



# THE INSCALE BASELINE SURVEY MOZAMBIQUE

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## **inSCALE – Innovations at Scale for Community Access and Lasting Effects**

The inSCALE programme, a collaboration between Malaria Consortium, London School of Hygiene and Tropical Medicine (LSHTM) and University College of London (UCL), aims to increase coverage of integrated community case management (ICCM) of children with diarrhoea, pneumonia and malaria in Uganda and Mozambique. inSCALE is funded by Bill & Melinda Gates Foundation and sets out to better understand community based agent (CBA) motivation and attrition, and to find feasible and acceptable solutions to CBA retention and performance which are vital for successful implementation of ICCM at scale.

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## 2 Glossary of Terms

**APE:** Agentes Polivalentes Elementares (CHW)

**CHW:** Community-based Health Worker

**CIDA:** Canadian International Development Agency

**CV:** Coefficient of variation

**DMEC:** Data Management and Ethics Committee

**EFA:** Exploratory Factor Analysis

**ENC:** Essential Newborn Care

**FDP:** Child with any of fever, diarrhoea (watery), or pneumonia

**iCCM:** Integrated Community Case Management of malaria pneumonia and diarrhoea

**IMCI:** Integrated Management of Childhood Illness

**InSCALE:** Innovations at Scale for Community Access and Lasting Effects

**RA:** Fieldwork Research Assistant

**RCT:** Randomised Controlled Trial

**RDT:** Rapid Diagnostic Test for malaria

**Stock-out:** the CHW ran out of any items (drugs, RDTs, respiratory rate timers) used in the diagnosis or treatment of fever, diarrhoea or pneumonia within the past 3 months.

**TAG:** Trial Advisory Group

## 3 Executive Summary

### 3.1 Project Rationale

The inSCALE project aims to show that by the use of best practices and innovative means, government-led integrated community case management programmes (iCCM) in Uganda and Mozambique can be rapidly driven to scale with high quality, leading to a sustained increase in the proportion of sick children receiving appropriate treatment for fever, diarrhoea and pneumonia.

**Background:** iCCM programmes utilize community health workers (CHWs) to promote healthy family practices in their local communities and to treat children under 5 years with diarrhoea, malaria and pneumonia.

Programmes involving CHWs can play an important role in closing the gap in access to adequate health care in poor and/or rural communities. In Mozambique CHWs, known as “*agentes polivalentes elementares*” (APEs), have been in existence since the late 1970s, however in its initial stages the quality and coverage of the APE programme was at best inconsistent (MOH 2010). In 2007 at the Mozambique Ministry of Health National Meeting on Community Involvement for Health, renewed momentum for the APE strategy led to a revitalisation of the programme. In 2010 a Malaria Consortium-Canadian International Development Agency (MC-CIDA) partnership was formed to implement an APE-led iCCM programme in the Inhambane region of the country. Operationalised through the Ministry of Health, this partnership was set up to train APEs in the management of childhood fever diarrhoea and pneumonia and provide them with the tools (diagnostic and treatment) to carry out this task. Whilst CHW programmes can be successful in increasing access to essential health care services, there are often reports of high rates of CHW attrition during the lifetime of a programme, due to in part to lack of adequate CHW supervision and support (Nkonki et al 2011). Lack of supervision and support can also impact on the performance of CHWs. These factors lead to decreased functionality of community based workers in the community and ultimately impact on the coverage of appropriately treated sick children.

**The inSCALE Project:** The inSCALE project team have developed an innovative mHealth intervention to improve APE performance and motivation in Mozambique, which we hope will lead to increased rates of appropriate treatment of children with fever, diarrhoea and pneumonia. The intervention is based on the provision of mobile phones and accessories to APEs and their health facility supervisors allowing them to contact each other free of charge, to use specially designed ‘apps’ on the phones to aid in diagnosis and treatment of sick children and in the submission of weekly activity data. APEs also receive motivational messages and targeted feedback from supervisors based on their weekly submitted reports.

The inSCALE project will be evaluated using a cluster randomised controlled trial involving 12 districts, 6 intervention and 6 control, in the Inhambane region of Mozambique. The trial will compare the percentage of children receiving appropriate treatment for fever, diarrhoea and pneumonia in the inSCALE technology-based intervention areas compared to those areas which will receive routine iCCM (‘control’ clusters).

**The Baseline Survey:** In order to minimise the effect of any chance imbalance between control and intervention arms in the percentage of appropriately treated children and other important indicators



at the beginning of the evaluation period, a baseline survey was conducted to collect illness, treatment and cost data from the included communities to inform the cluster level restricted randomisation and endline analysis.

**This document reports the results of this baseline survey for the inSCALE project in Mozambique.**

### **3.2 Methods**

The inSCALE Mozambique baseline survey and data analyses were conducted over the period September 2012 - December 2013. During the field survey, 2-8 government defined enumeration areas (EAs) containing active iCCM APEs were randomly selected within each of the 12 study districts. All households were visited in each EA. Where households included children under 5 years of age, data were collected on factors including household demographics, child illnesses in the past two weeks, care seeking, drug treatments, and awareness of the APE/iCCM programme. Baseline data was also collected on all the iCCM-trained APEs in the districts, and contained questions on drug stock levels, APE motivation, and knowledge of the correct management of fever, diarrhoea and pneumonia. Additional data was collected from APE supervisors at health facilities on facility-based treatment of sick children, and stocks of essential drugs/diagnostic equipment. All data were double entered and subject to consistency checks. Data were analysed and shared with the inSCALE technical management team for recommendations and inputs into the final analyses and this report.

### **3.3 Survey Outcomes**

Within the 12 study districts, a total of 2970 households with 4422 children between the ages of 2 months and 5 years of age were sampled. Data were also collected from 256 iCCM-trained APEs and the 80 health facilities to which they reported. Overall 32% of children had had symptoms of fever diarrhoea or pneumonia (FDP) in the two weeks prior to the survey.

**Prevalence of illness:** In the two weeks prior the interview 29% of children in the sample had had an episode of fever, 5% had had diarrhoea and 11% had had symptoms of pneumonia. Malaria was confirmed in 67% of cases of fever where a blood test was performed (blood tests were conducted in only 31% of cases of fever).

**Care seeking:** The majority of children with FDP were taken to a public health facility (53%), very few (0.2%) consulted a private clinic or doctor. The next most frequent choice was the APE (23%). Few caretakers reported seeking care at a pharmacy or herbalist (1% for both). No care outside the house was sought for 25% of children.

**Appropriate treatment:** At the time of the survey, APEs had been trained in iCCM but had not yet been provided with iCCM kits containing treatment and diagnostic materials, thus treatment data in this report does not reflect the status of appropriate treatment in the full iCCM context. Nonetheless we found that 28% of children with fever were appropriately treated with ACTs (rising to 89% where malaria was confirmed by blood test), 50% received ORS for diarrhoea but only 3% received both ORS plus zinc. 23% received an appropriate antibiotic for pneumonia. There was little variation between the rates of appropriate treatment received from the two main care providers (public facilities and APEs).

**Cost of care seeking:** Direct care seeking costs (including fees, prescriptions, transport, etc) were highest for those visiting private facilities (median cost USD 4.4). Those seeking care to traditional healers and pharmacies also incurred higher costs (up to 36 USD). On average, no costs were incurred by visiting an APE. The median cost of care seeking to public facilities was minimal at USD 0.04.

**Awareness of APE activities in the community:** 92% of households visited knew their local APE. 23% of households surveyed had been visited by an APE in the past month for any reason. APEs undertook a range of activities on their visits including providing health advice and observing family health practices.

**APE supervision and workload:** 72% of APEs reporting having had 3 or more supervision meetings with their health facility supervisors. APEs saw on average 17 children in the two week period preceding the interview (ranging from 13 to 29 children between districts).

**APE performance:** APE knowledge on the correct management and treatment of FDP was tested through their answers to a series of hypothetical scenarios involving sick children (vignettes). Out of a maximum of 58 available points, APEs scored a median of 22 (IQR 14.5-28.5). It is likely that this average performance score will improve once the iCCM programme is fully operational (i.e. when APEs have had significant experience using the drugs and diagnostic tools provided in the iCCM kits).

**APE motivation:** Field staff additionally administered a motivation measuring tool to all APEs in the survey. Data from the tool was used to rank APEs from 100-1 as most motivated (=100) to least motivated (=1). Motivation varied significantly by district (range 21-84).

**Health facilities in the study site:** There are 80 facilities in the study area with responsibility for training and supervision of APEs. The majority (93%) of the health facilities are health centres (mid-level facilities). Only staff at 1 hospital and 5 health posts have supervisory roles in the APE programme.

**Appropriate treatment in health facilities:** All (100%) of health facilities which had had a case of malaria in a child under 5 years in the previous two weeks had provided appropriately treatment (data collected directly from hospital records). In total, 90% provided appropriate treatment for diarrhoea (falling to 6% if zinc was included in the definition of appropriate treatment), and 87% of health facilities appropriately treated cases of pneumonia. These figures were higher than the rates reported in the communities even accounting for those who did not visit a public facility/did not seek care at all.

**Drug stock outs in health facilities (in previous quarter):** Facilities reported highest stock outs for amoxicillin (53%-70% in capsule and suspension form respectively), followed by coartem (18% and 32% for the blue and yellow capsules respectively) and the lowest overall for ORS (20%). As the majority of facilities did not routinely use or store zinc for the treatment of diarrhoea this was not included in the analysis of stock outs.

### **3.4 Summary**

This survey indicates a high community awareness of the APE programme and provides promising data on the functionality of the programme. However, further investigation will be necessary to assess the impact of full iCCM implementation on the prevalence of appropriately treated children. Additionally, data collected on cluster size, disease prevalence, care seeking and APE motivation allowed us to i) ensure intervention arms would be balanced according to these parameters during the restricted randomisation process and ii) improve the accuracy of estimates of the sample size needed to evaluate the effect of the intervention on appropriate treatment in the community.

## **4 Baseline Report**

### **4.1 Introduction**

This report presents data from the InSCALE Baseline Survey in Mozambique in 2012. It contains a short background section followed by the results of the analysis of the baseline survey data, including the key indicators used to ensure balance for the randomisation of the study clusters into intervention and control arms. Details of field activities, data management and analysis methods used are provided in the appendices at the end of the report.

#### **4.1.1 The APE Strategy and the iCCM Programme in Mozambique**

Agentes Polivalentes Elementares (APEs – ‘basic polyvalent agents’ or community health workers (CHWs)) have been in existence in Mozambique since the late 1970s. The APE programme was developed to provide health promotion and disease prevention activities at the community level, as well as providing first aid and referral services for sick community members (MoH 2010). The early APE system faced several key difficulties leading to at various times suspension of the programme (particularly during the protracted civil war throughout the 1980s and early 1990s), deficiencies in support at all levels and deficiencies in manpower needed to sustain the programme (MoH 2010). In 2007 a Mozambique Ministry of Health National Meeting on Community Involvement for Health led to a renewed commitment to the APE programme. In 2010, a policy of integrated community-based management of childhood illnesses (iCCM) was adopted by the Ministry of Health Mozambique (MoH) which allowed APEs to manage non-severe cases of fever, diarrhoea and pneumonia (FDP) in the community according to iCCM guidelines developed by the WHO (these guidelines build on the WHO facility-based Integrated Management of Childhood Illness strategy (WHO/UNICEF 2011), where funding was available. APEs would additionally receive monthly remuneration at 60% of the national minimum wage (~\$70). In the Inhambane region of Mozambique, the Malaria Consortium has secured funding through the Canadian International Development Agency (CIDA) to train APEs in iCCM and supply them with iCCM materials. This includes provision of an APE iCCM ‘kit’ containing rapid diagnostic tests (RDTs) for malaria, respiratory timers, supplies of artemether/lumefantrine (20mg/120mg tablets), amoxicillin (125mg dispersible tablets), low osmolarity ORS, zinc (20mg tablets) and rectal artesunate (50mg). The APEs also receive a job aid containing the iCCM diagnosis and treatment algorithms, and a register for recording the nature and frequency of all programme-related activities they undertake. APEs in the study were trained through this CIDA-MoH initiative in 2011 and 2012, and received kits at the end of 2012.

#### **4.1.2 The inSCALE Project**

Whilst CHW programmes can be successful in increasing access to essential health care services, there are often reports of high rates of CHW attrition during the lifetime of a programme. This is thought to be in part due to a lack of adequate CHW supervision and support for the workers (MoH 2010, Nkonki et al 2011). Lack of supervision and support can also impact on the performance of CHWs and ultimately on the coverage of appropriately treated sick community members. In light of this, the inSCALE project in Mozambique has developed an innovative approach to improve APE performance and motivation which we hope will lead to increased rates of appropriate treatment of children with diarrhoea, malaria and pneumonia.

**The inSCALE mHealth platform:** The inSCALE mHealth platform is a mobile phone and technology-based intervention intended to strengthen CHW performance, supervision and peer support networks. CHWs are provided with mobile phones and accessories which allow frequent feedback to and support from their CHW supervisors (who are also supplied with phones), district health teams and other CHWs free of charge. APEs can also take advantage of the inSCALE 'app' installed on the phone with algorithms and tools for the diagnosis and treatment of fever, diarrhoea and pneumonia. It is intended that this mHealth system will promote the connectedness of APEs to the health system, improve APE performance, lead to an increase in the frequency and quality of contact between the CHW and their supervisor and peers, and enhance the status of the CHW in their community.

The principal objective of the inSCALE programme is to demonstrate that government led Integrated Community Case Management (ICCM) programmes can be rapidly driven to scale with quality, leading to a sustained increase in the proportion of sick children receiving appropriate treatment. Objective two of the project is to evaluate the effectiveness and cost-effectiveness of the addition of this complementary mHealth strategy to the iCCM programme, in comparison to routine ICCM implementation. InSCALE will specifically test the effectiveness of the innovation using a two armed cluster randomised controlled trial in 12 districts in the Inhambane region of Mozambique (Funhalouro, Govuro, Homoine, Inharrime, Inhassouro, Jangamo, Mabote, Massinga, Morrumbene, Panda, Vilankulo, and Zavala). The intervention will be evaluated based on the number of children who receive appropriate treatment for fever, pneumonia and diarrhoea; factors that affect motivation, retention and coverage of community based workers will also be considered.

#### **4.1.3 The Baseline Survey**

The baseline survey was carried out primarily to provide the study with robust estimates of the proportion of children between the ages of 2 months and 5 years currently receiving appropriate treatment for fever, pneumonia and diarrhoea, irrespective of care provider within the context of the recently implemented routine iCCM programme and before the implementation of the mHealth intervention. Baseline levels of appropriate treatment were assessed to ensure comparability of the trial arms in terms of key factors during the restricted randomisation process and to allow for the adjustment of the trial sample size if necessary.

Due to a delay in the procurement of iCCM materials, APEs did not receive kits containing iCCM drugs and materials until near the end of the baseline survey period (end of October 2012). Because of this, appropriate treatment of children could not be reliably measured within the full routine iCCM context. Proxy indicators of appropriate treatment were explored as alternatives for use in the restricted randomisation, and the results of this investigation are presented in this report.

#### **4.1.4 Baseline Indicators**

Data were collected from three source groups, households, CHWs, and health facilities, using a tailored questionnaire tool for each group. Details of the survey tools are provided in Appendix section 5.2.

## 4.2 Household Survey

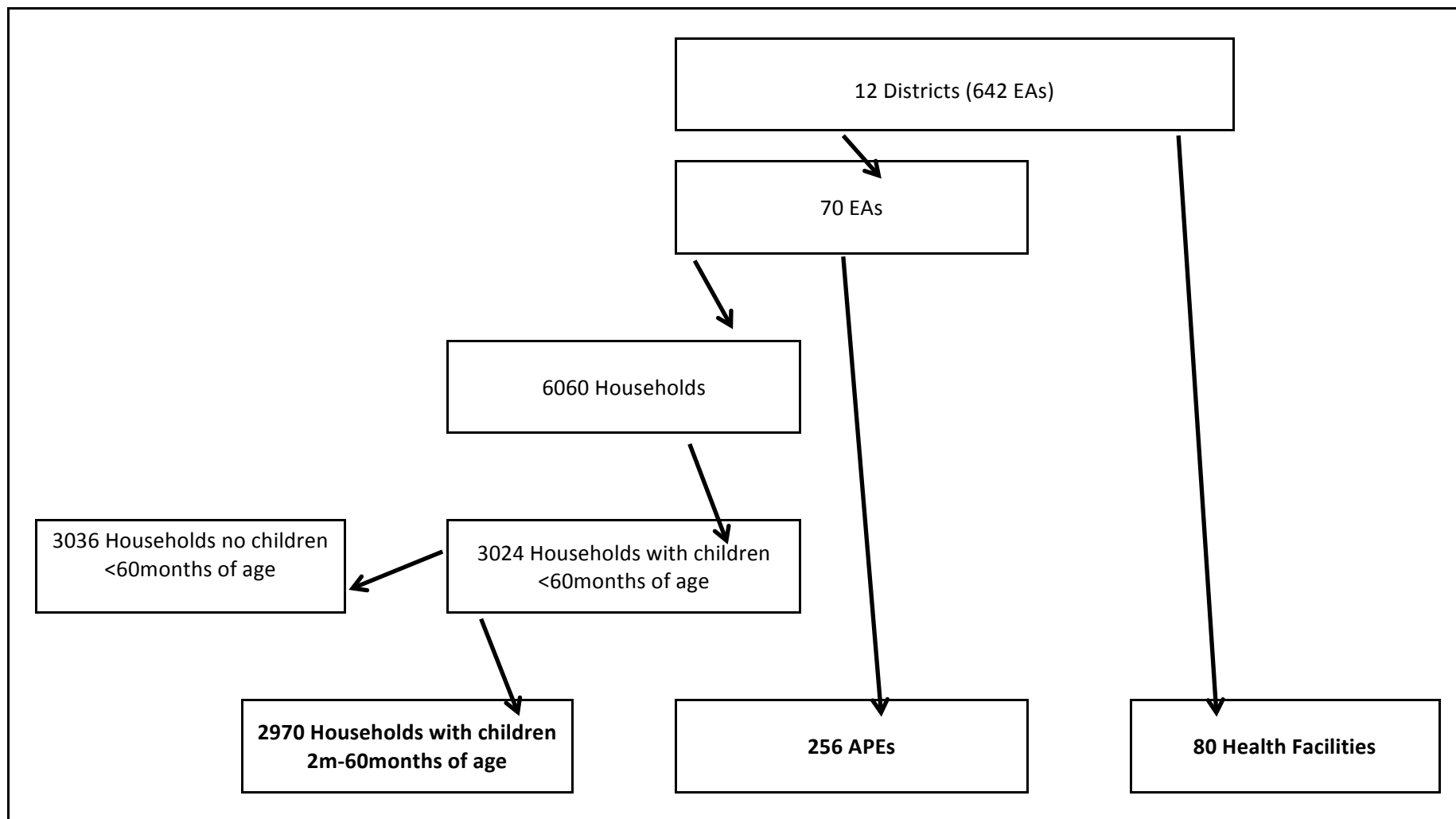
### 4.2.1 Survey sample

Data collection took place from 17<sup>th</sup> Sept – 15<sup>th</sup> November 2012. The study was conducted in 12 districts. Within the 12 study districts, a total of 2970 households with 4422 children between the ages of 2 months and 5 years of age were sampled across 70 randomly selected government defined enumeration areas (from a total of 642 possible EAs) . Data were also collected from 256 iCCM-trained APEs and the 80 health facilities to which they reported. The overall sampling profile is outlined in the flow chart below (Figure 1). Table 1 provides a breakdown of the number of children sampled per district and the numbers of these with any of fever diarrhoea or pneumonia (FDP) in the two weeks preceding the survey (overall 32% of children had FDP).

TABLE 1 NUMBER OF CHILDREN SAMPLED PER CLUSTER (DISTRICT) AND NUMBERS OF CHILDREN WITH EITHER OF FEVER, DIARRHOEA OR PNEUMONIA.

District	total no. children		no. children FDP	
	freq	% by total children	freq	% by district
FUNHALOURO	404	9.14	147	10.54
GOVURO	464	10.49	120	8.6
HOMOINE	362	8.19	109	7.81
INHARRIME	475	10.74	141	10.11
INHASSOURO	341	7.71	116	8.32
JANGAMO	286	6.47	82	5.88
MABOTE	509	11.51	177	12.69
MASSINGA	206	4.66	63	4.52
MORRUMBENE	272	6.15	83	5.95
PANDA	303	6.85	100	7.17
VILANKULO	284	6.42	84	6.02
ZAVALA	516	11.67	173	12.4
<b>TOTAL CHILDREN (N)</b>	<b>4422</b>		<b>1395</b>	

FIGURE 1 FLOW CHART OF DATA TOTALS AND SOURCES OF DATA COLLECTED AS PART OF THE INSCALE BASELINE SURVEY IN MOZAMBIQUE





#### 4.2.2 Household demographic data

Full demographic details of the primary caretaker were available for 4394 of the children (99%) and in cases where the caretaker was not the head of the household, 1577 (or 76%) of children (Table 2)

TABLE 2 DEMOGRAPHIC INFORMATION OF CARETAKERS AND HEADS OF HOUSEHOLDS (ONLY THOSE WHO WERE NOT PRIMARY CARETAKERS) OF CHILDREN IN THE STUDY SITE

Parameter	caretaker		household head	
	freq	%	freq	%
<b>age group (yrs)</b>				
<20	132	3.0	1	0.06
20-29	1146	26.1	264	16.74
30-39	1121	25.5	379	24.03
40-49	722	16.4	229	14.52
50+	763	17.4	199	12.62
not known	510	11.6	-	-
<b>education (level completed)</b>	freq	%	freq	%
no education	1650	37.6	407	25.8
some primary or above	2737	62.3	1170	74.2
not known	7	0.2	-	-
<b>occupation</b>	freq	%	freq	%
salaried worker (public or private)	143	3.3	396	25.11
farmer or fisherman	3099	70.5	428	27.14
works in own house	694	15.8	109	6.91
unemployed	46	1.1	18	1.14
Other*	412	9.4	626	39.7
<b>ethnicity</b>	freq	%	freq	%
bitonga	395	8.99	170	10.78
citsua	2,774	63.13	1,086	68.86
cichopi	901	20.51	264	16.74
other	324	7.37	57	3.61
<b>Marital status (caretaker)</b>	freq	%	freq	%
single/widowed	638	14.5		
married/living with partner	3568	81.2	-	-
separated/divorced	188	4.3		
<b>Gender</b>	freq	%	freq	%
Female	2978	67.8	100	6.3

\*Heads of household in 'other' category: majority in this category worked in casual labour market (44%) or were self-employed (31%)

*Demographic information continued*

<b>Relationship of respondent to children in household</b>	freq	%	freq	%
mother	3572	81.3	n/a	n/a
father	129	2.9		
sibling	22	0.5		
aunt/uncle	98	2.2		
grandparent	516	11.7		
other	57	1.3		
<b>Relationship of respondent to household head (n=4386)</b>	freq	%	freq	%
respondent was HoH	2339	53.3	n/a	n/a
spouse	1738	39.6		
other/not related	309	7.05		

Of the households in the study area, all used firewood as their main source of fuel (100%), mainly relied on a well as their main source of water for the household (52%), and a pit latrine for human waste (61%). An overall index of household 'wealth' was created by combining this information with a range of additional data on household assets including information on house construction materials, ownership of household items including electrical goods, and ownership of land and/or animals. Households were ranked into quintile groups based on their asset scores (the higher the individual score, the higher the perceived wealth) relative to other households. Details of the development of the full asset index are presented in (Section 455.3). Information on direct cash income was also collected during the survey.

HOUSEHOLD ASSET DATA WERE AVAILABLE FOR ALL OF THE 1395 HOUSEHOLDS WITH ILL CHILDREN, WHILST HOUSEHOLD CASH INCOME DATA WERE AVAILABLE FOR 1155 OF THE HOUSEHOLDS WITH ILL CHILDREN. GIVES ONLY PARTIAL INFORMATION ABOUT INCOME BRINGING ACTIVITIES IN A SETTING DOMINATED BY ACTIVITIES, HOWEVER IT IS A USEFUL INDICATOR OF AVAILABLE INCOME WHICH IS ESSENTIAL AT TIMES OF ILLNESS. OF RESPONDING HOUSEHOLDS, 54% REPORTED A MONTHLY CASH INCOME OF MZN 1,000 (USD 36) LESS; 8% OF ALL HOUSEHOLDS REPORTED NO CASH INCOME AT ALL (FIGURE 2

).

The proportion of household with a monthly cash income of MZN 1,000 or less ranged from 35% (in Inhassoro) to nearly 70% (in Inharrime) across districts. Zavala, Mabode and Inharrime had the highest share of households reporting that they did not have any cash income at all.

FIGURE 2 HOUSEHOLD MONTHLY CASH INCOME BY DISTRICT

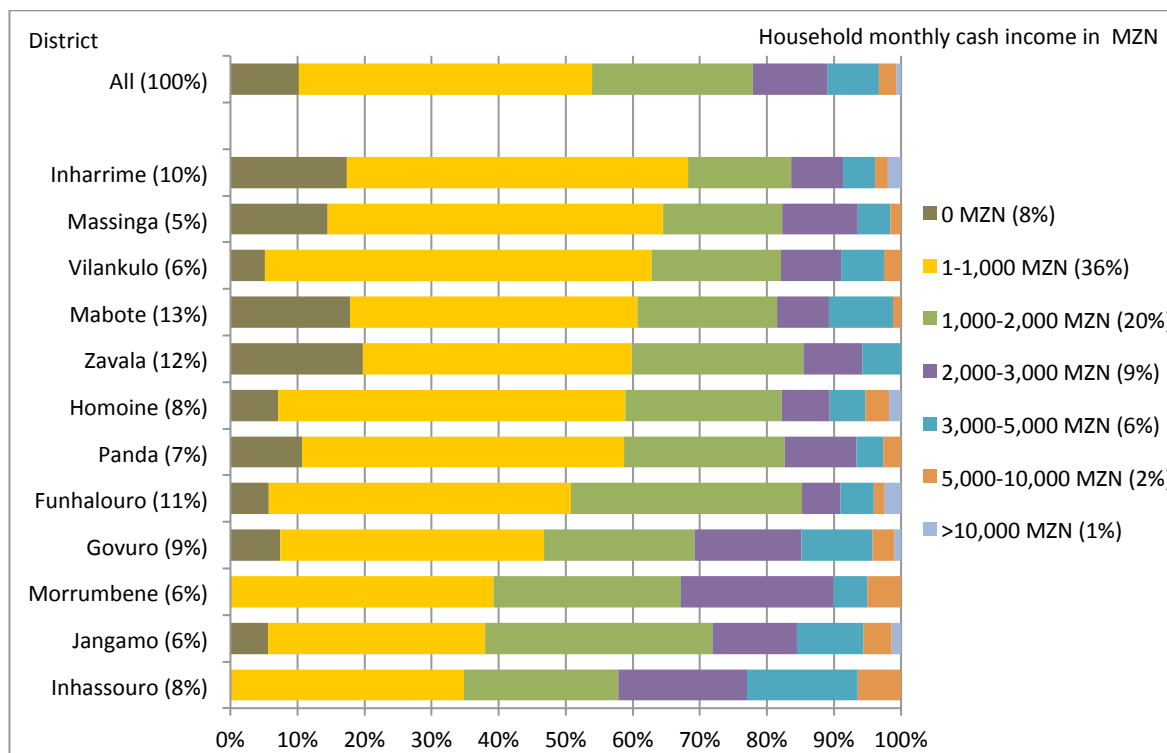
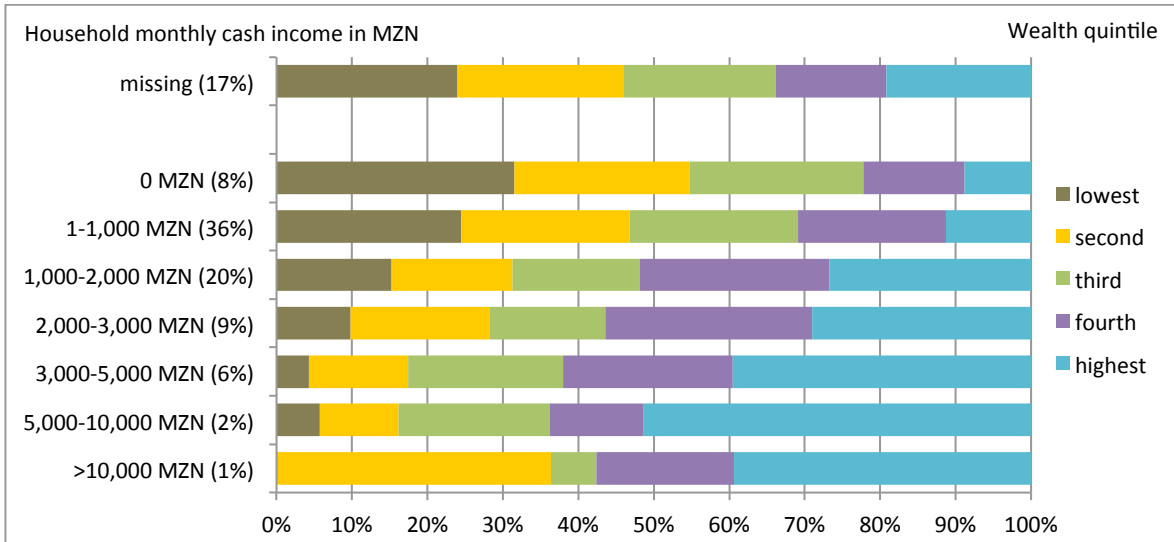


Figure 3 presents the derived asset and utilities (wealth) index in relation to household monthly cash income. The 19% of households with missing information was quite evenly distributed across wealth quintiles and thus did not affect interpretation of responses received to any great extent. The monthly cash income correlates to the wealth index for all but the highest cash income (which had few observations).

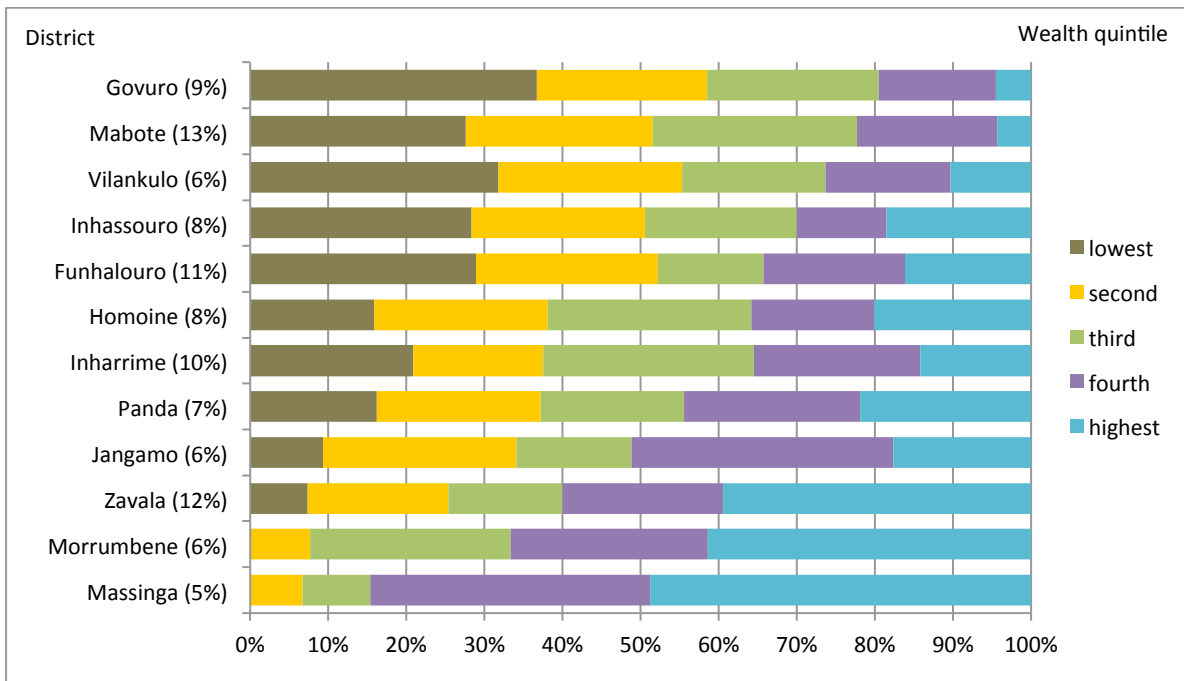
FIGURE 3 HOUSEHOLD WEALTH BY MONTHLY HOUSEHOLD CASH INCOME



\*1 USD=28 MZN

In Morrumbene and Massinga less than 10% of the households surveyed belonged to the two lowest wealth quintiles compared to over 50% in Govuro, Vilanculo, Funhaloro, Mabote, and Inhassoro (Figure 4). The poorest districts are situated in the northern part of the study area.

FIGURE 4 HOUSEHOLD WEALTH BY DISTRICT



#### 4.2.3 Prevalence of illness and Care seeking

Of the 1395 children who had had symptoms of FDP in the two weeks preceding the survey, the most common was fever (29%). Fever was associated with malaria in 67% of cases where a test for malaria was performed (Table 3).

TABLE 3 PREVALENCE OF SYMPTOMS OF KEY CHILDHOOD ILLNESSES

parameter	freq	%	total
<b>Total children with FDP</b>	1395	<b>31.55</b>	4422
Fever*	1244	<b>29.24</b>	4255
<i>Confirmed as malaria in 67% (255/381) of cases where a blood test (RDT or blood slide) was performed</i>			
watery diarrhoea <sup>†</sup>	230	<b>5.20</b>	4422
pneumonia	473	<b>10.70</b>	4422

\*fever – in 4255 children aged 4 months and above †all future references to ‘watery diarrhoea’ in this document be given as “diarrhoea”

Caretakers of sick children were asked whether care for the illness was sought outside the home, and the nature of the care sought. Caretakers were asked to provide details of up to two care providers used. Analysis of care seeking patterns for children with FDP indicated that the majority of sick children were taken to a health facility, which, in the vast majority of cases was a public facility (Table 4). The APE was the next most popular choice (23%). However in nearly 25% of children with symptoms of FDP, no care was sought; the principal reported reasons for this being that the illness was not severe (22%), it could be managed at home (20%), or the family did not have money or the transport means to seek care (27%).

TABLE 4 CARE SEEKING FOR CHILDREN WITH FEVER, DIARRHOEA OR MALARIA

Location	freq	%
<b>Health facility</b>	738	<b>52.9</b>
Public facility	736	52.7
health post	207	<b>14.84</b>
health centre	394	<b>28.24</b>
hospital	141	<b>10.11</b>
Private facility	3	0.2
<b>Outreach services (mobile/temporary)</b>	6	<b>0.43</b>
<b>APE</b>	320	<b>22.94</b>
<b>Pharmacy</b>	15	<b>1.08</b>
<b>Herbalist/traditional practitioner</b>	20	<b>1.43</b>
<b>No care sought</b>	345	<b>24.73</b>

Seeking care to more than one location is possible

Care seeking patterns were also assessed by provider, showing little change: children with fever, diarrhoea or pneumonia were taken to an APE in approximately a quarter of cases (23%, 27%, and 23% for fever, diarrhoea and pneumonia respectively), and to a public facility just over half the time (53%, 58%, and 55% for FDP respectively). No care outside the home was sought for fever or pneumonia in about a quarter of cases (24% and 23% respectively), though this was less likely for diarrhoea (16%).

#### 4.2.4 Appropriate treatment for FDP

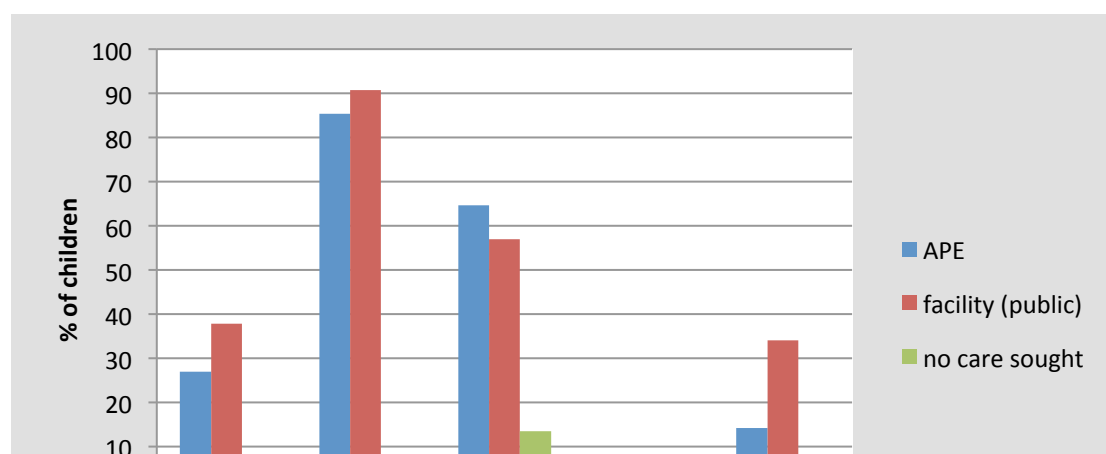
Appropriate treatment for FDP was analysed overall and by care provider only (a by district comparison was not appropriate given the delayed iCCM drug roll-out schedule). No more than half the children with FDP had been appropriately treated for any symptom. The exception was in cases of confirmed malaria where appropriate treatment with an ACT was nearly 90% (Table 5). The definitions of appropriate treatment for each condition are based on IMCI guidelines and can be found in (Appendix Section 5.4)

symptom	freq	%
fever	343	27.6
malaria	228	89.4
diarrhoea	116	50.4
diarrhoea (+Zn)	6	2.6
pneumonia	109	23.0

TABLE 5 PERCENTAGES OF CHILDREN RECEIVING APPROPRIATE TREATMENT FOR FDP.

The chances of receiving appropriate treatment were dependent on the provider from which care was sought (Figure 5). Numbers of families who sought care to private facilities, traditional healers and pharmacies were too small to assess differences reliably and so have not been included.

FIGURE 5 APPROPRIATE TREATMENT FOR FEVER, CONFIRMED MALARIA, DIARRHOEA AND PNEUMONIA BY CARE PROVIDER



“+Zn” – those treated with ORS and ZN as opposed to ORS only. No observations available for the ‘no care’ option for malaria (no blood test performed if no care sought)

#### 4.2.5 Cost of care seeking and treatment

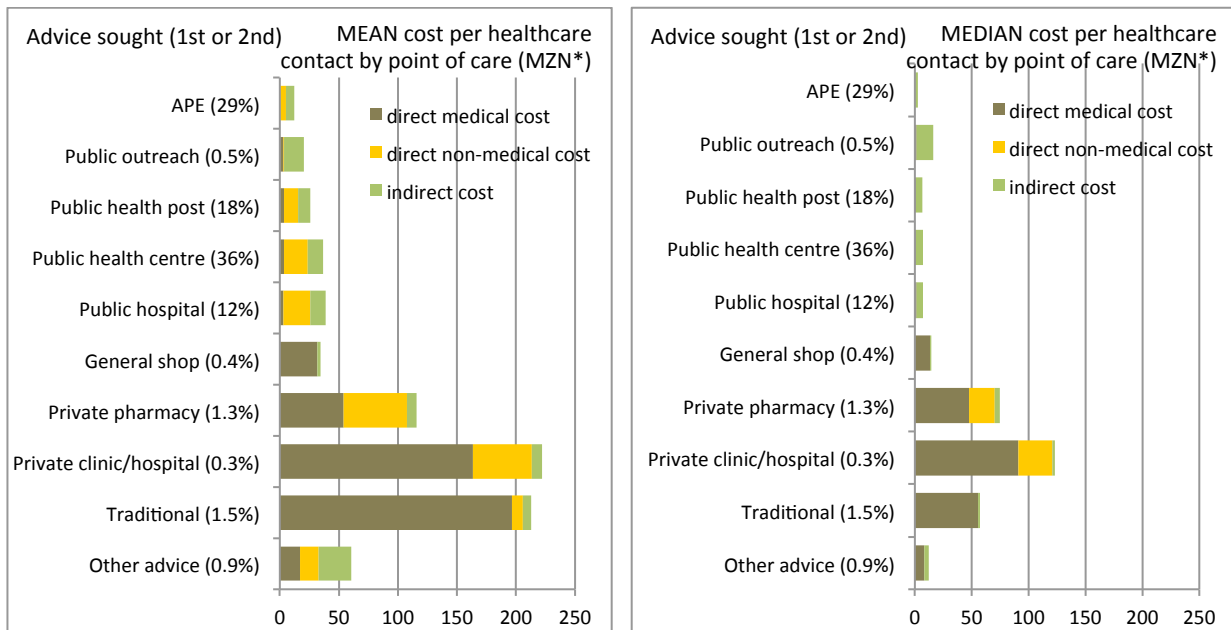
Figure 6 **Error! Reference source not found.** presents the mean and median cost of care-seeking by point of care for those that sought any kind of advice/treatment. Cost are divided into three categories:

- **Direct medical costs** including fees, medicines, cost of diagnostics, inpatient stay etc.
- **Direct non-medical costs**, which included transportation costs and subsistence cost for child and caretaker during time spent away from home
- **Indirect costs of care-seeking** i.e. opportunity cost of the time of travelling to the health facility (note the opportunity cost estimate is not comprehensive, as data information was not collected about any time spent waiting and time of consultation at the point of care).

As is often the case with health care expenditure, the cost data were skewed (having a small number of cases of very high costs which distort otherwise normally distributed cost data).

The highest total costs were associated with seeking care at a private health facility, with a mean direct medical cost of MZN 222 (USD 7.9) and a median cost of MZN 123 (USD 4.4), the mean cost of careseeking with a traditional healer was the second highest - of the 16 caretakers that sought care with a traditional healer 6 caretakers reportedly paid MZN 200-1000 (USD 7-36). The average cost of consulting an APE was MZN 12 (USD 0.4). Caretakers that sought care with an APE reported a mean direct medical cost of MZN 0.5 (USD 0.02). Mean costs of careseeking at public facilities other than APEs ranged between MZN 20-39 (USD 0.7-1.4). The median direct cost of careseeking was **MZN 0.0** for APEs and MZN 1-1.5 (USD 0.04-0.04) for other public facilities. The median non-medical costs of careseeking were **0.0** for all public care options. Median indirect costs of careseeking with an APE was MZH 3 (USD 0.1) and MZN 7-16 (USD 0.24-0.57) for other public facilities.

FIGURE 6 MEAN AND MEDIAN COST OF CARE-SEEKING BY POINT OF CARE (N=4030 HEALTH CARE CONTACTS FOR CHILDREN AGED 2 MONTHS TO 5 YEARS)



\*1 USD=28 MZN

As part of the understanding of how household costs are allocated across the careseeking process, careseeking behaviour was disaggregated by first and second care provider seen. However, few careseekers reported seeking advice from more than one provider (7.4% overall). A public health post or health centre was the most common place to first seek advice (54% of first consulted such a facility). 30% of caretakers with an ill child first consulted an APE. 10% of first consultations were in public hospitals. Only 3% of first consultations were in non-public facilities (Figure 7)

12% of caretakers that first consulted an APE went to seek advice or were referred to a 2<sup>nd</sup> provider compared to 5% of those that first sought care at a public health post/centre or hospital. The baseline survey did not capture information about the reason for seeking 2<sup>nd</sup> advice, thus to what extent this was because of referral, drug stock-outs or unsatisfactory outcome of the 1<sup>st</sup> advice sought is unknown. 18% of caretakers that first sought care with a traditional healer sought 2<sup>nd</sup> advice.

FIGURE 7 CARE SEEKING PATTERN 1ST AND 2ND ADVICE SOUGHT



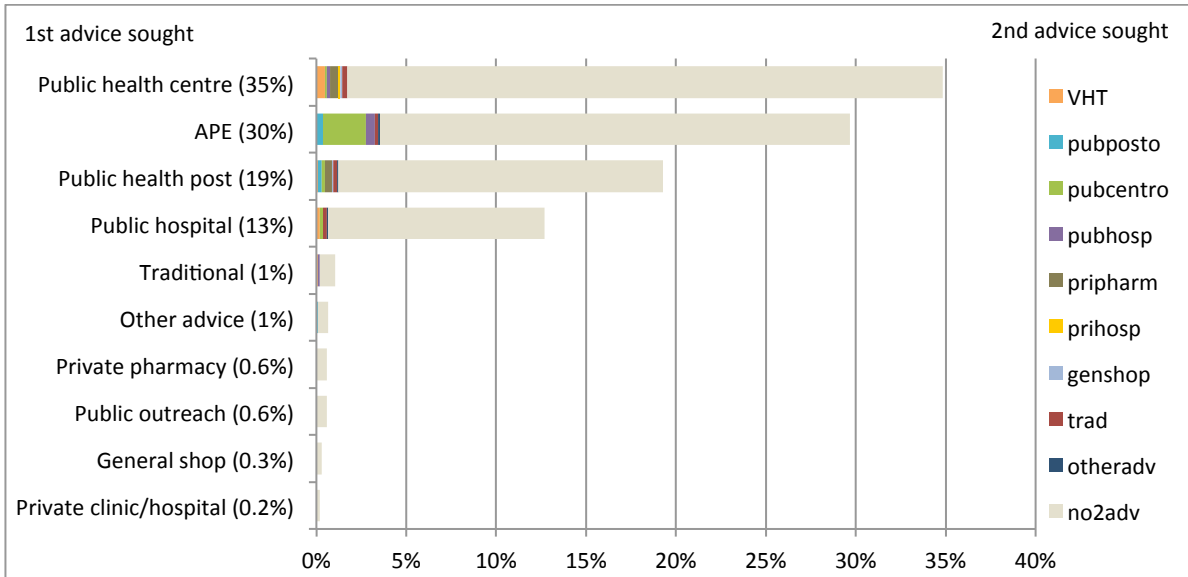


Figure 8 presents 1<sup>st</sup> advice sought in relation to household wealth. As can be noted, the caretakers that first consulted an APE were evenly spread across wealth quintiles, as were the caretakers will children according to the definitions used in the baseline that had not sought care. A slightly higher proportion of caretakers from the higher quintiles sought care with public health posts/centres/hospitals.

FIGURE 8 1ST ADVICE SOUGHT BY HOUSEHOLD WEALTH

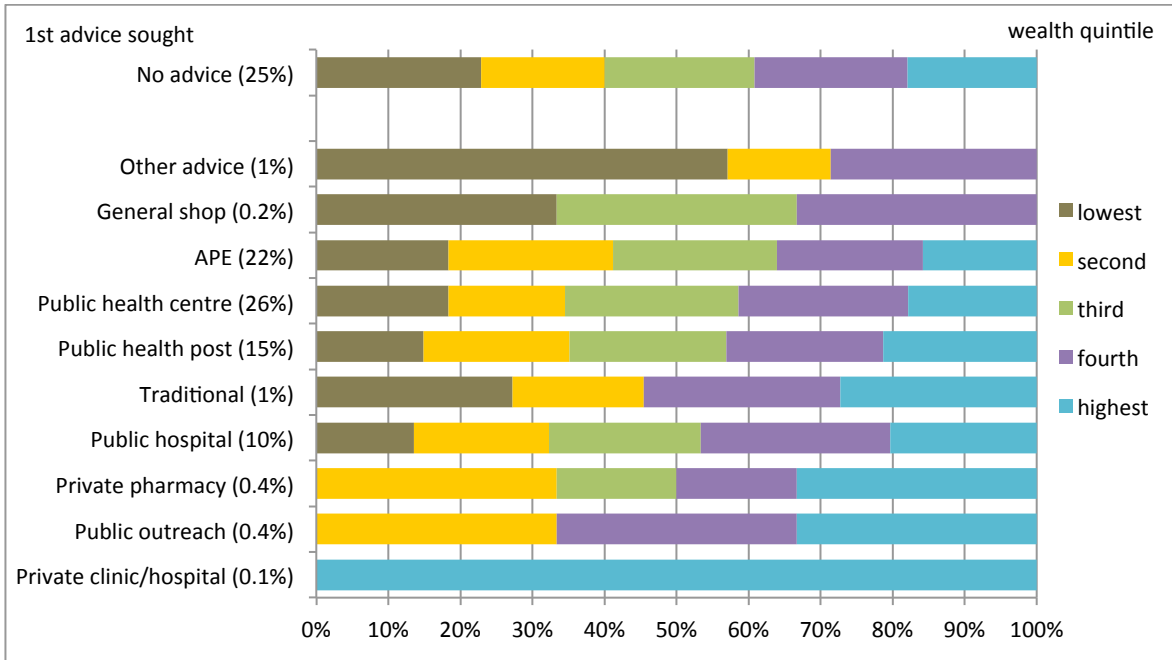
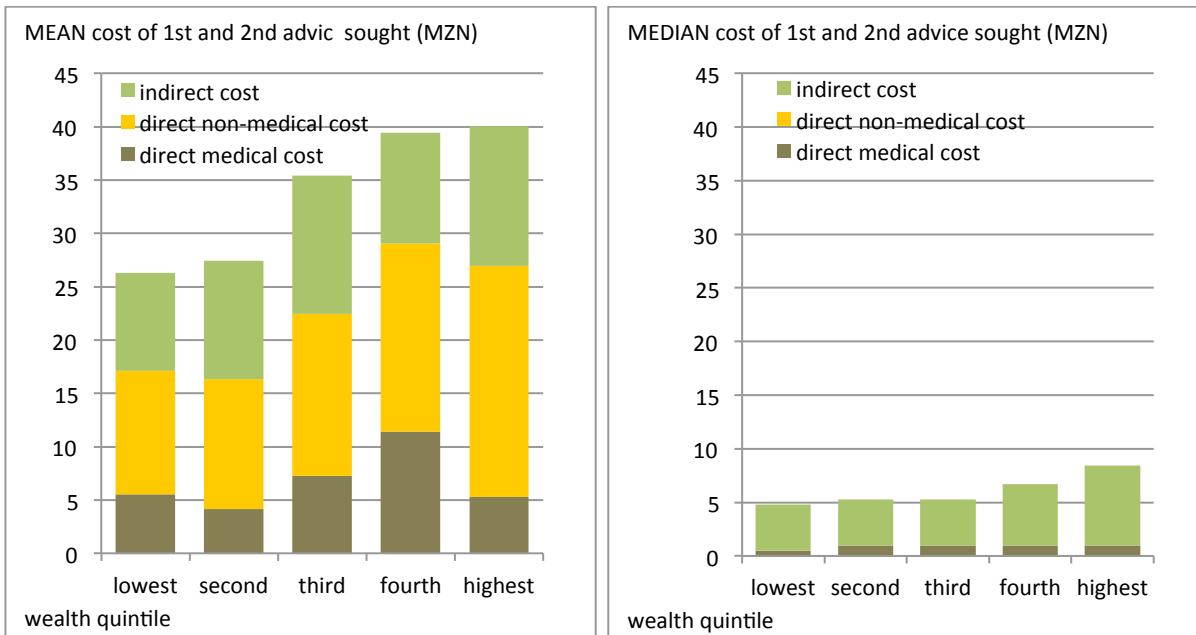


Figure 9 depicts cost of care seeking in relation to household wealth quintile. Households in the higher health quintiles reported higher mean as well as median costs of careseeking.

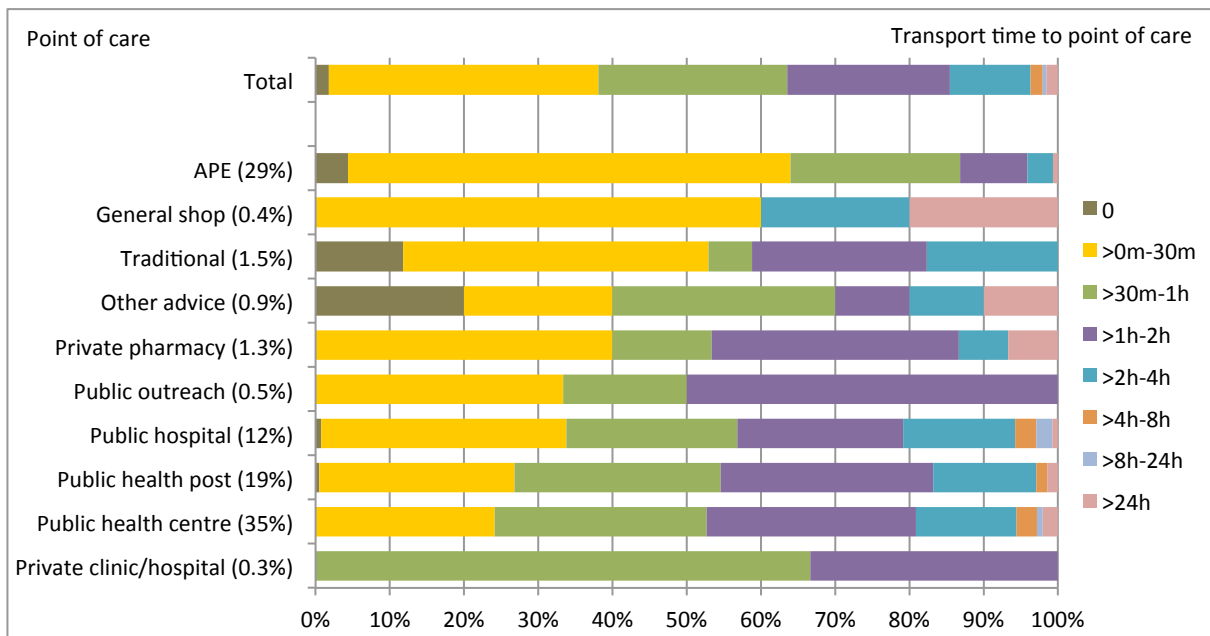
FIGURE 9 MEAN AND MEDIAN COST OF CARE SEEKING (1<sup>ST</sup> AND 2<sup>ND</sup> ADVICE SOUGHT, IN 2 WEEK PERIOD) BY HOUSEHOLD WEALTH



\*1 USD=28 MZN

64% of caretakers that consulted an APE, and 38% of caretakers overall, reported that it took them less than 30 minutes to reach the point of care (Figure 10). 19% of caretakers that consulted a public health posts centre or hospital reported that it took 2 hours or more to reach the facility compared to less than 4% of caretakers that consulted an APE.

FIGURE 10 TRANSPORT TIME TO CARE-SEEKING BY POINT OF CARE



The most common way of reaching the point of care was walking (75% of caretakers), followed by bus/joint transport (21%). 4% of caretakers used a bicycle.

#### 4.2.6 Sub-Survey: Children under 2 months of age

Data was available for 158 mothers of 164 children (including 6 pairs of twins) who had been born less than 2 months before the administration of the baseline survey questionnaire. All mothers (100%) reported making at least one antenatal care visit during their pregnancy. 36% of mothers delivered at home and 58% delivered in a public facility (a small number – 2% – delivered using a traditional birth attendant). 13% of mothers were visited after delivery by an APE, with a mean of 1 visit made within the first post-delivery week.

Mothers were also questioned about essential newborn care (ENC) practices including washing of the baby after delivery, cord care, and initiation of breastfeeding (Table 6).

	freq	%
<i>substances applied to cord</i>		
medicine	16	10.13
baby powder	5	3.16
ashes	13	8.23
cow dung	1	0.63
alcohol	1	0.63
herbs	23	14.56
nothing	74	46.84
can't remember	25	15.82
<i>drying after birth</i>		
<15min	52	32.91
between 15 and 30 mins	9	5.7
between 30 mins and 1hr	11	6.96
between 1 and 3hrs	26	16.46
>3hrs	35	22.15
not dried fully	5	3.16
never dried at all	20	12.66
<i>Initiation of breastfeeding</i>		
<1hr	71	44.94
between 1 and 3hrs	38	24.05
between 3 and 12 hrs	26	16.46
between 12 and 24hrs	8	5.06
>24hrs	8	5.06
can't remember	7	4.43

TABLE 6 ENC PRACTICES IN SUB-SAMPLE OF RECENTLY DELIVERED MOTHERS

### 4.3 APE Survey

A total of 256 APEs were surveyed during the baseline, with an average of 21 APEs surveyed per district. 55% of APEs were male - Table 7 provides a breakdown of key APE demographics.

Parameter		
<b>age group (yrs)</b>	freq	%
12	4.69	12
64	25	64
79	30.86	79
65	25.39	65
36	14.06	36
<b>education (level completed)</b>	freq	%
no education	0	<b>0.00</b>
primary not completed	65	25.39
primary	158	61.72
standard secondary/above	33	12.89
<b>occupation</b>	freq	%
public sector worker	127	49.61
private sector worker	27	10.55
farmer/fisherman	80	31.25
unemployed	1	<b>0.28</b>
other	22	8.59
<b>ethnicity</b>		
bitonga	26	10.16
citsua	180	70.31
cichopi	41	16.02
other	9	3.52

TABLE 7 KEY DEMOGRAPHICS OF APES IN THE STUDY AREA

Data was collected from 4333 households in the study site on their awareness of the APE in their area, and about their understanding of APE activities. 92% of households knew of or had been visited by their local APE (Table 8).

TABLE 8 APE ACTIVITIES DURING HOUSEHOLD VISITS

	freq	%	total
APE activities during visit (912 families had been visited in past month)			
asked about vaccinations	614	67.3	912
kept a health record for family	764	83.8	912
gave advice about health	732	80.3	912
asked/observed health practices	661	72.5	912

### 4.3.1 Supervision and Workload

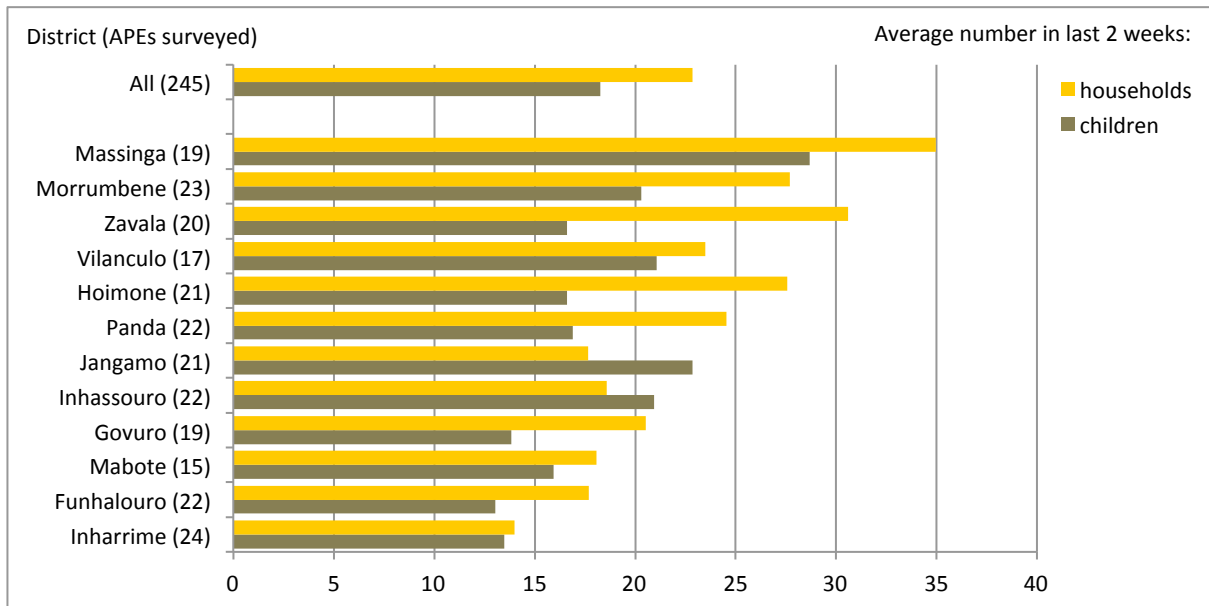
APEs are required to meet regularly with the programme supervisor at the nearest health facility for supervision and replenishment of materials. The majority of APEs had met with their supervisors 3 or more times (max 24) in the previous quarter (Table 9), though this varied by district.

TABLE 9 APE SUPERVISION IN PAST 3 MONTHS (NUMBER OF TIMES APE MET WITH HEALTH FACILITY SUPERVISOR)

Number of visits	none		1		2		3+	
	freq	%	freq	%	freq	%	freq	%
Funhalouro	1	5.3	1	5.3	1	5.3	16	84.2
Govuro	0	0.0	3	17.7	5	29.4	9	52.9
Homoine	0	0.0	1	4.6	2	9.1	19	86.4
Inharrime	0	0.0	3	16.7	6	33.3	9	50.0
Inhassouro	0	0.0	0	0.0	2	10.0	18	90.0
Jangamo	0	0.0	1	4.6	3	13.6	18	81.8
Mabote	0	0.0	4	28.6	6	42.9	4	28.6
Massinga	1	5.0	1	5.0	1	5.0	17	85.0
Morrumbene	0	0.0	0	0.0	6	26.1	17	73.9
Panda	0	0.0	1	8.3	2	16.7	9	75.0
Vilankulo	0	0.0	0	0.0	0	0.0	11	100.0
Zavala	0	0.0	0	0.0	9	64.3	5	35.7
<b>total</b>	2	0.9	15	7.1	43	20.3	152	71.7

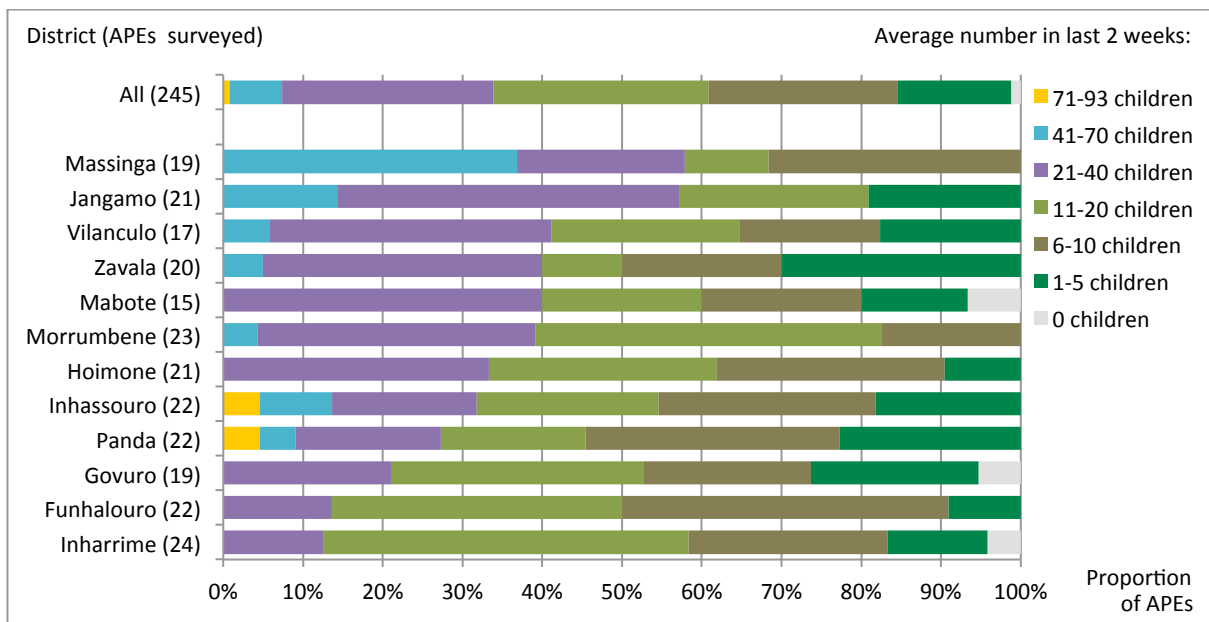
During the 2 weeks prior to being interviewed, the APEs saw on average 18 children and visited 23 households. APEs in Massinga had the highest average number of contacts: 29 children and 35 households per APE in the 2-week period (Figure 11).

FIGURE 11. AVERAGE NUMBER OF CHILDREN SEEN AND HOUSEHOLDS VISITED PER APE BY DISTRICT (N=245 - 11 OBSERVATIONS MISSING)



Overall, 77% of the APEs surveyed saw between 10 and 40 children in the 2-week period. 1% of APEs did not see any children at all. 7% of APEs saw more than 40 children in the 2-week period. As can be seen in Figure 112, Massinga also had the highest proportion of VHTs that saw more than 40 children in the last 2 weeks.

FIGURE 12. CHILDREN UNDER 5 SEEN IN LAST 2 WEEKS (TIME INTERVAL SEP-NOV 2012) BY DISTRICT (N=245 - 11 OBSERVATIONS MISSING)



67% of the APEs reported that they had had other activities as APEs in the last 2 weeks, predominantly information sessions for the community (*palestras*) - concerning nutrition, common diseases, hygiene and sanitation - and in a few cases meetings, own capacity development, accompanying children to a health facility and administrative work. The APEs that had dedicated time to such activities spent on average 1½ hour during the 2-week period (median time: ½ hour, range: 0 minutes to 9½ hours).

Questions were not asked in a way that allowed for a comprehensive estimate of time dedicated to APE work in the 2-week period, but an approximate calculation (multiplying the number of children seen/households visited with the average time per child/household plus time spend on other activities as reported) gave that the APEs spent on average 18½ hours on APE work in the 2-week period, ranging across districts from an average of 12 hours in Inharrime to 29 hours in Massingao (overall median time dedicate to VHT work was 13¼ hours, range: 0 to 111 hours, n=235, 20 observations missing).

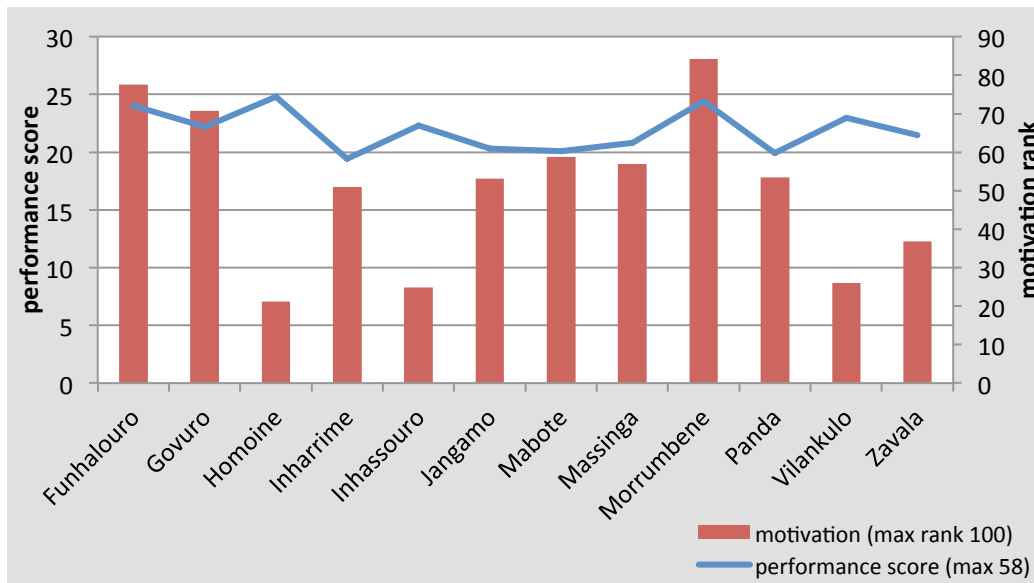
#### **4.3.2 Performance and Motivation**

APE knowledge of the correct management of FDP was tested using a series of vignettes (hypothetical scenarios involving sick children), which were later double-scored by inSCALE technical management team members (Mozambique). A maximum score of 58 was possible if the APE correctly mentioned all the key points necessary for correct diagnosis, treatment and referral according to their training algorithm. The baseline survey did not attempt to break down performance by illness type, nor was a minimum 'acceptable' performance level specified at this stage. Overall the average median score was 22/58 (IQR 14.5-28.5). Whilst all APEs had been trained in iCCM prior to the survey, none had yet received supplies of iCCM drugs and materials which will have impacted on the possible achievable scores.

APEs were read a set of 29 statements relating to feelings of motivation and identity, to which they indicated their level of agreement with each statement using a likert scale of 1 (strongly agree) to 5 (strongly disagree). Factor analysis was conducted to streamline the tool (several statements were dropped after the survey as not representative - see appendix section 5.3.1). This produced a percentage motivation score which ranked CHWs from the most motivated (100%) to least motivated (1%). APEs in Homoine, the district which demonstrated the lowest motivation, were ranked on average in the 21<sup>st</sup> percentile and those in Morrumbene (the district with the highest motivation) in the 84<sup>th</sup> percentile. Figure 13 shows average motivation and performance scores by district.



FIGURE 13 AVERAGE MOTIVATION RANK AND PERFORMANCE SCORES OF APES BY DISTRICT



## 4.4 Health Facility Survey

In the study area, 80 health facilities had been provided with the capacity to train and supervise iCCM APEs, and act as referral facilities for children with severe illness identified by APEs in the communities they serve. There is a 3-tier health facility system in Mozambique corresponding to the varying capacities of facilities to treat and manage sickness; health posts (lowest tier), health centres (subdivided into 3 levels), and hospitals (highest). Table 10 provides a breakdown of the 80 facilities in the study site by tier.

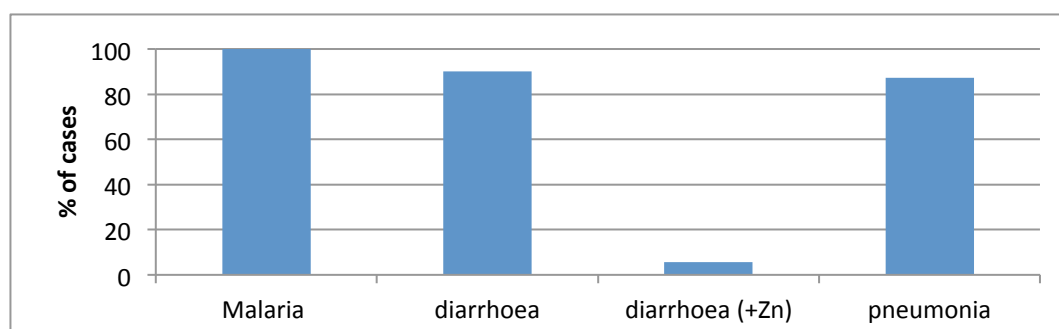
Facility level district	hospital		health centre		health post	
	freq	%	freq	%	freq	%
Funhalouro	0	0.0	5	100.0	0	0.0
Govuro	0	0.0	7	100.0	0	0.0
Homoine	0	0.0	7	70.0	3	30.0
Inharrime	0	0.0	6	85.71	1	14.3
Inhassouro	0	0.0	3	75.0	1	25.0
Jangamo	0	0.0	5	100.0	0	0.0
Mabote	0	0.0	5	100.0	0	0.0
Massinga	1	11.1	8	88.9	0	0.0
Morrumbene	0	0.0	7	100.0	0	0.0
Panda	0	0.0	5	100.0	0	0.0
Vilankulo	0	0.0	7	100.0	0	0.0
Zavala	0	0.0	9	100.0	0	0.0
<b>total</b>	<b>1</b>	<b>1.3</b>	<b>74</b>	<b>92.5</b>	<b>5</b>	<b>6.3</b>

TABLE 10 HEALTH FACILITIES BY LEVELS IN THE INSCALE STUDY AREA

### 4.4.1 Appropriate treatment of FDP

Overall 91% of facilities had seen at least one child under 5 years with malaria within the previous week, 88% had had a case of diarrhoea and 89% a case of pneumonia. Figure 14 shows the proportions of these children who received appropriate drugs, which was universally high in contrast to the estimates from the caretakers' perspective (see Figure 5). This may be partially due to the improved ability for confirmation of malaria and pneumonia in facilities (although details of diagnostic tests were not collected).

FIGURE 14. PERCENTAGE OF FACILITIES APPROPRIATELY TREATING THE LAST CASE OF FDP ON RECORD



#### 4.4.2 Stock outs at health facilities

Details of stock outs of key drugs by facility level, in the three months prior to the survey are found in (Table 11) for the 76 facilities which had data for all options. Zinc has been excluded from the list as the vast majority of facilities in the area did not stock zinc tablets routinely at the time of the survey (hence the low proportion of cases of diarrhoea treated with zinc seen).

Whilst the length of a stock out was unknown, the high rates of amoxicillin stock-outs across facilities (53% and 70% for tablets and suspension respectively) implies that stockouts did not last long enough to have a major impact on treatment for pneumonia (see above Figure 14. Percentage of facilities appropriately treating the last case of FDP on record Figure 14 ), and/or that cases of pneumonia were treated with other antibiotics (cotrimoxazole was the most common alternatives).

Drug type	Overall	
	freq	%
ORS	15	<b>19.7</b>
Amoxicillin capsules	40	<b>52.6</b>
Amoxicillin suspension	53	<b>69.7</b>
Coartem blue	14	<b>18.4</b>
Coartem yellow	24	<b>31.6</b>

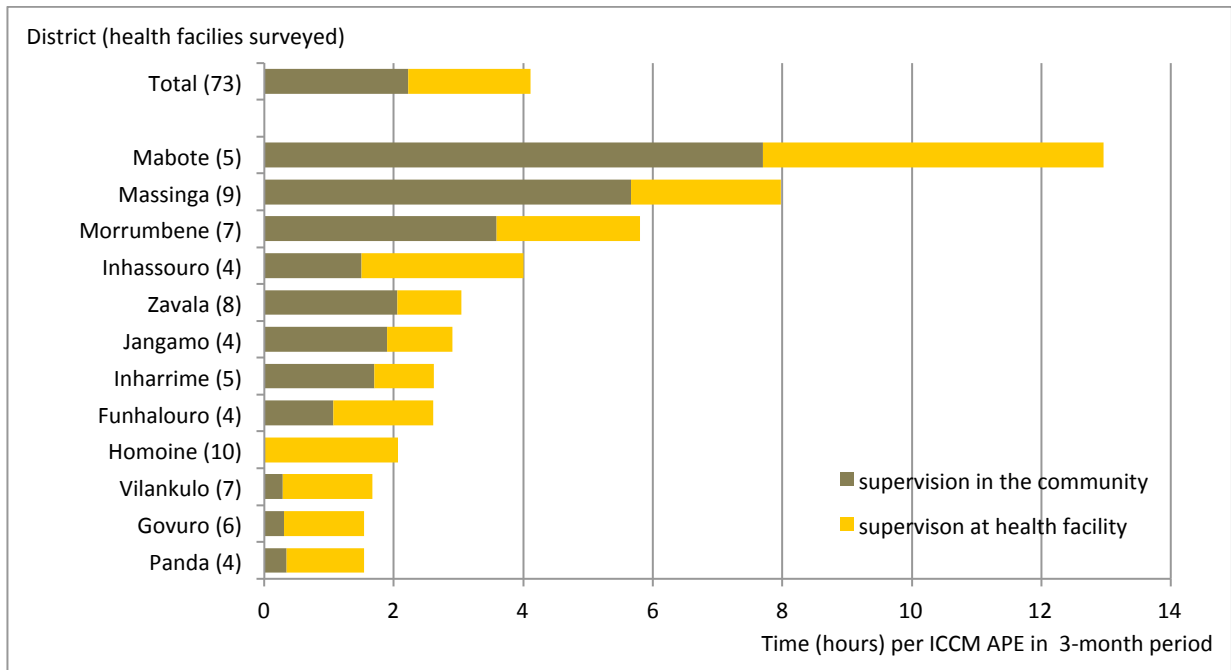
TABLE 11 STOCK OUTS OF DRUGS FOR KEY CHILDHOOD ILLNESSES IN 76 HEALTH FACILITIES IN THE STUDY AREA

#### 4.4.3 APE supervision

9 facilities did not have an APE supervisor currently in post at the time of the survey. Overall APE supervisors had an average of 3 supervisory meetings in the previous quarter (at the facility or in the community) with APEs attached to their facility, and only 6% had had no contact in this time period.

Figure 15 presents the average time spent on supervision per APE by district. Health facilities in Vilankulo, Govuro and Panda reported less than 2 hours per ICCM APE of supervision in the last 3 months prior to the baseline survey. Health facilities in Mabote and Massinga reported 13 and 8 hours of supervision per APE respectively in the same period. The reported average time dedicated to APE supervision in the 3 months across district was just over 4 hours per APE.

FIGURE 15. AVERAGE TIME SPEND ON SUPERVISION (APE HOME VISITS AND IN FACILITY) PER ICCM APE ALLOCATED TO FACILITY, OVERALL AND BY DISTRICT (N=73 – 7 OBSERVATIONS MISSING)



## 4.5 Endline Survey: Sample Size estimation and Restricted Randomisation

### 4.5.1 Sample Size Estimation

Several assumptions were made prior to the baseline survey in Mozambique regarding the sample size needed to be able to detect a difference in the main outcome indicator between arms at endline. The original sample size calculation was based on information from a 2010 Malaria Consortium/CIDA iCCM implementation survey in the study area. Data from the baseline survey (see Table 12 below) provided up to date estimates of the prevalence of fever, diarrhoea and pneumonia in the study site. This survey indicated that the prevalence of diarrhoea and pneumonia were lower than expected. A revised sample size calculation for the Mozambique endline survey was performed. The revised calculation was that the study would require 390 children to be sampled district to provide 80-90% power to detect differences in appropriate treatment of 20% (fever) and 25% (pneumonia and diarrhoea) between arms.

TABLE 12 ESTIMATES USED TO CALCULATE THE SAMPLE SIZE FOR OUR ENDLINE EVALUATION WERE MODIFIED AFTER THE BASELINE SURVEY IN MOZAMBIQUE. \*CV BASED ON BETWEEN-CLUSTER VARIATION FOR APPROPRIATE TREATMENT IN UGANDA

Sample	Pre-baseline estimate	Post-baseline
% Households with children >2months & <5yrs	47.4	<b>48.1</b>
Average num. of children/HH	1.53	<b>1.51</b>
<b>Prevalence of</b>		
fever	23.2%	<b>29.2%</b>
diarrhoea (watery)	9.9%	<b>5.2%</b>
pneumonia	20.5%	<b>10.7%</b>
<b>Control arm/baseline rate of appropriate treatment for</b>		
fever	<80%	<b>&lt;50%</b>
diarrhoea (watery)	<80%	<b>&lt;50%</b>
pneumonia	<80%	<b>&lt;50%</b>
<b>CV* for appropriate treatment of</b>		
fever		<b>0.16</b>
diarrhoea (watery)	0.15	<b>0.16</b>
pneumonia		<b>0.16</b>

#### 4.5.2 Restricted Randomisation

The inSCALE intervention in Mozambique will be evaluated using a two armed cluster randomized controlled trial with 6 clusters per arm. The trial will compare the inSCALE technology based intervention with routine iCCM trained APEs, to routine iCCM care in the control arm.

In order to assign districts (clusters) to each arm, a restricted randomization was performed to minimize the differences between the arms on key indicators:

1. APE motivation score – no more than a **0.5 difference in scores** between arms
2. Cost (log10) of care seeking – no more than a **0.1 difference** in log cost between arms
3. % care seeking to an APE – no more than an **3.5% difference** between arms
4. % care seeking to a public facility – no more than a **5% difference** between arms

Indicators 3 and 4 were chosen in lieu of using % appropriate treatment, as appropriate treatment could not be reliably measured at baseline as previously described.

A programme was created which randomly allocated districts to the technology or control arms, whilst ensuring that the resulting allocations fit the above criteria. 84 schemes (out of a possible 924) fit all the above criteria and of these, one scheme was chosen at random.

The characteristics of the chosen scheme are presented in Table 13 below, and illustrate how the balance between intervention arms for our key variables is actually closer than above the requirement.

TABLE 13 COMPARISON OF INTERVENTION ARMS (ABSOLUTE DIFFERENCE (|1-2|) OR RATIO (1/2)) FOR KEY INDICATORS. SHADED INDICATORS ARE THOSE WHICH WERE INCLUDED IN THE RESTRICTED RANDOMISATION. \*L=LOG10 AL=ANTI-LOG

	cluster size	caretaker	disease prevalence			APE	careseeking*			
stats	HH/APE ratio	education	fever	diarrhoea	pneum	motivation	to facility	to APE	cost(L)	cost(aL)
<b>control</b>										
mean	854.64	60.74	27.96	5.21	9.96	<b>2.29</b>	<b>50.96</b>	<b>22.51</b>	<b>1.11</b>	13.05
sd	493.01	9.13	2.84	2.10	1.89	<b>0.46</b>	<b>21.63</b>	<b>23.03</b>	<b>0.09</b>	2.80
<b>technology</b>										
mean	1080.61	67.15	28.10	4.87	11.42	<b>2.38</b>	<b>48.79</b>	<b>22.77</b>	<b>1.14</b>	14.49
sd	612.07	10.62	2.27	2.23	2.22	<b>0.50</b>	<b>14.80</b>	<b>16.92</b>	<b>0.14</b>	4.79
<b>comparison of arms (ratio)</b>										
mean difference ( 1-2 )	225.96	6.41	0.14	0.34	1.46	<b>0.09</b>	<b>2.17</b>	<b>0.26</b>	<b>0.03</b>	1.44
ratio (1/2)	0.79	0.90	1.00	1.07	0.87	0.96	1.04	0.99	0.97	0.90

## 4.6 Summary

The baseline survey in Mozambique was conducted primarily to characterise pre-intervention levels of the main InSCALE parameters in the study area, and to use this information to ensure that following restricted randomisation, the intervention arms would be balanced for these characteristics. This survey allowed for the successful randomization of the 12 clusters into two study arms as part of the evaluation of the InSCALE cluster randomized controlled trial. There was minimal difference between clusters in the proportions of sick children who were taken to a facility or an APE, the average level of APE motivation, and the average (log10) cost of treatment for children with FDP.

In addition to this primary task, further analysis of the survey data showed that the public sector health care providers (APEs and health facilities) were the most popular care seeking choice for caretakers of sick children as well as the cheapest option. No additional care was sought for nearly a quarter of children with FDP. Whilst data from facilities indicated high levels of appropriate treatment of children seen in the past week, overall rates of appropriate treatment were significantly lower based on caretakers' understanding of illness symptoms and treatment, where no more than 23%-50% of sick children received appropriate treatment for their condition (excluding those with confirmed malaria). This may be partially due to the unavailability of iCCM drugs for APEs at the time of the survey, but may also indicate the issues with accurate caretaker recall of diagnosis and treatment information.



## 5 Appendix

### 5.1 Study design, sample size calculation and sampling strategy

The sample size calculation for the baseline survey was based on a requirement for a sample containing a sufficient number of sick children to be able to evaluate the main inSCALE outcome – to detect a difference between intervention arms in:

**The % children receiving appropriate treatment during illness episodes for each of pneumonia, diarrhoea and fever.**

This is also the outcome that requires the largest samples, as not all children surveyed will have had a recent illness episode. The sample size calculation was intended for use in both the study end-line evaluation, and the baseline survey.

There are 12 study districts in the chosen research site of Inhambane, each responsible for administration and coordination of local iCCM APE programmes within neighbourhoods without a nearby referral facility. These districts thus formed the clusters to be randomised to receive the inSCALE intervention or routine iCCM.

The sample size calculation was therefore based on a cluster RCT with 6 districts per arm, and assumed a coefficient of variation (CV) of 0.05 (between-cluster coefficient of variation –estimate based on the variation between clusters in the Uganda site inSCALE baseline survey as we had no study site-specific data to inform us at the time), and 5% significance level. The number of sick children required/cluster was determined by varying this number in the formula for the number of clusters (as given in Hayes & Moulton (Cluster Randomised Controlled Trials Taylor & Francis USA Chapman and Hall (Pub) 2008)) until the number of clusters/arm equalled 6.

The calculation was based on the formula for comparison of proportions, adjusted for cluster effects stated in equation 7.7 from Hayes & Moulton (see above reference), i.e. where  $k$  is the between cluster coefficient of variation:

$$C = 1 + (z_{\alpha/2} + z_{\beta})^2 \left( (\pi_0(1 - \pi_0)/m + \pi_1(1 - \pi_1)/m + k^2(\pi_0^2 + \pi_1^2)) / (\pi_0 - \pi_1)^2 \right)$$

Table 14 below shows i) the number of children with a recent illness episode needed per cluster for each of pneumonia, diarrhoea and fever in order to detect absolute differences between each intervention arm and the control arm, or between the two intervention arms. Sample sizes were estimated based on a requirement for 90% power to detect a 15-20% difference in appropriate treatment between arms. The table also shows ii) the total number of children that needed to be surveyed in order to yield the required number with a recent episode of illness, iii) the number of households containing children less than 5 years of age that would need to be visited in order to ensure we reach at least the number of children in ii, and iv) the total number of households required to visit overall given that only a proportion of houses have any children under 5yrs of age. Prevalence estimates, average numbers of children per household (1.53), and the proportion of

households with any children (0.45) were taken from a recent (2010) baseline survey conducted within the trial area by CIDA/Malaria Consortium.

TABLE 14 RESULTS OF THE MOZAMBIQUE POWER CALCULATION SHOWING THE NUMBERS OF CHILDREN TO BE INCLUDED PER CLUSTER AND THE ESTIMATED NUMBER OF HOUSEHOLDS TO BE SURVEYED TO REACH THIS NUMBER OF CHILDREN

6 clusters per arm (12 total)		pneumonia (20.5%)	diarrhoea (9.9%)	fever (23.2%)	iii) number of HH with children under 5 (1.53/HH, based on requirement of 350 children)	iv) total households to sample (0.45 HH with children) per cluster
90% power, 20% difference in appropriate treatment	i) number of children with symptom	30	30	30	229	508
	ii) number of children to sample per cluster given prevalence of symptom	147	304	130		
90% power, 15% difference in appropriate treatment	i) number of children with symptom	55	55	55		
	ii) number of children to sample per cluster given prevalence of symptom	269	556	238		

Based on this we proposed to conservatively sample **350 children under five years of age per cluster** (i.e. more than the 304 required according to the above table, as it was likely that prevalence figures for fever, diarrhoea and pneumonia would have decreased since 2010) for the baseline survey. **508 households per cluster would need to be sampled** to yield this number of children.

The study site in Inhambane includes 642 government defined enumeration areas (EAs) covered by the iCCM APE programme. These EAs are sub-divisions within 44 Localities ('Localidades') in the 12 districts – an average of 54 EAs per district<sup>1</sup>. Each EA contains on average 102 households (inter-quartile range: 69-129).

In order to achieve geographic spread in each cluster, we included all households within several EAs within each district. EAs were selected at random and without replacement within each district until our target of at least 508 households was reached. On average 5 EAs were selected per district (range 2-8), plus additional 'back-up' EAs with households totalling an additional 500+ in case for any reason we had to discard one or more of the original EAs after the start of the survey (due to problems with access, low household numbers, etc).

<sup>1</sup> This list of all the EAs covered by APEs in the 12 districts was provided to the technical team from the Mozambique Government Bureau of Statistics. This list also contained address details for the EAs (District, Localidade, Aldeia), the approximate number of households in each EA and GPS coordinates. This list became the official SAMPLING FRAME.

All the APEs in 12 districts (approximately 22/district), and the health facilities to which they report were also sampled as part of the baseline.

## 5.2 Timeline of key activities: Survey tool development, Baseline Survey and Data Management

### August 2012

**SAMPLING FRAME DEVELOPMENT:** A list of all the EAs covered by APEs in the 12 districts was provided to the technical team from the Mozambique Government Bureau of Statistics. This list also contained address details for the EAs (District, Localidade, Aldeia), the approximate number of households in each EA and GPS coordinates. This list became the official SAMPLING FRAME

**QUESTIONNAIRE AND FIELD TOOL DEVELOPMENT I:** Survey tools were modified from those used in the inSCALE Uganda baseline survey (inSCALE Study Group 2012), to fit the Mozambican context. Household questionnaires retained the main sections on socio-demographic and socio-economic profiles (both Household and APE questionnaires) information on number of children (household questionnaires), illness episodes in the past two weeks, who treated the child(ren), where they were treated, the type of treatment given, and whether treatment was given according to instruction (collected on a separate child form). As in the Uganda survey, there were additional questionnaires for APEs (timing and type of volunteer work done) and for the health facilities in the study area (stock levels, capacity for treatment, supervision and training of APEs). Also modified were the accompanying sheets containing pictures of drugs used to treat childhood illnesses ('drug cards') to aid household members in identifying treatments. Questionnaires were written in English and translated into Portuguese, after which followed several rounds of modifications and checking of translations between the technical team members based at the LSHTM and Mozambique. Household listings sheets were created for each EA containing blank rows for entry of the basic details of each household visited (name of household head, presence of children under 5 years of age).

**ETHICAL APPROVAL:** All ethical approvals for the survey were granted on or before the 17<sup>th</sup> August from both LSHTM ethics board and the Mozambique Ministry of Health ethics board.

### September 2012

**STUDY SITE SENSITISATION:** Sensitisation meetings were held with district-level stakeholders and coordinated by the MC.

**FIELDWORKER TRAINING:** Training of field team supervisors (each responsible for 3 fieldworkers) and fieldworkers took place within the MC field offices in Inhambane. Field staff were able to pilot draft versions of the questionnaires and thus contribute to modifications.

**QUESTIONNAIRE AND FIELD TOOL DEVELOPMENT II:** Questionnaires went through several stages of development after valuable input from the recruited field teams before final versions were printed.

Drug cards were updated to include additional pictures of drugs with packaging found in local pharmacies and drug shops.

**BASELINE SURVEY:** Took place from 17<sup>th</sup> September until 15<sup>th</sup> November. Quality control checks (re-sampling of 10% of household sickness and treatment data where there were children under 5 years of age) were implemented to monitor the quality of data.

**DATA MANAGEMENT SYSTEM DEVELOPMENT:** An IT consultancy (Crafts Passion) was hired in September to install a data management system modified from the inSCALE Uganda Baseline Survey capable of creating permissions, entering forms, checking data for inconsistencies and creating an audit trail. The Data manager from the Uganda inSCALE site also provided technical assistance at this time.

### October-December 2012

**DATA MANAGEMENT SYSTEM DEVELOPMENT:** Final checks and modifications to the data management system were made and a minimum functioning system was available by the 15<sup>th</sup> November allowing for data entry and storage.

**DATA ENTRY:** Data entry clerks (DECs) were trained and started entering form data on the 15<sup>th</sup> October and completed this activity by mid December.

### January-April 2013

**DATA CHECKING AND CLEANING:** The data management system was finalised, data were uploaded and went through several stages of consistency, range, and inter-database checks. In some cases this included returns to field sites to verify data from respondents. Database tables were sent to the LSHTM Epidemiology/Economics teams.

**RANDOMISATION and SAMPLE SIZE CALCULATIONS:** Sample sizes necessary for the evaluation of the Mozambique intervention were re-calculated based on the data obtained during the baseline survey. The baseline data were also used to inform the restricted randomisation of districts to intervention arms.

### May-June 2013

**DATA CHECKING AND CLEANING:** Outstanding database queries were raised and corrections made to the databases. Final versions of all databases were shared with the LSHTM team in June 2013.

**DATA ANALYSIS:** Analysis of key baseline health and cost related indicators continued into the final quarter of 2013.

### 5.3 Analytical Methods

Excluding the creation of an asset index for households/ APEs and an APE motivation score (see below), all remaining indicators presented in this report were summarised via simple cross-tabulations of percentages and averages. All analyses were carried out in Stata v10.2 (StataCorp, Texas USA), and graphs created in MS Office Excel for Windows 2007 (MSN, Washington USA).

#### Definitions

A list of criteria used to define the indicators reported in the results section of this report is recorded in section 5.4 below. All definitions of illness and appropriate drug types were based on IMCI guidelines (WHO/UNICEF 2012).

#### 5.3.1 APE motivation score - Factor analysis (EFA)

Data on APE motivation was collected using a 29-question tool with topics ranging from, but not limited to, reported motivation, programme commitment, job security, identify, self-efficacy, and management and supervision (each question asked the APE how strongly they agreed or disagreed with a statement using a 5-point Likert scale (1=strongly agreed, 5=strongly disagreed)). The tool was initially compiled using pre-tested material from several sources (Chandler et al 2009, Alex Haslam (pers. comm.)). The 29 question tool was administered to APEs as part of the larger questionnaire on CHW performance, supervision and motivation.

In order to create a standardised motivation/identity score and to explore the relationships between the items in the questionnaire, standard item-reduction methods were used (we dropped highly correlated questions and questions whose meanings were agreed to be ambiguous). Multiple factor analysis runs followed in which items which did not load on any factor to at least 0.4 after each analysis were dropped, and promax oblique rotations carried out after each run to further explore the data in instances where questions cross-loaded onto more than one factor (Basto and Pereira 2012, Hilari et al 2003). Internal consistency of the grouped items was measured using Cronbach's alpha (Bland and Altman 1997) following each FA run. FA of this type attempts to define how well groups of questions are correlated with each other, and scree checks of the resulting output indicates the optimum number of factors (groups) needed to explain the underlying relationships between the questions (Chandler et al 2009, Hilari et al 2003).

This analysis resulted in a single-factor tool of 19 questions that explained the majority of the variation in motivation and identity between CHWs. The items in this final tool showed good consistency with each other ( $\alpha=0.84$ ). Standardised motivation scores were then calculated for each APE by multiplying the regression coefficients generated from the final factor analysis by the original Likert value for each question (DiStefano et al 2009). APEs were additionally grouped into centiles based on their scores to allow further interpretation of relative APE motivation on a scale from 1 (low) to 100 (highest).

An additional motivation indicator was calculated based on the simple addition of the likert values for 28/29 questions (one question was permanently dropped as non-representative) for each APE. In this case, a value of 28 was the lowest possible score and indicated the highest motivation, and 140 was the highest score and indicated lowest motivation. Both this simple score and the above factor score are cited in the body of this report, and show good agreement ( $r^2 = 0.9$ , Figure 16).

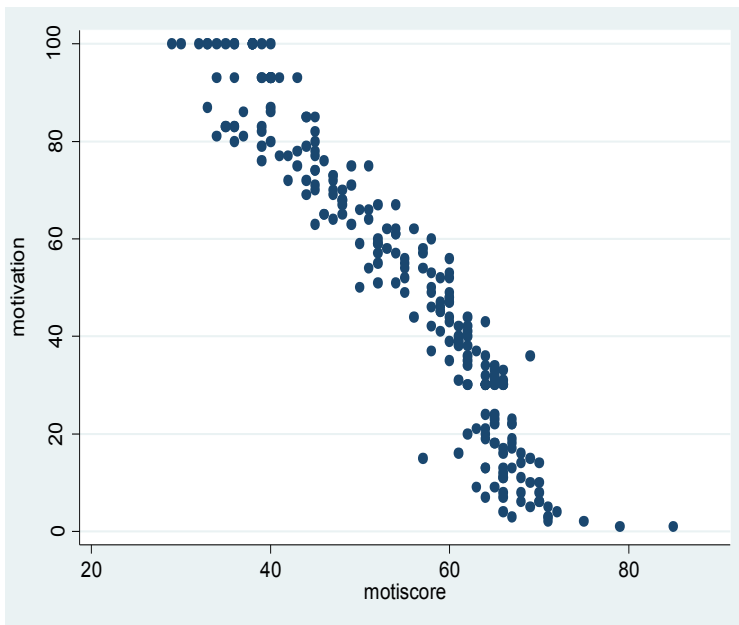


FIGURE 16 SCATTERGRAPH OF APE MOTIVATION SCORE ('MOTISCORE' - SIMPLE ADDITION OF ANSWERS GIVEN FOR QUESTIONS ON MOTIVATION) AGAINST THE FA MOTIVATION SCORE ('MOTIVATION'). FA SCORE IS BOUND AT 1 AND 100.

### 5.3.2 Household and APE asset index - Principle Component Analysis (PCA)

Questions in the baseline household and APE surveys on house construction, ownership of household items, land, animals and transport means, and water and sanitation infrastructure were used to create a single indicator representing household wealth. This is an often used method to estimate relative wealth/(socio)economic circumstances in settings where a substantial part of the population are self-sustaining farmers and/or work in the informal sector.

The wealth indicator was developed by running a principal components analysis, which assigns a coefficient to each variable included in the asset index by means of an iterative model based on its importance in relation to the other variables. The sum of the coefficients for each household/APE is then used to calculate an overall wealth index (Vyas and Kumaranayake 2006). Households and APEs were then categorised by relative wealth (individual indices ranked from lowest to highest and grouped into quintiles).

The individual indicators that weighted heaviest in the analysis were house construction material (material of roof, walls and floor) and type of toilet facility used. Different ways of deriving the wealth index were explored (such as excluding some of the variables collected to see how this would affect the wealth indicator, or grouping similar answers to some of the questions to reduce the number of variables); however it was decided to use the complete set of asset variables and the full sets of responses given to each question collected, as this approach seemed to give the best representation of wealth after validation of the index against related factors such as average monthly household cash income and the education level and occupation of the head of household (Vyas and Kumaranayake 2006)

## 5.4 Definitions (based on WHO guidelines for integrated management of childhood illness)

- **Illness**

**Diarrhoea:** child had diarrhoea episode(s) AND 3+ loose stools were passed in a day in previous two weeks. For **Watery Diarrhoea**, additional criteria = AND diarrhoea type was watery.

**Fever:** child had fever episode(s) in previous two weeks

**Malaria:** child had fever episode AND a blood test positive for malaria in previous two weeks

**Pneumonia:** child had a cough AND fast breathing at least one time in previous two weeks. Alternatively child had chest indrawing AND another danger sign in previous two weeks.

- **Appropriate treatment of FDP**

**Fever:** Any ACT: Coartem, Duo-Cotecxin, Amodiaquin-Artesunate, or Artesunate-Fansidar taken. Others: Rectal Artesunate. Included in health facility criteria: Quinine (omitted from household criteria as only approved for treatment of children <4 months, who were excluded from the household survey sample).

**Diarrhoea:** ORS, or homemade ORS taken. ORS plus zinc supplementation was analysed as a secondary indicator.

**Pneumonia:** Amoxicillin, Cotrimoxazole, Chloramphenicol, Erythromycin, Ceftriaxone, Septrin, Azithromycin, Gentamycin, or Cephalexin taken

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