

QUALITY OF MALARIA CASE MANAGEMENT IN ZAMBIA, 2011

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ABSTRACT

The Zambian Ministry of Health (MOH) National Malaria Control center (NMCC) adopted artemisinin combination therapy (ACT) as a first-line antimalarial drug for uncomplicated malaria in 2003, and included rapid diagnostic testing (RDT) in its case management guidelines to reduce over-diagnosis of malaria and over-prescription of antimalarials. Prior research has highlighted gaps in the malaria case management process in Zambia, especially in diagnosis and treatment. The first paper of this study aimed to build quality indices or indicators for the four components of malaria case management: assessment, diagnosis, treatment and counseling. The Zambia MOH/NMCC conducted a nationally representative health facility survey in 2011 with the Malaria Control and Evaluation Partnership in Africa. The mean assessment quality (percentage of assessment items correctly completed) rate was 49.9%. The diagnostic quality (concordance with gold standard diagnosis) rate was 82.4%, with 86.9% sensitivity and 79.4% specificity. The treatment quality rate (correct treatment for those needing antimalarials and no treatment for patients not needing it) was 89.6%, and the mean counseling quality (percentage of counseling items correctly completed) rate was 48.6%. The second paper investigated factors association with each of the four components of malaria case management. Supervision was significantly associated with assessment and counseling but not diagnosis and treatment. Health facility managing authority was associated with assessment and diagnosis. Availability of blood tests was associated with correct diagnosis, and diagnosis was strongly associated with treatment. Malaria endemicity and availability of IMCI guidelines were associated with counseling quality. The third paper investigated the association between counseling and patient recall of treatment regimen, and found that they were associated as hypothesized. The Zambia NMCC has improved the quality of malaria case management over previous years, although it is recommended that more health facility surveys are conducted in order to study the change in health worker performance over time.

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List of Acronyms

ACT	Artemisinin combination therapy
AL	Artemether lumefantrine
CHW	Community health worker
DHMT	District health management team
HRP	Histidine-rich protein
HW	Health worker
ICT	Immunochromatographic test
IMCI	Integrated Management of Childhood Illnesses
ITN	Insecticide-treated net
MACEPA	Malaria Control and Evaluation Partnership in Africa
MCE	Multi-country evaluation
MCM	Malaria case management
MIS	Malaria Indicator Survey
MOH	Ministry of Health
NMCC	National Malaria Control Programme
RDT	Rapid diagnostic test
SD-Bioline™	Standard Diagnostics-Bioline™
SP	Sulphadoxine-pyrimethamine
WHO	World Health Organization

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I. Background and General introduction

There was a high burden of malaria in Zambia in 2011. Children aged under 5 years are most at risk for malaria morbidity and mortality, but adolescents and adults also suffer from malaria. The Zambia Malaria Index Surveys (MIS) from 2010 and 2012 revealed that malaria parasite prevalence in children under 5 years was 16% and 14.9%, respectively (1, 2). The same surveys found that in 2010 and 2012, 31.2% and 24.5%, respectively, of children aged under 5 years with fever were brought to a health facility within 24 hours of fever onset.

Malaria case management in primary care facilities is an important element of Zambia's Ministry of Health (MOH) National Malaria Control Center (NMCC). Artemisinin combination therapy (ACT) was adopted as Zambia's first-line antimalarial drug in 2002, and implementation began in 2003. ACTs are expensive drugs, and also parasite resistance to ACT has appeared in Southeast Asia, so there is a need to improve diagnostics and reduce over-treatment (3-6). Accordingly, starting in 2005, Zambia NMCC distributed rapid diagnostic tests (RDTs) in a phased fashion to health facilities, with nationwide scale-up in 2009 (7).

The malaria case management policy in Zambia in 2011 was that all fever cases should be checked for temperature and patients with a current fever or history of fever (at least 37.5°C) in the previous 48 hours should be tested with either a rapid diagnostic test, or with microscopy (8). For children aged under 5 years, the health worker should follow the results of the blood test and only diagnose and treat for malaria if the blood test is positive. If there is no blood test available, then the health worker should follow the IMCI guidelines and check for potential other causes of fever before diagnosing a fever as malaria. The first-line drug for uncomplicated malaria is artemether-lumefantrine (AL) for children weighing at least 5kg and adults. For children weighing under 5kg, sulphadoxine-pyrimethamine (SP) was recommended as the first line antimalarial drug. Quinine was the second line drug for uncomplicated malaria and was the first line drug for severe malaria.

At the time the 2011 Zambia NMCC Health Facility Survey was conducted (March to April 2011) the Zambian MOH and NMCC used Standard Diagnostics-Bioline™ brand rapid diagnostic tests (RDTs), which ranked above other brands in internal tests by NMCC (10). SD-Bioline™ RDTs were also used by the survey team for re-examination of fever patients. SD-Bioline™ is an immunochromatographic assay for detecting *P. falciparum* and *P. vivax*. According to the company documentation the sensitivity is 87% for *P. falciparum* and 86% for *P. vivax*, while the specificity is 99.5% for both (11). Most (over 95%) of malaria in Zambia is caused by *P. falciparum*, while *p. vivax* is rare (12).

The NMCC 2011 goal for case management coverage was that 90% of all suspected malaria cases should be tested with parasitological diagnosis and prompt, effective treatment(13). Effective treatment according to national guidelines at the time of the survey was ACT for uncomplicated malaria, and quinine for severe malaria; quinine was also the second line drug for uncomplicated malaria. (8)

The 2011 Zambia National Malaria Control Action Plan notes that in 2010, within the Zambian health system, malaria case management challenges included low adherence to diagnostic test results by health workers, and over-prescribing of ACTs, including for non-malaria fevers. The action plan also pointed out that stock management problems persisted at both district and health facility level (13). In addition, there is high turnover among health workers and a deficit of well-trained health workers, leading to performance gaps in malaria case management (14).

There have been studies in the past which evaluated quality of case management; the World Health Organization (WHO) Integrated Management of Childhood Illnesses (IMCI) program during the years 2001 to 2005 conducted several studies with this goal in mind (15-24). In addition, several researchers have conducted malaria case management quality studies (3-6, 25-31). Gouws and colleagues calculated a correlation matrix of four indices for IMCI which had been constructed using principle components analysis: assessment, vaccine availability, drug availability and health worker knowledge of management of severe illness among infants (32). A study by Littrell et al (2013) used a

systems effectiveness analysis for the same Zambia health facility data used in this study, combined with data from household surveys (33). The summary system effectiveness index used in that study takes into account certain elements of case management quality, while also factoring in the proportion of fever patients who seek treatment at a health facility. However, no prior studies have determined whether a summary index of malaria case management quality is appropriate and valid based on the significance of associations between its components.

To improve health worker performance, it is important to understand what factors are associated with malaria case management quality. Rowe and colleagues, in the same study of malaria case management in Angola mentioned above (12), found that correct clinic diagnosis was associated with health worker caseloads of less than 25 patients per day and elevated patient temperature. There was borderline association between correct testing and malaria case management training. The same study found no factors associated with correct treatment in multiple regression analysis. The Malawi study of malaria case management by Steinhardt and colleagues mentioned above (16) found that patient-level clinical symptoms had the strongest level of association with quality of correct case management. In that study, multiple regression analysis found that presence of fever was the only factor associated with correct treatment.

Studies have also been conducted on factors associated with health worker performance on IMCI quality of care. IMCI quality of care is relevant because the Zambia NMCC has incorporated IMCI fever management guidelines into the national guidelines for health facilities which do not have diagnostic testing for malaria. A study by Naimoli and colleagues of IMCI quality of care in Morocco found several factors were associated with adherence to IMCI guidelines, including IMCI training, being a female health worker, patient age and number of health complaints and not reporting lack of supervision as a problem (14). Another IMCI study by Bryce and colleagues in Tanzania found that better case management was associated with IMCI training (18).

WHO recommends supportive supervision from district level to health facility staff; in Zambia this supervision is provided by the district health management teams (DHMT). WHO also recommends that every district have a malaria focal point who is responsible for malaria control activities (19). Zambia's healthcare system has been decentralized to the district level since the late 1990s (20). Each health center in a district should be visited at least once quarterly (every 3 months) (21); during these visits supervisors are expected to check on, among other things, health worker performance and stock management, to ensure that service delivery is effective.

Researchers have had varying results in analyzing the association between supportive supervision and health worker performance. For example Rowe and colleagues in their 2003 study of factors associated with treatment errors in Benin found that at least one supervisory visit in the previous 6 months was associated with minor treatment errors (22). Edward and colleagues in their 2012 study of quality of IMCI care (23) in Afghanistan found that at least 6 supervisory visits in the previous 6 months was associated with better quality of care. Another malaria treatment study by Rowe and colleagues (12) found that supervision had no association with quality of malaria treatment. A study of supervisor-provider interactions in primary care facilities found that supervisors spent less than 5% of their time on patient care issues (24).

Data from the 2011 Zambia National Health Facility are still highly relevant in 2016. Most malaria surveys conducted in Zambia in the past 10 years have been household surveys, which yield valuable data on health-seeking behaviors, malaria parasitemia, and coverage of malaria control strategies. However, health facility data also provide important information on facility-based case management, health worker performance and malaria supplies and medicines. The regression analyses in this study provide information which can be helpful to NMCC malaria program managers years later.

Artemisinin combination therapy (ACT) was adopted in 2002 as Zambia's first-line drug to treat uncomplicated malaria (1-3). Other antimalarials which had been used prior to ACT were chloroquine

and sulfadoxine-pyremethamine (SP) (brand name Fansidar™), both of which are now less effective due to parasite resistance (3, 4). Since ACT was adopted as the first-line antimalarial in Zambia, there has been an effort to increase its cost effectiveness by reducing over-prescription. Subsequently, malaria rapid diagnostic tests (RDTs) were integrated into the Zambia National Malaria Control Centre's (NMCC) malaria control strategy in 2003 and were scaled up in a phased approach starting in 2005 (5). There is also a need to ensure that after it has been prescribed to patients diagnosed with malaria, that patients or caretakers follow the correct AL treatment regimen. Parasite resistance to ACT has been detected in Thailand and Cambodia (6), and there is concern that this resistance could spread to other regions including sub-Saharan Africa if AL is overprescribed and misused. A 2014 study of artemisinin resistance in *Plasmodium falciparum* found that between 2011 and 2013, study patients in Africa had parasite half-life clearance rates below 5 hours (7) indicating that artemisinin resistance has not yet arrived in sub-Saharan Africa.

A study in Uganda by Fogg and colleagues (8) found that ACT adherence was high at 90% and was likely to remain so as long as malaria patients receive clear dosing explanations. Lack of formal education was found to be associated with non-adherence to the recommended ACT treatment regimen. Adherence is not a simple matter since the regimen for the formulation used in Zambia is 3 days, twice daily, with evenly spaced dosages to be taken with fatty foods for optimum efficacy. Correct understanding of treatment regimen is therefore an important issue to investigate.

Few studies have been conducted to assess factors associated with ACT adherence at home, nor have studies been conducted assessing factors associated with patient understanding of treatment regimen; no studies in Zambia have been identified on this subject. Data collected in the Zambia 2011 Health Facility Survey can still provide valuable information on factors associated with patient or caretaker understanding of treatment regimen, which is assumed to be associated with adherence to the treatment regimen at home. Since a recent study by Ashley and colleagues (7) showed that

artemisinin resistance has not yet been detected in three countries in Sub-Saharan Africa, there is still a high priority on keeping antimalarial resistance from forming and taking root in Zambia. However, high rates of incomplete adherence to the correct AL treatment regimen could lead to treatment failure, which in turn could lead to AL resistance in *P. falciparum*. This study aims to improve understanding of factors associated with patient or caretaker correct knowledge of ACT treatment regimen following fever consultation at a primary care facility. Specifically, this study aims to quantify the association between quality of counseling from the health worker regarding AL treatment, and whether the patient has correct understanding of the AL treatment regimen.

This study first aims to evaluate the quality of malaria case management in Zambia by developing case management quality indices for assessment, diagnosis, treatment, and counseling, and to determine whether a summary index of malaria case management quality would be a valid measurement instrument. Next, the four case management components listed above are tested for association with supervision, controlling for other factors. Finally, patient recall of the correct treatment regimen is tested for association with quality of counseling, controlling for other factors.

Bibliography

1. A. K. Rowe *et al.*, Quality of malaria case management at outpatient health facilities in Angola. *Malar J* **8**, 275 (2009).
2. L. C. Steinhardt *et al.*, Patient-, health worker-, and health facility-level determinants of correct malaria case management at publicly funded health facilities in Malawi: results from a nationally representative health facility survey. *Malar J* **13**, 64 (2014).
3. J. F. Naimoli, A. K. Rowe, A. Lyaghfour, R. Larbi, L. A. Lamrani, Effect of the Integrated Management of Childhood Illness strategy on health care quality in Morocco. *Int J Qual Health Care* **18**, 134-144 (2006).
4. J. Bryce *et al.*, Improving quality and efficiency of facility-based child health care through Integrated Management of Childhood Illness in Tanzania. *Health Policy Plan* **20 Suppl 1**, i69-i76 (2005).
5. W. G. M. Programme, "Malaria Case Management Operations Manual," (Geneva, Switzerland, 2009).
6. T. Bossert, M. B. Chitah, D. Bowser, Decentralization in Zambia: resource allocation and district performance. *Health Policy Plan* **18**, 357-369 (2003).
7. M. Hawela. (2013).
8. A. K. Rowe, F. Onikpo, M. Lama, M. S. Deming, Risk and protective factors for two types of error in the treatment of children with fever at outpatient health facilities in Benin. *Int J Epidemiol* **32**, 296-303 (2003).
9. A. Edward *et al.*, The association of health workforce capacity and quality of pediatric care in Afghanistan. *Int J Qual Health Care* **24**, 578-586 (2012).
10. P. Tavrow, Y. M. Kim, L. Malianga, Measuring the quality of supervisor-provider interactions in health care facilities in Zimbabwe. *Int J Qual Health Care* **14 Suppl 1**, 57-66 (2002).
11. J. Miller, L. Rosencrans, Ed. (2014).
12. *Guidelines for the diagnosis and treatment of malaria in Zambia* (2010).
13. D. H. Hamer *et al.*, Improved diagnostic testing and malaria treatment practices in Zambia. *JAMA* **297**, 2227-2231 (2007).
14. M. Mulenga *et al.*, Safety and efficacy of lumefantrine-artemether (Coartem) for the treatment of uncomplicated Plasmodium falciparum malaria in Zambian adults. *Malar J* **5**, 73 (2006).
15. D. Zurovac *et al.*, Paediatric malaria case-management with artemether-lumefantrine in Zambia: a repeat cross-sectional study. *Malar J* **6**, 31 (2007).
16. M. Littrell *et al.*, Case management of malaria fever in Cambodia: results from national anti-malarial outlet and household surveys. *Malar J* **10**, 328 (2011).
17. E. A. Ashley *et al.*, Spread of artemisinin resistance in Plasmodium falciparum malaria. *N Engl J Med* **371**, 411-423 (2014).
18. C. Fogg *et al.*, Adherence to a six-dose regimen of artemether-lumefantrine for treatment of uncomplicated Plasmodium falciparum malaria in Uganda. *Am J Trop Med Hyg* **71**, 525-530 (2004).

II. Measuring malaria case management quality in Zambia

Abstract

The Zambian Ministry of Health (MOH) National Malaria Control center (NMCC) adopted artemisinin combination therapy (ACT) as a first-line antimalarial drug for uncomplicated malaria in 2003, and included rapid diagnostic testing (RDT) in its case management guidelines to reduce over-diagnosis of malaria and over-prescription of antimalarials. Prior research has highlighted gaps in the malaria case management process in Zambia, especially in diagnosis and treatment. It is important to have measurable case management quality indices to facilitate program evaluation of primary care facilities. This study aimed to build quality indices or indicators for the four components of malaria case management: assessment, diagnosis, treatment and counseling. This study also aimed to determine whether these malaria case management components were associated with each other since significant association among all 4 components would mean that a summary index could be valid and appropriate for program evaluation purposes. The Zambia MOH/NMCC conducted a nationally representative health facility survey in 2011 with the Malaria Control and Evaluation Partnership in Africa (MACEPA). Using data from this survey (n=850 fever patients aged at least 2 months), the four case management quality indices were built and tested for association with each other. The mean assessment quality (percentage of assessment items correctly completed) rate was 49.9%. The diagnostic quality (concordance with gold standard diagnosis) rate was 82.4%, with 86.9% sensitivity and 79.4% specificity. The treatment quality rate (correct treatment for those needing antimalarials and no treatment for patients not needing it) was 89.6%, and the mean counseling quality (percentage of counseling items correctly completed) rate was 48.6%. Of the four indices, two pairs of case management components were associated: diagnosis and treatment quality were significantly associated (Pearson $\chi^2=136.9$; $p<.0001$), and assessment and counseling quality were significantly associated (Wald $\chi^2=30.8$, $p<0.0001$). These results indicate that the four components of malaria case management should not be aggregated into a summary index, as it

would not be a valid measurement instrument. Areas to target for improvement in health worker performance include checking for danger signs and differential diagnoses during fever assessment; using RDTs where available and then adhering to the results; clarifying NMCC treatment guidelines to make them easier to follow; and ensuring that the patient or caretaker understands the treatment regimen and when to return to the health facility for a follow up visit.

1. Introduction

There was a high burden of malaria in Zambia in 2011. Children aged under 5 years are most at risk for malaria morbidity and mortality, but adolescents and adults also suffer from malaria. The Zambia Malaria Index Surveys (MIS) from 2010 and 2012 revealed that malaria parasite prevalence in children under 5 years was 16% and 14.9%, respectively (1, 2). The same surveys found that in 2010 and 2012, 31.2% and 24.5%, respectively, of children aged under 5 years with fever were brought to a health facility within 24 hours of fever onset.

Malaria case management in primary care facilities is an important element of Zambia's Ministry of Health (MOH) National Malaria Control Center (NMCC). Artemisinin combination therapy (ACT) was adopted as Zambia's first-line antimalarial drug in 2002, and implementation began in 2003. ACTs are expensive drugs, and also parasite resistance to ACT has appeared in Southeast Asia, so there is a need to improve diagnostics and reduce over-treatment (3-6). Accordingly, starting in 2005, Zambia NMCC distributed rapid diagnostic tests (RDTs) in a phased fashion to health facilities, with nationwide scale-up in 2009 (7).

The malaria case management policy in Zambia in 2011 was that all fever cases should be checked for temperature and patients with a current fever or history of fever (at least 37.5°C) in the previous 48 hours should be tested with either a rapid diagnostic test, or with microscopy (8). For children aged under 5 years, the health worker should follow the results of the blood test and only diagnose and treat for malaria if the blood test is positive. If there is no blood test available, then the health worker should follow the IMCI guidelines and check for potential other causes of fever before diagnosing a fever as malaria. The first-line drug for uncomplicated malaria is artemether-lumefantrine (AL) for children weighing at least 5kg and adults. For children weighing under 5kg, sulphadoxine-

pyrimethamine (SP) was recommended as the first line antimalarial drug. Quinine was the second line drug for uncomplicated malaria and was the first line drug for severe malaria.

At the time the 2011 Zambia NMCC Health Facility Survey was conducted (March to April 2011) the Zambian MOH and NMCC used Standard Diagnostics-Bioline™ brand rapid diagnostic tests (RDTs), which ranked above other brands in internal tests by NMCC (10). SD-Bioline™ RDTs were also used by the survey team for re-examination of fever patients. SD-Bioline™ is an immunochromatographic assay for detecting *P. falciparum* and *P. vivax*. According to the company documentation the sensitivity is 87% for *P. falciparum* and 86% for *P. vivax*, while the specificity is 99.5% for both (11). Most (over 95%) of malaria in Zambia is caused by *P. falciparum*, while *p. vivax* is rare (12).

The NMCC 2011 goal for case management coverage was that 90% of all suspected malaria cases should be tested with parasitological diagnosis and prompt, effective treatment(13). Effective treatment according to national guidelines at the time of the survey was ACT for uncomplicated malaria, and quinine for severe malaria; quinine was also the second line drug for uncomplicated malaria. (8)

The 2011 Zambia National Malaria Control Action Plan notes that in 2010, within the Zambian health system, malaria case management challenges included low adherence to diagnostic test results by health workers, and over-prescribing of ACTs, including for non-malaria fevers. The action plan also pointed out that stock management problems persisted at both district and health facility level (13). In addition, there is high turnover among health workers and a deficit of well-trained health workers, leading to performance gaps in malaria case management (14).

There have been studies in the past which evaluated quality of case management; the World Health Organization (WHO) Integrated Management of Childhood Illnesses (IMCI) program during the years 2001 to 2005 conducted several studies with this goal in mind (15-24). In addition, several researchers have conducted malaria case management quality studies (3-6, 25-31). Gouws and colleagues calculated a correlation matrix of four indices for IMCI which had been constructed using

principle components analysis: assessment, vaccine availability, drug availability and health worker knowledge of management of severe illness among infants (32). A study by Littrell et al (2013) used a systems effectiveness analysis for the same Zambia health facility data used in this study, combined with data from household surveys (33). The summary system effectiveness index used in that study takes into account certain elements of case management quality, while also factoring in the proportion of fever patients who seek treatment at a health facility. However, no prior studies have determined whether a summary index of malaria case management quality is appropriate and valid based on the significance of associations between its components.

This study aims to evaluate the quality of malaria case management in Zambia by developing case management quality indices for assessment, diagnosis, treatment, and counseling, and to determine whether a summary index of malaria case management quality would be a valid measurement instrument. Each component is studied independently, in order to improve understanding of where the strengths and weaknesses lie in health worker performance. The associations between these components are also studied; if all four components are found to be significantly associated with each other, then a summary case management index (combining the four quality indices) would be considered a valid tool for understanding how well health workers are performing malaria case management as a whole. A summary malaria case management index, if found to be a valid measurement, could be useful to malaria program managers at the national, provincial and district levels. A valid summary index scaled from 0 to 100 would also be easy to interpret for malaria program managers who may have little or no formal statistical training.

Specifically, this study aimed to answer the following research questions and to investigate the accompanying hypotheses.

1.1 Research questions and hypotheses

1. Would a summary index for malaria case management quality be a valid measurement instrument?

2. Are there significant associations among the quality of malaria case management component indices?

- a. Is quality of assessment associated with quality of diagnosis?
- b. Is quality of assessment associated with quality of treatment?
- c. Is quality of assessment associated with quality of counseling?
- d. Is quality of diagnosis associated with quality of treatment?
- e. Is quality of diagnosis associated with quality of counseling?
- f. Is quality of treatment associated with quality of counseling?

Hypotheses:

- 1. A summary index for malaria case management provides a valid instrument for measuring the overall quality of malaria case management.
- 2. There is a significant, positive association between quality of assessment and quality of diagnosis.
- 3. There is a significant, positive association between quality of assessment and quality of treatment.
- 4. There is a significant, positive association between quality of assessment and quality of counseling.
- 5. There is a significant, positive association between quality of diagnosis and quality of treatment.
- 6. There is a significant, positive association between quality of diagnosis and quality of counseling.
- 7. There is a significant, positive association between quality of treatment and quality of counseling.

2. Methodology

2.1 Study site

The Zambian MOH offers free healthcare services for many of its citizens, including children aged under 5 years, low income families and pregnant women. Nearly 80% of health facilities in Zambia are operated by the Zambian MOH (34). Provincial health offices are responsible for coordinating the activities of the district health offices within each province, although there is more district autonomy since decentralization in the late 1990s. District Health Management Teams (DHMTs) are responsible for coordinating malaria activities such as malaria case management and insecticide-treated net (ITN) distribution. There are three levels of health facilities in Zambia: hospitals, health centers and health posts. Health centers are meant to serve a population of approximately 10,000 people. Health posts are smaller, more rural facilities which are meant to serve 500 to 1,000 households. Antimalarial drugs are provided free of charge in government health facilities. In 2010 there were 1,882 health facilities in Zambia; of those, 71% were in rural areas (34).

2.2 Study design

The 2011 Zambia health facility survey analyzed here was a cross-sectional study design that used a two-stage cluster survey of health facilities in Zambia. Health facilities were the primary sampling unit, with patients clustered at facility level. The facilities were selected from a MOH sampling frame of all 1843 registered health facilities existing at that time in Zambia. The survey strata were hospital outpatient clinics (n=107); urban health facilities (n=428); rural health facilities (n=1042) and health posts (n=266). Systematic random sampling was used to select facilities from each stratum. The WHO health facility survey guide suggests that 25 to 35 facilities per stratum are sampled (35). Intraclass correlation (ICC) is the level of correlation between observations in a cluster; in this context it is the correlation of quality of care for a cluster of patients in a facility. To reduce the ICC and increase precision, the number of observations per facility was limited to 13 and the number of facilities selected

for inclusion in the survey was increased, to 37. This number was then adjusted to 42 facilities per stratum assuming that 10% of facilities selected in the sample might not be operational or open at the time of the survey.

The minimum sample size was calculated as 96 observations per stratum, to have a precision of $\pm 10\%$ and 95% level of confidence based on an assumed prevalence of 50% for diagnostic and treatment parameters based on prior malaria case management research in Zambia (2). To account for the assumed ICC within facilities due to each health worker having some assumed consistency in how they conduct consultations, a design effect of 3.8 was used based on prior research by Rowe and colleagues (30), bringing the observations per strata to 365. The estimated daily caseload per facility was used to calculate the sampling fraction of patients. In low-volume facilities, the survey teams attempted to follow every patient. In high-volume facilities, a sampling fraction of patients was determined using an estimated daily caseload for each high-volume facility, and patients were systematically sampled every N^{th} patient, depending on patient volume. Case load was calculated as the daily average from the previous 5 work days. Health workers were selected by default by following the patient through the consult.

Included in the survey were 168 primary care facilities, with 225 health workers observed performing consultations on a total of 1,394 patients of all ages. However the dataset analyzed for this study was limited to the 850 patients of all ages with fever to assess quality of malaria case management; these patients were seen by a total of 204 health workers in 145 primary care health facilities.

This study included the following types of health facility managing authority: government (public), private, and non-governmental organization (NGO)/other. Health workers studied include medical doctor, registered nurse, enrolled nurse, environmental health technician, clinical officer, community health worker and “other”.

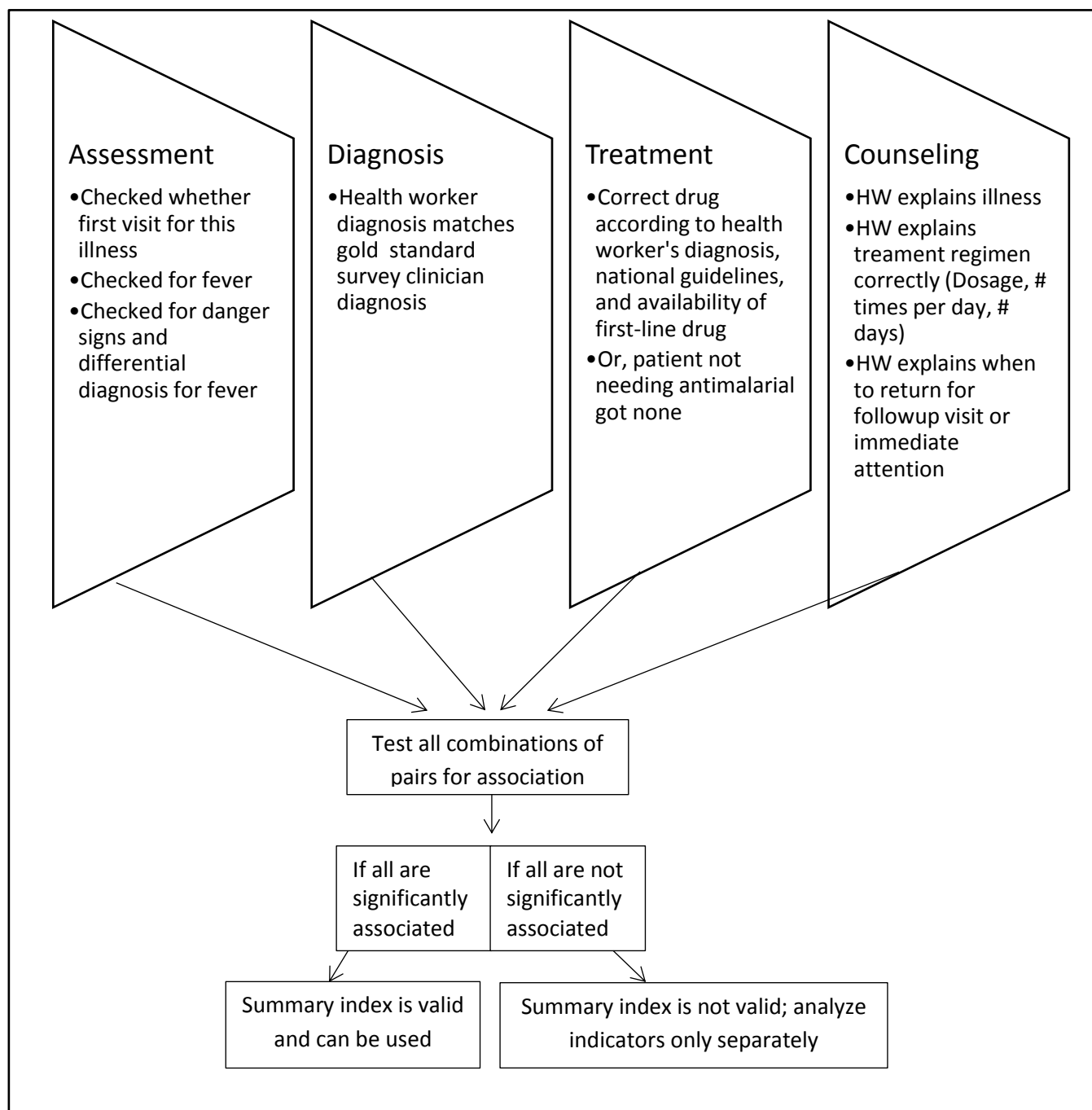
Four questionnaires, listed below, were used; the first three were conducted using paper-based forms, and the fourth questionnaire was conducted using personal digital assistants.

1. *Observation of outpatient consultations, including assessment of sick patients and case management:* Surveyors observed fever consultations, and noted health worker performance using a case management checklist.
2. *Exit Interview for Patient/Caretaker of Sick Child and Re-Examination:* Patients with fever were interviewed and re-examined by survey clinician. Surveyors used RDTs for the gold standard diagnosis.
3. *Health worker questionnaire:* Health workers who were observed in consultations with sick patients were asked questions regarding their pre-service training, in-service trainings, experience at the health facility, job aid availability, and visits by supervisors. In addition the health worker malaria case management knowledge is assessed with suspected malaria case scenarios.
4. *Health facility audit:* Stocks of essential medicines, vaccines and supplies were checked for continuous availability on the day of the visit, and for availability during the previous 3 months.

2.3 Conceptual framework

The four malaria case management quality indices are depicted in Figure 1 below. Each possible pair of quality indices was tested for association. If all pairs of case management components were significantly associated then a summary malaria case management quality index would be considered valid. If the component pairs were not all significantly associated, then no summary case management index would be used. The tests of association are described in detail in section 2.2.5 (Analytic strategy) below.

Figure 1: Quality of case management component indices



2.4 Measurement

2.4.1 Quality of assessment

The quality of assessment index is adapted from the 2010 Zambia NMCC malaria case management guidelines and the list of quality of malaria treatment core indices from the survey

protocol (8, 36) as well as the IMCI guidelines for fever assessment (37). Each dichotomous item is coded in the data as 0 (item not completed) or 1 (item completed). Items were chosen to be in accordance with the malaria case management guidelines at the time of the survey. The guidelines indicate that for fever patients of all ages, there should be an attempt made by the health worker to rule out other causes of fever before diagnosing as malaria, and that the health worker should check for danger signs in case of severe malaria or some other severe condition. All the items listed below conform to the guidelines for assessment of fever patients. This index is calculated as the percentage of assessment tasks listed below which were performed by the health worker. This percentage will be referred to here as the “assessment score”. The assessment score is a patient consultation-level index, meaning that an assessment score from 0 to 100 is generated for each patient-health worker consultation.

The assessment index is an aggregate of 13 dichotomous, yes/no variables, listed below:

General questions

1. Did the health worker ask if this is an initial or a follow-up visit?
2. Does the health worker ask the age of the patient or have the age available?
3. Is the patient weighed?

Assess for fever:

4. Ask whether child has fever (≥ 37.5 degrees centigrade)
5. Is the patient's temperature checked?

Differential diagnosis:

6. Did the health worker ask whether the patient had ear problems?
7. Did the health worker ask whether the patient has a cough?
8. Did the health worker ask whether the patient has diarrhea?

Check for danger signs:

9. Did the health worker ask about change in behavior or altered consciousness (lethargy, agitation or confusion)
10. Did the health worker check whether the patient is able to drink or breastfeed
11. Did the health worker check whether the patient has difficulty eating
12. Did the health worker check whether the patient vomits everything?
13. Generalized convulsions (>2 episodes within 24 hours)

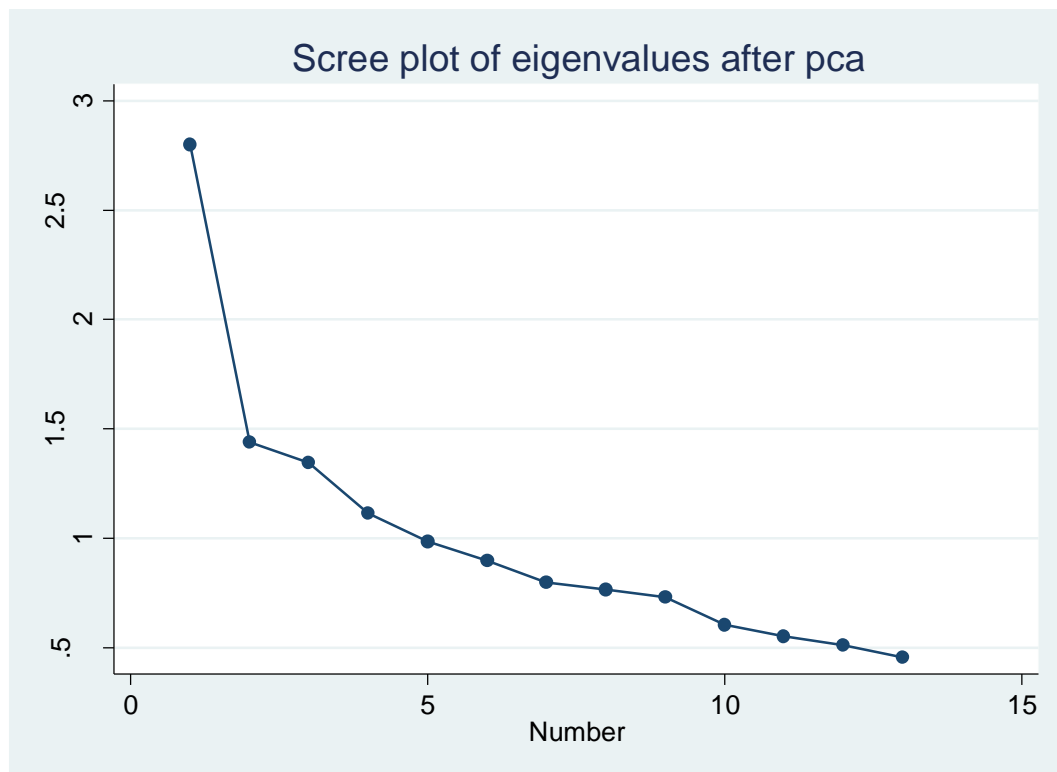
It should be noted that the assessment data for these items only include whether the health workers asked or completed certain assessment tasks; the data do not include what answer was given by the patient or caretaker. For example, these data show whether the health worker asked whether the patient had fever but the consultation data do not show whether the patient did or did not have fever. This database includes only patients who were identified in the exit interview as having come to the health facility with fever as a complaint.

The WHO IMCI and Zambia NMCC guidelines for fever case management include checking for presence or recent history of measles as a possible differential diagnosis for fever (8, 37). It should be noted that following the mass measles immunization campaigns in 2000-2003, the measles morbidity rate had dropped precipitously; in 2009 there were only 342 measles case reported nationally (38). However in 2010 - 2011 there was a measles outbreak with about 15,500 cases and 13,324 cases in 2010 and 2011, respectively (39) (40, 41), and health workers should have been on the lookout for measles cases as a possible cause of fever for patients of all ages. Of the 850 fever patients studied, 7 were diagnosed with measles during the consultation with the health worker.

The assessment quality index was tested for content validity using principal components analysis (PCA). PCA was conducted for the assessment index to measure its internal consistency (to what degree did the items measure the same latent concept, "assessment quality"). This approach uses Cronbach's alpha coefficient as a measure of how well the selected variables represent a single concept (42). The

same assessment items were used for both age groups (children aged under 5 years and patients aged 5 years and older). PCA yielded four factors with eigenvalues over 1; the eigenvalue for the first factor was 2.8 indicating that this factor explains 21.6% of the variance in the 13 items (since $2.8/13=21.6$). The screeplot below in Figure X indicates that only the first component (represented by the upper left-most point) needed to be retained.

Figure 2: Screeplot of eigenvalues after PCA



Factor loadings represent the correlation between the response to each item and the latent concept. The factor loadings of the 13 variables which comprise the Assessment index ranged from 0.23 to 0.65, showing that no variables needed to be dropped from the list (using a cutoff of 0.1 as in prior IMCI research)(32). Cronbach's alpha coefficient of reliability was 0.68 for this index which is considered adequate (43). These results indicate that the 13 assessment tasks adequately represent a single concept, namely assessment quality.

A mean assessment score was calculated using proportions of assessment tasks which were completed by the health worker in each patient fever consultation. Each task in the data is measured dichotomously with 1 for “Yes, health worker completed task” or 0 for “No, health worker did not complete task”. Thus, for each patient – health worker consultation, an assessment score was generated which was a proportion of tasks completed out of 13 possible tasks, with equal weight for each assessment item. A factor score was also generated for the assessment quality index at both patient level as well as a summary score. The factor score was weighted according to the factor loadings from the PCA.

Finally, assessment scores calculated from proportions were compared with factor scores generated from the PCA, using Pearson’s correlation coefficient. Assessment scores calculated using proportions of tasks completed were highly correlated with the factor scores calculated from PCA, with Pearson’s r of 0.98. Since the mean score (percentage) is simpler than factor scores for program managers at national and sub-national to interpret (being scaled from 0 to 100), those scores were chosen for this study rather than the factor scores.

2.4.2 Quality of diagnosis

Diagnosis quality was measured as the proportion of clinic diagnoses that matched the study diagnosis, with a dichotomous result: clinic diagnosis matched the study diagnosis or did not match the study diagnosis. The study diagnosis was performed by a survey clinician after the exit interview, if the patient or caretaker agreed to be re-examined. The study diagnostic test used by survey clinicians was ICT Malaria Pf™, which is produced in South Africa and is a rapid immunochromatographic test which detects *Plasmodium falciparum*-specific histidine-rich protein 2 antigen (HRP2). The Zambia NMCC malaria case definition is as follows:

Case definition of malaria, from facility survey protocol (36):

For children aged 2 months to 59 months:

- a) history of fever in last 48 hours,
- b) first attendance for illness, without history of prior anti-malarial treatment for current illness,
and
- c) positive malaria parasitological test if available as recommended in IMCI guidelines;

Or, if no parasitological test available:

- a) history of fever in last 48 hours,
- b) first attendance for illness, without prior anti-malarial treatment for current illness;

For patients aged 5 years and older:

- a) history of fever in last 48 hours,
- b) first attendance for illness, without history of prior anti-malarial treatment for current illness
and
- c) a positive parasitological test (RDT or microscopy)

Or, if no parasitological test available *and ruled out other causes*:

- a)** history of fever in last 48 hours,
- b)** first attendance for illness, without history of prior anti-malarial treatment for current illness

2.4.3 Quality of treatment

Treatment quality was calculated as a dichotomous index, whether or not the health worker provided appropriate treatment for the fever patient, based on NMCC malaria case management guidelines which were current at the time of the study (2011). This was determined according to the diagnosis made by the health worker, not whether that diagnosis matched the gold standard. In this way the health worker was not penalized for subsequent steps after a diagnostic mistake was made. For example, if a patient was incorrectly diagnosed with malaria when the gold standard surveyor diagnosed

no malaria, the health worker treatment practice was judged on that patient being diagnosed with malaria. As with the other quality indices, this is a patient consultation-level analysis; for each patient consultation a result was generated of either correct treatment or incorrect treatment.

Malaria treatment was considered correct if the patient needing an antimalarial (based on health worker diagnosis) was prescribed the drug according to the NMCC national treatment guidelines based on drug availability on the day of the survey, diagnostic capacity, patient weight and age, and also if patients not needing an antimalarial were not prescribed an antimalarial. At the time of the survey, artemether-lumefantrine (AL) (Coartem™) was the first-line drug, and quinine was the second-line drug for uncomplicated malaria. According to national guidelines, sulfadoxine-pyremethamine (SP or Fansidar™) is appropriate only for children weighing less than 5kg (6). At the time of the survey, quinine was the NMCC-recommended drug for any patient with severe malaria.

Correct prescribing of antimalarials is determined by several factors. For patients diagnosed with uncomplicated malaria, if AL is not available then the second-line treatment quinine is recommended. Infants weighing less than 5 kg diagnosed with malaria should receive SP since AL is contra-indicated for that weight category. Women in their third trimester of pregnancy should be treated with oral quinine while those in their 2nd or 3rd trimester can be treated with AL. However data on the trimester of pregnancy in this survey were not collected; consequently pregnant women are considered correctly treated if they were diagnosed with uncomplicated malaria and were treated with AL. As mentioned above, any patient diagnosed with severe malaria should have received quinine (if available) and a referral to a higher-level facility able to provide proper care for patients with severe malaria.

2.4.4 Quality of counseling

Quality of counseling was calculated (similar to quality of assessment, above) as the patient/consultation-level proportion of counseling items completed by the health worker during the

consultation with the fever patient. Only patients who were prescribed an antimalarial (correctly or incorrectly) and were counseled (N=387) were included in this analysis. Patients who were prescribed an antimalarial incorrectly were included in this analysis with the assumption that the health worker thought the patient had malaria. Even with an incorrect antimalarial drug prescription, it is important that the health worker provides correct counseling. The items used to build the counseling index are listed below:

1. Health worker explained the illness to the patient (Y/N)
2. Health worker explained how to administer antimalarials (Y/N)
3. Health worker demonstrated how to administer antimalarials (Y/N)
4. Health worker asked the patient or caretaker a question to verify understanding of the antimalarial drug regimen (Y/N)
5. Health worker explained when to return for follow up (Y/N)
6. Health worker explained under what circumstances to return immediately to health facility (Y/N)

Principle components analysis was conducted on this index, and the main factor identified had an eigenvalue of 2.03, meaning that the factor explained 34% of the variance of the variables it contains (2.03/6). The factor loadings ranged from 0.39 to 0.65, which indicate that the variables all explained the same factor. The alpha reliability coefficient was 0.62, which is considered an acceptable level of internal consistency (42). Importantly, the variables have face validity since they all represent items which are relevant to measure quality of counseling and were available in this survey.

As with the assessment quality index above, to calculate a patient/consultation-level counseling score, there was a choice between using either mean scores or factor scores. There was a high correlation between proportions and factor scores ($r=0.99$), indicating that the choice is one of preferred measurement method. As with the Assessment index above, a mean score with equal weights

for each item was used instead of factor scores because mean scores are easier to interpret for program managers at national and subnational level, being scaled from 0 to 100.

2.5 Analytic strategy

Included in all analyses are patients:

- With fever aged at least 2 months, since IMCI does not cover neonates and malaria before 2 months is rare due to maternal antibodies
- Who were not yet treated with antimalarials for the current fever
- Who agreed to participate in the observed consultation, exit interview and re-examination
- Who went through the full consultation process with the health worker and at least through fever assessment with the gold standard re-examination with a surveyor, as well as an exit interview
- Seen by health workers who gave consent to be interviewed for the survey

Tests of association were used to test the hypotheses about the strength of the associations among each of six possible pairs of malaria case management components. For each pair of case management components tested, multilevel mixed effects univariate regression was used, with the independent variable set as the fixed effect and health facility set as the random effect variable. Multilevel mixed effects univariate regression was used because it was important to allow results to vary by facility since health facilities are expected to differ from one another in quality of care. For each pair of indicators being tested using univariate regression, the independent variable was the index which takes place before the dependent variable in the sequence of case management.

Each of the pairs is tested for strength of association using simple, multilevel regression. Table 1 below shows each pair being tested for significance of association, what type of simple regression is used, and the regression model.

Table 1: Tests of association for each pair of case management components

Associations between components being tested	Regression method	Regression model
Assessment and Diagnosis	Multilevel logistic	$Pr(Diagnosis_i) = \text{logit}^{-1}(\beta_{j(i)} \text{Assessment}) + \epsilon_i$
Assessment and Treatment	Multilevel logistic	$Pr(Treatment_i) = \text{logit}^{-1}(\beta_{j(i)} \text{Assessment}) + \epsilon_i$
Assessment and Counseling	Multilevel linear	$Counseling_{ij} = \alpha_{j(i)} + \beta \text{Assessment}_i + \epsilon_i$
Diagnosis and Treatment	Multilevel logistic	$Pr(Treatment_i) = \text{logit}^{-1}(\beta_{j(i)} \text{Diagnosis}) + \epsilon_i$
Diagnosis and Counseling	Multilevel linear	$Counseling_{ij} = \alpha_{j(i)} + \beta \text{Diagnosis}_i + \epsilon_i$
Treatment and Counseling	Multilevel linear	$Counseling_{ij} = \alpha_{j(i)} + \beta \text{Treatment}_i + \epsilon_i$

3. Results

3.1 Quality of assessment

The quality of assessment scores for all patients had a mean of 49.9, ranging from 7.7 to 92.3.

Below, Table 2 shows the frequency and percentage (adjusted for survey weights, clustering and stratification) of assessment items which were asked or checked during the consultations.

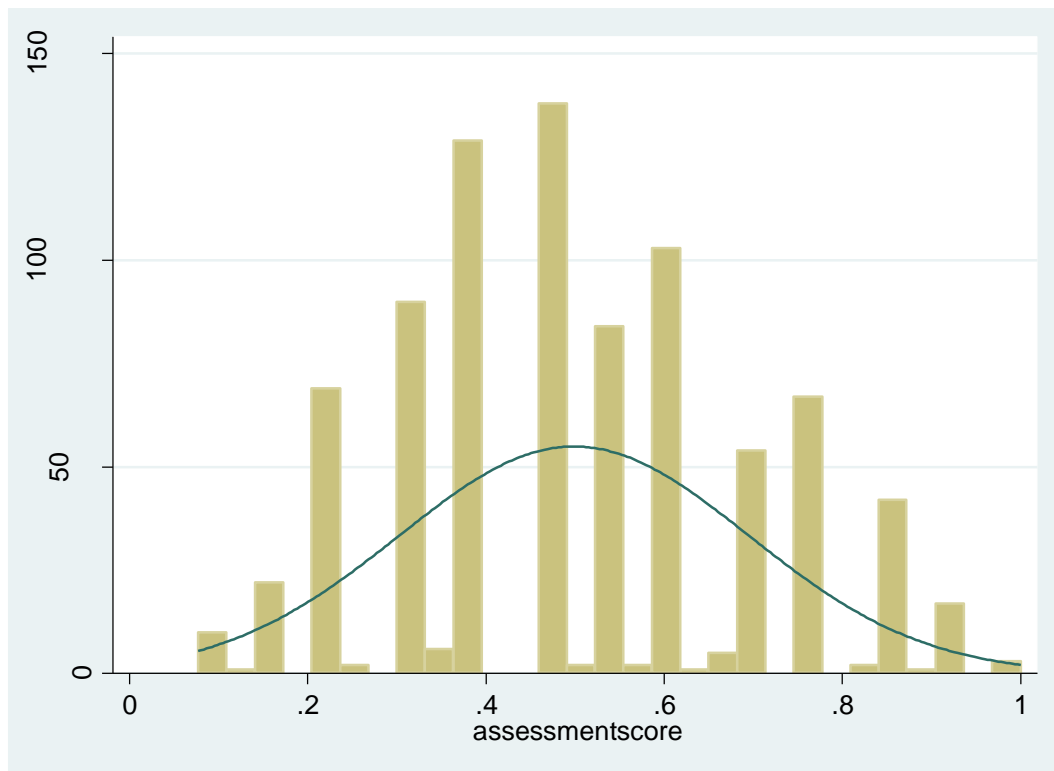
Table 2: Frequencies of assessment items asked/checked

Assessment item	Category	Frequency/total (mean % using survey weights)[95% CI]
Initial or follow-up visit	General questions	583/850 (63) [56 - 69]
Asked age of patient	General questions	724/850 (83) [78 - 89]
Weighed patient	General questions	439/850 (41) [33 - 50]
Asked if fever	Fever questions	767/850 (90) [87 - 93]
Checked temperature	Fever questions	627/850 (67) [56 - 79]
Asked ear problems	Differential diagnosis	226/850 (25) [19 - 31]
Asked if cough	Differential diagnosis	629/850 (71) [66 - 77]
Asked if diarrhea	Differential diagnosis	446/839 (47) [38 - 56]
Asked if patient had altered consciousness or confusion	Danger sign	115/844 (12) [8 - 16]
Asked whether patient could drink or breastfeed	Danger sign	219/833 (22) [16 - 27]
Asked if patient has difficulty eating	Danger sign	321/844 (28) [22 - 34]
Asked if patient vomiting everything	Danger sign	275/850 (27) [21 - 33]
Asked if >2 convulsions within 24 hours	Danger sign	115/844 (11) [7 - 15]

For each patient, there is an individual mean score of the items which were completed out of the total possible number of items.

The histogram in Figure 3 below depicts the distribution of the assessment quality index. The scores ranged from 8% to 92% of assessment items completed. The skewness is 0.24, only slightly skewed to the right. The kurtosis is 2.38, which is slightly less than that of normal distribution, which would be 3; the assessment quality distribution approximates normal distribution.

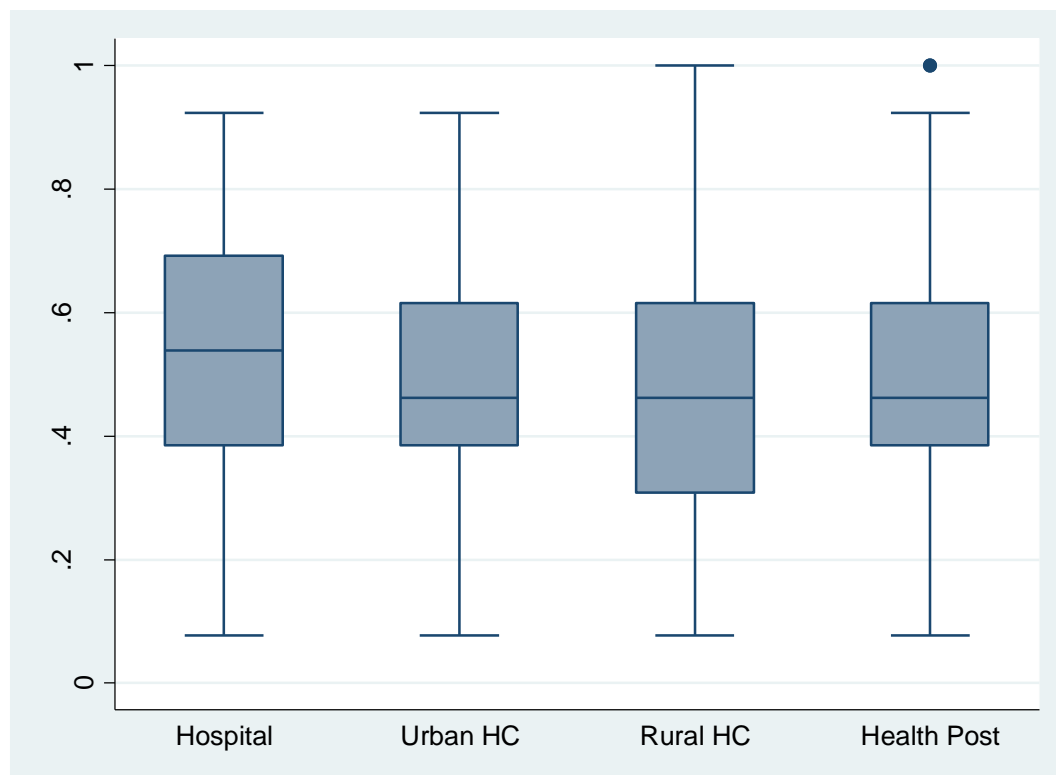
Figure 3: Histogram of assessment scores, all ages



Assessment scores varied by health facility type, as seen in the box plot in Figure 4 below. The shaded boxes depict the 25th to 75th percentile range; the horizontal line in each box represents the median; the lines represent the data points within 1.5 times the nearest inter-quartile range; and the dot is an outlier. Patients seen in hospital outpatient clinics had on average the highest median assessment scores as well as the highest scores in the 25th to 75th percentile range and the mean score

was 50%. The lowest assessment scores on average were in rural health centers, where the mean score was 36.3%. Mean assessment scores in urban health centers was 39.3% and in health posts the mean score was 41.3%.

Figure 4: Box plot of assessment scores by health facility type



3.2 Quality of diagnosis

The sample size for this indicator was 708 (of 850 total fever patients). This reflects that 83.2% of patients who were seen in consultation also agreed to be re-examined and completed blood tests were conducted by a study clinician. All patients in the database (N=850) presented with fever. Sixty-eight percent (68.0%) (SE=5.9%, 95% CI=56.3% - 79.8%) were tested for malaria parasitemia in the facility using RDT or microscopy. Where diagnostic tests were available [83.2% of consultations (SE=6.5%; 95% CI=70.4% - 96.0%) and 88.6% (SE=4.8%; 95% CI=79.1% - 98.2%) of facilities, 82.0% (SE=3.6%, 95% CI=74.7% - 89.1%) of fever patients were tested. Of consultations for which a diagnostic

blood test was performed, 95.8% (SE=1%, 95% CI=93.7% - 97.8%) were tested by RDT and 3.8% (SE=1%, 95% CI=1.8% - 5.7%) were tested by microscopy.

In addition, as seen in Table 3 below, there were 265 of 348 true positives and 40 of 360 false negatives. Diagnosis sensitivity (the probability of testing positive in consultation when the patient had malaria) was 86.9% (95% CI=82.6% - 90.5%) and specificity (the probability of testing negative in consultation when there was no malaria) was 79.4% (95% CI=75.1% - 83.2%). The positive predictive value was 76.1% (95% CI=71.3% - 80.5%). The overall diagnostic accuracy (the percent of patients having had a clinic diagnosis which matched the study diagnosis) was 82.4% (SE=2.4%, 95% CI=77.6% - 87.2%).

Table 3: Comparison of clinic diagnoses and study diagnoses

Blood test results	Clinic Positive	Clinic negative	Clinic Total
Study Positive	320	83	403
Study Negative	40	265	305
Study Total	360	348	708

Table 4: Correct diagnosis (clinic diagnosis matched study diagnosis)

Health worker diagnosis accuracy	Number correctly diagnosed	% Correctly diagnosed	% SE	95% CI	
Negative	320	80.8	3.6	73.6	88.0
Positive	265	84.0	2.7	78.5	89.5
Total	585	82.4	2.4	77.6	87.2

Table 5: Incorrect diagnosis (clinic diagnosis did not match study diagnosis)

Health worker diagnosis inaccuracy	Number incorrectly diagnosed	% Incorrectly diagnosed	%SE	95% CI	
Negative	40	16.0	2.7	10.5	21.5
Positive	83	19.2	3.6	12.0	26.4
Total	123	17.6	2.4	12.8	22.4

3.3 Quality of treatment

The percentage of treatments correctly prescribed, as seen in Table 6, was 89.6% (95% CI =86.3 – 92.8).

As described above, the proportion reflects the appropriateness of each treatment according to the

clinic diagnosis; the patient's weight (Sulfadoxine-pyrimethamine is only appropriate for children weighing <5kg); and availability of each antimalarial in the health facility on the day of the survey. It was not possible to determine whether quinine was appropriately prescribed for pregnant women in their first trimester since pregnancy trimester data were unavailable. There were 9 patients weighing under 5 kg, two of whom were diagnosed with malaria; they both were prescribed with ACT, incorrectly since the NMCC treatment guidelines called for SP for children diagnosed with uncomplicated malaria and weighing under 5kg.

Table 6: Appropriateness of malaria treatment

Appropriateness of malaria treatment*	Number and weighted percentage of patients	
	n/Total	% (95% CI)
Overall adherence to treatment policy – all ages	743/850	89.6 (86.3 - 92.8)
Overall adherence to treatment policy <5 years	366/408	92.1 (88.9 – 95.3)
Overall adherence to treatment policy 5+ years	377/442	87.2 (82.7 – 91.7)

*Irrespective of whether the clinic diagnosis matched the survey diagnosis

3.4 Quality of counseling

The overall mean counseling score for all patients receiving an antimalarial was 48.6 on a scale of 0 to 100; the scores ranged from 0 to 100 and the standard deviation was 26.9. The histogram below (Figure 4) depicts the distribution of counseling scores, with a low skewness of 0.22 and a kurtosis of 2.21, indicating a moderately right-tailed distribution.

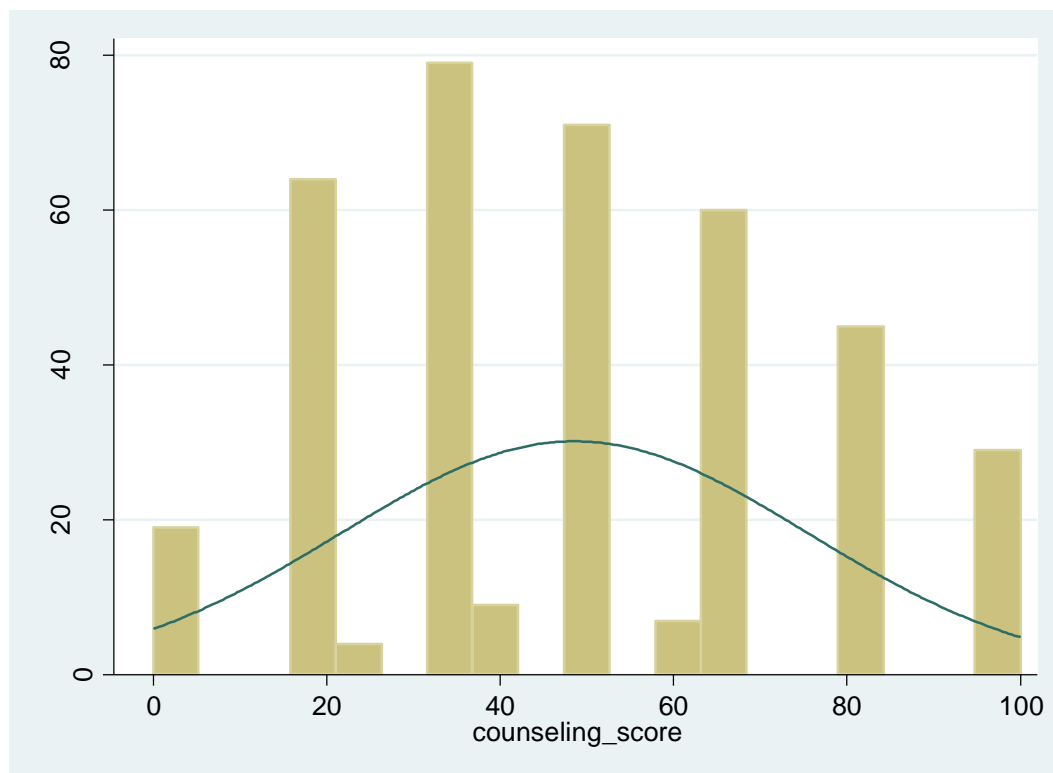


Figure 5: Distribution of counseling score

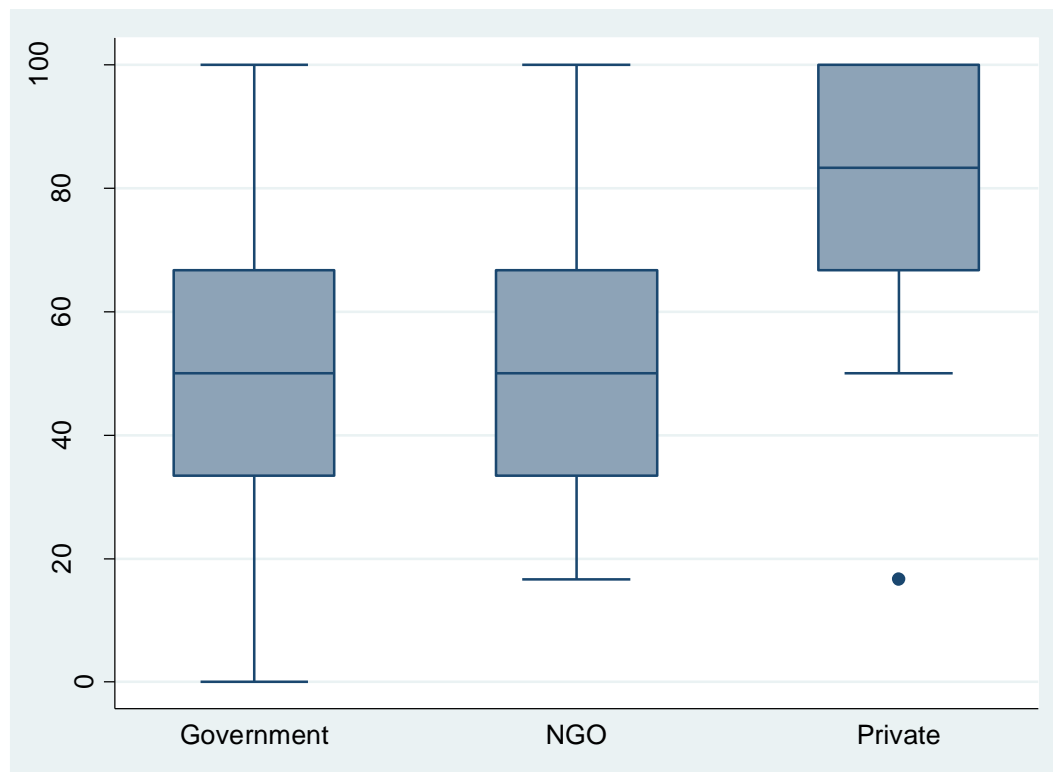
Table 7 shows that of the six variables comprising the counseling index, only the second (“Explained how to administer the antimalarial”) was completed by a high proportion of health workers. However the other elements are also important; counseling is described in the WHO malaria case management operations manual as one of the essential components of malaria case management. Counseling with explanation of when to return for follow-up is recommended by WHO (44).

Table 7: Mean % of each counseling task conducted by health workers

Counseling task by health worker	Percentage (using survey weights)	SE (%)	95% CI (%)
Explained illness to patient or caretaker	43.5	5.0	33.4 to 53.5
Explained how to take the medication	96.1	1.3	93.4 to 98.8
Demonstrated how to take the medication	37.6	6.7	24.2 to 50.9
Verified whether the patient understood	21.3	3.7	13.8 to 28.7
Explained when to come back for a follow up visit	46.7	5.0	36.7 to 56.6
Explained when to come back urgently	20.1	2.9	14.3 to 25.9

Counseling scores were similar across health worker type and facility type, but as seen in the boxplot below (Figure 6) health workers in privately-operated facilities had markedly higher counseling scores (however only 17 consultations were conducted in which the patient received an antimalarial and received counseling in a private clinic). In this boxplot, the dot in the private health center section represents an outlier, an especially low counseling score in an otherwise high-performing set of scores.

Figure 6: Box plot of counseling score by managing authority



The counseling scores by stratum were 44.0% for hospital outpatient clinics (S.E. 6.3%, 95% C.I. 31.0% to 57.0%); 45.4% for urban health centers (S.E. 3.0%, 95% C.I. 39.3% to 51.6%); 42.1% for rural health centers (S.E. 3.6%, 95% C.I. 34.8% to 49.3%) and 48.9% for health posts (S.E. 5.3%, 95% C.I. 37.8% to 59.9%), indicating very little variation between facility type.

3.5 Associations between case management components

Table 7 below displays the results of the tests of association between each possible pair of case management components. Only two of six pairs had statistically significant associations: assessment with counseling, and diagnosis with treatment. Those pairs were highly significantly associated, both with $p < 0.0001$.

Table 8: Association test regression results

Components being tested	Regression method	Regression model	Significance
Assessment and Diagnosis	Multilevel logistic	$Pr(Diagnosis_i) = \text{logit}^{-1}(\beta_{j(i)} \text{ Assess}) + \epsilon_i$	P=0.55
Assessment and Treatment	Multilevel logistic	$Pr(Treatment_i) = \text{logit}^{-1}(\beta_{j(i)} \text{ Assess}) + \epsilon_i$	P=0.80
Assessment and Counseling	Multilevel linear	$\text{Counseling}_{ij} = \alpha_{j(i)} + \beta \text{Assessment}_i + \epsilon_i$	P<0.0001
Diagnosis and Treatment	Multilevel logistic	$Pr(Treatment_i) = \text{logit}^{-1}(\beta_{j(i)} \text{ Diagnosis}) + \epsilon_i$	P<0.0001
Diagnosis and Counseling	Multilevel linear	$\text{Counseling}_{ij} = \alpha_{j(i)} + \beta \text{Treatment}_i + \epsilon_i$	P=0.39
Treatment and Counseling	Multilevel linear	$\text{Counseling}_{ij} = \alpha_{j(i)} + \beta \text{Treatment}_i + \epsilon_i$	P=0.25

4. Discussion

The purpose of this study was to test whether a summary malaria case management quality indicator would be a valid measurement instrument. Four malaria case management quality indicators were created and then the four indicators were tested for association with each other. A statistically significant association between each combination of case management quality indicators would indicate that a summary case management quality indicator would be an appropriate measurement tool for malaria program managers in Zambia. The results showed that a summary malaria quality indicator would not be a valid measurement tool. However, there were statistically significant associations between quality of assessment and counseling, and between quality of diagnosis and treatment. These findings are important because they provide quantitative evidence that a summary malaria quality case

management indicator would be an inappropriate measurement tool. In addition, the findings provide evidence that while diagnosis and testing are relatively strong in Zambia, assessment and counseling are areas to target for improvement.

4.1 Case management quality indices

4.1.1 Assessment quality

The mean overall quality of assessment score was low, at 0.50, with scores ranging from 8.3% to 100%. Although the overall score was low, it is apparent from Table 1 in section 2.3.1 (Frequencies of assessment items checked or asked) that most patients of all ages were asked whether they had fever; were checked for temperature; and were asked whether this was a follow-up visit. For patients under 5 years, the mean for these basic fever questions was 83%, and for patients aged 5 years and older the mean was 73%. Health workers much less frequently investigated danger signs and differential diagnoses, both of which are recommended for assessment by guidelines from WHO/IMCI and Zambia MNCC. For example, only 12.9% and 11.1% caretakers of under-5s and patients aged 5 and older respectively were asked if they had experienced a change in behavior or altered consciousness, a sign of severe malaria.

An explanation of the low assessment scores is that there is a much stronger focus on diagnosis and treatment in malaria case management training and supervision; diagnosis is dependent on whether there is a history of fever in the previous 48 hours and whether the consultation is a follow-up visit. It is plausible that health workers and supervisors focus on assessing for suspected malaria only and subsequently check less often for signs of severe malaria. Likewise, many health workers in areas of high malaria endemicity may be accustomed to seeing malaria cases and may not do a full assessment since they suspect malaria after the initial check for fever. In a study conducted in 2003 by Eriksen and colleagues (45) of health worker performance in malaria case management in Tanzania for children aged under 5 years, only 10% of health workers asked about the presence of danger signs. Rowe and

colleagues in their study of malaria case management in Angola found that most health workers conducted the fever history while neglecting other assessment items (27).

4.1.2 Diagnosis quality

Of fever patients aged less than 5 years, 48.7% were diagnosed with malaria, while those aged 5 years and older, 45% were diagnosed with malaria. Diagnosis quality was higher, with an overall correct diagnosis (concordance with gold standard survey diagnosis) rate of 82%, with rates ranging only between 80% and 84% in the 4 strata (types of health facilities) (Table 3, section 2.3.2). Diagnostic sensitivity and specificity were 87% and 79%, respectively, which compared favorably with a study of malaria case management in Malawi conducted the same year as this study (2011); the diagnostic sensitivity rate there was 73% and sensitivity was 65% (25). In a study of malaria case management quality by Rowe and colleagues in Angola in 2009, only 27 patients were tested both by the health worker and by survey clinicians; 2 of 2 patients were correctly diagnosed by RDT or microscopy and the specificity was 19 of 25 (76%) (27), however these numbers are too small for a statistically significant comparison.

Table 9: Diagnostic concordance rate by facility type

Correct diagnosis	Number observations	% Correctly diagnosed	% SE	95% CI	
Hospital clinic	174	84.0	3.6	77	91
Urban HF	181	79.7	4.7	70	89
Rural HF	200	85.6	3.5	78	93
Health post	153	73.7	6.7	60	87

Table 9 shows a diagnosis concordance rate by facility type; the total concordance rate was 82%. There was no significant difference between concordance rates of different types of health facilities.

In 2006 Hamer and colleagues conducted a study of diagnostic and treatment practices in 4 districts in Zambia, finding that 73% of facilities had either RDTs or microscopy available, and of patients with fever, 27.8% were tested (4). By comparison, the 2011 facility survey found that 88.6% of facilities had either RDT or microscopy available, and 68% of patients with fever were tested. In facilities with diagnostic testing available, 82% of patients were tested parasitologically. These results indicate that health facilities in Zambia have improved their readiness to provide quality malaria case management, and although health workers are still under-using diagnostic tests, the rate of diagnostic test usage has increased since 2006. Of patients who received a negative test result for malaria (either RDT or microscopy) from the health worker, 20.3% were diagnosed as having malaria. This indicates that in 2011 there was still some mistrust of negative test results, although there was improvement compared with the 2006 study by Hamer and colleagues, in which 35.5% and 58.4%, respectively, of patients receiving a negative RDT or microscopy result were diagnosed with malaria (4).

4.1.3 Treatment quality

Treatment quality was relatively high; 89.6% of consultations resulted in correct use of antimalarials, in which patients not needing an antimalarial were not prescribed one, and patients diagnosed with malaria were correctly prescribed one according to national case management guidelines. Among patients with clinic-diagnosed malaria, 92% were prescribed an antimalarial (correct or incorrect prescription). Of patients who were diagnosed with malaria, 85% received the correct antimalarial, compared with 83% of those with health worker malaria diagnosis in the Malawi study who were correctly prescribed antimalarials (25). Of consultations in which the patient was diagnosed with not having malaria, 7.1% were prescribed an antimalarial drug. As noted in Table 9 below, of patients who received an ACT antimalarial, 93% were prescribed correctly. These results indicate that compared with

the 2006 study of malaria diagnostics and treatment in Zambia, use of RDTs are resulting in more cost-effective ACT prescription practices (4).

Table 10: Percentages of antimalarials correctly prescribed

Antimalarial drug	Number correctly prescribed/Total	% correctly prescribed	Standard error %	95% confidence interval	
AL/ACT/Coartem	298/321	93.3	2.2	89.0	97.6
SP/Fansidar	0/42	0			
Quinine	15/25	76.6	8.6	58.4	94.8
All	388	90	2.0	86.0	93.0

4.1.4 Counseling quality

Quality of counseling as noted in the results section above was much better in privately-owned facilities compared with government and with NGO-run facilities. However, only eight private facilities with a total of 17 patients had generated a counseling score since most of those who received an antimalarial drug were in government facilities (N=316). For consultations in which the patient was prescribed an antimalarial medicine, 96% (SE 1.3%, 95% CI 93.3% to 98.8%) of health workers explained how to take the medicine. However, that was the only counseling item which was conducted by most health workers. For patients who were diagnosed with malaria, in only 43.5% of consultations did health workers explain that the patient had malaria. Data were not collected on whether the health worker correctly explained full dosing instructions: definition of a dose, how many doses per day and how many days. In Rowe's 2009 study of malaria case management in Angola, 88% of health workers gave complete dosing instructions but overall counseling quality was mixed with several items not completed by health workers (27).

4.2 Associations between quality of malaria case management indices

4.2.1 Association between assessment and diagnosis quality

As described in the results section above, there was no statistically significant association between quality of assessment and quality of diagnosis. This association was tested both with the full assessment index (all variables including danger signs and differential diagnosis) and with an alternate, partial assessment quality index (only basic fever assessment), with the same result. At the time of the study, health worker training for malaria case management was more focused on diagnosis and treatment, compared with assessment. In the 2011 Zambia NMCC action plan the case management objective was “To have 90% of all suspected malaria cases in all districts receive parasitological diagnosis and prompt effective treatment and 90% of pregnant women receive malaria management and prevention by the end of 2011.” (13) The specific case management objectives also do not target assessment quality, but rather focus on the diagnosis and treatment of malaria. The WHO malaria case management operations manual published in 2009 states that for clinical diagnosis in the absence of testing, “Malaria is suspected clinically mainly on the basis of fever or a history of fever.” (44) By contrast the IMCI guidelines from 2008 specifically state that the clinician should rule out other causes and check for danger signs during the assessment (37). The 2010 Zambia NMCC malaria case management guidelines also suggest checking for danger signs and differential diagnosis for fever (8) but the deployment of these guidelines was not fully implemented by the time the health facility survey was conducted; dissemination of these guidelines was through cascade trainings which had not reached all health workers or supervisors in mid-2011 (3). Considering that there is more of a focus on diagnosis and treatment in malaria case management guidelines and training, it is not surprising that quality of assessment is independent of quality of diagnosis.

4.2.2 Association between diagnosis and treatment quality

By contrast, quality of diagnosis and treatment are highly and significantly associated. In Zambia since the adoption of ACT, there has been a consequent focus on parasitological diagnosis of malaria since ACTs are expensive and there is a need to avoid unnecessary ACT treatment. The dissemination of RDTs to health facilities throughout Zambia has been priority of the Zambia NMCC (2, 4, 13, 34) and by the time the survey was conducted both ACT and RDTs had been key elements of the Zambian malaria case management guidelines for several years. Among health workers, Artemether-lumefantrine is widely known to be the first-line antimalarial drug in Zambia since Zambia was the first country in sub-Saharan Africa to adopt it (5). Diagnosis and treatment form the most essential aspects of malaria case management (2, 4, 8, 13, 44) and it makes programmatic sense that correct diagnosis would be highly associated with correct treatment.

4.2.3 Association between treatment and counseling quality

There was no statistically significant association between quality of treatment and quality of counseling ($p=0.25$). Although counseling is an important component of malaria case management, in the WHO malaria case management operations manual (44) only two sentences are given to the issue of counseling, and there is no section specifically on counseling in the Zambia NMCC guidelines from 2010 (8). Although there is information in the Zambian case management guidelines on first-line and second-line treatment with dosages by weight and age, the counseling recommendations are scanty. Therefore, it makes sense that counseling quality would be independent of treatment quality.

4.2.4 Association between assessment and treatment quality

Assessment and treatment quality were not statistically associated; multilevel logistic regression yielded $p=0.97$, and the Spearman correlation coefficient showed similar results with a correlation of 0.0189 with $N=850$ and $p=0.5826$.

4.2.5 Association between assessment and counseling quality

As noted in the Results section, assessment and counseling quality were found to be highly significantly associated with each other. Of the assessment items which comprise the assessment quality index, only three (asked whether patient had fever, checked temperature and asked whether this was a follow up consultations) were asked during the majority of HW-patient consultations. Of the 6 counseling items which comprise the counseling quality index, only one – whether the HW explained the administration of the antimalarial drug – was done in most (96%) of the HW-patient consultations. The other five counseling items were done in fewer than 50% of the consultations. In other words, many health workers who did not conduct several assessment items also did not conduct several counseling items correctly.

5. Limitations

There are several limitations in this study. The observation of the consultation by survey staff may have created a “Hawthorne effect”, causing the health worker to conduct the consultation in a differently than normal. For example, some health workers may have been more careful than normal since they were being observed, or conversely the observation could have made the health worker more nervous and thus reduce the quality of care. Likewise, the Hawthorne effect could have affected patient or caretaker behavior in the consultation, potentially affecting answers to questions posed by the health

workers. Misclassification bias may be present in the data if the survey staff did not conduct the survey in a uniform manner.

The health worker diagnosis was compared against the “gold standard” diagnosis by a study clinician using an RDT. In cases where the consultation health facility lab used microscopy, if the microscope was maintained and used properly, the consult used a higher diagnostic standard than RDT; therefore, in these cases it does not make sense to compare against the “gold standard” RDT. This is a flaw in the study design.

This survey is representative only of malaria case management for the 50% of fever patients who seek treatment at a health facility (33). The systems effectiveness approach used by Littrell et al (2013) takes this into account.

During the patient-health worker consultation, the surveyors noted whether the health worker asked certain questions or completed certain tasks, but the answers to those questions were not recorded. This was a missed opportunity for data collection and a flaw in the study design.

Severe malaria was not included in the exit interview as an option for entering the survey clinician diagnosis, and so it was not possible to analyze quality of diagnosis for severe malaria. Thus this paper was focused on uncomplicated malaria. If the coding had been better, then this research could have included severe malaria analyses.

The original Stata coding of the raw data was not saved and therefore variables cannot be properly validated as measuring what they purport to measure.

Several variables, such as whether the HW asked if the patient had measles, include the response option “not applicable”. However, this variable is inconsistently used and different survey staff may have interpreted this differently, indicating interviewer bias.

The 850 fever patients analyzed in this study were identified in the data as having fever through the exit interview, not through their responses to the health worker questions during the consultation. This is because the patients' responses to the health workers questions during the consultation were not recorded by the surveyors. It is possible that some patients may not have told the health worker of a fever complaint, but subsequently did list fever as a current complaint during the exit interview with the survey clinician. If this is the case then the patient may have been misdiagnosed as not having fever or malaria due to patient error, not due to health worker error.

Some skip patterns were not properly used by all survey interviewers. For example, for the consultation the health worker was supposed to ask whether the patient has fever. If the patient has no fever then the health worker is not expected to ask the remaining fever questions, and if the patient does have fever then the health worker should have asked the follow up questions to understand what the cause may be. However, the interviewers did not follow this protocol in some cases. Of the 850 fever patients in the database, 767 were asked whether they had fever. Because we do not know the exact answer to the question (we can infer from other questions whether the patient had fever), we do not know whether the health worker was expected to have asked the follow up fever questions such as whether the patient had measles. As a result, the variables for measles differential diagnosis (whether the HW asked if patient had measles, checked for rash, checked for conjunctivitis) included many missing and were subsequently not able to be included in the Assess quality index.

6. Conclusions

The findings in this study indicate that there is less association among the malaria case management quality indices than was originally hypothesized. Considering this, building and using a summary malaria case management index would be inadvisable. A summary index should only be used if

the components used to build it are significantly associated with each other, otherwise it would be inappropriate to use for analysis.

Health worker training and supervision should focus on all four components of malaria case management. Assessment and counseling are two areas in which most health workers underperformed. During assessment, health workers should check for danger signs and differential diagnoses, rather than only focusing on the fever itself and testing for malaria. In areas of lower malaria endemicity especially, there may be other causes of fever which should be investigated, for patients of all ages. During counseling, health workers should check to ensure that the patient or caretaker understands the correct treatment regimen; that ACT should be taken with fatty foods; and the caretaker understands when to return for a follow up visit. Health worker performance on diagnosis can be targeted for improvement; when a diagnostic test is available it should always be used, and the health worker should adhere to the test results for the diagnosis. Malaria treatment, which is being performed relatively well with 90% correct treatment rate, can be further improved by ensuring that the only patients receiving SP are children weighing under 5 kg, and that ACT stock-outs are kept to a minimum.

Clearer malaria case management guidelines which were produced and distributed in late 2014 (12) have potentially enabled improvements in health worker performance. Supervisors can also be trained to more frequently observe case management during supportive supervision visits and provide effective feedback where needed. Supervisors would benefit from refresher trainings on proper malaria case management. In-service trainings for health workers and job aids could also benefit health worker performance, if the guidelines are clear and concise.

7. References

1. Z. NMCC, "2012 Zambia Malaria Indicator Survey," (Zambia Ministry of Health, Lusaka, Zambia, 2012).
2. Z. MOH, "Zambia National Malaria Indicator Survey 2010," (Zambian Ministry of Health, National Malaria Control Program, 2010).
3. J. Miller, L. Rosencrans, Ed. (2014).
4. D. H. Hamer *et al.*, Improved diagnostic testing and malaria treatment practices in Zambia. *JAMA* **297**, 2227-2231 (2007).
5. D. Zurovac *et al.*, Paediatric malaria case-management with artemether-lumefantrine in Zambia: a repeat cross-sectional study. *Malar J* **6**, 31 (2007).
6. M. Mulenga *et al.*, Safety and efficacy of lumefantrine-artemether (Coartem) for the treatment of uncomplicated Plasmodium falciparum malaria in Zambian adults. *Malar J* **5**, 73 (2006).
7. J. O. Yukich *et al.*, Reductions in artemisinin-based combination therapy consumption after the nationwide scale up of routine malaria rapid diagnostic testing in Zambia. *Am J Trop Med Hyg* **87**, 437-446 (2012).
8. *Guidelines for the diagnosis and treatment of malaria in Zambia* (2010).
9. *Guidelines for the Diagnosis and Treatment of Malaria in Zambia* (2010).
10. M. Hawela. (2013).
11. SDInc.
12. NMCC. (NMCC, Lusaka, Zambia, 2014).
13. *National Malaria Control Action Plan 2011* (2011).
14. *National Malaria Control Programme Strategic plan for FY 2011-2015* (2011).
15. A. Edward *et al.*, The association of health workforce capacity and quality of pediatric care in Afghanistan. *Int J Qual Health Care* **24**, 578-586 (2012).
16. A. K. Rowe, F. Onikpo, M. Lama, M. S. Deming, The rise and fall of supervision in a project designed to strengthen supervision of Integrated Management of Childhood Illness in Benin. *Health Policy Plan* **25**, 125-134 (2010).
17. A. K. Rowe *et al.*, A multifaceted intervention to improve health worker adherence to integrated management of childhood illness guidelines in Benin. *Am J Public Health* **99**, 837-846 (2009).
18. L. Huicho, R. W. Scherpbier, A. M. Nkowane, C. G. Victora, M.-C. E. o. I. S. Group, How much does quality of child care vary between health workers with differing durations of training? An observational multicountry study. *Lancet* **372**, 910-916 (2008).
19. J. Bryce *et al.*, Improving quality and efficiency of facility-based child health care through Integrated Management of Childhood Illness in Tanzania. *Health Policy Plan* **20 Suppl 1**, i69-i76 (2005).
20. J. Bryce *et al.*, Programmatic pathways to child survival: results of a multi-country evaluation of Integrated Management of Childhood Illness. *Health Policy Plan* **20 Suppl 1**, i5-i17 (2005).
21. L. Huicho *et al.*, Implementation of the Integrated Management of Childhood Illness strategy in Peru and its association with health indicators: an ecological analysis. *Health Policy Plan* **20 Suppl 1**, i32-i41 (2005).
22. G. W. Pariyo, E. Gouws, J. Bryce, G. Burnham, U. I. I. S. Team, Improving facility-based care for sick children in Uganda: training is not enough. *Health Policy Plan* **20 Suppl 1**, i58-i68 (2005).
23. C. G. Victora *et al.*, Context matters: interpreting impact findings in child survival evaluations. *Health Policy Plan* **20 Suppl 1**, i18-i31 (2005).
24. J. Armstrong Schellenberg *et al.*, The effect of Integrated Management of Childhood Illness on observed quality of care of under-fives in rural Tanzania. *Health Policy Plan* **19**, 1-10 (2004).

25. L. C. Steinhardt *et al.*, Patient-, health worker-, and health facility-level determinants of correct malaria case management at publicly funded health facilities in Malawi: results from a nationally representative health facility survey. *Malar J* **13**, 64 (2014).
26. S. Alba *et al.*, Improvements in access to malaria treatment in Tanzania after switch to artemisinin combination therapy and the introduction of accredited drug dispensing outlets - a provider perspective. *Malar J* **9**, 164 (2010).
27. A. K. Rowe *et al.*, Quality of malaria case management at outpatient health facilities in Angola. *Malar J* **8**, 275 (2009).
28. D. Zurovac, B. Midia, S. A. Ochola, M. English, R. W. Snow, Microscopy and outpatient malaria case management among older children and adults in Kenya. *Trop Med Int Health* **11**, 432-440 (2006).
29. D. Zurovac, A. K. Rowe, Quality of treatment for febrile illness among children at outpatient facilities in sub-Saharan Africa. *Ann Trop Med Parasitol* **100**, 283-296 (2006).
30. A. K. Rowe, F. Onikpo, M. Lama, M. S. Deming, Risk and protective factors for two types of error in the treatment of children with fever at outpatient health facilities in Benin. *Int J Epidemiol* **32**, 296-303 (2003).
31. A. K. Rowe *et al.*, Predictors of correct treatment of children with fever seen at outpatient health facilities in the Central African Republic. *Am J Epidemiol* **151**, 1029-1035 (2000).
32. E. Gouws *et al.*, Measuring the quality of child health care at first-level facilities. *Soc Sci Med* **61**, 613-625 (2005).
33. M. Littrell *et al.*, Documenting malaria case management coverage in Zambia: a systems effectiveness approach. *Malar J* **12**, 371 (2013).
34. *Malaria Operational Plan Zambia 2012* (2011).
35. *Health Facility Survey: Tool to evaluate the quality of care delivered to sick children attending outpatients facilities* (2003).
36. M. Ndholu, "Zambia National Health Facility Survey 2011: Evaluation of the quality of malaria-related care for outpatients," (National Malaria Control Centre, Lusaka, Zambia, 2013).
37. WHO. (WHO, Geneva, Switzerland, 2008).
38. WHO, Measles outbreaks and progress towards meeting measles pre-elimination goals: WHO African region, 2009–2010. *WHO Weekly Epidemiological Record* **14**, 129-140 (2011).
39. E. Simons *et al.*, Assessment of the 2010 global measles mortality reduction goal: results from a model of surveillance data. *Lancet* **379**, 2173-2178 (2012).
40. Rubella, Initiative, Measles. (Measles Rubella Initiative, 2012).
41. WHO, WHO, Ed. (United Nations, Geneva, Switzerland, 2013).
42. A. C. Acock, *Discovering Structural Equation Modeling Using Stata*. (Stata Press, 2013).
43. R. Kline, *Principles and Practice of Structural Equation Modeling*. (Guilford, 2011).
44. W. G. M. Programme, "Malaria Case Management Operations Manual," (Geneva, Switzerland, 2009).
45. J. Eriksen *et al.*, Assessing health worker performance in malaria case management of underfives at health facilities in a rural Tanzanian district. *Trop Med Int Health* **12**, 52-61 (2007).

III. Factors associated with malaria case management quality in Zambia

Abstract

Effective case management in primary care health facilities is an important component of malaria control in Zambia. The use of diagnostic testing with rapid diagnostic tests (RDTs) or microscopy for parasitemia and prescription of artemisinin combination therapy (ACT) for fever patients in primary care health facilities are now cornerstones of case management policy from Zambia National Malaria Control Center (NMCC). A health facility survey was conducted in 2011 by NMCC in partnership with the Malaria Control and Evaluation Partnership in Africa to better understand factors associated with health worker performance in malaria case management. Multilevel mixed effects regression was used to determine which patient, health worker and health facility level factors were associated with each of four case management quality indicators: assessment, diagnosis, treatment and counseling. Supervision in the previous 6 months without observation of the health worker's malaria case management was associated with assessment scores 6.8 points lower compared with no supervision at all in the previous 6 months ($p=0.008$). Consultations with patients aged under 5 years were associated ($p<0.001$) with higher assessment scores than those with patients aged 5 years or older. Presence of an RDT job aid doubled (odds ratio 2.08, $p=0.026$) the likelihood of correct diagnosis. Patients whose diagnosis matched that of the survey clinician were more likely ($p<0.001$) to also have appropriate antimalarial treatment compared with those with incorrect diagnosis. The presence of Integrated Management of Childhood Illnesses (IMCI) guidelines during fever consultation was associated ($p=0.011$) with a 9.4-point increase in counseling scores compared with consultations without IMCI guidelines available. Availability of RDT job aids and IMCI guidelines can have a positive effect on case management quality and should be made more widely available. Assessment and counseling quality depend on going beyond the basics of fever assessment and explaining how to take medicines; more effective supervision and training on these aspects of malaria case management could improve health worker performance.

1. Introduction

1.1 Malaria case management

There was a high burden of malaria in Zambia in 2011 (1). Children aged less than 5 years are most at risk for malaria morbidity and mortality, but adolescents and adults also suffer from malaria. The Zambia Malaria Index Surveys (MIS) from 2010 and 2012 revealed that malaria parasite prevalence in children under 5 years was 16% and 14.9%, respectively (1, 2). The same surveys found that in 2010 and 2012, 31.2% and 24.5%, respectively, of children aged less than 5 years with fever were brought to a health facility within 24 hours of fever onset.

Malaria case management in primary care health facilities is an important element of Zambia's Ministry of Health (MOH) National Malaria Control Center (NMCC). Artemisinin combination therapy (ACT) was adopted as Zambia's first-line antimalarial drug in 2002, and implementation began in 2003 (3). ACTs are expensive drugs, and also parasite resistance to ACT has appeared in Southeast Asia, so there is a need to improve diagnostics and reduce over-treatment (3-6). Accordingly, starting in 2005, Zambia NMCC distributed rapid diagnostic tests (RDTs) in a phased fashion to health facilities, with nationwide scale-up in 2009 (7).

The Zambia NMCC Case definition of malaria, from facility survey protocol (36):

For children aged 2 months to 59 months:

- c) History of fever in last 48 hours, first attendance for illness, without history of prior anti-malarial treatment for current illness, and positive malaria parasitological test if available as recommended in IMCI guidelines;
- d) Or, if no parasitological test available: history of fever in last 48 hours, first attendance for illness, without prior anti-malarial treatment for current illness;

For patients aged 5 years and older:

- d) History of fever in last 48 hours, first attendance for illness, without history of prior anti-malarial treatment for current illness and a positive parasitological test (RDT or microscopy)
- e) Or, if no parasitological test available *and ruled out other causes*: history of fever in last 48 hours, first attendance for illness, without history of prior anti-malarial treatment for current illness

A depiction of the NMCC malaria case management algorithm can be found in Appendix 5.

Malaria treatment was considered correct if the patient needing an antimalarial (based on health worker diagnosis) was prescribed the drug according to the NMCC national treatment guidelines based on drug availability on the day of the survey, diagnostic capacity, patient weight and age, and also if patients not needing an antimalarial were not prescribed an antimalarial. At the time of the survey, Artemether-lumefantrine (AL) (Coartem™) was the first-line drug, and quinine was the second-line drug for uncomplicated malaria. According to national guidelines, sulfadoxine-pyremethamine (SP or Fansidar™) is appropriate only for children weighing less than 5kg (6). At the time of the survey, quinine was the NMCC-recommended drug for any patient with severe malaria.

Correct prescribing of antimalarials is determined by several factors. For patients diagnosed with uncomplicated malaria, if ACT is not available then the second-line treatment quinine is recommended. Infants weighing less than 5 kg diagnosed with malaria should receive SP since ACT is contra-indicated for that weight category. Women in their third trimester of pregnancy should be treated with oral quinine while those in their 2nd or 3rd trimester can be treated with ACT. However, data on the trimester of pregnancy in this survey were not collected; consequently, pregnant women are considered correctly treated if they were diagnosed with uncomplicated malaria and were treated with ACT. As mentioned above, any patient diagnosed with severe malaria should have received quinine (if available) and a referral to a higher-level facility able to provide proper care for patients with severe malaria.

Several studies have been conducted on quality of malaria case management in sub-Saharan African countries in the past decade. Many of these studies were designed to evaluate malaria diagnostics and treatment. In their review of health worker performance studies, Rowe and colleagues identified a gap in quality of care research and recommended using the Integrated Management of Childhood Illnesses (IMCI) Multi-Country Evaluation (MCE) studies as a framework for future quality of case and quality of case management studies (8). Other researchers have used this evaluation framework, such as Huicho and colleagues (9) in a multi-country study of health worker performance, and Eriksen and colleagues in a study of quality of malaria case management in a district in Tanzania (10). Maestad and colleagues studied the relationship between health worker workload and health worker performance in Tanzania using this framework (11), and Rowe, Naimoli and colleagues (12-14) used modified versions of the framework in several quality of care studies.

In Zambia, Hamer, Zurovac and others have conducted valuable research on the use of malaria diagnostics and treatment by health workers (3-6, 15). One study by Hamer, Zurovac and colleagues (2007) found that only 27.4% of fever patients in primary care facilities had a diagnostic test. Of patients who were tested by microscopy with negative test results, 58.4% were diagnosed with malaria despite the test; of those with negative RDT results, 35.5% were diagnosed with malaria. The same study found that of those who had positive parasitological tests, 75% of those with positive blood slide and 70.4% of those with positive RDT result were prescribed with an ACT, when ACTs were in stock. However, ACT was also prescribed to patients with a negative blood smear (30.4%) or negative RDT (26.7%). These results highlight the gaps in health worker performance in primary care facilities in Zambia. Similarly, a 2014 study of malaria case management in Malawi by Steinhardt and colleagues (16), 31% of patients without confirmed malaria were over-treated with antimalarials, and a 2009 study by Rowe and colleagues in Angola (12) found that only 49% of malaria treatments were correct. The Angola study also

found that assessments were often incomplete, and counseling was of varying quality, with only 10.7% of patients observed taking the first dose of antimalarial medicine.

As described in the first manuscript of this dissertation (17), in the 2011 Zambia Health Facility Survey, the mean assessment score was 49.9%, with most health workers neglecting to check for danger signs or differential diagnoses. The diagnostic quality (concordance with gold standard survey diagnosis) rate was 82%, and treatment quality rate (correct treatment for those needing antimalarials and no treatment for patients not needing it) was 90%. The mean counseling quality score was 48.6%, with most health workers explaining the antimalarial treatment regimen but neglecting other counseling items such as explaining when to return for a follow-up visit. These findings highlight both an improvement in Zambian health worker performance since the 2007 studies by Zurovac and Hamer, as well as the need to study reasons for ongoing gaps in health worker performance in Zambia.

1.2 Factors associated with case management

To improve health worker performance, it is important to understand what factors are associated with malaria case management quality. Rowe and colleagues, in the same study of malaria case management in Angola mentioned above (12), found that correct clinic diagnosis was associated with health worker caseloads of less than 25 patients per day and elevated patient temperature. There was borderline association between correct testing and malaria case management training. The same study found no factors associated with correct treatment in multiple regression analysis. The Malawi study of malaria case management by Steinhardt and colleagues mentioned above (16) found that patient-level clinical symptoms had the strongest level of association with quality of correct case management. In that study, multiple regression analysis found that presence of fever was the only factor associated with correct treatment.

Studies have also been conducted on factors associated with health worker performance on IMCI quality of care. IMCI quality of care is relevant because the Zambia NMCC has incorporated IMCI

fever management guidelines into the national guidelines for health facilities which do not have diagnostic testing for malaria. A study by Naimoli and colleagues of IMCI quality of care in Morocco found several factors were associated with adherence to IMCI guidelines, including IMCI training, being a female health worker, patient age and number of health complaints and not reporting lack of supervision as a problem (14). Another IMCI study by Bryce and colleagues in Tanzania found that better case management was associated with IMCI training (18).

1.3 Supportive supervision and health worker performance

WHO recommends supportive supervision from district level to health facility staff; in Zambia this supervision is provided by the district health management teams (DHMT). WHO also recommends that every district have a malaria focal point who is responsible for malaria control activities (19). Zambia's healthcare system has been decentralized to the district level since the late 1990s (20). Each health center in a district should be visited at least once quarterly (every 3 months) (21); during these visits supervisors are expected to check on, among other things, health worker performance and stock management, to ensure that service delivery is effective.

Researchers have had varying results in analyzing the association between supportive supervision and health worker performance. For example Rowe and colleagues in their 2003 study of factors associated with treatment errors in Benin found that at least one supervisory visit in the previous 6 months was associated with minor treatment errors (22). Edward and colleagues in their 2012 study of quality of IMCI care (23) in Afghanistan found that at least 6 supervisory visits in the previous 6 months was associated with better quality of care. Another malaria treatment study by Rowe and colleagues (12) found that supervision had no association with quality of malaria treatment. A study of supervisor-provider interactions in primary care facilities found that supervisors spent less than 5% of their time on patient care issues (24).

Data from the 2011 Zambia National Health Facility are still highly relevant in 2016. Most malaria surveys conducted in Zambia in the past 10 years have been household surveys, which yield valuable data on health-seeking behaviors, malaria parasitemia, and coverage of malaria control strategies. However, health facility data also provide important information on facility-based case management, health worker performance and malaria supplies and medicines. The regression analyses in this study provide information which can be helpful to NMCC malaria program managers years later.

1.4 Research questions

This study aims to answer the following research questions:

1. Is supervision associated with better quality malaria case management (assessment, diagnosis, treatment and counseling) by health workers, compared with no supervision during the previous 6 months?
2. Is supervision with observation of malaria case management associated with higher quality malaria case management (assessment, diagnosis, treatment and counseling) compared with supervision without observation of malaria case management during the previous 6 months?

1.5 Hypotheses

1. Patient-level fever consultations in which the health worker had reported having had at least one supervisory visit during the previous 6 months had better quality assessment, diagnosis, treatment and counseling, compared with no supervisory visits during that time period.
2. Patient-level fever consultations in which the health worker had reported having had supervision during which the supervisor observed malaria case management had higher quality assessment, diagnosis, treatment and counseling, compared with consultations in which the health worker had reported having had supervision during which the supervisor had not observed malaria case management.

2. Methodology

2.1 Study site

The Zambian MOH offers free healthcare services for many of its citizens, including children aged less than 5 years, low income families and pregnant women. Nearly 80% of health facilities in Zambia are operated by the Zambian MOH (25). Provincial health offices are responsible for coordinating the activities of the district health offices within each province, although there is more district autonomy since decentralization in the late 1990s. District Health Management Teams (DHMTs) are responsible for coordinating malaria activities such as malaria case management and insecticide-treat net (ITN) distribution. There are three levels of health facilities in Zambia: hospitals, health centers and health posts. Health centers are meant to serve a population of approximately 10,000 people. Health posts are smaller, more rural facilities which are meant to serve 500 to 1,000 households. Antimalarial drugs are provided free of charge in government health facilities. In 2010 there were 1,882 health facilities in Zambia; of those, 71% are in rural areas (25).

2.2 Study design and sampling methodology

The study design and methodology are described in detail in the research protocol for the 2011 Zambia National Health Facility Survey and by Rosencrans et al (unpublished research) (17). Briefly, the survey analyzed here was a cross-section study design that used a two-stage cluster survey in which health facilities were the primary sampling unit, with patients clustered at facility level. The facilities were selected from a MOH sampling frame of all 1,882 registered health facilities existing at that time in Zambia. The survey strata were hospital outpatient clinics (n=107); urban health facilities (n=428); rural health facilities (n=1,042) and health posts (n=266). Given the large differences in the number facilities of different strata (especially the small number of hospital outpatient clinics), disproportionate stratified sampling was used in order to ensure that an adequate number of HFs in each strata was sampled with adequately precise estimators. To reduce the intraclass correlation (ICC) and increase precision, the

number of observations per facility was limited to 13 and the number of facilities selected for inclusion in the survey was increased, to 37. This number was then adjusted to 42 facilities per stratum assuming that 10% of facilities selected in the sample might not be operational or open at the time of the survey. Systematic random sampling was used to select facilities from each stratum.

The survey included four questionnaires: a) observation of outpatient consultations, including assessment of sick patients and case management; b) an exit interview for the patient or caretaker and re-examination; c) a health worker questionnaire; and d) a health facility audit of medicines and supplies.

Included in the survey were 168 primary care facilities, with 225 health workers observed performing consultations on a total of 1,394 patients of all ages. However, the dataset analyzed for this study was limited to the 850 patients aged over two months with fever to assess quality of malaria case management; these patients were seen by a total of 204 health workers in 145 primary care health facilities.

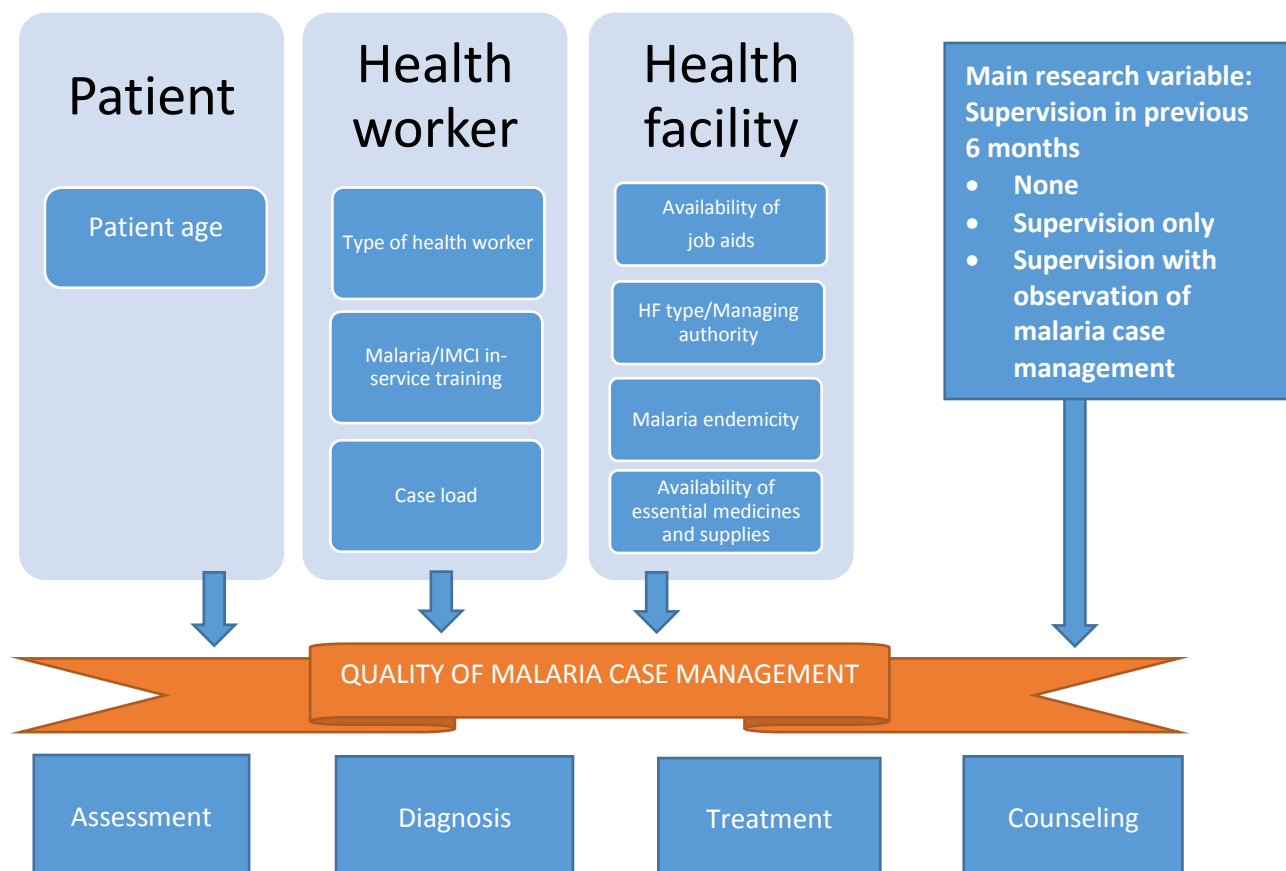
This study included the following types of health facility managing authority: government (public), private, and non-governmental organization (NGO)/other. Health workers studied include medical doctor, registered nurse, enrolled nurse, environmental health technician, clinical officer, community health worker and “other”.

2.3 Conceptual framework

Figure 1 below depicts the concepts underlying this research manuscript. Quality of case management is divided into 4 components, as described above: assessment, diagnosis, treatment and counseling. The main research variable, supervision, has three categories: no supervision in the previous 6 months; supervision in the previous 6 months but not with observation of malaria case management; and supervision with observation of malaria case management. Supervision is hypothesized to be

associated with higher quality of each component of malaria case management, compared with no supervision; while supervision with observation of malaria case management is hypothesized to be associated with better quality malaria case management compared with supervision without observation of case management. The control variables are listed in the two boxes on the upper left, divided into patient level, health worker level and facility level variables. Specific descriptions of each control variable are provided in the Analytic Strategy section below; there is some variation in control variables among the 4 regression models.

Figure 7: Conceptual framework: factors associated with malaria case management quality



2.4 Measurement of primary outcomes

The four case management quality indicators – assessment, diagnosis, treatment and counseling – are measured as described in greater detail in the unpublished dissertation draft manuscript

“Measuring Malaria Case Management in Zambia” (17). All four are patient-health worker consultation level indicators.

The quality of assessment index is adapted from the 2010 Zambia NMCC malaria case management guidelines and the list of quality of malaria treatment core indices from the survey protocol (8, 36) as well as the IMCI guidelines for fever assessment (37). Each dichotomous item is coded in the data as 0 (item not completed) or 1 (item completed). Items were chosen to be in accordance with the malaria case management guidelines at the time of the survey. This index is calculated as the percentage of assessment tasks listed below which were performed by the health worker. This percentage will be referred to here as the “assessment score”. The assessment score is a patient consultation-level index, meaning that an assessment score from 0 to 100 is generated for each patient-health worker consultation. Below, Table 1 shows the assessment items which were asked or checked during the consultations, and were used to build the index. The quality of assessment scores for all 850 patient-level fever consultations had a mean of 49.9, ranging from 7.7 to 92.3.

Table 11: Assessment items asked/checked by health worker

Assessment item	Category
1. Asked if this was patient’s initial or follow-up visit	General question
2. Asked age of patient	General question
3. Weighed patient	General question
4. Asked if patient had fever	Fever question
5. Checked patient’s temperature	Fever question
6. Asked if patient had ear problems	Differential fever diagnosis
7. Asked if patient had cough	Differential fever diagnosis
8. Asked if patient had diarrhea	Differential fever diagnosis
9. Asked if patient had altered consciousness or confusion	Danger sign
10. Asked whether patient could drink or breastfeed	Danger sign
11. Asked if patient had difficulty eating	Danger sign
12. Asked if patient was vomiting frequently	Danger sign
13. Asked if patient had >2 convulsions within 24 hours	Danger sign

The outcome variable, quality of diagnosis, is binary: whether or not the clinic diagnosis matched the gold standard survey diagnosis. As described in greater detail elsewhere (17), the sample size for this indicator was 708 (of 850 total fever patients). The overall diagnostic accuracy (the percent of patients having had a clinic diagnosis which matched the survey diagnosis) was 82% (SE=2%, 95% CI=78% - 87%).

Treatment quality (a binary indicator measuring whether the treatment was correct or not was determined by whether the health worker followed Zambia NMCC national treatment guidelines for malaria, based on the diagnosis, patient weight and availability of NMCC-recommended antimalarials. At the time of the 2011 Zambia Health Facility Survey, the NMCC treatment guidelines called for artemether-lumefantrine as the first-line treatment for uncomplicated malaria except for children weighing below 5kg, who should be treated with sulphadoxine-pyrimethamine. Second-line treatment in case of failure of first-line treatment was quinine for all age groups. The percentage of treatments correctly prescribed was 89.6% (95% CI =86.3 to 92.8). The proportion reflects the appropriateness of each treatment according to the clinic diagnosis; the patient's weight (sulfadoxine-pyrimethamine is only appropriate for children weighing <5kg); and availability of each antimalarial in the health facility on the day of the survey.

The counseling quality outcome variable is an index created from six yes/no questions or tasks which the health worker should have completed after prescribing the antimalarial treatment. The index measures whether the health worker: 1) explained the illness to the patient; 2) explained how to administer the antimalarial; 3) demonstrated how to take the antimalarial; 4) verified the patient's or caretaker's understanding of the treatment regimen; 5) explained when to return for follow up; and 6) under which circumstances to return immediately to the health facility. As described in detail in the manuscript "Measuring Malaria Case Management in Zambia, 2011", the mean counseling score for the 387 consultations in which a patient was prescribed an antimalarial drug was 48.6 on a scale of 0 to 100.

The mean assessment and counseling scores were both low due primarily to the fact that most health workers correctly asked a few core questions but neglected to ask more probing questions such as those which would discern a differential diagnosis, or verified whether the patient understood the antimalarial treatment regimen. The goal of the manuscript “Measuring Malaria Case Management in Zambia, 2011” was to measure these malaria case management quality indicators. The current research can take this a step further, shedding light on patient, health worker and facility level factors associated with quality of assessment and counseling. Meanwhile the diagnosis and treatment quality was relatively good; again, the current paper can provide deeper insight into the potential reasons for the good performance of health workers regarding diagnosis and treatment.

2.5 Analytical strategy

2.5.1 Multilevel mixed effects modeling

Due to the cluster survey design, all four regression models included a random effect at the health facility level to account for non-independent observations within health facilities, and to allow baseline measures across health facilities to vary.

2.5.2 Testing for association between quality of assessment and supervision

A linear, varying intercept multilevel model with mixed effects was run with clustering at health facility level, using maximum likelihood estimation, regressing the mean assessment score on the research and control variables. Supervision and the control variables were the fixed effects, while health facility was set as the random effect since clustering is at facility level. Independent variables were chosen *a priori* and based on previous research. A detailed description of each independent variable is in Appendix 1.

Regression model:

$$Y_{ij} = \beta_{0j(i)} + \beta X_{i1} + \beta X_{i2} + \beta X_{i3} + \beta X_{i4} + \beta X_{i5} + \beta X_{i6} + \beta X_{i7} + \beta X_{i8} + \beta X_{i9} + \epsilon_i$$

Where:

Y_1 =Assessment score (Possible range 0 to 100)

$\beta_{0j(i)}$ =Intercept varying by health facility (j)

X_1 =Supervision (None in previous 6 months, Supervision but no observation of malaria case management, Supervision with no observation of malaria case management)

X_2 =Health facility managing authority (Government, NGO, Private)

X_3 =Health facility type (Hospital outpatient, urban health center, rural health center, health post)

X_4 =Health worker type (Doctor or nurse, Clinical officer, Community health worker/other)

X_5 =Health worker had malaria case management in-service training (yes, no)

X_6 =Malaria case management guidelines available (yes, no)

X_7 =IMCI guidelines available (yes, no)

X_8 =Malaria endemicity of the area in which the health facility is located (<5%, ≥ 5 to <25%, $\geq 25\%$)

X_9 =Age of patient (under 5 years, 5 years and older)

Level of analysis: Patient consultation with health worker, nested within health facility.

2.5.3 Testing for association between quality of diagnosis and supervision

A logistic multilevel model with mixed effects and maximum likelihood estimation was used to test for association between supervision and quality of diagnosis, controlling for other factors. The independent variables were considered fixed effects, while health facility type was the random effect since that is where the data were clustered (patients in health facilities). As described above, the survey clinicians used rapid diagnostic tests to determine presence of malaria parasites in patients. Regression models stratified by health facility type and age group were tested but these models were found not to be significant. Multicollinearity was checked for using the Stata <collin> command; there were no independent variables with a variance inflation factor over 10. VIFs ranged from 1.02 to 1.61, with a

mean VIF of 1.2, indicating no multicollinearity in the model. A detailed description of each independent variable is in Appendix 2.

$$\text{Pr}(y_i=1) = \text{logit}^{-1}(\beta_{0j(i)} + \beta_{1i}X_{i1} + \beta_{2i}X_{i2} + \beta_{3i}X_{i3} + \beta_{4i}X_{i4} + \beta_{5i}X_{i5} + \beta_{6i}X_{i6} + \beta_{7i}X_{i7} + \beta_{8i}X_{i8} + \beta_{9i}X_{i9}) + \epsilon_i$$

Level of analysis: Patient consultation with health worker

Where:

Y=Clinic diagnosis in concordance with survey diagnosis (Yes, no)

$\beta_{0j(i)}$ =Intercept varying by health facility (j)

X_1 =Supervision (None in previous 6 months, Supervision but no observation of malaria case management, Supervision with no observation of malaria case management)

X_2 = Health facility managing authority (Government, NGO, Private)

X_3 =Type of health facility (Hospital outpatient, urban health center, rural health center, health post)

X_4 =How many years worked as health worker (years, continuous; range 0 to 43)

X_5 =Malaria RDT job aid available in consultation room (yes, no)

X_6 =Diagnostic blood test conducted by health worker or facility laboratory (yes, no)

X_7 =Age of the patient (Under 5 years, 5 years and older)

X_8 =RDT in-service training (yes, no)

X_9 =Health worker caseload (<25, \geq 25 patients)

ϵ_{ij} = model error term

2.5.4 Testing for association between quality of treatment and supervision

Correct treatment was regressed on supervision and covariates using a logistic multilevel model with mixed effects and maximum likelihood estimation. Supervision and the control variables were the fixed effects, while health facility was set as the random effect since clustering is at facility level. It was

important to allow variation at health facility level because it is likely health facilities vary in terms of capacity to provide service in ways that cannot be completely controlled for using covariates.

Independent variables were chosen primarily *a priori* and based on previous research. As described above, correct antimalarial treatment included prescribing when the patient was diagnosed with malaria, according to national guidelines with regards to availability of antimalarials and the patient's weight. The term "correct treatment" here also includes not prescribing an antimalarial when the patient was not diagnosed with malaria. The health worker's diagnosis was used for this criteria even when it did not match the gold standard (survey clinician RDT test result) so as not to penalize the health worker twice. Pregnancy in the first trimester is another criterion in the Zambia NMCC treatment guidelines but while pregnancy status was determined in the survey, trimester was not; therefore, it was not included in this analysis. A detailed description of each independent variable is in Appendix 3.

Level of analysis: Patient consultation with health worker

$$\Pr(y_i=1) = \text{logit}^{-1}(\beta_{j(i)} X_{i1} + \beta_2 X_{i2} + \beta_3 X_{i3} + \beta_4 X_{i4} + \beta_5 X_{i5} + \beta_6 X_{i6} + \beta_7 X_{i7} + \beta_8 X_{i8} + \beta_9 X_{i9} + \beta_{10} X_{i10} + \beta_{11} X_{i11}) + \epsilon_i$$

Where:

Y =Correct treatment (yes, no)

X_1 =Supervision (None in previous 6 months, Supervision but no observation of malaria case management, Supervision with no observation of malaria case management)

X_2 = Type of health facility (Hospital outpatient, urban health center, rural health center, health post)

X_3 = Health worker type (Doctor or nurse, Clinical officer, Community health worker/other)

X_4 = Health facility managing authority (Government, NGO, Private)

X_5 =Correct diagnosis (yes, no)

X_6 =How long worked as health worker (years, continuous)

X_7 =Health worker participated in a malaria-related in-service training (yes, no)

X_8 =Age of the patient (Under 5 years, 5 years and older)

X₉=Malaria case management guidelines available (yes, no)

X₁₀=ACT job aid available (yes, no)

X₁₁=Malaria endemicity of the area in which the health facility is located (<5%, 5 to <25%, ≥25%)

2.5.5 Testing for association between quality of counseling and supervision

A linear regression, varying intercept multilevel model with mixed effects was run with clustering at health facility level, using maximum likelihood estimation, regressing the counseling quality index for each health worker-patient consultation on supervision and control variables. Supervision and the control variables were the fixed effects, while health facility was set as the random effect since clustering is at facility level. It was important to allow variation at health facility level because it is likely health facilities vary in terms of capacity to provide service in ways that cannot be completely controlled for using covariates. Independent variables were chosen *a priori* and based on prior research. A detailed description of each independent variable is in Appendix 4.

Level of analysis: Patient consultation with health worker

$$Y_{ij} = \beta_{0(j)} + \beta_1 X_{i1} + \beta_2 X_{i2} + \beta_3 X_{i3} + \beta_4 X_{i4} + \beta_5 X_{i5} + \beta_6 X_{i6} + \beta_7 X_{i7} + \beta_8 X_{i8} + \beta_9 X_{i9} + \beta_{10} X_{i10} + \epsilon_i$$

Where:

Y₁=Counseling score (possible range 0 to 100)

β_{0(j)}=Intercept varying by health facility (j)

X₁=Supervision (None in previous 6 months, Supervision but no observation of malaria case management, Supervision with no observation of malaria case management)

X₂=Health worker type (Doctor or nurse, Clinical officer, Community health worker/other)

X₃=Type of health facility (Hospital outpatient, urban health center, rural health center, health post)

X₄=Health facility managing authority (Government, NGO, Private)

X₅=Malaria case management guidelines available in consultation room (yes, no)

X₆=Malaria endemicity of the area in which the health facility is located (<5%, 5 to <25%, ≥25%)

X₇=Age of the patient (Under 5 years, 5 years and older)

X₈=Health worker had IMCI in-service training (yes, no)

X₉=ACT job aid available in consult room (yes, no)

X₁₀=IMCI guidelines available in consult room (yes, no)

3. Results

3.1 Factors associated with quality of assessment

Table 2 below shows the multilevel regression results. Supervision was significantly and negatively associated with assessment scores. Specifically, supervision in the previous 6 months without observation of the health worker's malaria case management was associated with assessment scores 6.8 points lower compared with no supervision at all in the previous 6 months ($p=0.008$). Since the direction of this association was the opposite of the hypothesized direction, the regression model was tested for endogeneity. Endogeneity is a form of missing variable bias, in which the absence of a variable not available in the dataset can cause unexpected regression results.

To test for endogeneity an instrumental variable (IV) was identified (whether a supervisory schedule was available) which was associated with the potentially endogenous variable (supervision) (Pearson's χ^2 result $p<0.0001$) but was not associated with the dependent variable (assessment score) (simple linear regression result $p=0.823$). In Stata SE 12.1 the <ivregress 2sls> command was run to conduct a 2-stage least squares test followed by the <estat endogenous> command to determine whether the IV indicated the presence of endogeneity in this model's main research variable, supervision. The null hypothesis, that the variables were exogenous, was retained because the robust

regression result was nonsignificant ($p=0.308$). Therefore, endogeneity was not indicated using supervisory schedule as an instrumental variable.

Among the four categories of health facilities (hospital, urban health center, rural health center and health post), urban health centers were significantly associated ($p=0.045$) with assessment scores 6.4 points lower compared with the reference category, hospitals. The health facilities' managing authority was significantly associated with assessment scores as well: non-governmental organizations and private health facilities were associated with assessment scores 8.7 points ($p=0.016$) and 11 points ($p=0.006$) higher than government-run health facilities, respectively.

Patient age under 5 years was highly significantly associated ($p<0.001$) with assessment scores 9.8 points higher than patients aged 5 years or older. Malaria endemicity was also associated with assessment score: fever consultations in health facilities in highly endemic areas (at least 25% of children aged 2 to 10 years with malaria parasitemia from a previous study) (26) were associated with assessment scores 6.9 points lower ($p=0.031$) compared with consultations in health facilities in areas with under 5% malaria endemicity.

Table 12: Regression of assessment quality

n=808 observations; 142 health facilities

Wald χ^2 (17 DF) = 121.51

p < 0.0001

Dependent var: Assessment score	Coef.	SE	z	P>z	95% CI
Supervision Reference category: no supervision					
Supervision w/o observation of MCM	-6.80	2.56	-2.66	0.008*	-11.81 to -1.79
Supervision with observation of MCM	-4.50	2.68	-1.68	0.093**	-9.74 to 0.75
Health worker type Reference category: Doctor/nurse					
Clinical officer	-2.58	2.33	-1.11	0.268	-7.15 to 1.98
CHW/other	-1.66	2.42	-0.69	0.492	-6.40 to 3.08
Health facility type (stratum) Reference category: Hospital clinic					
Urban health center	-6.42	3.20	-2.00	0.045*	-12.69 to -0.14
Rural health center	-4.28	3.55	-1.21	0.228	-11.23 to 2.68
Health post	-2.19	3.80	-0.58	0.563	-9.63 to 5.25
Facility managing authority Reference category: Government					
NGO	8.68	3.60	2.41	0.016*	1.63 to 15.72
Private	10.96	3.97	2.76	0.006*	3.17 to 18.74
Malaria case management IST	-2.76	1.84	-1.50	0.133	-6.36 to 0.84
Malaria case mgmt. guidelines available	2.96	2.20	1.35	0.178	-1.35 to 7.27
IMCI guidelines available	1.44	1.95	0.74	0.459	-2.37 to 5.25
Malaria endemicity Reference category: <5%					
5 to <25%	-2.34	2.67	-0.88	0.381	-7.58 to 2.90
≥25%	-6.89	3.19	-2.16	0.031*	-13.14 to -0.65
Patient aged under 5 years	9.79	1.13	8.63	0.000*	7.57 to 12.01
Intercept	54.09	4.27	12.68	0.000	45.73 to 62.45

*p< 0.05; **p<0.10

The relationship between supervision and assessment was investigated further. A reduced version of the assessment index was created, which included only the three following tasks: 1) whether the health worker asked if the patient had fever; 2) health worker checked the patient's temperature; and 3) health worker asked if this was a follow-up visit. The multilevel regression model was run with the same covariates which as in Table 2 above, and the association between assessment and supervision was found to be negative and non-significant. Finally, a third regression model was run in which the outcome variable was binomial: whether the health worker check the patient's temperature. In this

regression model the association between supervision and assessment item was positive and, for supervision which included observation of malaria case management, significant (odds ratio=5.21 compared with no supervision; $p=0.012$).

Table 13: Regression results of modified assessment indicator

Supervision independent variable	Full original Assess index β (p)	Reduced Assessment index* β (p)	Checked temperature OR (p)
Supervision no MCM**	-6.80 (0.008)	-2.96 (0.381)	2.55 (0.120)
Supervision with MCM**	-4.50 (0.093)	0.13 (0.969)	5.21 (0.012)

*Asked if fever, checked temperature, asked if follow-up visit

**MCM = Observation of malaria case management by supervisor

3.2 Factors associated with quality of diagnosis

Table 4 below shows that all three categories of supervision (none, supervision with no observation of malaria case management, supervision with observation of malaria case management) were non-significant in this regression model. Fever patient consultations with health workers at NGO-run health facilities were strongly ($p=0.008$) and negatively associated with quality of diagnosis. Health workers in these facilities were 73% less likely to perform a diagnosis which matched the survey diagnosis, as compared with health workers at government facilities.

Presence of an RDT job aid significantly ($p=0.026$) increased the likelihood of correct diagnosis. Health workers who had an RDT job aid available were more than twice as likely to have diagnostic concordance with the gold standard survey diagnosis compared with health workers with no RDT job aid available. None of the other independent variables were significantly associated with correct clinic diagnosis.

Table 14: Regression of diagnosis quality

n=692 observations of fever patient consultations with health worker; 136 health facilities

Wald χ^2 (13 DF) = 22.87

p = 0.043

Dependent variable: Diagnosis	OR	SE	z	P>z	95% CI
Supervision Reference category: no supervision					
Supervision w/o observation of MCM	1.24	0.54	0.49	0.622	0.53 – 2.90
Supervision with observation of MCM	1.30	0.61	0.58	0.563	0.52 – 3.27
Facility managing authority Reference category: Government					
NGO	0.27	0.13	-2.67	0.008*	0.10 – 0.70
Private	0.89	0.69	-0.15	0.880	0.19 – 4.11
Health facility type Reference category: Hospital clinic					
Urban health center	0.44	0.20	-1.82	0.068	0.18 – 1.06
Rural health center	0.91	0.45	-0.19	0.848	0.34 – 2.41
Health post	0.42	0.23	-1.60	0.109	0.14 – 1.21
RDT job aid available	2.08	0.69	2.23	0.026*	1.09 – 3.97
RDT in-service training attended	1.17	0.37	0.52	0.604	0.64 – 2.16
Blood test conducted	1.53	0.47	1.37	0.171	0.83 – 2.79
Patient aged under 5 years	1.26	0.30	0.99	0.324	0.79 – 2.02
Workload <25 patients on day of survey	0.71	0.24	-1.00	0.319	0.36 – 1.39
How long worked as health worker	1.00	0.01	-0.32	0.747	0.97 – 1.02
Intercept	4.86	2.80	2.74	0.006	1.57 – 15.05

**p<0.05

3.3 Factors associated with quality of treatment

As seen in Table 5 below, supervision was not significantly associated with treatment quality.

The only independent variable associated with treatment quality was correct diagnosis, which was highly associated (p<.001) with quality of treatment; patients whose clinic diagnosis matched that of the survey clinician were 22.8 times more likely to also have appropriate antimalarial prescription compared with those whose clinic diagnosis did not match the survey diagnosis.

Table 15: Regression of treatment quality

n=678 observations; 134 health facilities

Wald χ^2 (17 DF) = 70.46

p < 0.001

Dependent variable: Correct treatment	OR	SE	z	P>z	95% CI
Supervision					
Reference category: no supervision					
Supervision without observation of MCM	0.95	0.50	-0.09	0.929	0.34 - 2.65
Supervision with observation of MCM	1.78	1.02	1.00	0.315	0.58 - 5.47
Health worker type					
Reference category: Doctor/nurse					
Clinical officer	0.80	0.37	-0.49	0.626	0.32 - 1.99
CHW/other	1.44	0.73	0.73	0.465	0.54 - 3.86
Health facility type					
Reference category: Hospital clinic					
Urban health center	1.17	0.62	0.30	0.766	.42 - 3.30
Rural health center	1.77	1.15	0.88	0.381	0.49 - 6.32
Health post	1.48	0.99	0.59	0.557	0.40 - 5.49
Facility managing authority					
Reference category: Government					
NGO	2.74	1.71	1.62	0.106	0.81 - 9.29
Private	1.34	1.20	0.32	0.747	0.23 - 7.73
Malaria case management IST	1.28	0.48	0.64	0.519	0.61 - 2.69
Malaria case management guidelines available	1.25	0.53	0.52	0.601	0.54 - 2.86
ACT job aid available	1.12	0.46	0.27	0.784	0.50 - 2.49
Correct diagnosis	22.80	8.90	8.00	0.000*	10.60 - 49.02
Malaria endemicity					
Reference category: <5%					
5 to <25%	0.84	0.37	-0.40	0.692	0.35 - 2.01
≥25%	0.76	0.41	-0.51	0.611	0.27 - 2.18
Patient aged under 5 years	1.24	0.37	0.72	0.469	0.69 - 2.24
Years worked as health worker	0.99	0.03	-0.38	0.706	0.96 - 1.03
Intercept	0.45	0.40	-0.90	0.367	0.08 - 2.54

**p<0.05

3.4 Factors associated with quality of counseling

As seen in Table 6 below, supervision was not significantly associated with quality of counseling at the $\alpha=.05$ level but both levels were associated at the $\alpha=.1$ level. Specifically, consultations with health workers who reported being supervised in the previous 6 months but without the supervisor observing malaria case management were mildly associated ($p=0.064$) with counseling scores 8.8 points

lower compared with the reference category of health workers reporting no supervision. Similarly, consultations with health workers who reported being supervised with the supervisor observing malaria case management were weakly associated ($p=0.067$) with counseling scores 8.9 points lower compared with the reference category of health workers reporting no supervision in the previous 6 months.

Private health facilities were highly significantly associated with higher counseling scores. Consultations conducted at private facilities were associated with a 37.8-point increase in counseling score compared with consultations held at government health facilities ($p<.001$). The presence of IMCI guidelines during fever consultation was associated ($p=0.011$) with a 9.4-point increase in counseling scores compared with consultations without IMCI guidelines available. This is not surprising given that the IMCI guidelines were available in 65.0% (SE=5.6%, 95% CI=53.9% to 76.1%) of consultations whereas the Integrated Management of Adolescent and Adult Illness (IMAI) guidelines, which target patients 5 years and older, were available in only 23.2% of consultations (SE=4.7%, 95% CI=13.9% to 32.6%).

Consultations conducted in areas with high malaria endemicity ($\geq 25\%$ of children aged 2 to 10 with malaria parasitemia from a previous study) (26) were significantly associated ($p=0.045$) with counseling scores 10.6 points higher than consultations conducted in areas with the lowest endemicity level. Lastly, consultations with health workers in which a blood test to detect malaria parasites was conducted were highly associated ($p=0.003$) with a 12-point increase in counseling score compared with those in which there was no blood test conducted.

Table 16: Regression of counseling quality

n=363 observations; 108 health facilities

Wald χ^2 (18 df) = 64.85

P < 0.001

Independent variables	Coef.	SE	z	P>z	95% CI
Supervision Reference category: no supervision					
Supervision w/o observation of MCM	-8.81	4.75	-1.85	0.064**	-18.12 to 0.50
Supervision with observation of MCM	-8.92	4.86	-1.84	0.066**	-18.44 to 0.59
Facility managing authority Reference category: Government					
NGO	7.20	5.93	1.21	0.225	-4.42 to 18.81
Private	37.84	8.06	4.69	0.000*	22.04 to 53.64
Health worker type Reference category: Doctor/nurse					
Clinical officer	-4.80	4.44	-1.08	0.279	-13.50 to 3.89
CHW/other	3.52	4.27	0.82	0.410	-4.84 to 11.88
Health facility type Reference category: Hospital clinic					
Urban health center	4.43	5.66	0.78	0.434	-6.66 to 15.51
Rural health center	-1.11	6.01	-0.19	0.853	-12.89 to 10.66
Health post	0.51	6.61	0.08	0.938	-12.44 to 13.46
IMCI in-service training (IST)	4.31	4.02	1.07	0.284	-3.57 to 12.19
Malaria case management IST	1.59	3.36	0.47	0.636	-4.99 to 8.17
IMCI guidelines available	9.41	3.71	2.54	0.011*	2.14 to 16.68
Malaria case management guidelines available	-7.10	4.32	-1.64	0.100	-15.55 to 1.36
ACT job aid available	-1.32	3.74	-0.35	0.725	-8.65 to 6.02
Malaria endemicity Reference category: <5%					
5 to <25%	2.36	4.61	0.51	0.608	-6.67 to 11.40
≥25%	10.59	5.28	2.01	0.045*	0.24 to 20.94
Diagnostic blood test conducted	12.94	4.31	3.00	0.003*	4.49 to 21.38
Patient aged under 5 years	2.49	2.29	1.09	0.277	-2.00 to 6.98
Intercept	35.24	8.60	4.10	0.000	18.38 to 52.09

**p<0.05

Since (as with Assessment) there was an unexpectedly negative association between supervision and quality of counseling, this association was investigated in more depth. A reduced version of the counseling index was created consisting of only 1) whether the health worker had explained the illness and 2) whether the health worker had explained how to take the antimalarial medication. As seen in Table 7 below, this reduced version of the counseling quality index, similarly to the full version, was

negatively associated with supervision. Another regression model was run in which the outcome variable was binomial, whether or not the health worker had explained how to take the antimalarial medication. In this case the association switched to positive, and was significant at the $\alpha=0.1$ level ($p=0.091$): for consultations in which the health worker had reported having had supervision in the previous 6 months, the odds were 6.46 times greater that the health worker had explained how to take the antimalarial medication.

Table 17: Regression results of modified counseling indicator

Supervision independent variable	Counseling original β (p)	Reduced counseling* β (p)	Explained meds (OR) (p)
Supervision no MCM**	-8.8 (0.064)	-10.19 (0.068)	0.89 (0.894)
Supervision MCM**	-8.9 (0.066)	-5.87 (0.306)	6.46 (0.091)

*Explained illness and how to take the antimalarial

**MCM = Observation of malaria case management by supervisor

4. Discussion

Multilevel mixed effects regression was used to determine which patient, health worker and health facility level factors were associated with each of four case management quality indicators: assessment, diagnosis, treatment and counseling. Supervision in the previous 6 months without observation of the health worker's malaria case management was associated with assessment scores 6.8 points lower compared with no supervision at all in the previous 6 months ($p=0.008$). There was no association between supervision and either diagnosis quality or treatment quality. Supervision both with and without observation of malaria case management were weakly associated with counseling scores 9 points lower than consultations in which the health worker had no supervisory visit ($p=0.064$ and $p=0.066$, respectively). These findings are contrary to the study hypotheses, and indicate that supervision by the district health management teams needs to be improved in Zambia.

4.1 Assessment

The negative association between supervision and both assessment and counseling was unexpected although there are plausible explanations. One explanation is that there was endogeneity in the regression models. For the assessment regression, in which there was statistically significant association, this was tested for using an instrumental variable (whether there was a supervisory schedule available), explained in Results section 3.1 above. However strong instrumental variables are notoriously difficult to find, and it is possible that there was still a missing variable bias despite the two-stage least squares regression conducted. For example, supervision quality may have been a missing variable causing endogeneity: the 2011 Zambia health facility survey included data on whether there was supervision, as well as some data on what the supervisor did during his or her visit(s) to the health facilities; however, there was insufficient data available on the quality of supervision. It is possible that some supervisors erroneously provided misinformation during supervision leading to lower-quality assessment and counseling.

Another possible explanation of the negative association between supervision and assessment and counseling is reverse causality: supervisors conducted more visits to health facilities in which health workers were low-performing. If this were true then one could expect to see better health worker performance over time. However, this hypothesis is difficult to test in the absence of a subsequent health facility survey.

At the time of the survey, the 2010 NMCC “Guidelines for the Diagnosis and Treatment of Malaria, Third Edition” were in use. These guidelines were somewhat confusing and, in places, self-contradictory. For example, Chapter 1.2 “Policy on Parasite-Based Diagnosis” states that “all suspected malaria cases, without exception, should be diagnosed according to the blood test result. However, for children under 5 years treatment should be initiated according to IMCI guidelines.” (27) In the IMCI chapter, the guidelines state that a blood test should be done, but if there is a negative blood test, look

for other causes of fever; if no other cause of fever is found then diagnose and treat for malaria. This leave unclear what the health worker should do when another potential cause of fever is found but the health worker still suspects malaria.

The conflicting messages in the 2010 guidelines may have led to confusion among health workers and supervisors about how to proceed with diagnosis when a blood test is negative but there are signs of malaria for both patients aged under 5 years and those aged 5 years and older. With clearer guidelines it is possible that in 2011 the rate of correct diagnosis would have been higher than 82.4%, as measured in an unpublished dissertation manuscript by this author (17).

The fourth edition of the Zambia Guidelines for Diagnosis and Treatment of Malaria were published in 2014 (28). However, the 2014 guidelines while overall more clear than the 2010 guidelines, are somewhat confusing regarding what the health worker should do in cases in which there was a negative blood test. The NMCC malaria case management algorithms from the 2011 Zambia Health Facility Survey Protocol and the 2014 NMCC Diagnosis and Treatment Guidelines can be found in Appendix 5 and 6, respectively. The next (fifth) edition of the Zambia Guidelines for Diagnosis and Treatment of Malaria should state clearly that if there is a malaria blood test available then the diagnosis should be based on the test results. There should be no ambiguous and confusing statements accompanying this, as there have been in the last 2 editions of the guidelines.

The health facilities' managing authority was significantly associated with higher assessment quality: both NGO and private health facilities performed better than government health facilities in this regard. Health workers in government-run health facilities would benefit from additional job aids explaining the importance of more complete assessments. Most health workers asked or completed certain tasks such as asking whether the patient had fever and checking the temperature. However most health workers also did not ask or complete other tasks such as checking for other causes of fever.

Consultations in which the patient was aged less than five years were significantly associated with higher assessment scores. This is somewhat expected given that there is more focus on children aged under 5 years in the 2010 Zambia Malaria Diagnosis and Treatment Guidelines (29) since this age group is at higher risk for malaria morbidity and mortality (19). Patient age under 5 years was not significantly associated with quality of diagnosis, treatment or counseling. The effect of this age group in the regression models for diagnosis, treatment and counseling may have been accounted for by other independent variables such as availability of IMCI guidelines in the consultation room.

The significant association between lower assessment scores and consultations which occurred in areas of high malaria endemicity may have resulted from health workers in those areas being used to seeing many malaria cases. Health workers who see many malaria cases may have looked less often for other possible causes of fever during the assessment, leading to lower assessment scores. Also, the 2010 Zambia Malaria Diagnosis and Treatment Guidelines state that in areas of high malaria risk, there is a high likelihood of fever patients having malaria (29); this may have led to fewer assessment questions being asked before making a diagnosis.

As stated in the Results section, it was found that although there was a negative association between the full Assessment index and supervision, this relationship became positive and significant when the outcome variable was changed to simply whether the health worker had checked the temperature of the patient (binary variable with logistic regression). This indicates that the full Assessment index had a complicated association with supervision and, once simplified to a single outcome variable rather than an index comprised of 13 variables, the relationship with supervision was more straightforward. It is also notable that, when other binary outcome (whether the health worker asked about fever and whether the health worker had asked if this was a follow-up visit) variables were tested against the same independent variables, the negative relationship persisted. As described above,

there may have been endogeneity in which the missing variable was supervision quality, which was not measured in this survey.

4.2 Diagnosis

The importance of differential diagnosis, and especially checking for signs of measles and meningitis should be included in pre-service and in-service trainings as well as during supportive supervision visits. The WHO IMCI and the 2010 Zambia NMCC Diagnosis and Treatment Guidelines call for checking on differential diagnosis before diagnosing suspected malaria as confirmed malaria (29, 30). During the 2011 Zambia Health Facility Survey there was an ongoing and widespread measles outbreak with approximately 15,500 cases in 2010 and 13,324 cases in 2011 (31, 32). Health workers should have been on the lookout for measles as a cause of fever but health workers asked about recent history of measles in only 2.5% of consultations (SE=0.8%, 95% CI=1% to 4%). Better differential diagnosis could have led to fewer misdiagnoses in this study.

Health workers who had an RDT job aid available were twice as likely to have clinic diagnosis which matched the survey diagnosis compared with health workers with no RDT job aid available. This finding is supported by some prior research, in which RDT job aids, especially accompanied by training, improves the correct usage of RDTs by health workers (15, 33). This is a notable finding, although RDT job aids were available in only 54.0% of fever consultations (SE=6.8%, 95% CI=40.4% to 67.4%). RDT job aids are relatively inexpensive to produce since generic versions of them have been provided by the ACT Consortium (34), and increased availability of job aids in consultation rooms could significantly improve the rate of correct malaria diagnosis.

Fever consultations with health workers at NGO-managed health facilities were 73% less likely to make a correct malaria diagnosis, compared with consultations at government-run health facilities. This may be because RDT job aids were available in only 29.6% of fever consultations in NGO-managed

health facilities in this study, compared with 55.1% of government-run health facilities. More availability of RDT job aids in NGO-run facilities could improve health worker performance in this regard.

4.3 Treatment

The only factor associated with correct treatment was whether the diagnosis was correct. The strong association between diagnosis and treatment makes sense programmatically since the two are closely linked in the IMCI and Zambia NMCC malaria/fever case management guidelines and WHO case management operations manual (19, 29, 30). It was extremely rare for a non-malaria diagnosis to be followed by a treatment with an antimalarial drug and, conversely, it was rare for a diagnosis of malaria to not be followed by treatment with an antimalarial drug. One of the goals of including RDTs in the NMCC diagnosis policy was to reduce the rate of improper prescription of AL especially due to its high cost. The strong association between diagnosis and treatment is proof of the success of the Zambia NMCC in the implementation of RDTs and AL, despite the ambiguities in the 2010 NMCC diagnosis and treatment guidelines.

4.4 Counseling

Supervision with and without observation of malaria case management were both weakly ($p=0.064$ and $p=0.066$, respectively) associated with counseling scores 9 points lower, compared with no supervision at all in the previous 6 months. As in the discussion of the association between supervision and assessment quality above, it is difficult to fully understand the relationship between supervision and quality of counseling without having more detailed information on the content of the supervisory visits, and specifically the quality of supervision. There may be endogeneity resulting from a missing variable bias in which the missing data capture the quality of supervision regarding counseling for antimalarials. It is possible that supervisors are giving feedback focusing on diagnosis and treatment while spending little time on counseling quality. There may be a reverse causality effect in which there is more supervision occurring where the counseling quality is lower. Since this is a cross-sectional survey with only a snapshot of health worker performance, we cannot know the change across time and thus

whether there might be a positive effect on counseling quality if there is more supervision. Another nationally representative health facility would help to shed light on this issue.

Fever patient consultations conducted in private health facilities were strongly associated with higher counseling scores (similar to the association between private health facilities and assessment scores) compared with consultations conducted in government health facilities. Clinicians at private health facilities are completing more of the counseling tasks, such as explaining when the patient should be brought back to the health facility in case of complications, and verifying the patient's or caretaker's understanding of the treatment regimen. This is especially important given that in areas where the treatment regimen is not adhered to over time, there is a risk of antimalarial drug resistance developing in the malaria parasite (6, 35-37).

The availability of IMCI guidelines in consultation rooms during fever consultations was associated with higher counseling quality compared with consultations for which IMCI guidelines were not available. This is in contrast to the IMCI in-service trainings, and malaria case management in-service trainings, which were not associated with counseling quality. It may be that the health workers consult the guidelines periodically when necessary, and this leads to better comprehension of the counseling advice to provide to the fever patient or caretaker.

Fever consultations conducted in health facilities in areas of high malaria endemicity were associated ($p=0.045$) with better counseling scores, in contrast to assessment scores, which were significantly lower in these areas. This makes sense: in areas with more malaria cases, the health workers are providing more complete information on the antimalarial treatment regimen because. However even with the 10.6-point increase associated with highly malaria-endemic areas, the counseling scores are still low, and there is a need to prioritize higher quality antimalarial drug regimen counseling by health workers.

For fever consultations in which a diagnostic blood test was conducted, there was a significant association ($p=0.003$) with higher counseling quality. Health workers who conducted blood tests and subsequently prescribed antimalarial treatment also addressed significantly more counseling items compared with those who had not conducted a blood test but who did prescribe an antimalarial treatment. This may be because health workers who conducted blood tests were in better-equipped health facilities which also included more job aids such as guidelines which addressed all the counseling messages which should be communicated to patients who were prescribed an antimalarial drug.

As described above, the association between counseling and supervision was explored in more depth, since there was an unexpectedly negative association. When the counseling index was reduced to just one variable (whether the health worker had explained how to take the medications) this association was flipped to a positive and significant one. This indicates that, as with the assessment variable, the counseling index was perhaps too complex to accurately measure the association with supervision. It is easier to understand the association between supervision and counseling with a univariate indicator.

5. Limitations

There were several limitations in this study. The observation of the health workers by survey staff may have created a Hawthorne effect, in which the observation caused a change in behavior by the health worker, resulting in either better or worse case management than if the health worker were not being studied.

If survey staff did not all follow survey protocol in the same way, misclassification bias may have resulted. For example, some surveyors appear to have skipped parts of the supervision section of the health worker interview if the respondent said that there had been no supervision in the previous 6 months.

Due to the potential reverse causality between supervisory visits and health worker performance on malaria case management, it is difficult to understand associations between health worker performance and certain interventions meant to improve performance using a cross-sectional survey. A panel data study for example would allow study of change before and after these interventions and could detect whether there was any effect over time of supervision on malaria case management quality. There may have been recall bias in the patient exit interview and during the health worker interview. The question of what the supervision did during the previous visit may not be representative of supervision generally.

The survey protocol does not describe what is supposed to occur when a supervisor “observes” malaria case management. The survey records whether the supervisor provided feedback or not, but it does not record what that feedback was.

There was little data collected on the demographics of the health workers surveyed. For example we do not have the age and sex of the health worker, although we do have data on the number of years worked at the health facility, as well as data on in-service training and pre-service training. More demographic information could have been useful when studying health worker performance on the quality of malaria case management.

The health worker diagnosis was compared against the “gold standard” diagnosis by a study clinician using an RDT. In cases where the consultation health facility lab used microscopy, if the microscope was maintained and used properly, the consult used a higher diagnostic standard than RDT; therefore, in these cases it does not make sense to compare against the “gold standard” RDT. This is a flaw in the study design.

This survey is representative only of malaria case management for the 50% of fever patients who seek treatment at a health facility. The systems effectiveness approach used by Littrell et al takes this into account (38).

The 850 fever patients analyzed in this study were identified in the data as having fever through the exit interview, not through their responses to the health worker questions during the consultation. This is because the patients' responses to the health workers' questions during the consultation were not recorded by the surveyors. It is possible that some patients may not have told the health worker of a fever complaint, but subsequently did list fever as a current complaint during the exit interview with the survey clinician. If this is the case then the patient may have been misdiagnosed as not having fever or malaria due to patient error, not due to health worker error.

Several variables, such as whether the HW asked if the patient had measles, include the response option "not applicable". However, this variable is inconsistently used and different survey staff may have interpreted this differently, indicating interviewer bias.

6. Conclusions

High quality malaria case management is an important component of malaria control in Zambia.

Determining which factors are associated with quality of malaria assessment, diagnosis, treatment and counseling can help the Zambia NMCC to identify programmatic areas on which to focus for improvement, and also identify areas which have been successful and therefore should continue.

Nationally representative health facility surveys can provide valuable information for program improvement and can also be analyzed together with household surveys to better understand issues of health care access especially in resource-poor areas (38). Malaria endemicity, supervision, health facility type, health facility managing authority, and availability of IMCI guidelines and RDT job aids were all

identified as statistically significant factors associated with quality of malaria case management in Zambia. The main research variable, supervision, was found to have had no association with quality of diagnosis and treatment, a negative association with assessment quality, and a weak negative association with counseling quality. Therefore, the research hypotheses were rejected. Periodic nationally representative health facility surveys can provide important data to observe change over time in factors associated with malaria case management, allowing for more in-depth decision-making by Zambia NMCC program managers.

7. Bibliography

1. Z. MOH, "Zambia National Malaria Indicator Survey 2010," (Zambian Ministry of Health, National Malaria Control Program, 2010).
2. Z. NMCC, "2012 Zambia Malaria Indicator Survey," (Zambia Ministry of Health, Lusaka, Zambia, 2012).
3. D. H. Hamer *et al.*, Improved diagnostic testing and malaria treatment practices in Zambia. *JAMA* **297**, 2227-2231 (2007).
4. J. Miller, L. Rosencrans, Ed. (2014).
5. D. Zurovac *et al.*, Paediatric malaria case-management with artemether-lumefantrine in Zambia: a repeat cross-sectional study. *Malar J* **6**, 31 (2007).
6. M. Mulenga *et al.*, Safety and efficacy of lumefantrine-artemether (Coartem) for the treatment of uncomplicated *Plasmodium falciparum* malaria in Zambian adults. *Malar J* **5**, 73 (2006).
7. J. O. Yukich *et al.*, Reductions in artemisinin-based combination therapy consumption after the nationwide scale up of routine malaria rapid diagnostic testing in Zambia. *Am J Trop Med Hyg* **87**, 437-446 (2012).
8. A. K. Rowe, D. de Savigny, C. F. Lanata, C. G. Victora, How can we achieve and maintain high-quality performance of health workers in low-resource settings? *Lancet* **366**, 1026-1035 (2005).
9. L. Huicho, R. W. Scherpbier, A. M. Nkowane, C. G. Victora, M.-C. E. o. I. S. Group, How much does quality of child care vary between health workers with differing durations of training? An observational multicountry study. *Lancet* **372**, 910-916 (2008).
10. J. Eriksen *et al.*, Assessing health worker performance in malaria case management of underfives at health facilities in a rural Tanzanian district. *Trop Med Int Health* **12**, 52-61 (2007).
11. O. Maestad, G. Torsvik, A. Aakvik, Overworked? On the relationship between workload and health worker performance. *J Health Econ* **29**, 686-698 (2010).
12. A. K. Rowe *et al.*, Quality of malaria case management at outpatient health facilities in Angola. *Malar J* **8**, 275 (2009).
13. A. K. Rowe, F. Onikpo, M. Lama, M. S. Deming, The rise and fall of supervision in a project designed to strengthen supervision of Integrated Management of Childhood Illness in Benin. *Health Policy Plan* **25**, 125-134 (2010).
14. J. F. Naimoli, A. K. Rowe, A. Lyaghfour, R. Larbi, L. A. Lamrani, Effect of the Integrated Management of Childhood Illness strategy on health care quality in Morocco. *Int J Qual Health Care* **18**, 134-144 (2006).
15. S. A. Harvey *et al.*, Improving community health worker use of malaria rapid diagnostic tests in Zambia: package instructions, job aid and job aid-plus-training. *Malar J* **7**, 160 (2008).
16. L. C. Steinhardt *et al.*, Patient-, health worker-, and health facility-level determinants of correct malaria case management at publicly funded health facilities in Malawi: results from a nationally representative health facility survey. *Malar J* **13**, 64 (2014).
17. L. Rosencrans, Tulane University, (2016).
18. J. Bryce *et al.*, Improving quality and efficiency of facility-based child health care through Integrated Management of Childhood Illness in Tanzania. *Health Policy Plan* **20 Suppl 1**, i69-i76 (2005).
19. W. G. M. Programme, "Malaria Case Management Operations Manual," (Geneva, Switzerland, 2009).
20. T. Bossert, M. B. Chitah, D. Bowser, Decentralization in Zambia: resource allocation and district performance. *Health Policy Plan* **18**, 357-369 (2003).
21. M. Hawela. (2013).

22. A. K. Rowe, F. Onikpo, M. Lama, M. S. Deming, Risk and protective factors for two types of error in the treatment of children with fever at outpatient health facilities in Benin. *Int J Epidemiol* **32**, 296-303 (2003).
23. A. Edward *et al.*, The association of health workforce capacity and quality of pediatric care in Afghanistan. *Int J Qual Health Care* **24**, 578-586 (2012).
24. P. Tavrow, Y. M. Kim, L. Malianga, Measuring the quality of supervisor-provider interactions in health care facilities in Zimbabwe. *Int J Qual Health Care* **14 Suppl 1**, 57-66 (2002).
25. *Malaria Operational Plan Zambia 2012* (2011).
26. M. M. A. Project, M. A. Project, Ed. (2010).
27. *Guidelines for the Diagnosis and Treatment of Malaria in Zambia* (2010).
28. NMCC. (NMCC, Lusaka, Zambia, 2014).
29. *Guidelines for the diagnosis and treatment of malaria in Zambia* (2010).
30. WHO. (WHO, Geneva, Switzerland, 2008).
31. E. Simons *et al.*, Assessment of the 2010 global measles mortality reduction goal: results from a model of surveillance data. *Lancet* **379**, 2173-2178 (2012).
32. Rubella, Initiative, Measles. (Measles Rubella Initiative, 2012).
33. W. Rennie *et al.*, Minimising human error in malaria rapid diagnosis: clarity of written instructions and health worker performance. *Trans R Soc Trop Med Hyg* **101**, 9-18 (2007).
34. A. Consortium, A. Consortium, Ed.
35. J. H. Amuasi *et al.*, Access to artesunate-amodiaquine, quinine and other anti-malarials: policy and markets in Burundi. *Malar J* **10**, 34 (2011).
36. M. Littrell *et al.*, Case management of malaria fever in Cambodia: results from national anti-malarial outlet and household surveys. *Malar J* **10**, 328 (2011).
37. A. Das, T. S. Ravindran, Factors affecting treatment-seeking for febrile illness in a malaria endemic block in Boudh district, Orissa, India: policy implications for malaria control. *Malar J* **9**, 377 (2010).
38. M. Littrell *et al.*, Documenting malaria case management coverage in Zambia: a systems effectiveness approach. *Malar J* **12**, 371 (2013).
39. A. K. Rowe *et al.*, A multifaceted intervention to improve health worker adherence to integrated management of childhood illness guidelines in Benin. *Am J Public Health* **99**, 837-846 (2009).
40. P. M. Hansen *et al.*, Determinants of primary care service quality in Afghanistan. *Int J Qual Health Care* **20**, 375-383 (2008).
41. K. L. Leonard, M. C. Masatu, Variations in the quality of care accessible to rural communities in Tanzania. *Health Aff (Millwood)* **26**, w380-392 (2007).

8. Appendices

Appendix 1: Justification for inclusion of independent variables for Assessment regression

- Supervision (8, 22, 23, 39, 40): Prior research has shown that health workers who had been supervised at least once in the previous 6 months could benefit from this supervision, if it is effective and supportive supervision. If the supervisor also observed malaria case management then there is potential for health worker performance in this regard could be improved or reinforced.
- Type of health facility (14, 22, 23, 41): Health workers at the lowest level health facility (health post) are assumed to have more performance problems compared with health workers at higher level facilities, especially hospital outpatient clinics.
- Health facility managing authority: The managing authority type will determine the supervision and stock management systems. It may be that for example in private facilities supervision is less case management-based and more based on stock management.
- Type of health worker (14, 22, 23, 41): Pre-service training may have an effect on quality of health worker performance since doctors and nurses for example may be expected to have a more thorough clinical training and background compared with community health workers who are based in health posts.
- In-service training for malaria case management (14, 18, 23, 39): Health workers were asked whether they had attended in-service trainings (ISTs) for malaria case management. During an in-service training health workers typically are gathered in a central location for a period of a few days for training on the relevant topic. Health workers who had an in-service training on malaria case management may be expected to perform better on the quality of case management indices compared with those who had not, depending on the quality of the training.
- Malaria endemicity of HF (<5%, ≥5 to <25%, ≥25% of children aged 2 to 10 years with parasitemia): Endemicity was measured using data from a 2010 Zambia endemicity study by the Malaria Atlas

Project (MAP) (26). MAP measured endemicity as the annually averaged infection *Plasmodium falciparum* prevalence in children aged 2 to 10 years old. Using ArcGIS the health facilities in the HF survey study were layered on top of the endemicity map from the 2010 study. The spatial analyst function was then used to extract the nearest endemicity point to each health facility from the survey. MAP calculated the probability distribution of each pixel, each of which corresponds to approximately 1 km². This assumes that the level of endemicity for the health facility locations was the same as endemicity for the areas in which patients attending that health facility resided during the survey period.

- IMCI guidelines available: If these guidelines were available in the consultation room then the health worker could read them and thereby gain or reinforce knowledge on recommended case management procedures for children aged under 5 years.
- Malaria case management guidelines available: If these guidelines were available in the consultation room then the health worker could read them and thereby gain or reinforce knowledge on recommended malaria case management procedures.
- Age of patient: Malaria diagnosis recommendations in the NMCC guidelines and IMCI guidelines are stratified by age under 5 years and patients aged 5 years and older. Quality of diagnosis may vary according to the patient's age category.

Appendix 2: Justification for inclusion of independent variables for Diagnosis regression

- Supervision (8, 22, 23, 39, 40): Health workers who had been supervised at least once in the previous 6 months could benefit from this supervision, if it is effective and supportive supervision. If the supervisor also observed malaria case management then there is potential for health worker performance in this regard could be improved or reinforced.

- Type of health facility (14, 22, 23, 41): Health workers at the lowest level health facility (health post) are assumed to have more performance problems compared with health workers at higher level facilities, especially hospital outpatient clinics.
- Health facility managing authority: The managing authority type will determine the supervision and stock management systems. It may be that for example in private facilities supervision is less case management-based and more based on stock management.
- In-service training for malaria RDT (14, 18, 23, 39): Health workers were asked whether they had attended in-service trainings (ISTs) on use of RDTs. During an in-service training health workers typically are gathered in a central location for a period of a few days for training. Health workers who had an in-service training on malaria RDT use may be expected to perform better quality diagnosis compared with those who had not, depending on the quality of the training.
- Patient age: Malaria diagnosis recommendations in the NMCC guidelines and IMCI guidelines are stratified by age under 5 years and patients aged 5 years and older. Quality of diagnosis may vary according to the patient's age category.
- RDT job aid available: If an RDT job aid were available in the consultation room then the health worker could read them and thereby gain or reinforce diagnostic knowledge on recommended RDT procedures and thereby improve performance.
- Blood test conducted: A blood test (either microscopy or RDT) conducted to test for presence of malaria parasites is more reliable than clinical diagnosis.
- Time worked as health worker: Health workers with more years of experience may be expected to have better understanding of correct procedure, and may have been exposed to more in-service trainings and supportive supervision.
- Caseload (12, 14): Taken from the health worker interview, from the question "How many patients (all ages) have you seen in consultation today?" The survey protocol states that the health worker

interview was to be conducted at the end of the health workers' shift, therefore this question should capture the full caseload for each health worker. A high case load may lead to less time with each patient which could adversely affect diagnosis.

Appendix 3: Justification for inclusion of independent variables for Treatment regression

- Supervision (8, 22, 23, 39, 40): Health workers who had been supervised at least once in the previous 6 months could benefit from this supervision, if it is effective and supportive supervision. If the supervisor also observed malaria case management then there is potential for health worker performance in this regard could be improved or reinforced.
- Type of health facility (14, 22, 23, 41): Health workers at the lowest level health facility (health post) are assumed to have more performance problems compared with health workers at higher level facilities, especially hospital outpatient clinics.
- Health facility managing authority: The managing authority type will determine the supervision and stock management systems. It may be that for example in private facilities supervision is less case management-based and more based on stock management.
- Type of health worker (14, 22, 23, 41): Pre-service training may have an effect on quality of health worker performance since doctors and nurses for example may be expected to have a more thorough clinical training and background compared with community health workers who are based in health posts.
- Correct diagnosis: Health workers whose diagnosis matched that of the gold standard clinician may be expected to have a better understanding of malaria case management compared with those whose diagnosis was not correct.
- In-service training for malaria case management (14, 18, 23, 39): Health workers were asked whether they had attended in-service trainings (ISTs) on use of malaria case management. Health workers who had an in-service training on malaria case management use may be expected to

perform better quality treatment compared with those who had not, depending on the quality of the training.

- ACT job aid available: If an ACT job aid were available in the consultation room then the health worker could read them and thereby gain or reinforce diagnostic knowledge on recommended treatment with ACT and thereby improve performance.
- Malaria case management guidelines available: If malaria case management guidelines were available then there is potential for the health worker to read them and gain better understanding of correct case management procedures.
- Patient age: Malaria diagnosis recommendations in the NMCC guidelines and IMCI guidelines are stratified by age under 5 years and patients aged at least 5 years. Quality of diagnosis may vary according to the patient's age category.
- Time worked as health worker: Health workers with more years of experience may be expected to have better understanding of correct procedure, and may have been exposed to more in-service trainings and supportive supervision.
- Malaria endemicity of HF (<5%, ≥ 5 to <25%, $\geq 25\%$ of children aged 2 to 10 years with parasitemia): Endemicity was measured using data from a 2010 Zambia endemicity study by the Malaria Atlas Project (MAP) (26). MAP measured endemicity as the annually averaged infection *Plasmodium falciparum* prevalence in children aged 2 to 10 years old. Using ArcGIS the health facilities in the HF survey study were layered on top of the endemicity map from the 2010 study. The spatial analyst function was then used to extract the nearest endemicity point to each health facility from the survey. MAP calculated the probability distribution of each pixel, each of which corresponds to approximately 1 km². This assumes that the level of endemicity for the health facility locations was the same as endemicity for the areas in which patients attending that health facility resided during the survey period.

Appendix 4: Justification for inclusion of independent variables for Counseling regression

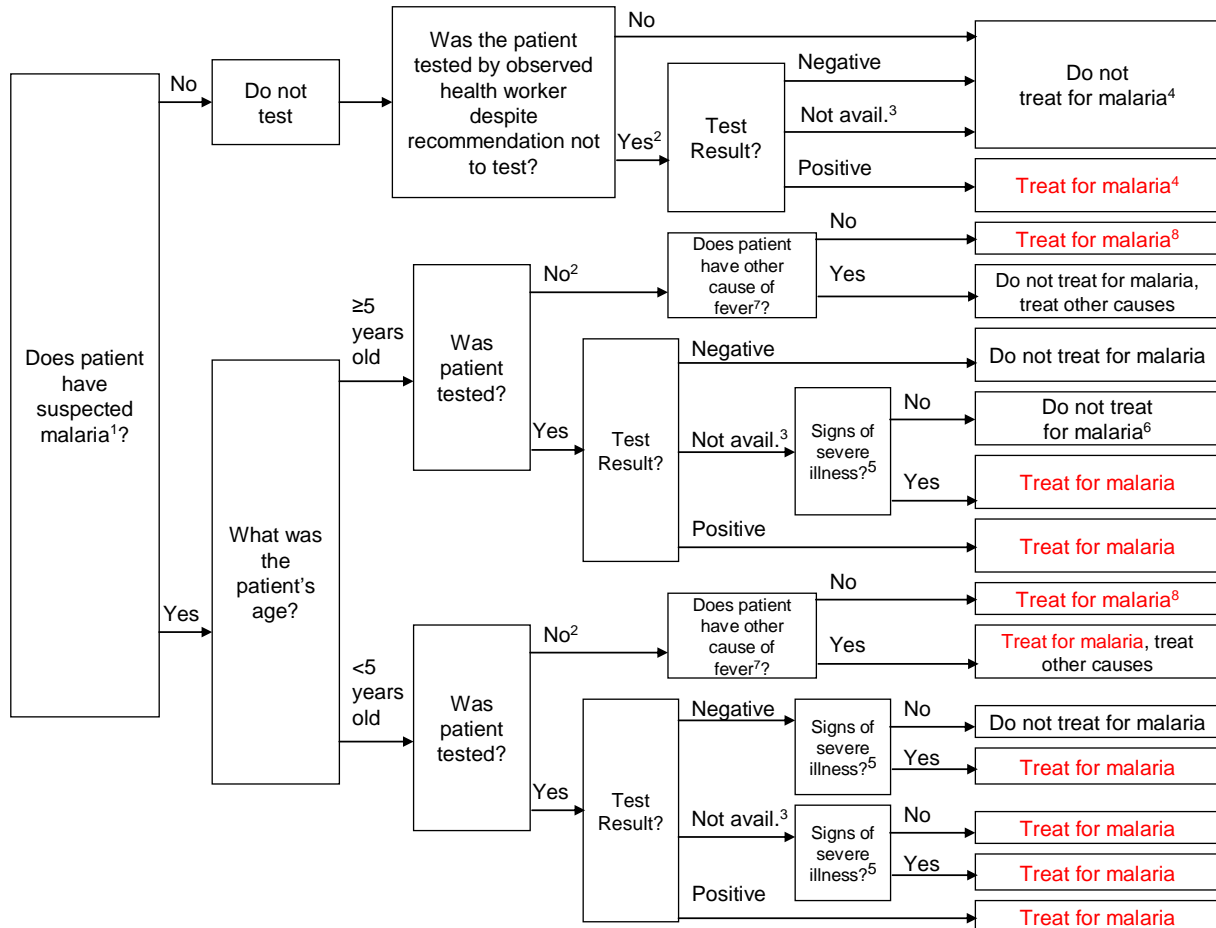
- Supervision (8, 22, 23, 39, 40): Health workers who had been supervised at least once in the previous 6 months could benefit from this supervision, if it is effective and supportive supervision. If the supervisor also observed malaria case management then there is potential for health worker performance in this regard could be improved or reinforced.
- Type of health facility (14, 22, 23, 41): Health workers at the lowest level health facility (health post) are assumed to have more performance problems compared with health workers at higher level facilities, especially hospital outpatient clinics.
- Health facility managing authority: The managing authority type will determine the supervision and stock management systems. It may be that for example in private facilities supervision is less case management-based and more based on stock management.
- Type of health worker (14, 22, 23, 41): Pre-service training may have an effect on quality of health worker performance since doctors and nurses for example may be expected to have a more thorough clinical training and background compared with community health workers who are based in health posts.
- In-service training for IMCI: Health workers who had an in-service training on IMCI use may be expected to perform better quality counseling compared with those who had not, depending on the quality of the training.
- IMCI guidelines available: If these guidelines were available in the consultation room then the health worker could read them and thereby gain or reinforce knowledge on recommended case management procedures for children aged under 5 years.
- In-service training for malaria case management (14, 18, 23, 39): Health workers were asked whether they had attended in-service trainings (ISTs) on use of malaria case management. Health

workers who had an in-service training on malaria case management use may be expected to perform better quality treatment compared with those who had not, depending on the quality of the training.

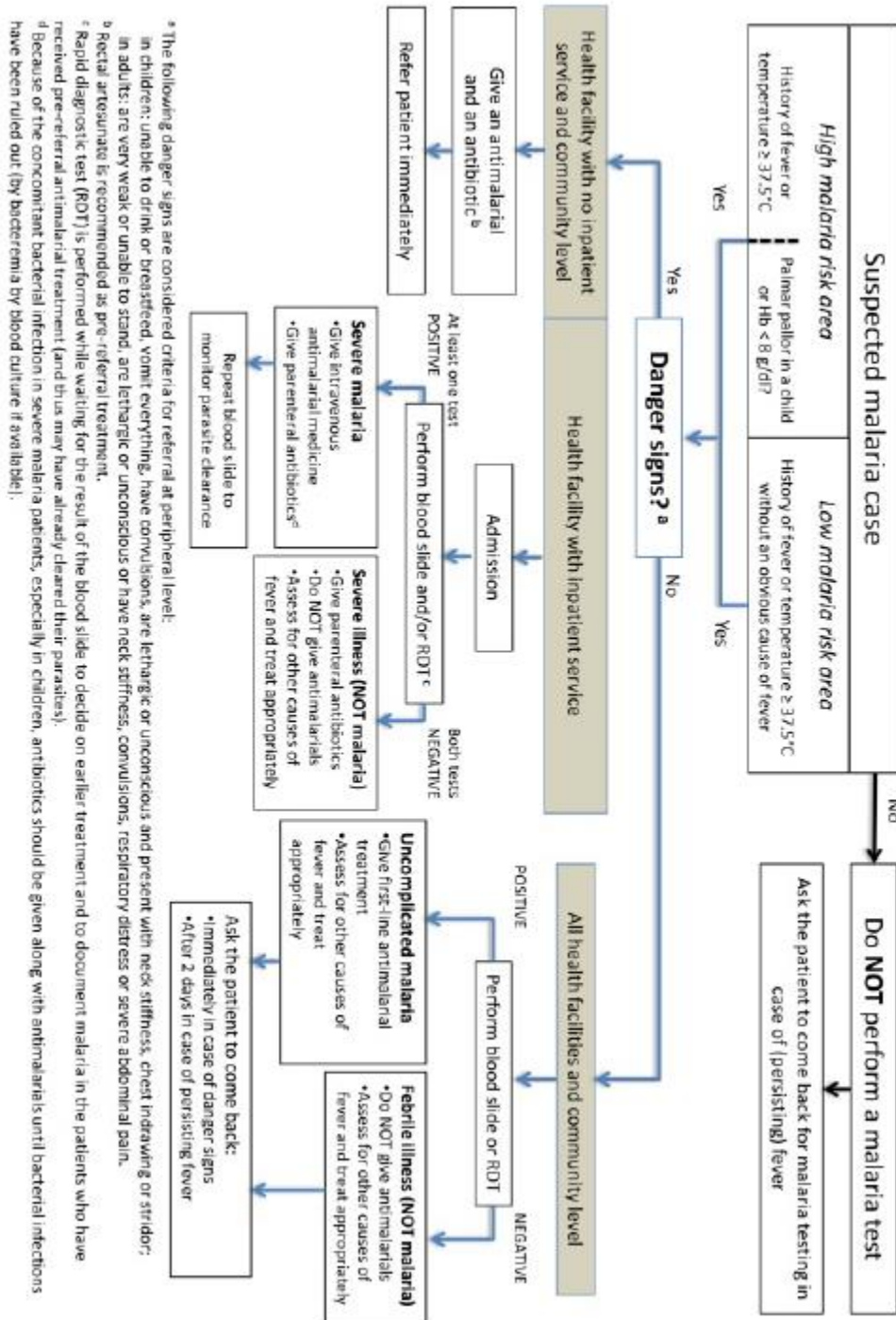
- ACT job aid available: If an ACT job aid were available in the consultation room then the health worker could read them and thereby gain or reinforce diagnostic knowledge on recommended counseling with ACT and thereby improve performance, since most antimalarials prescribed were ACT.
- Malaria case management guidelines available: If malaria case management guidelines were available then there is potential for the health worker to read them and gain better understanding of correct case management procedures.
- Patient age: Malaria diagnosis recommendations in the NMCC guidelines and IMCI guidelines are stratified by age under 5 years and patients aged at least 5 years. Quality of diagnosis may vary according to the patient's age category.
- Malaria endemicity of HF (<5%, ≥ 5 to <25%, $\geq 25\%$ of children aged 2 to 10 years with parasitemia): Endemicity was measured using data from a 2010 Zambia endemicity study by the Malaria Atlas Project (MAP) (26). MAP measured endemicity as the annually averaged infection *Plasmodium falciparum* prevalence in children aged 2 to 10 years old. Using ArcGIS the health facilities in the HF survey study were layered on top of the endemicity map from the 2010 study. The spatial analyst function was then used to extract the nearest endemicity point to each health facility from the survey. MAP calculated the probability distribution of each pixel, each of which corresponds to approximately 1 km². This assumes that the level of endemicity for the health facility locations was the same as endemicity for the areas in which patients attending that health facility resided during the survey period.

- Blood test conducted: A health worker who conducted a diagnostic blood test to test for presence of malaria parasites may be more knowledgeable on case management procedures including counseling antimalarial treatment regimen.

Appendix 5: NMCC algorithm for malaria diagnosis and treatment from protocol
(From 2011 Zambia National Health Facility Survey Protocol)



Appendix 6: NMCC algorithm for malaria diagnosis and treatment from guidelines (from 2014 NMCC case management guidelines)



IV. Factors associated with patient recall of ACT treatment regimen in Zambia

Abstract

Zambia's Ministry of Health (MOH) adopted artemether-lumefantrine (AL) as its first-line antimalarial drug in 2002. It is important for patients to follow the proper antimalarial treatment regimen, especially for AL since in some parts of the world *P. falciparum* is becoming resistant to artemisinin. Better patient or caretaker adherence to drug treatment protocol can help prevent AL drug resistance. Little research has been conducted on factors associated with patient or caretaker understanding of AL treatment regimen. This study aimed to better understand factors associated with patient or caretaker knowledge of AL treatment regimen, and specifically whether this knowledge is associated with quality of counseling by the health worker during fever consultation in primary care facilities in Zambia. Quality of counseling was measured the percentage of six questions or items the health worker completed correctly while counseling patients who had been prescribed AL for malaria. Patient or caretaker understanding of AL treatment regimen was measured as a binary outcome: whether or not they correctly knew all three of the following AL drug regimen elements: how many pills were in one dose; how many doses per day; and how many days to take the antimalarials. Of 319 patients of all ages who were prescribed AL, the percentage who had correct understanding of the treatment regimen was 62% (95% confidence interval: 52% to 72%). A multilevel logistic mixed effects regression was used to determine association of counseling quality and other factors with patient understanding of regimen. Counseling quality was weakly associated ($p=0.54$) with better patient/caretaker understanding of AL treatment regimen. Patient/caretaker having completed secondary school or higher education was associated with better knowledge of treatment regimen (odds ratio=3.2; $p=0.039$) compared with no education. Patients aged under 5 years (odds ratio=4.5, $p<0.001$) and whether the patient was also the respondent (odds ratio=3.3, $p=0.001$) were strongly associated with correct understanding of the ACT treatment regimen. Health workers should ensure that the patient or caretaker understands the

treatment regimen, beyond only explaining the treatment. Verifying the understanding and explaining when to follow up are also important and can help reduce treatment failure due to non-adherence.

1. Introduction

Artemisinin combination therapy (ACT) was adopted in 2002 as Zambia's first-line drug to treat uncomplicated malaria (1-3). Other antimalarials which had been used prior to ACT were chloroquine and sulfadoxine-pyremethamine (SP) (brand name Fansidar™), both of which are now less effective due to parasite resistance (3, 4). Since ACT was adopted as the first-line antimalarial in Zambia, there has been an effort to increase its cost effectiveness by reducing over-prescription. Subsequently, malaria rapid diagnostic tests (RDTs) were integrated into the Zambia National Malaria Control Centre's (NMCC) malaria control strategy in 2003 and were scaled up in a phased approach starting in 2005 (5). There is also a need to ensure that after it has been prescribed to patients diagnosed with malaria, that patients or caretakers follow the correct AL treatment regimen. Parasite resistance to ACT has been detected in Thailand and Cambodia (6), and there is concern that this resistance could spread to other regions including sub-Saharan Africa if AL is overprescribed and misused. A 2014 study of artemisinin resistance in *Plasmodium falciparum* found that between 2011 and 2013, study patients in Africa had parasite half-life clearance rates below 5 hours (7) indicating that artemisinin resistance has not yet arrived in sub-Saharan Africa.

A study in Uganda by Fogg and colleagues (8) found that ACT adherence was high at 90% and was likely to remain so as long as malaria patients receive clear dosing explanations. Lack of formal education was found to be associated with non-adherence to the recommended ACT treatment regimen. Adherence is not a simple matter since the regimen for the formulation used in Zambia is 3 days, twice daily, with evenly spaced dosages to be taken with fatty foods for optimum efficacy. Correct understanding of treatment regimen is therefore an important issue to investigate.

Few studies have been conducted to assess factors associated with ACT adherence at home, nor have studies been conducted assessing factors associated with patient understanding of treatment regimen; no studies in Zambia have been identified on this subject. Data collected in the Zambia 2011 Health Facility Survey can still provide valuable information on factors associated with patient or caretaker understanding of treatment regimen, which is assumed to be associated with adherence to the treatment regimen at home. Since a recent study by Ashley and colleagues (7) showed that artemisinin resistance has not yet been detected in three countries in Sub-Saharan Africa, there is still a high priority on keeping antimalarial resistance from forming and taking root in Zambia. However, high rates of incomplete adherence to the correct AL treatment regimen could lead to treatment failure, which in turn could lead to AL resistance in *P. falciparum*. This study aims to improve understanding of factors associated with patient or caretaker correct knowledge of ACT treatment regimen following fever consultation at a primary care facility. Specifically, this study aims to quantify the association between quality of counseling from the health worker regarding AL treatment, and whether the patient has correct understanding of the AL treatment regimen. The study hypothesis is that higher quality counseling is associated with correct understanding of the AL treatment regimen.

2. Methodology

2.1 Study site, design, data and sample

The Zambian MOH offers free healthcare services for many of its citizens, including children aged less than 5 years, low income families and pregnant women. Nearly 80% of health facilities in Zambia are operated by the Zambian MOH (9). Provincial health offices are responsible for coordinating the activities of the district health offices within each province, although there is more district autonomy since decentralization in the late 1990s. District Health Management Teams (DHMTs) are responsible for coordinating malaria activities such as malaria case management and insecticide-treated net (ITN) distribution. There are three levels of health facilities in Zambia: hospitals, health centers and health

posts. Health centers are meant to serve a population of approximately 10,000 people. Health posts are smaller, more rural facilities which are meant to serve 500 to 1,000 households. Antimalarial drugs are provided free of charge in government health facilities. In 2010 there were 1,882 health facilities in Zambia; of those, 71% are in rural areas (9).

2.2 Study design and sampling methodology

The study design and methodology are described in detail in the research protocol for the 2011 Zambia National Health facility Survey (10). The survey analyzed here was a cross-section study design that used a two-stage cluster survey in which health facilities were the primary sampling unit, with patients clustered at facility level. The facilities were selected from a MOH sampling frame of all 1,882 registered health facilities existing at that time in Zambia. The survey strata were hospital outpatient clinics (n=107); urban health facilities (n=428); rural health facilities (n=1042) and health posts (n=266). Given the large differences in the number facilities of different strata (especially the small number of hospital outpatient clinics), disproportionate stratified sampling was used in order to ensure that an adequate number of HFs in each strata was sampled with adequately precise estimators. The WHO facility survey guide suggests that 25 to 35 facilities per stratum are sampled (11). Intraclass correlation (ICC) is the level of correlation between observations in a cluster; in this context it is the correlation of quality of care for a cluster of patients in a facility. To reduce the ICC and increase precision, the number of observations per facility was limited to 13 and the number of facilities selected for inclusion in the survey was increased, to 37. This number was then adjusted to 42 facilities per stratum assuming that 10% of facilities selected in the sample might not be operational or open at the time of the survey. Systematic random sampling was used to select facilities from each stratum.

The minimum sample size was calculated as 96 observations per stratum, to have a precision of $\pm 10\%$ and 95% level of confidence based on an assumed prevalence of 50% for diagnostic and treatment

parameters based on prior malaria case management research in Zambia (12). To account for the assumed ICC within facilities due to each health worker having some assumed consistency in how they conduct consultations, a design effect of 3.8 was used based on prior research by Rowe and colleagues (13), bringing the observations per strata to 365. The estimated daily caseload per facility was used to calculate the sampling fraction of patients. In low-volume facilities, the survey teams attempted to follow every patient. In high-volume facilities, a sampling fraction of patients was determined using an estimated daily caseload for each high-volume facility, and patients were systematically sampled every 2nd or 3rd patient, depending on patient volume. Case load was calculated as the daily average from the previous 5 work days. Health workers were selected by default by following the patient through the consult.

Included in the survey were 168 primary care facilities, with 225 health workers observed performing consultations on a total of 1,394 patients of all ages. However the dataset analyzed for this study was limited to the 850 patients aged over two months with fever to assess quality of malaria case management; these patients were seen by a total of 204 health workers in 145 primary care health facilities.

This study included the following types of health facility managing authority: government (public), private, and non-governmental organization (NGO)/other. Health workers studied include medical doctor, registered nurse, enrolled nurse, environmental health technician, clinical officer, community health worker and “other”.

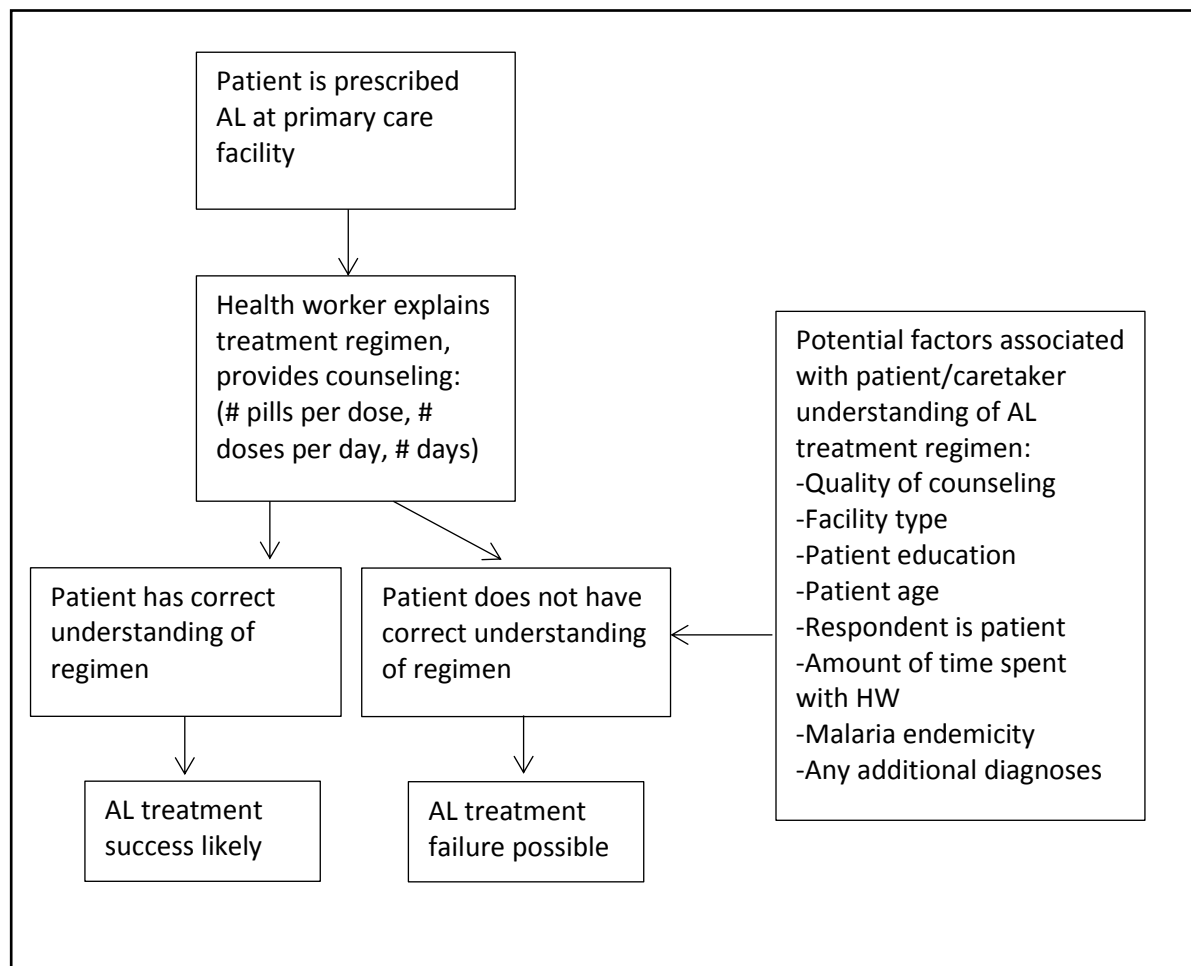
Four questionnaires were used; the first three listed below were paper-based while the health facility audit was administered using a personal digital assistant (PDA). Data from the paper-based forms were entered into computers using Microsoft Access with built-in range and consistency checks.

1. *Observation of outpatient consultations, including assessment of sick patients and case management:* Surveyors observed fever consultations, and noted health worker performance using a case management checklist.
2. *Exit Interview for Patient/Caretaker of Sick Child and Re-Examination:* Patients with fever were interviewed and re-examined by survey clinician. Surveyors used RDTs for the gold standard diagnosis.
3. *Health worker questionnaire:* Health workers who were observed in consultations with sick patients were asked questions regarding their pre-service training, in-service trainings, experience at the health facility, job aid availability, and visits by supervisors. In addition, the health worker malaria case management knowledge is assessed with suspected malaria case scenarios.
4. *Health facility audit:* Stocks of essential medicines, vaccines and supplies were checked for continuous availability on the day of the visit, and for availability during the previous 3 months.

2.3 Conceptual Framework

As seen in the conceptual framework below in Figure 1, this paper is concerned with patients who were prescribed AL in primary care facilities and whether they had correct understanding of the treatment regimen since that could affect whether the treatment is effective or not. The quality of counseling is hypothesized to be significantly associated with whether the patient correctly understands the AL treatment regimen; other factors which may be associated with regimen understanding are listed in the box to the right. If counseling quality is found to be associated with correct patient or caretaker AL regimen understanding, then more efforts could be made by district health management teams to ensure that health workers provide high quality counseling.

Figure 8: Conceptual framework correct AL understanding by patient or caretaker



2.4 Measurement

After the consultation with the health workers, participants were interviewed by a survey clinician and were asked a series of questions on each drug prescribed to the patient. Study participants were either the patient or the caretaker of the patient; patients of all ages were included in this study. For AL, the questions were asked to determine whether the patient understood how many tablets constituted one dose, how many doses per day, and how many days to take the medicine.

The responses were compared with the recommended treatment regimens from the 2010 Zambia NMCC Diagnosis and Treatment Guidelines (14), which have also been used in prior case management studies (2, 10, 15). The standard drug concentration for AL in Zambia is 20mg of

artemether and 120 mg of lumefantrine. The answers were checked against NMCC guidelines for dosing of AL, which is ideally done by patient's weight (see Table 2 below), which was recorded by the health worker and noted by survey staff. An assumption was made that the health worker provided the correct dosing instructions since that information was not available in all cases.

Table 18: AL/Coartem patient dosage table

Body weight	Day 1	Day 2	Day 3
5 to <15 kg	am: 1 tab pm: 1 tab	am: 1 tab pm: 1 tab	am: 1 tab pm: 1 tab
15 to <25 kg	am: 2 tabs pm: 2 tabs	am: 2 tabs pm: 2 tabs	am: 2 tabs pm: 2 tabs
25 to <35 kg	am: 3 tabs pm: 3 tabs	am: 3 tabs pm: 3 tabs	am: 3 tabs pm: 3 tabs
35+ kg	am: 4 tabs pm: 4 tabs	am: 4 tabs pm: 4 tabs	am: 4 tabs pm: 4 tabs

2.5 Analytical strategy

The patient-level outcome variable studied here was binary: whether the patient or caretaker had correct understanding of the treatment regimen. The survey data were clustered, with patients nested in health facility. Accordingly, a logistic multilevel regression model was used, since it was important to allow for differences between health facilities which could not all be controlled for by the facility-level covariates. Random intercepts were used with mixed effects; the fixed effects were the independent variables while the random effect was health facility, and maximum likelihood estimation was used. A likelihood-ratio post-estimation test showed that the data were weakly ($p=0.08$) significantly clustered; therefore, multilevel modeling was retained for this analysis.

2.6 Potential confounding factors

The association between patient or caretaker recall of proper treatment regimen and quality of counseling could be affected by various factors.

1. The level of malaria endemicity in which the health facility is located could affect the patients' or caretakers' recall of treatment regimen. For example, those in hyperendemic areas may already be familiar with the AL treatment regimen from prior experience. This is controlled for in the

model by a variable which measures the level of malaria endemicity in children aged 2 to 10: <5%, 5 to 25% and over 25%.

2. More time spent with a patient in the consultation may allow a fuller patient or caretaker understanding of the malaria treatment regimen, assuming that longer consultation means the patient may have more time during the consultation to ask questions. This was controlled for in the model with a variable which measured the amount of time the patient or caretaker reported having spent in consultation with the health worker. The categories were a) too short; b) short; c) just the right amount of time; d) long; and e) too long.
3. A patient with other illnesses in addition to malaria (coinfection) may be less likely to recall the proper treatment regimen for each illness including malaria. This was controlled for in the regression model with a variable which measured whether the patient had more than one diagnosis by the health worker.
4. If the respondent is the patient, then the patient could be sicker and less able to remember instructions. This is controlled for by a variable which recorded whether the patient was the same person as the respondent in the exit interview.
5. If the patient is aged <5 years then the caretaker may be more attentive to the treatment instructions since the risk of malaria mortality is higher for children in this age group. This is controlled for in the model by patient age under 5 years or 5 years and older.
6. Health facility type could affect the patient or caretaker's understanding of the AL treatment regimen because there may be better quality of care at health facilities which are hospital-associated versus a rural health post. A higher proportion of health posts compared with other types of health facilities have health workers who had no pre-service training. This is controlled for in the model by a variable with the categories hospital, urban health center, rural health center, or health post.

7. Patient's or caretaker's education level can be associated with better health outcomes, and in the regression model this was controlled for by a variable with the following categories: No education, primary school only, and secondary school or higher.

Logistic regression model:

$$\Pr(y_i=1) = \text{logit}^{-1}(\beta_{j(i)} + \beta_1 X_{i1} + \beta_2 X_{i2} + \beta_3 X_{i3} + \beta_4 X_{i4} + \beta_5 X_{i5} + \beta_6 X_{i6} + \beta_7 X_{i7} + \beta_8 X_{i8}) + \varepsilon_i$$

Level of analysis: Patient consultation with health worker, from exit interview.

Where:

y_i = Respondent correct knowledge of ACT treatment regimen: Patient/caretaker displayed correct knowledge (correct definition of one dose, correct number of doses per day, correct total days of treatment) of ACT drug administration instructions from health worker. (Yes, No)

$\beta_{j(i)}$ = Intercept i varying by health facility j

X_1 = Quality of counseling for patients prescribed an ACT (Index ranges from 0 to 100)

X_2 = Health facility type (hospital, urban health center, rural health center, health post)

X_3 = Patient education level (None, Primary school, Secondary school or higher)

X_4 = Patient opinion of amount of time spent with health worker (Too short, Short, Just about right, Long, Too long)

X_5 = Malaria endemicity (5%, 5 to <25%, $\geq 25\%$)

X_6 = Other diagnoses in addition to malaria (Yes, no)

X_7 = Age of the patient (under 5 years, 5 years and older)

X_8 = Exit interview respondent is patient (Yes, no)

The counseling quality index from the first two research questions will be used in this section as the main research variable. The items used to build the counseling index were:

7. Health worker explained the illness to the patient (Y/N)

8. Health worker explained how to administer antimalarials (Y/N)
9. Health worker demonstrated how to administer antimalarials (Y/N)
10. Health worker asked the patient or caretaker a question to verify understanding of the antimalarial drug regimen (Y/N)
11. Health worker explained when to return for follow up (Y/N)
12. Health worker explained under what circumstances to return immediately to health facility (Y/N)

Multilevel logistic regression will be used to test whether there is an association between patient recall and quality of counseling, controlling for covariates. Bivariate analyses will be run to test whether there is an association between control variables and the outcome variable, although the model selection will be based mainly on prior research and *a priori* variable selection.

3. Results

3.1 Descriptive results

Of the 319 patients (or caretakers of patients) who were prescribed AL by the health worker, 222 (62%, 95% CI 52%-72%) demonstrated full correct knowledge of the treatment regimen: number of pills per dose, number of doses per day and number of days of treatment.

Descriptive results for the independent variables are listed below in Table 2.

Table 19: Descriptive statistics of independent variables from regression model

Independent variable	% (n/total)	SE	95% CI
Counseling score	Mean 49.1% (319)	(SD) 26.3	
Health facility type:			
Hospital-associated facility	7.7 (79/319)	1.5	4.6 – 10.8
Urban health facility	23.8 (60/319)	5.6	12.7 – 34.9
Rural health facility	60.6 (114/319)	5.9	48.9 – 72.3
Rural health post	7.9 (66/319)	1.4	5.1 – 10.7

Patient or caretaker education level:			
None	13.7 (55/319)	2.5	8.7 – 18.6
Primary school	55.3 (145/319)	4.5	46.3 – 64.3
Secondary school	24.3 (78/319)	4.1	16.1 – 32.5
College or university	6.7 (41/319)	1.4	38.5 – 95.8
Time spent with health worker			
Too short	15.8 (39/316)	2.9	10.1 – 21.4
Short	40.3 (130/316)	4.3	31.7 – 48.8
Just right	32.9 (100/316)	4.8	23.3 – 42.5
Long	6.1 (26/316)	1.8	2.4 – 9.7
Too long	4.9 (21/316)	1.5	1.9 – 8.0
Malaria endemicity level			
<5%	23.4 (59/319)	8.7	6.2 – 40.6
5% to <25%	44.0 (144/319)	8.5	27.1 – 60.9
>=25%	32.6 (116/319)	8.0	16.7 – 48.4
Patient age			
<5 years	47.9 (147/319)	4.8	38.5 – 57.4
>=5 years	52.1 (172/319)	4.8	42.6 – 61.5
Other diagnosis in addition to malaria			
No	74.9 (237/318)	3.9	67.1 – 82.6
Yes	25.1 (81/318)	3.9	17.4 – 32.9
Patient was respondent			
No	74.9 (220/313)	3.4	68.1 – 81.7
Yes	25.1 (93/313)	3.4	18.2 – 31.9

3.2 Regression results

As seen in Table 2 below, health worker counseling score was marginally significantly associated with patient's understanding ($p=0.095$): for every point increase in counseling score there was association with having a 1% higher odds that the patient had correct understanding of the treatment regimen. Patients in areas with the middle level of malaria endemicity (in which 5 to <25% of children had malaria parasitemia) were associated ($p=0.049$) with being 2.5 times more likely to have correct understanding of the AL treatment regimen. Patients who had the highest level of education (senior secondary school or above) were 4.3 times more likely to have correct understanding of the treatment regimen ($p=0.036$), compared with those who had not completed primary school. Time spent with the health worker was a weakly significant factor: patients who reported that the consultation time was

“long” were 3.2 times more likely ($p=0.071$) to have correct understanding of the treatment regimen, compared with those who said the time spent in consultation was “short”. Caretakers of patients aged under 5 years were highly significantly associated ($p<.001$) with being 5.4 times more likely to have correct understanding of the treatment regimen, compared with patients (or their caretakers) aged at least 5 years. People who were interviewed and were themselves patients were 3.5 times more likely to have correct understanding of the treatment regimen, compared with those who were caretakers and brought the patient ($p=0.003$).

Table 20: Multilevel regression results of understanding treatment regimen

N=308 observations; 99 health facilities

Wald χ^2 (18 df) = 30.57

P=0.0153

Independent variables	OR	SE	Z	P	95% CI	
Health worker counseling score	1.01	0.01	1.67	0.095**	1.00	1.02
Health facility type						
Reference category: Hospital clinic						
Urban health center	0.60	0.32	-0.94	0.347	0.21	1.73
Rural health center	0.53	0.25	-1.33	0.184	0.21	1.35
Health post	0.57	0.30	-1.06	0.288	0.20	1.62
Patient/caretaker education completed						
Reference category: no education						
Primary school	1.50	0.62	0.98	0.325	0.67	3.36
Junior secondary school	2.11	1.03	1.54	0.125	0.81	5.47
Senior secondary/College/university	4.30	2.99	2.10	0.036**	1.10	16.80
Time spent with health worker						
Reference category: short						
Too short	1.25	0.62	0.45	0.650	0.48	3.29
Long	3.22	2.08	1.81	0.071	0.90	11.45
Too long	1.08	0.68	0.12	0.901	0.31	3.73
Just about right	1.36	0.49	0.86	0.388	0.67	2.76
Malaria endemicity						
Reference category: <5%						
5 to <25%	2.49	1.15	1.97	0.055*	1.01	6.18
≥25%	1.70	0.87	1.05	0.395	0.63	4.62
Patient aged under 5 years	5.39	2.11	4.29	0.000**	2.50	11.62
Additional diagnosis	0.85	0.29	-0.49	0.624	0.44	1.64
Brought self to facility	3.54	1.49	3.02	0.003**	1.56	8.06
Intercept	0.22	0.16	-2.12	0.034	0.05	0.89

* P<0.1

**P<0.05

4. Discussion

In this study we assessed the association between quality of counseling and the patient or caretaker's understanding of the treatment regimen, controlling for other factors using data from the 2011 Zambia National Health Facility Survey. The health worker's counseling quality score was positively associated with patient or caretaker's understanding of the treatment regimen (p = 0.056). This finding

support the study hypothesis that better quality of counseling is associated with better comprehension of the treatment regimen, and indicates that counseling is an important facet of malaria case management. In addition, patients who reported that the time spent with the health worker in consult was “long” more likely to have a better understanding of the treatment compared with those who said the consult time was “short”. Longer time in consultation has been associated in prior research with higher quality of care (16, 17), which makes sense programmatically since more time with the health worker increases the opportunity for the health worker can clarify the treatment regimen.

Consultations in areas of medium malaria endemicity (ranging from 5 to <25% of children aged 2 to 10 with parasitemia) were associated ($p=0.013$) with higher patient understanding of the treatment regimen compared with those at the lowest endemicity level (<5%). It is possible that patients or caretakers in this level of endemicity are familiar with the treatment regimen already since they may have had experience with going to the facility with malaria in the past. AL has been the first-line antimalarial drug in Zambia since 2002, and over the 9 years between AL introduction and the facility survey it is possible that people in mesoendemic areas are more familiar with the treatment regimen.

The factor most highly associated ($p<.0001$) with correct caretaker understanding of treatment regimen was age of patient being under 5 years. Children in this age category are at the highest risk of dying from malaria and their caretakers may subsequently be more attentive to the instructions provided by the health worker compared with patients (or their caretakers) aged at least 5 years. Patients who had brought themselves as opposed to being caretakers were also more likely to have correct treatment understanding ($p=0.001$); possibly people are more keen to understand the correct treatment when their own health is in question.

5. Limitations

There were several limitations in this study. The observation of the health workers by survey staff may have created a Hawthorne effect, in which the observation caused a change in behavior by the health worker, resulting in either better or worse case management than if the health worker were not being studied.

It is difficult to understand associations between health worker performance and certain interventions meant to improve performance using a cross-sectional survey. A panel data study for example would allow study of change before and after these interventions. There may have been recall bias in the patient exit interview and during the health worker interview.

This survey is representative only of malaria case management for the 50% of fever patients who seek treatment at a health facility (18). The systems effectiveness approach used by Littrell et al (2013) takes this into account.

6. Conclusions

Counseling quality is associated with patient's understanding of treatment regimen; therefore, counseling should be considered an important element of malaria case management. If patient understanding of AL treatment regimen is associated with better adherence and lower resistance, then malaria program managers in Zambia should support higher quality counseling by health workers and highlight the importance of counseling quality in the NMCC case management guidelines. Patients or caretakers with little or no education should receive extra counseling instructions from the health worker. The health worker should verify patients' understanding of the treatment regimen and provide any corrective explanations if the patient or caretaker has a misunderstanding.

7. Bibliography

1. J. Miller, L. Rosencrans, Ed. (2014).
2. *Guidelines for the diagnosis and treatment of malaria in Zambia* (2010).
3. D. H. Hamer *et al.*, Improved diagnostic testing and malaria treatment practices in Zambia. *JAMA* **297**, 2227-2231 (2007).
4. M. Mulenga *et al.*, Safety and efficacy of lumefantrine-artemether (Coartem) for the treatment of uncomplicated *Plasmodium falciparum* malaria in Zambian adults. *Malar J* **5**, 73 (2006).
5. D. Zurovac *et al.*, Paediatric malaria case-management with artemether-lumefantrine in Zambia: a repeat cross-sectional study. *Malar J* **6**, 31 (2007).
6. M. Littrell *et al.*, Case management of malaria fever in Cambodia: results from national anti-malarial outlet and household surveys. *Malar J* **10**, 328 (2011).
7. E. A. Ashley *et al.*, Spread of artemisinin resistance in *Plasmodium falciparum* malaria. *N Engl J Med* **371**, 411-423 (2014).
8. C. Fogg *et al.*, Adherence to a six-dose regimen of artemether-lumefantrine for treatment of uncomplicated *Plasmodium falciparum* malaria in Uganda. *Am J Trop Med Hyg* **71**, 525-530 (2004).
9. *Malaria Operational Plan Zambia 2012* (2011).
10. M. Ndholu, "Zambia National Health Facility Survey 2011: Evaluation of the quality of malaria-related care for outpatients," (National Malaria Control Centre, Lusaka, Zambia, 2013).
11. *Health Facility Survey: Tool to evaluate the quality of care delivered to sick children attending outpatients facilities* (2003).
12. Z. MOH, "Zambia National Malaria Indicator Survey 2010," (Zambian Ministry of Health, National Malaria Control Program, 2010).
13. A. K. Rowe, F. Onikpo, M. Lama, M. S. Deming, Risk and protective factors for two types of error in the treatment of children with fever at outpatient health facilities in Benin. *Int J Epidemiol* **32**, 296-303 (2003).
14. *Guidelines for the Diagnosis and Treatment of Malaria in Zambia* (2010).
15. A. K. Rowe *et al.*, Quality of malaria case management at outpatient health facilities in Angola. *Malar J* **8**, 275 (2009).
16. S. E. Nsimba *et al.*, Case management of malaria in under-fives at primary health care facilities in a Tanzanian district. *Trop Med Int Health* **7**, 201-209 (2002).
17. J. Eriksen *et al.*, Assessing health worker performance in malaria case management of underfives at health facilities in a rural Tanzanian district. *Trop Med Int Health* **12**, 52-61 (2007).
18. M. Littrell *et al.*, Documenting malaria case management coverage in Zambia: a systems effectiveness approach. *Malar J* **12**, 371 (2013).

V. General Conclusions

The findings in this study indicate that there is less association among the malaria case management quality indices than was originally hypothesized. Considering this, building and using a summary malaria case management index would be inadvisable. A summary index should only be used if the components used to build it are significantly associated with each other, otherwise it would be inappropriate to use for analysis.

Health worker training and supervision should focus on all four components of malaria case management. Assessment and counseling are two areas in which most health workers underperformed. During assessment, health workers should check for danger signs and differential diagnoses, rather than only focusing on the fever itself and testing for malaria. In areas of lower malaria endemicity especially, there may be other causes of fever which should be investigated, for patients of all ages. During counseling, health workers should check to ensure that the patient or caretaker understands the correct treatment regimen; that ACT should be taken with fatty foods; and the caretaker understands when to return for a follow up visit. Health worker performance on diagnosis can be targeted for improvement; when a diagnostic test is available it should always be used, and the health worker should adhere to the test results for the diagnosis. Malaria treatment, which is being performed relatively well with 90% correct treatment rate, can be further improved by ensuring that the only patients receiving SP are children weighing under 5 kg, and that ACT stock-outs are kept to a minimum.

Clearer malaria case management guidelines which were produced and distributed in late 2014 have potentially enabled improvements in health worker performance. Supervisors can also be trained to more frequently observe case management during supportive supervision visits and provide effective feedback where needed. Supervisors would benefit from refresher trainings on proper malaria case management. In-service trainings for health workers and job aids could also benefit health worker performance, if the guidelines are clear and concise.

Counseling quality is associated with patient's understanding of treatment regimen; therefore, counseling should be considered an important element of malaria case management. If patient understanding of AL treatment regimen is associated with better adherence and lower resistance, then malaria program managers in Zambia should support higher quality counseling by health workers and highlight the importance of counseling quality in the NMCC case management guidelines. Patients or caretakers with little or no education should receive extra counseling instructions from the health worker. The health worker should verify patients' understanding of the treatment regimen and provide any corrective explanations if the patient or caretaker has a misunderstanding.

High quality malaria case management is an important component of malaria control in Zambia. Determining which factors are associated with quality of malaria assessment, diagnosis, treatment and counseling can help the Zambia NMCC to identify programmatic areas on which to focus for improvement, and also identify areas which have been successful and therefore should continue. Nationally representative health facility surveys can provide valuable information for program improvement and can also be analyzed together with household surveys to better understand issues of health care access especially in resource-poor areas. Malaria endemicity, supervision, health facility type, health facility managing authority, and availability of IMCI guidelines and RDT job aids were all identified as statistically significant factors associated with quality of malaria case management in Zambia. The main research variable, supervision, was found to have had no association with quality of diagnosis and treatment, a negative association with assessment quality, and a weak negative association with counseling quality. However, reduced versions of the assessment and counseling indices were found to be positively and significantly associated with supervisions. Indices which are comprised of numerous variables, even if confirmed as statistically valid by principle components factor analysis, may be too complex to use as regression model outcomes. Periodic nationally representative

health facility surveys can provide important data to observe change over time in factors associated with malaria case management, allowing for more in-depth decision-making by malaria program managers.