaker. On the other hand, mystery shoppers need to be recruited from within the community in which the study is being conducted in order to avoid arising suspicion. This is especially important in rural settings where strangers are unlikely to purchase drugs in local shops. Without the assistance of village-based DSS field-interviewers, identifying capable candidates would have been difficult, while in urban settings, applying this approach would be much easier.

## *12.2 Contributions to the understanding of access to malaria treatment*

Based on the set objectives, the following section reviews the contributions that the present thesis has made to the understanding of access to malaria treatment. Finally, it is discussed how this research contributed to the development of an access framework applicable to malaria and potentially other diseases.

### 12.2.1 Investigation of treatment-seeking behaviour for malaria related illness episodes

Our investigation of signs and symptoms as well as perceived causes of febrile illness episodes revealed a local understanding of malaria coming far closer to the biomedical model than described in earlier studies in Tanzania (Winch *et al.* 1996; Hausmann Muela *et al.* 2002). Nevertheless, traditional terminology was still used to describe certain illness patterns. A strong preference for biomedical treatment was noted, with 76% of children being brought to a health facility and 89% of children and 83% of adults being treated with an antimalarial. This pattern was also reflected at national level in the 2004-05 DHS (National Bureau of Statistics 2005) and both sources are demonstrating a significant improvement compared to 37% antimalarial use in 2001 (Njau *et al.* 2006).

These improvements over time are encouraging. They demonstrate that carefully developed social marketing and health education campaigns (such as the KINET

social marketing campaign) can be effective in sensitizing the community for a specific health issue. If carried out persistently over a period of time, this approach can result in notable behaviour change.

However, while general usage rates of antimalarials are high, there is still a long way to go to achieve community effectiveness of malaria treatment. Despite the simple dosage scheme of the first-line drug SP, the level of timely antimalarial use in the correct dosage had not improved since 2001. Whether it was a result of poor provider compliance or patient adherence is unclear. Taking into account that (1) health facility use did not result in more accurate dosage, (2) exemption systems were not functional and (3) much of the drugs for children and even more for adults were bought from private retailers, the provider side appeared to contribute significantly to the low community effectiveness of antimalarial treatment. The consequences of the current situation were higher than necessary expenditures and less appropriate treatments, which are likely to be most detrimental for already poor and more vulnerable households (Worrall *et al.* 2005).

### 12.2.2 Disease burden, access to health services, and responses to malaria related illness episodes of farming families during the cultivation period

Compared to the population average, people who moved temporarily to a distant field site (*shamba*) were not at increased risk of experiencing a fever episode. Fever incidence in the fields was even lower than in the villages, similar to what had been reported from other areas (Mutero *et al.* 2004). However, these results do not necessarily override the initial hypothesis that farming families may be more vulnerable to malaria than those remaining in the villages. Protection against malaria transmission was extremely good (98% net usage), but coping with a disease episode remained a bigger challenge in the *shamba* than in the village. While within the *shamba* survey*,* we did not find a difference in treatment-seeking between episodes recognised in the field and at home, the overall health facility usage rate (54%) was considerably lower than in the 2004 community survey on treatment-seeking (68%). Considering the characteristics of the two study samples, this could mean that families with a farming house located away from their residence would less

frequently attend a health facility than the population average. In the end, however, antimalarial use was equally high among all households, although home-stocking of drugs was not frequently reported. Mayumana and colleagues found in an in-depth exploratory study in the same area, that in the *shamba* more time is needed for the process of mobilising resources required to seek treatment (Mayumana 2007; Mayumana *et al.* 2007). This resulted in delayed treatment-seeking and consequently, children were already severely ill by the time they reached a health facility. They found that financial resources, passable roads, transport and social networks were most important for successful care-seeking. Considering that the poorest are more likely to live solely on farming activities (Njau *et al.* 2006), illness episodes occurring in the shamba may disproportionately affect the poor. In this situation, securing and improving the livelihoods of farming families alongside an investment in the quality of health service delivery might contribute to improved treatment effectiveness.

### 12.2.3 Availability of antimalarials in the private retail sector following the change of first-line treatment from chloroquine to SP

Treatment-seeking needs to be seen against the background of the availability of treatment sources. The study on availability of antimalarials described clearly how certain areas (villages) completely lacked any antimalarial provider and how there were 50% less antimalarial retailers in 2004 compared to 2001. More or less simultaneously, antimalarial stock-outs were recorded in 4/14 health facilities in the study area (Dillip *et al.* 2007). Interestingly, treatment-seeking rates with antimalarial drugs had not decreased between 2001 and 2004 (S.P. Kachur, cited in Hetzel *et al.* 2006). Partly, this was attributed to the low importance of general shops in which most of the decline in availability had happened (Goodman 2004).

Subsequent shop surveys in 2005 and 2006 showed that the retail sector was highly dynamic and that the number and locations of shops changed frequently. As shown in Figure 12.1, much of the 2001-2004 decline had been balanced by 2005 and 2006 in the Ulanga DSS villages, while in the Kilombero DSS a general declining trend could be observed.

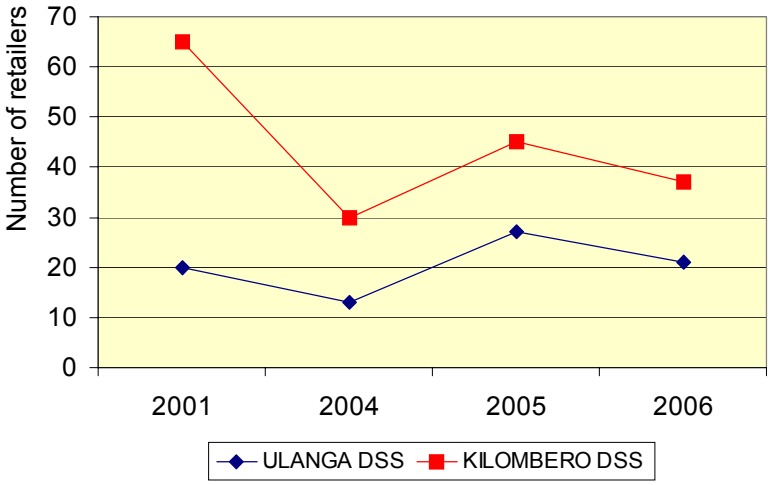


**Figure 12.1: Number of retailers (drug stores and general shops) selling antimalarials in the DSS.**

Most importantly the results show how a combination of changed drug policy and strengthened regulatory mechanisms had influenced availability of life-saving medicines at a peripheral level. The impact of such a change may not be reflected directly in treatment rates or morbidity and mortality. Yet, as transport costs may account for a considerable proportion of treatment expenditures (up to 21% reported by Njau *et al.* 2006), the loss of nearby treatment providers may impact on household economies. Implications on household livelihoods should therefore be taken into consideration and be further explored.

A reduction in the number of low-level treatment providers goes against the recommendations for an implementation of the community-component of IMCI (WHO 1998) or the WHO/RBM-promoted home management of malaria strategy (WHO 2005a). On the other hand, in the light of the recent switch to ACT there has been a controversy about the use of these drugs in the home management of malaria (Pagnoni *et al.* 2005; D'Alessandro *et al.* 2005). In Tanzania, neither of the two strategies has so far been implemented. But considering the results from our surveys, the availability of efficacious antimalarials (i.e. ACT) beyond health facilities seems absolutely essential. However, in order to avoid irrational use of ACTs, any provider – be it a community health worker, shopkeeper or health facility staff – needs to be appropriately trained and supervised.

### 12.2.4 Knowledge and behaviour of private drug retailers in terms of case-management of febrile illness episodes

The approach using mystery shoppers allowed validating the results obtained in the shop survey. It confirmed the low availability of antimalarial drugs in general shops. A justification for the ban of prescription-drugs from general shops can be seen in the ignorance of general shop keepers towards appropriate antimalarial treatment. While the quality of fever case management in drug stores was also not satisfactory, it is expected to improve with the roll-out of the ADDO project which includes shop keeper training as part of the upgrading procedure (Ndomondo-Sigonda *et al.* 2005). Similar approaches have led to considerable improvements in service delivery at shop-level in Kenya (Marsh *et al.* 1999).

Efforts to improve the performance of the retail sector through shopkeepers training should be coupled with a supportive national policy. Inefficacious drugs should be banned from the market and the dispensing of artemisinin monotherapies should be discouraged (Kachur *et al.* 2006a), while the quality of the drugs on the market needs to be monitored regularly. Drug regulatory authorities should issue and enforce regulations regarding the list of approved drug formulations, suitable packaging, and understandable dosage instructions. It was worrying that none of the medicines obtained in the mystery shoppers study contained dosage instructions in Swahili, the national language of Tanzania. While obviously tablets wrapped in newspaper pieces did not carry any instructions, those on pre-packed medicines were usually in English. Suspensions of different brands for example often carried different dosage instructions for exactly the same compound (ACCESS Programme, unpublished data).

Clear dosage instructions are essential to guide providers and patients, especially with more complicated dosage regimens, such as the three-day course of the new first-line drug arthemether-lumefantrine (trade name Coartem). Unfortunately, anecdotal evidence from the study area suggests that even the packaging of Coartem (Novartis, Switzerland), which was adapted for the African context, is not clearly understandable. With a literacy rate of 69% in 2002 (United Republic of

Tanzania 2005) it might be justified to complement the pictograms on the package with clear instructions printed in Swahili.

With the implementation of the ADDO project, the upgraded drug stores seem to be a realistic option for ACT delivery beyond the level of health facilities. Experiences with chloroquine have clearly shown, that even with a complex dosage regimen, training of shopkeepers can results in improved service-provision (Marsh *et al.* 2004). Importantly, however, ACTs should not only be available in ADDOs, but they should be sold at a highly subsidized price in order to achieve equitable access to treatment.

### 12.2.5 Contributions to a better understanding of access and to a generic access framework

The present thesis could contribute in several ways to an improved understanding of access to malaria treatment. First, it could be shown that a traditional understanding of febrile illness was not anymore a major barrier to access and that modern treatment was clearly preferred by most people in the study area. It results that demand-side barriers are likely to be rather related to the household's ability to mobilise resources needed for treatment-seeking (financial resources as well as social networks) (Chuma *et al.* 2007; Mayumana *et al.* 2007). The Health Access Livelihood Framework (chapter 10) allowed for this by embedding access into the context of livelihood insecurity.

While treatment-seeking action was initiated by virtually all study participants, young children and pregnant women did not appear to benefit fully from the interventions targeted at them. Exemption mechanisms for under-fives were not functional and many women did not receive IPTp, often due to stock-outs (K. Gross, personal communication). On the other hand, the new drug policy with SP as prescription-only drug was well implemented and enforced by the respective government bodies and private sector availability had consequently dropped. Hence, the degree to which existing policies are implemented "on the ground" can significantly influence patient's access to health care. In the access framework this aspect is represented by the "PIOP" (policies, institutions, organizations, and processes).

Several determinants of utilization of health care providers were made explicit in the presented research: for example drug stock outs in health facilities (Dillip *et al.* 2007), long distances from the fields to a health facility (median distance 8km), or fear of drug side-effects, such as the Stevens-Johnson syndrome as reaction to SP. In the access framework they are represented by the “five A” which determine the “fit” between health services and patients needs (Penchansky & Thomas 1981).

The high treatment rates and frequent health facility usage coupled with low treatment effectiveness points to an unsatisfactory level of quality of care. Drug stock-outs in health facilities and resulting diversion of patients to the private sector have a direct negative impact on quality of care, patient satisfaction and trust in formal health providers (Mamdani & Bangser 2004), as well as on household economies. Quality of care is consequently an integral and important part of the Health Access Livelihood Framework on the pathway from utilization to impact.

Complementary to the framework embedded in a poverty-vulnerability-livelihood context, a further model is currently being developed based on the insights gained through the research presented here. The access malaria framework presented in Figure 12.2 can be understood as a cut-out of the Health Access Livelihood Framework, focusing specifically on the treatment-seeking process for malaria episodes (C. Lengeler *et al.*, unpublished). The focus is thereby on specific issues concerning the interaction of patients and treatment providers, the pathways chosen in the treatment-seeking process and specific aspects of quality of care.

The final aim is to be able to quantify the different treatment barriers as well as treatment options chosen by patients (N, $n_1$-$n_4$) in order to obtain a measure of treatment effectiveness. From the treatment-seeking study presented in chapter 6, for example, it may be concluded that for children in that study, $n_1$=43/80 (53.8%), $n_2$=27/80 (33.8%), $n_3$=10/80 (12.5%), and $n_4$=0. Obviously, Figure 12.2 over-simplifies treatment-seeking processes since several treatment options may be chosen consecutively, or simultaneously. This framework is currently being refined using more detailed information derived from the thesis presented here, as well as from additional studies carried out within the frame of the ACCESS Programme.

Eventually, this should lead to a framework that can be applied more generally for the investigation of access to malaria treatment.

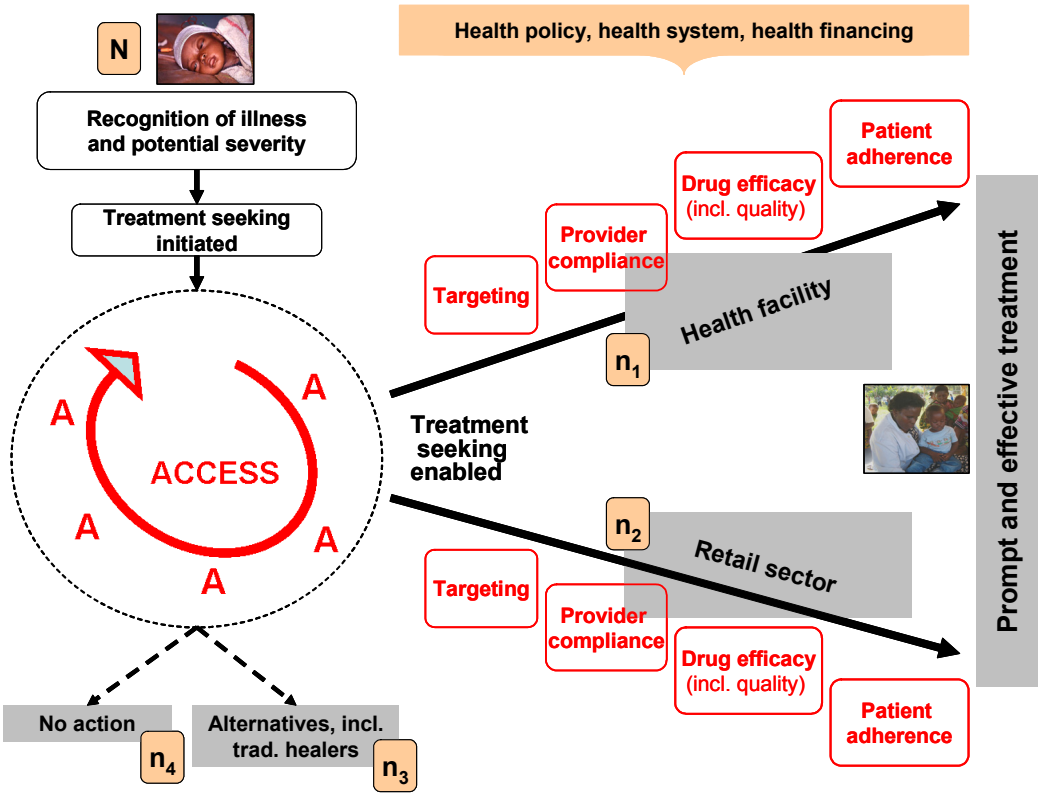


**Figure 12.2: Access malaria framework**

Lengeler *et al.*, unpublished

### 12.2.6 Recommendations for malaria control interventions

First and foremost, the results of this thesis demonstrate clearly the importance of health system factors in the effective delivery of health interventions. Specifically with regard to malaria control, it should be considered that strategies to reach those in need are unlikely to be effective if interventions are channelled exclusively through the public sector. Consequently, malaria treatment, and specifically the highly efficacious ACTs, should also be available at a subsidized price from trained retailers in the private sector. ADDOs are likely to be the most appropriate existing retail providers for ACTs in Tanzania. In order to guarantee effective delivery of care at health facilities, the drug supply systems needs to be strengthened and effective supportive supervision should enable facility staff to provide good quality of care. The INDENT system for medicine delivery to facilities needs to be revised and made to

function more effectively. Communities should be empowered to demand for the services to which they are entitled, particularly free treatment for under-fives and pregnant women, ITN vouchers, and IPTp. District authorities should regularly monitor and facilitate the effective implementation of exemption policies. In order to facilitate patient adherence, ACTs and other medicines should be dispensed in appropriate packaging and with easily understandable printed dosage instructions. These need to be standardised and printed in Kiswahili. Social marketing approaches, which can effectively deliver health messages to the community, should be integrated into the council health plans. In order to successfully plan and develop malaria control strategies, all involved government bodies, namely the National Malaria Control Programme and the Tanzania Food and Drugs Authority, need to work closely together. Finally, any implemented intervention should be monitored regularly with respect to community-effectiveness and be adjusted if deemed necessary.

### 12.2.7 Recommendations for further research

In order to target future interventions better, the following areas of research may be of importance. Firstly, it should be investigated how households can be strengthened so that they can more easily and more quickly initiate a treatment-seeking process and gain access to health services. It would be of particular interest to understand what resources are needed at household level to seek treatment, and how access to these resources may be facilitated. At the interface of patients and providers, the best ways to eliminate financial barriers should be explored (e.g. community health funds, conditional cash transfer, global subsidies). From a provider-perspective, new avenues have to be explored to improve services in health facilities. These interventions should be implemented and thoroughly evaluated. At the same time, complementary approaches to deliver treatment need to be tested, such as upgraded drug-stores (ADDO) or community-health workers. Deployment of ACT through these channels should be pilot-tested and their effectiveness evaluated. The impact of all these measures should be thoroughly evaluated with regard to cost-effectiveness and, most importantly, to equity.

In conclusion, the findings of this thesis underline the importance of a comprehensive approach to analyze and improve access to malaria treatment. In order to achieve a decline in malaria morbidity and mortality in Africa, a concerted effort of all stakeholders is needed to translate efficacious tools into effective, equitable and sustainable health interventions. It is the hope of the authors that the evidence gathered in the previous chapters can contribute to an improved understanding of the issues that need to be tackled in order to achieve a high community-effectiveness of malaria treatment.

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ACCESS road show in Ifakara, Oct 2005

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# APPENDIX 1: EXPLANATORY MODEL INTERVIEW CATALOGUE

Malaria-Related Illness in Children Under Five Years

Semi-Structured Interview for Caretakers

# EMIC for Children

With or without *degedege*

2004

# MALARIA-RELATED ILLNESS – INTERVIEW

**1. Respondent Study No:** _____ **Date:** Day _____ Month _____ Year _____

**2. Village Name:** _____

**3. Respondent Name:** First _____ Last _____ **Age:** _____ **Sex:** M W

**4. Name of child** *(patient)*: First _____ Last _____ **Child's permanent ID:** _____

**5. "What is the age and sex of the child/patient?"**

**Age:** *Months* _____ **Sex:** M F

**6. 'What is your relationship to this child?'**

*(Narrative)* _____

*Tick √ accordingly*

| Mother 1 | Father 2 | Grandmother 3 | Other specify 4 |
|---|---|---|---|

## RESPONDENT'S SOCIAL AND DEMOGRAPHIC INFORMATION

**7. House Number:** _____ _____ _____ _____ _____ ***As used in DSS HRS Books***

*Tick one only*

**8. Religion:**

| Traditional Religion 1 | Muslim 2 | Christian 3 | Other (specify) 6_____ |
|---|---|---|---|

*Tick one only*

**9. Marital Status:**

| Never married 1 | Married 2 | Sep / Div 3 | Remarried 4#_____ | Widowed 5 |
|---|---|---|---|---|

**10. Relationship with Household Head**

| Self 1 | Spouse 2 | Parent 3 | Child 4 | Other *(specify)* 5 | Sex: | M | F |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

**11. Children & Elders** *(of the HH head):*

| Sons | | | | | Daughters | | | | | Elders | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| <5 Yrs | | ≥5 Yrs | | | <5 Yrs | | ≥5 Yrs | | | ≥18yrs | | |
| Alive | Dead | Alive | Dead | | Alive | Dead | Alive | Dead | | Aliv | Dead | |
| | | | | | | | | | | | | |

**11.1. Apart from your children, how many other dependents live in your household at the moment (today)?** *Put total in the boxes*

**Under 5 Yrs** | **Elders (5 Yrs and older)**

**12. Education:** **Years** | *If no school*: **Functional Literacy?** No 0 | Yes 1

## Occupation

**13. "What is your main source of income and livelihood?"**
*If married*, **"What about your husband/wife, what is her/his occupation?"**

1 Nil
2 Student
3 Housewife
4 Unskilled labour
5 Skilled labour
6 Trade / Business
7 Service
8 Farmer
9 Fisherman
10 Farmer-Fisherman (both)
11 Retired
12 Teacher
**13 Deceased**
14 Other (specify)_____

*Specify codes:* **Personal Occupation:** | **Spouse's Occupation:**

**14. "Is your household income usually regular and dependable?"**

*Tick one only*

| Yes 3 | Possibly 2 | Uncertain 1 | No 0 |
|---|---|---|---|

*(Narrative)* _____

# PATTERNS OF DISTRESS

*Inclusion criteria: Caretaker noticed child was ill at most 14 days before interview, and child has been free of all symptoms for at least 24 hours at time of interview.*

## SPONTANEOUS ACCOUNT OF PROBLEM:

**'I appreciate your agreeing to talk to me about this child's problem. It is a problem that also affects many other people in this district. I want to understand how you think about this problem. Keep in mind that it is your ideas that I am interested in, so please do not feel there is a right or wrong answer to the questions."**

**15. "What was the problem that the child was suffering from? Please tell me all that you know about it."** *Record account of problem, as described in respondent's own words:*
*(Narrative)*

**16. "Where were you when you first noticed the child was not well?"**

| Home | Shamba |
|---|---|
| 1 | 2 |

**17. "How did you first know that something was wrong with the child?"**

*(Narrative)*

*Tick spontaneously reported symptoms under the columns for "spontaneously" and "early". Ask about the others: Have they been noticed? If yes tick "probe". Have they been noticed early on? If yes, tick also the block under the column "early".*

| Patterns of Distress | Spon | Probe |
|---|---|---|
| 1. No interest to play *(hataki kucheza)* | | |
| 2. Not happy *(hana raha)* | | |
| 3. Sleeps *(analala)* | | |
| 4. Loss of appetite *(hapendi kula)* | | |
| 5. Crying all the time *(analialia)* | | |
| 6. No strength *(hana nguvu)* | | |
| 7. Hot body *(mwili wa moto, joto kali sana)* | | |
| 8. Hot head *(kichwa cha moto)* | | |
| 9. Hot abdomen *(tumbo la moto)* | | |
| 10. Periodic fevers *(homa za vipindi)* | | |
| 11. Cough *(anakohoa)* | | |
| 12. Difficult breathing *(anahema kwa shida)* | | |
| 13. Yellow eyes *(macho ya njano)* | | |

| Patterns of Distress | Spon | Probe |
|---|---|---|
| 14. Diarrhoea *(kuharisha)* | | |
| 15. Vomiting *(kutapika)* | | |
| 16. Shivering *(anatetemeka)* | | |
| 17. Twitching *(anastuka)* | | |
| 18. Body becomes stiff *(mwili unakauka; anakakama)* | | |
| 19. Delirium *(anaweweseka)* | | |
| 20. Eyes turn white *(macho yanakuwa meupe)* | | |
| 21. Kicking of leg and arm *(anarusha mkono na mguu)* | | |
| 22. Froth in the mouth *(anatoa mate mdomoni)* | | |
| 23. Mouth twisted sideways *(mdomo ulienda pembeni)* | | |
| 24. Falling down *(anaanguka)* | | |
| 25. Easily startled/frightened *(anashtuka kwa urahisi/woga)* | | |
| 26. Other physical symptoms: | | |

**18. "Among all these symptoms, which one do you think is the single most dangerous?"**
*Code single most dangerous symptom from the above numbered list of patterns of distress*

**18.1. What is it about this symptom that makes it the most dangerous?**

*(Narrative)* _____

_____

**19. "How do you call this illness in your language?"** *Specify name, summary term, or short description in the patient's words.*
*(Narrative)*

_____

_____

Specify exact term used: _____

| | Yes | No |
|---|---|---|
| *Identified as homa?* | 1 | 0 |
| *Identified as malaria?* | 1 | 0 |
| *Identified as degedege?* | 1 | 0 |

**20. Did some particular features make you think it is the illness you identified** *(refer to the term mentioned above)***?**

*(Narrative)* _____

_____

**21. Did you know that yourself or did someone tell you? If so, who told you?**

*Tick all that apply*

| Resource Persons | Spon | Probe |
|---|---|---|
| 1. I knew it myself | | |
| 2. Female elder | | |
| 3. Male elder | | |
| 4. Aunt (of the child) | | |
| 5. Father/ uncle (of child) | | |
| 6. Neighbour | | |
| 7. Government health facility staff | | |
| 8. Private health facility staff | | |
| 9. Shopkeeper (general store) | | |
| 10. Shopkeeper (Pharmacy) | | |
| 11. Shopkeeper (drug store ) | | |
| 12. Community health worker | | |
| 13. Local healer | | |
| 14. Other (*mention):* | | |

**21.1. What made you ask this person** *(the first person consulted)***?**

*(Narrative)* _____

*Tick all that apply*

| | Spon | Probe |
|---|---|---|
| 1. I knew it myself | | |
| 2. It is someone I can talk to | | |
| 3. He/she is experienced/ knowledgeable | | |
| 4. He/she is a medical professional | | |
| 5. I am expected to consult him/her (customs) | | |
| 6. Other (mention): | | |

**22. "Do you think that the illness that the child had was serious? In your opinion, how serious was the child's condition? Might it be fatal?"'**

*Tick only one*

| Usually fatal | Sometimes fatal | Serious but not fatal | Not serious | Cannot say |
|---|---|---|---|---|
| 4 | 3 | 2 | 1 | 0 |

**22.1. What makes this condition serious?**

*(Narrative)* _____

# PERCEIVED CAUSES

**23. "I would like to know what you think may have caused this child's problem?"**
*Summarize respondent's ideas about causes in the respondent's own words (first-person account).*

*(Narrative)* _____

*Tick the block for each of the reported causes under the column for "spontaneously". Ask about the others, and for those affirmed tick the block under the column "probe".*

| Perceived Cause | Spon | Probe |
|---|---|---|
| ***Ingestion*** | | |
| 1. Impure water | | |
| 2. Eating leftover food | | |
| 3. Unbalanced diet | | |
| 4. Starchy food | | |
| 5. Breast feeding | | |
| ***Insects / Worms*** | | |
| 6. Mosquito bite | | |
| 7. Other insect bite | | |
| 8. Houseflies | | |
| 9. Worms | | |
| 10. Other | | |
| **Fatigue/Work/Constitution/blood strength** | | |
| 11. Physical hard work (parent) | | |
| 12. Stage of child growth | | |
| 13. Constitution/ blood weakness | | |
| 14. Hereditary | | |

| Perceived Cause | Spon | Probe |
|---|---|---|
| ***Environmental*** | | |
| 15. Sanitation/ Dirty environment | | |
| 16. Personal hygiene/not keeping clean | | |
| 17. Plant | | |
| 18. Contamination - contact | | |
| 19. Wind | | |
| 20. Heat (sun or fire) | | |
| 21. Cold weather | | |
| 22. Other | | |
| ***Supernatural*** | | |
| 23. Spirits *(upepo, majini, shetani)* | | |
| 24. Evil eyes or sorcery (uchawi) | | |
| 25. God | | |
| 26 Failure to abstain from sex (parent) | | |
| 27. Bird/ insect called *degedege* | | |
| 28. Other mention: | | |
| 29. Don't know | | |

# MOST IMPORTANT PERCEIVED CAUSE

**24. "Which of the causes that you have mentioned (or perhaps something else) do you consider the single most important cause of the problem in the child?**

*(Narrative)* _____

_____

*Code single most important cause from the above list* [ ]

**25. Did you know that yourself or did someone tell you? If so, who told you?**

*Tick all that apply*

| Resource Persons | Spon | Probe |
|---|---|---|
| 1. I knew it myself | | |
| 2. Female elder | | |
| 3. Male elder | | |
| 4. Aunt (of the child) | | |
| 5. Father/ uncle (of child) | | |
| 6. Neighbour | | |
| 7. Government health facility staff | | |
| 8. Private health facility staff | | |
| 9. Shopkeeper (general store) | | |
| 10. Shopkeeper (pharmacy) | | |
| 11. Shopkeeper (drug store) | | |
| 12. Community health worker | | |
| 13. Local healer | | |
| 14. Other (mention): | | |

**25.1. What made you consult this person** *(the first person consulted)***?**

*(Narrative)* _____

_____

_____

*Tick all that apply*

| | Spon | Probe |
|---|---|---|
| 1. I knew it myself | | |
| 2. It is someone I can talk to | | |
| 3. He/she is experienced/ knowledgeable | | |
| 4. He/she is a medical professional | | |
| 5. I am expected to consult him/her (customs) | | |
| 6. Other (mention): | | |

# HELP SEEKING

**26. What did you do for your child immediately after recognizing he/she was ill?**

*(Narrative)* _____

_____

(FOR THE ***WHEN*** PART**:** *Use 1= same day, 2= next day, 3= more than 2 days or 0 for none)*

*Tick all that apply*

| | Spon | Probe | When |
|---|---|---|---|
| 1. Give antipyretics (e.g. Panadol) | | | |
| 2. Give an antibiotic | | | |
| 3. Give an antimalarial | | | |
| 4. Give herbal medicine (home care) | | | |
| 5. Sponging | | | |
| 6. Ask for advice | | | |
| 7. Divination | | | |
| 8. Took child to a health facility | | | |
| 9. Urinated on the child | | | |
| 10. Give herbal medicine (from healer) | | | |
| 11. Other (*mention):* | | | |

**27. Why did you take that action first** *(specified above)***?**

*(Narrative)* _____

_____

**28. Where did you go for advice (who did you see for advice)?**

*(Narrative)* _____

_____

*For each of the following sources of help, mark whether respondent reported use either spontaneously in response to the open-ended query, or in response to probe. Note whether person lives in same household.*

| Help seeking Resource Persons | Spon. | Probe | Household | |
|---|---|---|---|---|
| | | | Same | Other |
| 1. I knew it myself | | | | |
| **2. Male elder** | | | | |
| **3. Female elder** | | | | |
| 4. Father/ uncle (of child) | | | | |
| 5. Aunt (of the child) | | | | |
| **6. Health facility staff (public or private)** | | | | |
| **7. Neighbour** | | | | |
| 8. Shopkeeper (general store) | | | | |
| 9. Shopkeeper (drug store) | | | | |
| 10. Community health worker | | | | |
| 11. Local healer | | | | |
| 12. Other (*mention):* | | | | |

**29. Who of the people who gave advice you think gave you "most useful" and who gave "least useful" advice?**

| | |
|---|---|
| **Most useful advice** | |
| **Least useful advice** | |

## Anti-malarial drugs

**30. Did you give any anti-malarial drug? If yes, which ones?**

| **Yes** | **No** |
|---|---|
| | |

**31. If the child was not given any antimalarial drug,** *go to Question 38.*

| **Drug type** | | **Order of giving** | | |
|---|---|---|---|---|
| | | **1** | **2** | **3** |
| **SP (and brands: Orodar etc)** | **go to Q 32** | | | |
| **Chloroquine** | **go to Q 33** | | | |
| **Amodiaquine** | **go to Q 34** | | | |
| **Quinine** | **go to Q 35** | | | |
| **Others** *(specify)* | **go to Q 36** | | | |
| **Others** *(specify)* | **go to Q 37** | | | |

## 32. SP

**32.1. How long after onset of symptoms did you give SP to your child?**

| Same Day 3 | Next Day 2 | > 2 days 1 |
|---|---|---|

**32.2. In what form was the drug that you gave the child?**

**1= Tablets** **4= Drip**
**2= Syrup** **5= Other (mention):_____**
**3= Injection**

**32.3. How much SP did you give?** *(Insert code in appropriate box – if syrup, estimates in teaspoon full)*

*(Narrative)* _____

*Codes: 1= Robo, 2=Nusu, 3=Kimoja, 4=Kimoja na nusu, 5=Viwili, 6=Vitatu, 7=Others*

| Morning | Midday | Evening |
|---|---|---|
| | | |

**32.4. Where did you get SP that you gave the child?** *For each of the following sources, mark whether respondent reported use spontaneously or in response to probe. Note why they went there. Codes: 1= Distance/time, 2=Timing, 3=Convenience, 4=Cost, 5=Good quality service, 6=Inconvenience, 7=other (mention)_____*

| Help Seeking | Spon. | Probe | Why *(note code)* |
|---|---|---|---|
| 1. I had them at home | | | |
| 2. Female elder | | | |
| 3. Male elder | | | |
| 4. Aunt (of the child) | | | |
| 5. Father/ uncle (of child) | | | |
| 6. Neighbour | | | |
| 7. Government / private health facility staff | | | |
| 8. Government / private health facility | | | |
| 9. Shopkeeper (general store) | | | |
| 10. Shopkeeper (drug store) | | | |
| 11. I knew myself | | | |
| 12. Community health worker | | | |
| 13. Local healer | | | |
| 14. Other (mention): | | | |

**32.5. How much did it cost?**

| | |
|---|---|
| **1. Consultation** | *Tsh.* |
| **2. Drugs** | *Tsh.* |

**32.6. Did you know yourself what drug to give the child or did someone tell you? If so, who told you?**
*(Based on the chart in Question 28 above)*

**32.7. And what did he/she say?**

*Narrative* _____

## 33. Chloroquine

**33.1. How long after onset of symptoms did you give Chloroquine to your child?**

| Same Day 3 | Next Day 2 | > 2 days 1 |
|---|---|---|

**33.2. In what form was the drug that you gave the child?**

**1= Tablets** **4= Drip**
**2= Syrup** **5= Other (mention):_____**
**3= Injection**

**33.3. How many tablets of Chloroquine did you give?** *(Insert code in appropriate box)*

*(Narrative)* _____

*Codes: 1= Robo, 2=Nusu, 3=Kimoja, 4=Kimoja na nusu, 5=Viwili, 6=Vitatu, 7=Others*

| Morning | Midday | Evening |
|---|---|---|
| | | |

**33.4. Where did you get Chloroquine from?** *For each of the following sources of help, mark whether respondent reported use spontaneously or in response to probe. Note why they went there.*

*Codes: 1= Distance/time, 2=Timing, 3=Convenience, 4=Cost, 5=Good quality service, 6=Inconvenience, 7=other (mention)_____*

| Help Seeking | Spon. | Probe | Why *(note code)* |
|---|---|---|---|
| 1. I had them at home | | | |
| 2. Female elder | | | |
| 3. Male elder | | | |
| 4. Aunt (of the child) | | | |
| 5. Father/ uncle (of child) | | | |
| 6. Neighbour | | | |
| 7. Government / private health facility staff | | | |
| 8. Government / private health facility | | | |
| 9. Shopkeeper (general store) | | | |
| 10. Shopkeeper (drug store) | | | |
| 11. I knew myself | | | |
| 12. Community health worker | | | |
| 13. Local healer | | | |
| 14. Other (mention): | | | |

**33.5. How much did it cost?**

| | |
|---|---|
| *1. Consultation* | *Tsh.* |
| *2. Drugs* | *Tsh.* |

**33.6. Did you know yourself what drug to give the child or did someone tell you? If so, who told you?**

*(Based on the chart in Question 28 above)*

**33.7. And what did he/she say?**

*Narrative* _____

## 34. Amodiaquine

**34.1. How long after onset of symptoms did you give Amodiaquine to your child?**

| Same Day 3 | Next Day 2 | > 2 days 1 |
|---|---|---|

**34.2. In what form was the drug that you gave the child?**

**1= Tablets** **4= Drip**
**2= Syrup** **5= Other (mention):_____**
**3= Injection**

**34.3. How many tablets of Amodiaquine did you give?** *(Insert code in appropriate box)*

*(Narrative)* _____

*Codes: 1= Robo, 2=Nusu, 3=Kimoja, 4=Kimoja na nusu, 5=Viwili, 6=Vitatu, 7=Others*

| Morning | Midday | Evening |
|---|---|---|

**34.4. Where did you get Amodiaquine from?** *For each of the following sources of help, mark whether respondent reported use spontaneously or in response to probe. Note why they went there.*

*Codes: 1= Distance/time, 2=Timing, 3=Convenience, 4=Cost, 5=Good quality service, 6=Inconvenience, 7=other (mention)*____

| Help Seeking | Spon. | Probe | Why *(note code)* |
|---|---|---|---|
| 1. I had them at home | | | |
| 2. Female elder | | | |
| 3. Male elder | | | |
| 4. Aunt (of the child) | | | |
| 5. Father/ uncle (of child) | | | |
| 6. Neighbour | | | |
| 7. Government / private health facility staff | | | |
| 8. Government / private health facility | | | |
| 9. Shopkeeper (general store) | | | |
| 10. Shopkeeper (drug store) | | | |
| 11. I knew myself | | | |
| 12. Community health worker | | | |
| 13. Local healer | | | |
| 14. Other (mention): | | | |

**34.5. How much did it cost?**

| | |
|---|---|
| *1. Consultation* | *Tsh.* |
| *2. Drugs* | *Tsh.* |

**34.6. Did you know yourself what drug to give the child or did someone tell you? If so, who told you?**

*(Based on the chart in Question 28 above)*

**34.7. And what did he/she say?**

*Narrative* _____

## 35. Quinine

**35.1. How long after onset of symptoms did you give Quinine to your child?**

| Same Day 3 | Next Day 2 | > 2 days 1 |
|---|---|---|

**35.2. In what form was the drug that you gave the child?**

**1= Tablets** **4= Drip**
**2= Syrup** **5= Other (mention):_____**
**3= Injection**

**35.3. How many tablets of Quinine did you give?** *(Insert code in appropriate box)*

*(Narrative)* _____

*Codes: 1= Robo, 2=Nusu, 3=Kimoja, 4=Kimoja na nusu, 5=Viwili, 6=Vitatu, 7=Others*

| Morning | Midday | Evening |
|---|---|---|

**35.4. Where did you get Quinine from?** *For each of the following sources of help, mark whether respondent reported use spontaneously or in response to probe. Note why they went there.*

*Codes: 1= Distance/time, 2=Timing, 3=Convenience, 4=Cost, 5=Good quality service, 6=Inconvenience, 7=other (mention)_____*

| Help Seeking | Spon. | Probe | Why *(note code)* |
|---|---|---|---|
| 1. I had them at home | | | |
| 2. Female elder | | | |
| 3. Male elder | | | |
| 4. Aunt (of the child) | | | |
| 5. Father/ uncle (of child) | | | |
| 6. Neighbour | | | |
| 7. Government / private health facility staff | | | |
| 8. Government / private health facility | | | |
| 9. Shopkeeper (general store) | | | |
| 10. Shopkeeper (drug store) | | | |
| 11. I knew myself | | | |
| 12. Community health worker | | | |
| 13. Local healer | | | |
| 14. Other (mention): | | | |

**35.5. How much did it cost?**

| | |
|---|---|
| *1. Consultation* | *Tsh.* |
| *2. Drugs* | *Tsh.* |

**35.6. Did you know yourself what drug to give the child or did someone tell you? If so, who told you?**

*(Based on the chart in Question 28 above)*

**35.7. And what did he/she say?**

*Narrative* _____

**36. Others** *(specify)* _____

**36.1. How long after onset of symptoms did you give the drug to your child?**

| Same Day 3 | Next Day 2 | > 2 days 1 |
|---|---|---|

**36.2. In what form was the drug that you gave the child?**

**1= Tablets** **4= Drip**
**2= Syrup** **5= Other (mention):_____**
**3= Injection**

**36.3. How many tablets of the drug did you give?** *(Insert code in appropriate box)*

*(Narrative)* _____

*Codes: 1= Robo, 2=Nusu, 3=Kimoja, 4=Kimoja na nusu, 5=Viwili, 6=Vitatu, 7=Others*

| Morning | Midday | Evening |
|---|---|---|

**36.4. Where did you get the drug from?** *For each of the following sources of help, mark whether respondent reported use spontaneously or in response to probe. Note why they went there.*

*Codes: 1= Distance/time, 2=Timing, 3=Convenience, 4=Cost, 5=Good quality service, 6=Inconvenience, 7=other (mention)_____*

| Help Seeking | Spon. | Probe | Why *(note code)* |
|---|---|---|---|
| 1. I had them at home | | | |
| 2. Female elder | | | |
| 3. Male elder | | | |
| 4. Aunt (of the child) | | | |
| 5. Father/ uncle (of child) | | | |
| 6. Neighbour | | | |
| 7. Government / private health facility staff | | | |
| 8. Government / private health facility | | | |
| 9. Shopkeeper (general store) | | | |
| 10. Shopkeeper (drug store) | | | |
| 11. I knew myself | | | |
| 12. Community health worker | | | |
| 13. Local healer | | | |
| 14. Other (mention): | | | |

**36.5. How much did it cost?**

| | |
|---|---|
| *1. Consultation* | *Tsh.* |
| *2. Drugs* | *Tsh.* |

**36.6. Did you know yourself what drug to give the child or did someone tell you? If so, who told you?**

*(Based on the chart in Question 28 above)*

**36.7. And what did he/she say?**

*Narrative* _____

**37. Others** *(specify)* _____

**37.1. How long after onset of symptoms did you give the drug to your child?**

| Same Day 3 | Next Day 2 | > 2 days 1 |
|---|---|---|

**37.2. In what form was the drug that you gave the child?**

**1= Tablets** **4= Drip**
**2= Syrup** **5= Other (mention):_____**
**3= Injection**

**37.3. How many tablets of the drug did you give?** *(Insert code in appropriate box)*

*(Narrative)* _____

*Codes: 1= Robo, 2=Nusu, 3=Kimoja, 4=Kimoja na nusu, 5=Viwili, 6=Vitatu, 7=Others*

| Morning | Midday | Evening |
|---|---|---|

**37.4. Where did you get the drug from?** *For each of the following sources of help, mark whether respondent reported use spontaneously or in response to probe. Note why they went there.*

*Codes: 1= Distance/time, 2=Timing, 3=Convenience, 4=Cost, 5=Good quality service, 6=Inconvenience, 7=other (mention)_____*

| Help Seeking | Spon. | Probe | Why *(note code)* |
|---|---|---|---|
| 1. I had them at home | | | |
| 2. Female elder | | | |
| 3. Male elder | | | |
| 4. Aunt (of the child) | | | |
| 5. Father/ uncle (of child) | | | |
| 6. Neighbour | | | |
| 7. Government / private health facility staff | | | |
| 8. Government / private health facility | | | |
| 9. Shopkeeper (general store) | | | |
| 10. Shopkeeper (drug store) | | | |
| 11. I knew myself | | | |
| 12. Community health worker | | | |
| 13. Local healer | | | |
| 14. Other (mention): | | | |

**37.5. How much did it cost?**

| | |
|---|---|
| *1. Consultation* | *Tsh.* |
| *2. Drugs* | *Tsh.* |

**37.6. Did you know yourself what drug to give the child or did someone tell you? If so, who told you?**

*(Based on the chart in Question 28 above)*

**37.7. And what did he/she say?**

*Narrative* _____

**38.** *Skip this question if SP has been used, otherwise ask*: **Why didn't you give the child SP (or other first line drug) tablets?**

*(Narrative)* _____

_____

_____

*Tick all that apply*

| | Spon | Probe |
|---|---|---|
| 1. Fear of side effects | | |
| 2. Too strong for the child | | |
| 3. Family members said not to | | |
| 4. Friend said not to | | |
| 5. Told by health facility staff | | |
| 6. Told by shopkeeper | | |
| 7. Does not know | | |
| 8. Other (*mention):* | | |

**39. In addition to (or apart from) giving anti-malarials, did you do anything else to treat the child?**

*Tick all that apply*

| | Spon | Prob |
|---|---|---|
| 1. Give antipyretics (e.g. Panadol) | | |
| 2. Give an antibiotic | | |
| 3. Give herbal medicine (home care) | | |
| 4. Sponging | | |
| 5. Ask for advice | | |
| 6. Divination | | |
| 7. Urinated on the child | | |
| 8. Give herbal medicine (from healer) | | |
| 9. I brought him to a health facility | | |
| 10. Give SP | | |
| 11. Give Amodiaquine | | |
| 12. Give Quinine | | |
| 13. Give other antimalarials (1) *specify* | | |
| 14. Give other antimalarials (2) *specify* | | |
| 15. Do something else | | |

**40. "Which of the treatment options mentioned (or something else) do you consider the most effective way of treating this problem?"** *(Regardless of whether it has been used or not in this particular disease episode)*

*(Narrative)* _____

_____

*(Based on the chart in Question 39)* | |

## PREVENTION AND CONTROL

**41. "Could this child's problem or condition have been prevented? Anything in particular that you think could have prevented it?'**

*Tick one only*

| Yes 3 | Possibly 2 | Uncertain 1 | No 0 |
|---|---|---|---|

*(Narrative)* _____

_____

*Tick accordingly for mentioned preventive measures, both for that particular child*

| | Prevention and control | Particular child | |
|---|---|---|---|
| | | Spon. | Probe |
| 1. | Use of mosquito net (untreated) | | |
| 2. | Use of a treated mosquito net | | |
| 3. | Taking medicines regularly (herbal or biomedical) | | |
| 4. | Parent to abstain from sex | | |
| 5. | Reduction in strenuous/hard work | | |
| 6. | Fumigation/ fogging | | |
| 7. | De-worming regularly | | |
| 8. | Avoid certain insect bites | | |
| 9. | Clean the environment | | |
| 10. | Keep personal hygiene | | |
| 11. | Drinking clean water | | |
| 12. | Attend to ancestral spirits and family gods | | |
| 13. | Avoid offending evil spirits, especially the witches | | |
| 14. | Mothers with malaria should not breast feed | | |
| 15. | Don't know/cannot tell | | |
| 16. | Cannot be prevented | | |
| 17. | Other *(mention):* | | |

## General Question on DEGEDEGE

**42. ''When was the last time you saw a child with convulsion or who was just recovering from convulsion?''**

*(Narrative)* _____

_____

*'Record number of days, weeks, months and years in appropriate box'*

| Days | Weeks | Months | Years |
|---|---|---|---|
| | | | |

*Tick for 'never seen a child with degedege'*

| Never seen a child with degedege |
|---|
| |

**43. What is that child's relationship to you**

| Own child 1 | Neighbour's child 2 | Extended family relation 3 | Other specify 4 |
|---|---|---|---|

## CONCLUDING ADVICE FROM RESPONDENT

**44. "Is there anything else you can tell me about this condition from your experience? Any further comments, advice or suggestions will be appreciated?''**

*(Narrative)* _____

_____

_____

**Interviewer:** | **Supervisor:**

**Interviewer Signature:** _____ **Supervisors Signature:** _____

**Interview Date:** | | | **Day/Month/Year**

**ADDITIONAL COMMENTS**

*Notes concerning subject's interest and the quality of the interview, and any other noteworthy features and details of this interview*

| |
|---|
| |
| |
| |
| |

**Supervisor:**

**Date of supervision:** | | | **Day/Month/Year**

# APPENDIX 2: ADDITIONAL FILES TO CHAPTER 7

**Patterns of distress (PD)**
**Children under five years of age**
**N=109**

| | Mean prominence | | | | | *P** | | |
|---|---|---|---|---|---|---|---|---|
| | Homa | Malaria | Degedege | Total | *P** | Homa-malaria | Homa-degedege | Malaria-degedege |
| **n** | **24** | **68** | **8** | **109** | | | | |
| No interest to play | 0.81 | 0.75 | 0.88 | 0.76 | 0.888 | | | |
| Not happy | 0.85 | 0.87 | 0.88 | 0.84 | 0.995 | | | |
| Sleeps | 0.78 | 0.77 | 0.75 | 0.79 | 1.000 | | | |
| Loss of appetite | 0.78 | 1.10 | 1.00 | 0.96 | 0.178 | | | |
| Crying all the time | 0.74 | 0.74 | 0.38 | 0.71 | 0.422 | | | |
| No strength | 0.52 | 0.93 | 1.00 | 0.79 | 0.068 | 0.023 | 0.202 | 0.835 |
| **Body strength** | **1.30** | **1.49** | **1.50** | **1.42** | **0.355** | **0.156** | **0.432** | **0.973** |
| | | | | | | | | |
| Hot body | 1.48 | 1.71 | 1.63 | 1.62 | 0.456 | | | |
| Hot head | 1.22 | 0.93 | 0.88 | 0.96 | 0.151 | | | |
| Hot abdomen | 0.96 | 0.94 | 0.88 | 0.92 | 0.953 | | | |
| Periodic fevers | 0.70 | 0.86 | 0.63 | 0.80 | 0.498 | | | |
| **Fever** | **1.74** | **1.87** | **1.75** | **1.81** | **0.589** | **0.370** | **0.937** | **0.515** |
| | | | | | | | | |
| Cough | 0.63 | 0.55 | 0.50 | 0.59 | 0.839 | | | |
| Difficult breathing | 0.33 | 0.46 | 0.50 | 0.44 | 0.537 | | | |
| **Respiration** | **0.78** | **0.71** | **0.63** | **0.74** | **0.879** | **0.744** | **0.637** | **0.739** |
| | | | | | | | | |
| Diarrhoea | 0.33 | 0.49 | 0.25 | 0.46 | 0.541 | 0.406 | 0.953 | |
| Vomiting | 0.56 | 1.03 | 1.00 | 0.96 | 0.105 | 0.033 | 0.346 | 0.947 |
| **Diarrhoea/vomiting** | **0.74** | **1.14** | **1.00** | **1.08** | **0.173** | **0.058** | **0.582** | **0.739** |
| | | | | | | | | |
| Twitching | 0.52 | 0.61 | 1.25 | 0.61 | 0.063 | 0.634 | 0.022 | 0.029 |
| Stiff body | 0.15 | 0.16 | 0.25 | 0.15 | 0.873 | | | |
| Delirium | 0.22 | 0.38 | 0.88 | 0.36 | 0.137 | 0.359 | 0.052 | 0.109 |
| Eyes turn white | 0.22 | 0.16 | 0.25 | 0.19 | 0.795 | | | |
| Kicking of leg/arm | 0.15 | 0.14 | 0.25 | 0.14 | 0.836 | | | |
| Froth in the mouth | 0.00 | 0.09 | 0.13 | 0.08 | 0.770 | | | |
| Mouth twisted sideways | 0.00 | 0.01 | 0.13 | 0.02 | 0.861 | | | |
| Falling down | 0.00 | 0.01 | 0.00 | 0.01 | 0.993 | | | |
| Easily startled/frightened | 0.30 | 0.28 | 0.63 | 0.29 | 0.258 | 0.813 | 0.163 | 0.102 |
| **Convulsions** | **0.59** | **0.77** | **1.25** | **0.75** | **0.099** | **0.299** | **0.036** | **0.092** |
| | | | | | | | | |
| Shivering | 0.41 | 0.52 | 0.13 | 0.44 | 0.313 | | | |
| Yellow eyes | 0.11 | 0.38 | 0.13 | 0.27 | 0.257 | | | |
| Other physical | 0.30 | 0.29 | 0.25 | 0.28 | 0.977 | | | |
| **Other** | **0.63** | **0.90** | **0.38** | **0.76** | **0.103** | **0.144** | **0.377** | **0.078** |

*Kruskal-Wallis test

**Patterns of distress (PD)**
**Adults 12 years of age and older**
**N=88**

| | Mean prominence | | | | | *P** |
|---|---|---|---|---|---|---|
| | Homa | Malaria | Degedege | Total | *P** | Homa-malaria |
| **n** | **29** | **54** | **2** | **88** | | |
| Loss of appetite | 0.62 | 0.76 | 1.00 | 0.71 | 0.634 | 0.369 |
| No strength | 1.04 | 0.93 | 0.00 | 0.93 | 0.220 | 0.576 |
| Headache | 1.38 | 1.39 | 0.00 | 1.35 | 0.140 | 0.963 |
| Dizziness | 0.42 | 0.57 | 0.00 | 0.53 | 0.450 | 0.432 |
| Pain | 0.15 | 0.41 | 0.00 | 0.31 | 0.610 | 0.361 |
| **Body strength, pain** | **1.62** | **1.63** | **1.00** | **1.62** | **0.743** | **0.861** |
| | | | | | | |
| Fever | 1.46 | 1.00 | 1.00 | 1.15 | 0.019 | 0.006 |
| Hot body | 1.08 | 1.07 | 2.00 | 1.08 | 0.242 | 0.967 |
| Hot head | 0.85 | 0.91 | 1.00 | 0.88 | 0.889 | 0.689 |
| Hot abdomen | 0.38 | 0.50 | 0.50 | 0.45 | 0.870 | 0.615 |
| Periodic fevers | 0.73 | 0.65 | 0.50 | 0.68 | 0.861 | 0.655 |
| **Fever** | **1.62** | **1.52** | **2.00** | **1.55** | **0.402** | **0.400** |
| | | | | | | |
| Cough | 0.38 | 0.24 | 1.00 | 0.32 | 0.545 | 0.485 |
| Difficult breathing | 0.23 | 0.22 | 1.50 | 0.25 | 0.105 | 0.869 |
| **Respiration** | **0.54** | **0.39** | **2.00** | **0.48** | **0.051** | **0.388** |
| | | | | | | |
| Diarrhoea | 0.23 | 0.17 | 0.00 | 0.20 | 0.961 | 0.939 |
| Vomiting | 0.42 | 0.56 | 1.00 | 0.51 | 0.685 | 0.518 |
| Nausea | 0.50 | 0.52 | 1.00 | 0.51 | 0.826 | 0.841 |
| **Diarrhoea/vomiting** | **0.92** | **0.85** | **1.00** | **0.87** | **0.946** | **0.766** |
| | | | | | | |
| Yellow eyes | 0.04 | 0.13 | 0.50 | 0.11 | 0.539 | 0.597 |
| Shivering | 0.38 | 0.48 | 1.00 | 0.46 | 0.683 | 0.565 |
| Other physical symptoms | 0.19 | 0.31 | 2.00 | 0.31 | 0.101 | 0.689 |
| Bad dreams | 0.27 | 0.24 | 0.00 | 0.25 | 0.817 | 0.837 |
| **Other** | **0.73** | **0.81** | **2.00** | **0.80** | **0.146** | **0.704** |

*Kruskal-Wallis test
** kwallis with categories "homa" and "malaria" only; "degedege" cases dropped

**Perceived causes (PC)**
**Children under five years of age**
**N=109**

| | Mean prominence | | | | | *P** | | |
|---|---|---|---|---|---|---|---|---|
| | Homa | Malaria | Degedege | Total | *P** | Homa-malaria | Homa-degedege | Malaria-degedege |
| **n** | **24** | **68** | **8** | **109** | | | | |
| Impure water | 0.37 | 0.39 | 0.63 | 0.38 | 0.486 | 0.903 | 0.255 | 0.249 |
| Eating leftover food | 0.19 | 0.23 | 0.38 | 0.22 | 0.718 | 0.723 | 0.421 | 0.510 |
| Unbalanced diet | 0.22 | 0.16 | 0.50 | 0.19 | 0.284 | 0.634 | 0.239 | 0.117 |
| Starchy food | 0.07 | 0.07 | 0.25 | 0.08 | 0.709 | 0.991 | 0.455 | 0.413 |
| Breast feeding / mother's milk | 0.11 | 0.09 | 0.25 | 0.12 | 0.716 | 0.779 | 0.556 | 0.423 |
| **Ingestion** | **0.59** | **0.52** | **0.75** | **0.55** | **0.493** | **0.560** | **0.480** | **0.263** |
| | | | | | | | | |
| Mosquito bite | 1.22 | 1.55 | 1.13 | 1.37 | 0.083 | 0.083 | 0.680 | 0.089 |
| Other insect bite | 0.41 | 0.19 | 0.38 | 0.26 | 0.211 | 0.096 | 0.891 | 0.390 |
| Houseflies | 0.22 | 0.14 | 0.63 | 0.20 | 0.084 | 0.557 | 0.088 | **0.027** |
| Worms | 0.44 | 0.26 | 0.63 | 0.32 | 0.130 | 0.164 | 0.444 | 0.093 |
| Bird/insect called degedege | 0.41 | 0.29 | 0.25 | 0.35 | 0.173 | 0.338 | 0.255 | 0.084 |
| **Insects / worms** | **1.41** | **1.62** | **1.38** | **1.51** | **0.176** | **0.110** | **0.844** | **0.223** |
| | | | | | | | | |
| Physical hard work (parent) | 0.11 | 0.06 | 0.13 | 0.08 | 0.895 | 0.687 | 0.953 | 0.757 |
| Stage of child growth | 0.78 | 0.46 | 0.63 | 0.56 | 0.093 | **0.033** | 0.596 | 0.428 |
| Constitution/ blood weakness | 0.41 | 0.20 | 0.13 | 0.25 | 0.245 | 0.121 | 0.231 | 0.720 |
| Hereditary | 0.15 | 0.10 | 0.00 | 0.10 | 0.813 | 0.723 | 0.530 | 0.640 |
| **Work / constitution** | **0.85** | **0.52** | **0.63** | **0.62** | **0.074** | **0.023** | **0.398** | **0.599** |
| | | | | | | | | |
| Sanitation/ Dirty environment | 0.63 | 0.54 | 0.63 | 0.55 | 0.730 | 0.483 | 0.969 | 0.628 |
| Personal hygiene/not keeping clean | 0.41 | 0.25 | 0.63 | 0.30 | 0.140 | 0.222 | 0.356 | 0.081 |
| Plant | 0.19 | 0.19 | 0.38 | 0.19 | 0.660 | 0.948 | 0.421 | 0.367 |
| Contamination - contact | 0.44 | 0.23 | 0.63 | 0.30 | 0.062 | 0.083 | 0.444 | 0.063 |
| **Contamination** | **0.70** | **0.62** | **0.88** | **0.64** | **0.421** | **0.483** | **0.455** | **0.226** |
| | | | | | | | | |
| Wind | 0.33 | 0.23 | 0.38 | 0.26 | 0.644 | 0.441 | 0.860 | 0.510 |
| Heat (sun or fire) | 0.44 | 0.43 | 0.75 | 0.44 | 0.292 | 0.705 | 0.195 | 0.125 |
| Cold weather | 0.85 | 0.46 | 0.75 | 0.60 | 0.044 | **0.023** | 0.814 | 0.161 |
| **Weather / climate** | **1.04** | **0.75** | **0.88** | **0.84** | **0.216** | **0.063** | **0.569** | **0.520** |
| | | | | | | | | |
| Spirits (upepo, majini, shetani) | 0.30 | 0.14 | 0.50 | 0.19 | 0.177 | 0.251 | 0.388 | 0.102 |
| Evil eyes or sorcery (uchawi) | 0.22 | 0.22 | 0.38 | 0.21 | 0.742 | 0.903 | 0.517 | 0.443 |
| God | 0.63 | 0.65 | 0.50 | 0.64 | 0.896 | 0.955 | 0.637 | 0.664 |
| Failure to abstain from sex (parent) | 0.15 | 0.09 | 0.38 | 0.12 | 0.401 | 0.642 | 0.336 | 0.184 |
| **Supernatural** | **0.74** | **0.80** | **0.63** | **0.77** | **0.839** | **0.820** | **0.666** | **0.570** |
| | | | | | | | | |
| Cannot tell | 0.19 | 0.28 | 0.25 | 0.27 | 0.893 | 0.642 | 0.937 | 0.854 |

*Kruskal-Wallis test

**Perceived causes (PC)**
**Adults 12 years of age and older**
**N=88**

| | Mean prominence** | | | | *P** |
|---|---|---|---|---|---|
| | Homa | Malaria | All Mean | *P** | Homa-malaria |
| **n** | **29** | **54** | **88** | | |
| Impure water | 0.35 | 0.41 | 0.40 | 0.110 | 0.350 |
| Eating leftover food | 0.19 | 0.15 | 0.15 | 0.855 | 0.670 |
| Unbalanced diet | 0.15 | 0.19 | 0.18 | 0.885 | 0.735 |
| Starchy food | 0.08 | 0.07 | 0.07 | 0.984 | 0.983 |
| Breast feeding | 0.00 | 0.13 | 0.08 | 0.632 | 0.350 |
| **Ingestion** | **0.54** | **0.57** | **0.58** | **0.220** | **0.545** |
| | | | | | |
| Mosquito bite | 1.12 | 1.50 | 1.34 | 0.173 | 0.062 |
| Other insect bite | 0.15 | 0.20 | 0.19 | 0.707 | 0.719 |
| Houseflies | 0.23 | 0.20 | 0.24 | 0.163 | 0.845 |
| Worms | 0.31 | 0.28 | 0.29 | 0.857 | 0.829 |
| Bird/insect called degedege | 0.23 | 0.20 | 0.22 | 0.163 | 0.845 |
| **Insects / worms** | **1.15** | **1.52** | **1.36** | **0.185** | **0.068** |
| | | | | | |
| Physical hard work | 0.96 | 0.57 | 0.66 | 0.086 | 0.057 |
| Stage of life | 0.23 | 0.43 | 0.35 | 0.350 | 0.229 |
| Constitution/ blood weakness | 0.27 | 0.24 | 0.26 | 0.817 | 0.837 |
| Hereditary | 0.04 | 0.04 | 0.04 | 0.996 | 0.991 |
| **Work / constitution** | **0.96** | **0.81** | **0.84** | **0.658** | **0.482** |
| | | | | | |
| Sanitation/ Dirty environment | 0.23 | 0.57 | 0.46 | 0.041 | 0.030 |
| Personal hygiene/not keeping clean | 0.19 | 0.30 | 0.27 | 0.641 | 0.453 |
| Plant | 0.12 | 0.30 | 0.22 | 0.427 | 0.235 |
| Contamination - contact | 0.15 | 0.13 | 0.14 | 0.933 | 0.861 |
| **Contamination** | **0.35** | **0.67** | **0.56** | **0.070** | **0.040** |
| | | | | | |
| Wind | 0.27 | 0.17 | 0.21 | 0.669 | 0.611 |
| Heat (sun or fire) | 0.54 | 0.37 | 0.42 | 0.496 | 0.246 |
| Cold weather | 0.58 | 0.31 | 0.39 | 0.259 | 0.152 |
| **Weather / climate** | **0.81** | **0.48** | **0.59** | **0.097** | **0.057** |
| | | | | | |
| Spirits (upepo, majini, shetani) | 0.27 | 0.17 | 0.21 | 0.669 | 0.611 |
| Evil eyes or sorcery (uchawi) | 0.15 | 0.11 | 0.13 | 0.635 | 0.758 |
| God | 0.62 | 0.41 | 0.51 | 0.241 | 0.267 |
| Failure to abstain from sex (parent) | 0.04 | 0.11 | 0.09 | 0.853 | 0.600 |
| **Supernatural** | **0.69** | **0.61** | **0.66** | **0.600** | **0.611** |
| | | | | | |
| Cannot tell | 0.12 | 0.33 | 0.27 | 0.529 | 0.295 |

*Kruskal-Wallis test
** degedege category omitted

# CURRICULUM VITAE


| | |
|---|---|
| Name | **Manuel Wolf-Werner HETZEL** |
| Nationality | German |
| Date and place of birth | 22nd of October 1978, Bern, Switzerland |
| E-mail | manuel.hetzel@unibas.ch, manuhetzel@gmail.com |
| Languages | German, English (fluent), French (good), Spanish (good), Portuguese (basic), Swahili (basic) |


## EDUCATION

| | |
|---|---|
| 02/2004-10/2007 | PhD in Epidemiology<br>Swiss Tropical Institute, University of Basel, Switzerland<br>based at Ifakara Heath Research and Development Centre, Tanzania |
| 10/1998-07/2003 | MSc in Biology (major: medical parasitology/epidemiology, minors: neurobiology, microbiology, vertebrate biology, plant ecology)<br>University of Basel, Switzerland<br>MSc thesis: “The public health impact of milk contamination in Bamako, Mali.” |
| 03-07/2001 | Studies in epidemiology, parasitology and microbiology<br>Centro de Pesquisas Epidemiológicas, Universidade Federal de Pelotas, Brazil |
| 03-06/1998 | Cambridge Certificate of Proficiency in English<br>Australian College of English, Sydney |
| 1994-1997 | Matura Typus B<br>Gymnasium in Muttenz, Switzerland |
| 07-10/1996 | Colegio Suizo de Santiago, Santiago de Chile |

## TRAINING

| | |
|---|---|
| 07/2005 | Certificate in Health District Management: Planning and Programme Design<br>Swiss Tropical Institute, University of Basel, Switzerland |
| 09/2001 | Short course: Diagnosis of human pathogenic parasites<br>Swiss Tropical Institute, Basel, Switzerland |
| 06-07/2001 | Internship, laboratories of protozoology and helminthology<br>Instituto de Medicina Tropical, Universidade de São Paulo, Brazil |
| 06/1997 | F. Hoffmann-La Roche AG, Basel (Switzerland)<br>Internship, synthesis of Trimethoprim and derivatives |

## EMPLOYMENT

| | |
|---|---|
| 02/2004-present | Scientific assistant<br>Development and implementation of the monitoring & evaluation component of an intervention research project, based in Ifakara, Tanzania<br>Swiss Tropical Institute, Basel |
| 2003-2007 | Network coordinator and webmaster<br>Healthy Milk for the Sahel Network (Réseau Lait Sain pour le Sahel) |
| 2000-2005 | Assistant, clinical research administration (part-time)<br>Swiss Pharma Contract Ltd., Allschwil, Switzerland |
| 2002 | Assistant, marine biology course in Banyuls-sur-Mer, France<br>Institute of Zoology, University of Basel,Switzerland |

## PROFESSIONAL MEMBERSHIP

- Swiss Society of Tropical Medicine and Parasitology
- European Young Epidemiologists (EYE)
- Medicus Mundi Schweiz

## PUBLICATIONS

**Hetzel MW**, Alba S, Fankhauser M, Mayumana I, Lengeler C, Obrist B, Nathan R, Makemba AM, Mshana C, Iteba N, Schulze A, Mshinda H (2007) Malaria risk and access to prevention and treatment in the paddies of the Kilombero Valley, Tanzania. *Malaria Journal* (in press)

**Hetzel MW**, Dillip A, Lengeler C, Obrist B, Msechu JJ, Makemba A, Mshana C, Schulze A, Mshinda H (2007) Malaria treatment in the retail sector: drug sellers' knowledge and practices in rural Tanzania. *PLoS ONE* (submitted)

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**Hetzel MW**, Iteba N, Makemba A, Mshana C, Lengeler C, Obrist B, Schulze A, Nathan R, Dillip A, Alba S, Mayumana I, Khatib RA, Njau JD, Mshinda H (2007) Understanding and improving access to prompt and effective malaria treatment and care in rural Tanzania: the ACCESS Programme. *Malaria Journal* 6: 83.

**Hetzel MW**, Msechu JJ, Goodman C, Lengeler C, Obrist B, Kachur SP, Makemba AM, Nathan R, Schulze A, Mshinda H. (2006) Decreased availability of antimalarials in the private sector following the policy change from chloroquine to sulphadoxine-pyrimethamine in the Kilombero Valley, Tanzania. *Malaria Journal* 5: 109.

**Hetzel MW**, Bonfoh B, Farah Z, Simbé CF, Alfaroukh IO, Tanner M, Zinsstag J. (2005) Milk consumption patterns in an area with traditional milk production: data from a case-control study in peri-urban Bamako, Mali. *Revue Africaine de Santé et de Productions Animales* 3(3-4): 174-177.

**Hetzel M**, Bonfoh B, Farah Z, Traoré M, Simbé CF, Alfaroukh IO, Schelling E, Tanner M, Zinsstag J. (2004) Diarrhoea, vomiting and the role of milk consumption: perceived and identified risk in Bamako (Mali). *Tropical Medicine and International Health* 9(10): 1132-1138.

**PRESENTATIONS AT SCIENTIFIC MEETINGS**

**Hetzel MW**, Iteba N, Lengeler C, Obrist B, Dillip A, Alba S, Makemba A, Mshana C, Schulze A, Mshinda H. Improving access to prompt and effective malaria treatment: better drugs are not enough. 5th European Congress on Tropical Medicine and International Health, Amsterdam, 25th May 2007. *Tropical Medicine and International Health* 2007, 12 (s1), p. 32-33.

**Hetzel MW**, Lengeler C, Obrist B, Makemba AM, Mshana C, Schulze A, Mshinda H. Barriers to prompt and effective malaria treatment in rural Tanzania: Better drugs is not enough. 55th Annual Meeting of the American Society of Tropical Medicine and Hygiene, Atlanta, 13 November 2006. *American Journal of Tropical Medicine and Hygiene* 2006; 75 (5) Suppl., p.9.

**Hetzel MW**, Msechu J, Lengeler C, Obrist B, Goodman C, Makemba A, Mponda H, Sono K, Mshinda H. Availability of antimalarials after the policy change from chloroquine to sulphadoxine–pyrimethamine in rural Tanzania. 4th MIM Pan-African Malaria Conference, Yaoundé, Cameroon, 17 November 2005. *Acta Tropica* 2005; 95S Supplement, p. S101.

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**Hetzel MW**, Bonfoh B, Fané A, Steinmann P, Traoré M & Zinsstag J. The public health impact of the contamination of milk and dairy products in Mali: Food-borne intoxications and transmission of zoonoses. Séminaire Sous *Régional Lait Sain pour le Sahel*. Bamako (Mali), 26 February 2003.