EVALUATING THE COST-EFFECTIVENESS OF A MOBILE DECISION SUPPORT TOOL IN MALAWI

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ACRONYMS

CHW	Community Health Worker
CRS	Catholic Relief Services
DHC	Dedza Health Commission
DHO	District Health Office
FTE	Full-time Equivalent
HSA	Health Surveillance Assistant
iCCM	Integrated Community Case Management
ICER	Incremental Cost-effectiveness Ratio
IMCI	Integrated Management of Childhood Illness
LA	Lumefantrine Artemether
NGO	Non-governmental Organization
ORS	Oral Rehydration Solution
TCO	Total Cost of Ownership
USAID	United States Agency for International Development
WHO	World Health Organization

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EXECUTIVE SUMMARY

Background and Objectives

Mobile applications are promising tools for strengthening service quality and have been an area of considerable mHealth innovation. Despite growing demand for data to guide policymakers, donors, and program managers in making sound investments, there is a paucity of evidence on the cost-effectiveness of mHealth technologies (Braun et al. 2013). To address this gap, USAID's Health Finance and Governance Project analyzed a mobile decision support tool with the following objectives: First, it aimed to provide a transparent and detailed methodology for categorizing the costs of building, deploying, and scaling-up mobile decision support tools in Malawi. Second, it evaluated the incremental cost-effectiveness of a mobile tool's use in improving clinical care. Finally, the evaluation addressed challenges faced in conducting cost-effectiveness analyses of mHealth interventions when they are scaled up and become multifunctional.

Mobile Application

D-tree International (D-tree), a health NGO, in partnership with the PEPFAR-funded IMPACT project and the Malawi Ministry of Health, developed a mobile-based decision support tool for health surveillance assistants (HSAs). The tool incorporates the World Health Organization's Integrated Community Case Management (iCCM) approach to child health through the application of checklists and decision information. The mobile iCCM application is designed to improve adherence to recommended steps in the assessment, diagnosis, and treatment of children presenting with symptoms commonly linked to childhood morbidity and mortality, such as fever, diarrhea, cough, and rapid breathing.

Methodology

Cost data on the iCCM mobile tool were collected for the period October 2010 through March 2013 from three program partners. Overall costs included project management, software development, a pilot, and the roll-out to 50 HSAs. The mobile iCCM version evaluated in this study was not a replacement for existing health worker training, record-keeping, or reporting requirements. Thus, cost data were collected and analyzed only for the mobile tool given that it supplements the existing system of paper job aids. Based on D-tree's experience through 2015, costs were presented based on the tool's scale-up to 5,000 HSAs.

Effect data were collected from a study conducted between March 2011 and March 2013. A convenience sample of 25 HSAs used the mobile tool to treat children in village health posts in three districts of Malawi, while another 25 HSAs delivered care to children at different village health posts (in the same districts) using only the existing paper-based registries. Treatment records from a random sample of 625 patients from the HSA mobile group and 625 from the HSA paper group were collected; data were recorded on patient medical conditions (fever, diarrhea, rapid breathing, and red eye), patient clinical severity, treatments received, whether patients with more severe illness were referred, reasons why providers failed to administer appropriate treatments, as well as other patient and village health post characteristics. The study evaluated whether the presence of the mobile decision support tool was associated with a greater probability of HSAs (a) asking follow-up diagnostic questions, (b) providing the correct treatment for a given medical condition, and (c) providing the correct medication dosage for a given treatment. It applied logit multivariate regressions to correct for potential biases.

The study assessed the mobile tool's incremental cost-effectiveness, relative to the standard paper-based system, by measuring the cost of a 1 percent change in the proportion of children correctly diagnosed and treated per HSA. Incremental cost-effectiveness ratios were developed for 50, 500, 1,000, and 5,000 HSAs to project how the tool's cost-effectiveness would change if scaled up nationally. These ratios were adjusted for inflation, annualized, and built on key assumptions, such as the maintenance of D-tree's existing cost structure in designing, piloting, and scaling up the tool to 1,000 HSAs in Malawi.

Results

Costs

The total cost of designing and implementing the mobile decision support tool for 50 HSAs amounted to $175,678, or $3,514 per HSA ($172,483 without adjusting for inflation). These costs, both capital and recurrent, were incurred by the three partners over the life of the pilot: D-tree ($149,469), Catholic Relief Services ($20,717), and Dedza Health Commission ($5,492). Labor costs accounted for roughly 73 percent of total costs, followed by other direct costs (13 percent), with mobile phones accounting for 2 percent of total costs.

The costs of the program for 50 HSAs under the scale-up assumptions is $24,035 per year (compared to $47,857 per year as observed); some of these lower costs reflect genuine savings from more efficient implementation and some reflect missing costs for program management. Under the various scenarios presented, the cost of the mHealth program would be about $66,000, $115,000, and $490,000 per year for 500, 1000, and 5,000 HSAs implementing the program.

Effects

Under the assumption that providers in both groups correctly diagnosed patients into general illness categories, providers in the mobile group and in the paper group asked the correct follow-up questions 99 percent of the time. While not statistically significant (p=0.28), the mobile tool was associated with 0.57 lower odds of prescribing the correct treatment for a given medical symptom. This finding is likely attributable to greater stock-out of drugs in the mobile group and not due to the tools used.

The sample size was too small to demonstrate whether providers using the mobile tool had significantly higher referral rates for patients experiencing danger signs for a given medical condition. However, providers were statistically more likely to prescribe the correct dosage of medication for a given treatment when they used the mobile tool (p<.001). Excluding oral rehydration solution (ORS) and tetracycline eye ointment, HSAs delivered the clinically appropriate medication dosage to patients 5 percent of the time when only using the existing paper-based registries, compared with 95 percent, on average, for those using the mobile tool. However, under assumptions about how HSAs using the existing paper-based registries may have misreported the data, these HSAs may have given the correct dosage to up to 91 percent of patients.

Unlike providers using the paper registries, from whom no data were recorded or collected explaining decisions, those using the mobile tool provided documentation about why they did not prescribe a particular medication. The latter group indicated that stock-outs were the most common reason for not prescribing recommended treatments such as ORS, zinc, lumefantrine arthmether, antibiotics, or paracetamol.

Cost-effectiveness

Compared with the existing paper-based system, the mobile tool added to the total cost of service during the introductory deployment to 50 HSAs, but also had a positive effect. Specifically, providers using the mobile tool (a) asked all necessary follow-up questions for a given condition; (b) delivered the appropriate treatment/medication for that condition; and (c) administered the correct dosage for that treatment/medication to almost 92 percent more patients than HSAs using the existing paper-based system. The cost-effectiveness ratio was interpreted as follows: compared with the existing paper-based system, the mobile tool costs an additional $10.43 per annum for an HSA to improve his/her diagnostic and treatment accuracy by 1 percent.

Assuming that the relative effect difference does not change over time or over the number of HSAs implementing the program, the tool's cost-effectiveness improves as more HSAs enter the program. The annual cost per HSA falls by 80 percent when scaled up from 50 HSAs to 5,000 HSAs. The resulting improvement in the tool's incremental cost-effectiveness ($1.07 for 5,000 HSAs) suggests that policymakers are more likely to witness greater returns on investment if the tool is scaled up nationally and maintained over time.

Limitations

This study was conceived and designed when evaluation funding became available, after the initial implementing partners had closed the project. Cost data were derived based on staff estimates post facto. Effect data used in this study lacked quality standards, because data collection relied only on health worker records rather than direct observation of treatment and client outcomes. In turn, these methodological limitations may have inflated the benefits of the mobile tool. In particular, research shows a significant gap between what health workers say they do, and what they actually do. The generalizability of results will vary depending upon local context for health system, mobile environment, and implementing partners.

Discussion

What does mHealth cost?

The total cost of developing and deploying an mHealth application is often underrepresented in mHealth budgets, which focus on software licensing, phones, and data plans. The quarter-by-quarter breakdown of costs, categorized as planning, stakeholder relations, training, monitoring, and program management, highlights the high upfront labor costs incurred by mHealth pioneers to design, refine, and deploy interventions. As demonstrated by the scale-up scenarios, these nonrecurring development costs can provide "sticker shock" at pilot level, but decline dramatically per HSA at scale.

Do mobile decision support tools work?

Data from this study suggest there is little room for improvement in whether HSAs ask follow-up questions, and prescribing the correct drug given diagnosis may be more a function of drug availability than the tool used. Mobile tools are likely associated with greater accuracy in treatment dosage decisions. Mobile tools also create the conditions for more systematic and complete documentation of case management.

What is the threshold for cost-effectiveness?

To compare the mobile decision support tool's cost-effectiveness with other health investments, it is critical to find interventions that also contribute toward improvements in process measures of quality (e.g., correct diagnosis and treatment). While commonly found in middle- and upper-income countries, such interventions have not been systematically introduced and measured in low-income countries. Translating process measures of quality to outcome measures of quality (e.g., health outcomes) can allow for comparison with a broader range of interventions that improve child health. However, that analysis was not undertaken in this study due to the data limitations linking reported diagnoses and treatments with correct diagnosis, and the inherent uncertainties in modelling the pathway from clinical processes to health outcomes. Given the lack of mHealth cost-effectiveness data, there is no benchmark for assessing whether the iCCM tool offers adequate value for money, nor is there consensus on what threshold is acceptable for a given intervention. Further study is needed to establish benchmarks for assessing value for money.

The challenge of expanding functionality of mHealth tools

The mobile application evaluated in this study was designed and deployed five years ago and has long since been superseded by enhanced versions, which built upon the initial functions at modest marginal cost. Each additional function of the tool – improved data capture, new content modules, improved data analysis and data visualization, supervisory checklists, automated client contacts, and automated referral follow-up – provides potential clinical effects as well as net program cost savings. The cost-effectiveness of today's decision support software is likely to be greater than results generated by the version used in the present study. However, methodologies are needed that integrate the interactive effects of mHealth applications producing disparate effects. Cost-benefit analyses offer one solution for future research, as they derive a monetary value for each effect.

Conclusion

The decision-support mobile application evaluated in this study demonstrated that the estimated $1.07 cost per health worker at scale is effective in improving accuracy of treatment dose, but paper based methods were equally effective in assessing clinical severity and referring cases presenting danger signs. The primary contribution of this study is the documentation of a systematic methodology and study design for evaluating the cost effectiveness of a mHealth application. To determine whether the investment in this case reaches a threshold of cost-effectiveness, policymakers would need to consider overall budget expenditures and baseline quality indicators for iCCM deployment, and data on cost-effectiveness of alternative interventions to improve adherence to iCCM protocols.

Additional research is needed to continue building the evidence base for mHealth cost effectiveness. One key topic not addressed by the present study is the link between improved process inputs (such as correct dose) with health outcomes such as QALYs, DALYs, or lives saved. Adjustments to the coverage assumptions for iCCM based on improved probability of correct adherence to protocol may not produce detectable effects on health in environments where many health interventions are underway. The measurable value of mHealth is likely to be demonstrated primarily in documenting lower costs per unit of service delivery.

1. INTRODUCTION

1.1 Background

Mobile phone penetration has increased rapidly in the developing world, with 89 percent of all individuals owning a mobile phone in 2013 (International Telecommunications Union 2013 Facts and Figures). As mobile technology access has increased, mHealth, or the use of mobile technology to improve health outcomes, has grown rapidly in sub-Saharan Africa. mHealth has potential to address many of the challenges health systems in Africa have faced, including the severe shortages in health workers. The use of Community Health Workers (CHWs) to deliver health interventions has greatly increased in the last decade. CHWs receive limited medical training and are often deployed to the frontline of health care, identifying cases in the community and providing basic treatment. Mobile applications are promising tools for strengthening service quality provided by this dispersed workforce, and have been an area of considerable mHealth innovation. In a systematic review of studies on the use of mobile technology by CHWs, one third of the studies reported using mHealth to increase CHW's adherence to health service delivery standards and guidelines (Braun et al. 2013).

Rigorous evaluation of mHealth interventions is limited, and there have been repeated calls for more evidence of mHealth's impact on outcomes of interest (Tomlinson et al. 2013). Several individual studies have found that the quality of care provided by health workers increases when using mHealth decision support tools. A study in Tanzania found that using mobile compared to the existing paper-based systems for Integrated Management of Childhood Illnesses (IMCI) improved the completeness of patient assessments (Mitchell et al. 2013). Using short message service (SMS) has been shown to increase family planning, reproductive health, and HIV communication between CHWs and supervisors, enabling more responsive care for patients, and improved outpatient malaria care in Malawi and Kenya (Lemay et al. 2012, Zurovac et al. 2011).

A recent review argued that there is "little or no evidence around calculating costs, including both initial investments and maintenance over time" related to mHealth interventions (Braun et al. 2013). A pilot at St. Gabriel's Hospital in Malawi found that giving 75 CHWs cell phones for patient adherence reporting, appointment reminders, and physician queries saved the hospital $2,750 in fuel costs and doubled the capacity of the hospital's TB program (Mahmud et al. 2010). Tools and frameworks for assessing costs are under development, and are just starting to be applied in real-world settings and shared in the literature (Dimagi 2014, Futures Group 2014, Johns Hopkins University 2015, Nethope 2014)). To guide decision-makers, studies aimed at assessing mHealth technologies must consider the total cost of ownership for designing, piloting, and scaling up such technologies.

Despite the numerous pilots, wide scale adoption of mobile decision support tools remains low. The World Health Organization (WHO) found that broader adoption of mHealth initiatives in high, upper-middle and lower-middle income countries is hampered by competing priorities as well as lack of knowledge of these tools' value for money (WHO 2011). The absence of evidence on value and cost-effectiveness limits investments in mHealth solutions (Mechael et al. 2010, Olale et al. 2014, Futures Group 2014, Betjeman et al. 2013). To make decisions about whether to invest in particular applications, ministries of health and other program officers need to know the anticipated effects on their programs, what it costs to add a mobile component to a health program, whether the addition of a mobile component raises or lowers overall program costs, whether mobile solutions are more cost-effective than alternative solutions for achieving program objectives, as well as the settings in which mobile tools offer the greatest value-for-money.

1.2 iCCM Mobile Tool

D-tree International (D-tree), a health NGO, uses mobile technology to provide decision support tools for health workers. The PEPFAR-funded IMPACT project, led by Catholic Relief Services (CRS), partnered with D-tree International in Malawi to support its development of a phone-based application incorporating WHO's Integrated Community Case Management (iCCM) approach to child health. CRS partnered with the Malawi Ministry of Health to improve the quality of care provided by CHWs, known in Malawi as Health Surveillance Assistants (HSAs). D-tree's electronic iCCM application uses checklists and decision information designed to promote thorough assessment of each child, reduce diagnostic errors, improve adherence to recommended treatment, and facilitate patient follow-up for acutely ill children to guide workers. It is designed for use by HSAs previously trained in the assessment of children presenting with common symptoms linked to childhood morbidity and mortality, including fever, diarrhea, cough, and rapid breathing.

The iCCM application evaluated in this study captures all the iCCM elements in the paper registers used by the HSAs. The iCCM form includes space to record personal information about the child (e.g., name, address, age), symptoms present (e.g., diarrhea, fever), danger signs (e.g., blood in the stool, fever more than seven days), decision to refer to a health facility or not, and treatment and dosage prescribed. D-tree's original mobile application served only as a decision support tool to help providers diagnose and treat childhood illnesses and was not designed to replace the existing paper-based system in Malawi. Rather, the tool offers a supplemental functionality to the health worker. Paper registries are still used to manage patient records and submit data, and all health workers receive identical iCCM face-to-face training. The tool has since been expanded to include additional functionality such as record management capabilities, but these functions were not in place during the time period covered by the data included in our study.

1.3 Study Context and Objectives

The present study is designed to contribute to mHealth evidence in several ways. Given the growing interest by policymakers and donors in designing, evaluating, and scaling up mHealth tools to improve health system performance, a primary objective of this study is to provide a transparent and detailed methodology for categorizing the total costs of building, deploying, and scaling mHealth interventions, particularly for mHealth decision support tools. It also provides an observational evaluation of the mobile application's effectiveness at improving clinical quality of care. In doing so, this study aims to contribute to evidence-based decisions about whether and under what conditions mobile decision support tools should be implemented.

A secondary objective of this study is to contribute evidence on the cost-effectiveness of D-tree's mobile iCCM decision support tool and its ability to improve the quality of health worker management of childhood illness. Specifically, this study aims to provide an analytical approach for quantifying the cost per child correctly diagnosed and treated for the mobile application relative to the existing paper-based system. This analysis will also inform policymakers, donors, and program managers on how the cost-effectiveness of such tools change as they are scaled up, in addition to how value for money changes as mHealth tools expand from single function to multifunctional devices.

In conducting cost-effectiveness analyses, this study deviates from some commonly used methodologies (Drummond et al. 2005; Briggs 2001). First, this study collected secondary data on process measures such as adherence to protocol, diagnoses, and treatment decisions, but not outcome measures (Donabedian 1988). Summary health outcome indicators that measure child mortality and/or morbidity are commonly used in cost-effectiveness evaluations and provide a common metric for policymakers to compare the cost-effectiveness of disparate interventions. Because this study includes only process measures, it would need to take an additional step of translating the process measures into health outcomes such as lives saved or DALYs. Existing tools, such as LiST, provide modeling software that enable programs to estimate the impact of scaling up community-based interventions on health outcomes. However, this study does not attempt to model health impact, because it does not have the data to quantify the relationship between process quality and health impact with strong statistical validity and confidence. There is nonetheless growing evidence linking the positive impact of improved clinical process measures, such as diagnoses and treatment decisions, on health outcomes (Rubin et al. 2001; Donabedian 1988).

Second, the nature of mobile applications such as the D-tree decision support tool is that they facilitate many independent micro decisions, behaviors, and processes. This study focuses on understanding and measuring the tool's overall effectiveness at facilitating adherence to multiple steps within the iCCM protocol and for multiple clinical conditions. Thus, understanding the changes in the proportion of children correctly diagnosed and treated provides a means of illuminating the overall value for money of investing in the tool directly linked to behavior changes directly targeted by the tool. However, it does not attempt to assess the relative cost-effectiveness for each clinical condition or behavioral outcome.

Finally, the tool evaluated in this study is an early-stage prototype developed in 2011 that has since been completely redesigned and enhanced. As such, the dollar amounts per improvement are not intended to inform investment in this particular tool, which has been superseded by a later edition. D-tree's updated application has since evolved to integrate extensive additional functionality including case management, data collection and reporting, referral management, and client follow-up messages. Mobile tools with more functionality offer savings and efficiencies across more service elements, providing more bang for each investment buck. Future studies will face the challenge of monetizing and aggregating the cumulative benefits of timely accurate data, reduced health worker administrative burdens, and other health system savings to determine the cost-effectiveness of the current iterations of multifunctional mHealth tools.

2. ANALYTICAL FRAMEWORK

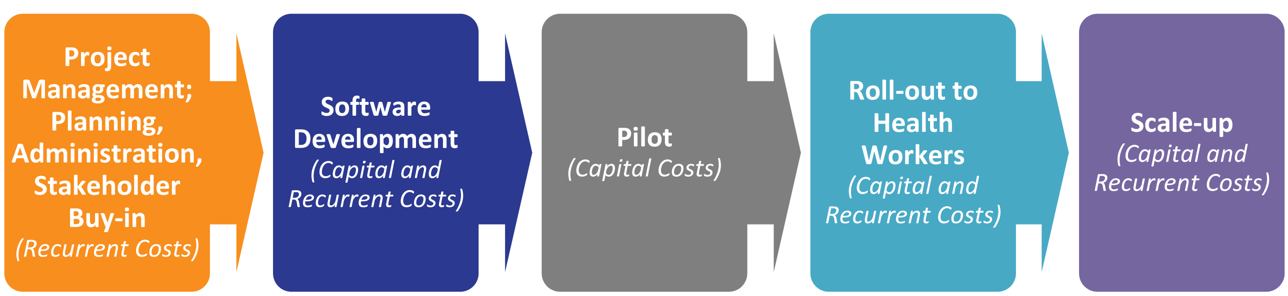
2.1 Analytical Framework

This study used the WHO guidelines contained in "Cost Analysis in Primary Health Care" to develop the costing model and categorize costs (Creese and Parker 1994). The WHO model classifies input costs into two categories: capital and recurrent. Capital costs are purchased a single time, and used for longer than one year. The length of time such a resource can be used is considered the expected useful life, and the cost of the resource is typically annualized across the expected life. Recurrent costs are used up within the course of a year, and are usually purchased regularly.

In identifying the costs to be included, the study used the Total Cost of Ownership (TCO) Life Cycle Analysis, commonly used for decision making in business and for IT infrastructure acquisition. The TCO Life Cycle Analysis considers the costs at each stage of ownership or implementation, from purchase through retirement. For the purposes of this study, the costs of evolving and maintaining the tool, and retiring the technology were not included, as the study was a pilot and did not extend to these stages. Rather, the study assessed the first four stages: development/purchasing, set-up and installment, deployment, and management support of the tool.

Using the WHO and TCO models to guide the development of the analytical framework, costs were categorized by life cycle stage and type of input: capital or recurrent. The life cycle stages were defined as: project management, including planning, administration, and obtaining stakeholder buy-in; developing the software; piloting the tool with a small group of health workers; rolling out the tool to additional health workers; and finally scale-up (see Figure 1).

FIGURE 1: COSTING FRAMEWORK



The stages in this study's costing framework are not necessarily sequential. The costs of project management, software development, licensing fees, and training health workers to use the tool continue throughout the life of the tool's implementation. While most stages include both capital and recurrent costs, some include only capital costs, others only recurrent costs.

2.2 Cost Categories

Based on the costing framework presented in Figure 1, this section discusses specific costs that were included in each life cycle stage of D-tree's mobile decision support tool (see Table 1). Expense items are classified as either start-up costs or recurrent costs. Start-up costs are defined as the costs associated with activities needed at the start of the program and are not expected to be incurred again over the life of the program. Recurrent costs are defined as costs associated with activities that are needed on an annual basis in order to operate the program. Additionally, costs are divided into national-level costs and HSA-level costs. National costs are activities that need to occur no matter how many HSAs are using the mobile decision support tool, whereas HSA-level costs depend directly on the number of HSAs engaged in the program. Note that potential costs at the district level, such as for supportive supervision, are not included in these analyses because district-level staff already engage in these activities for the paper-based system.

TABLE 1: COST CATEGORIES AND ACTIVITIES

Expense item	Activities
National-level costs	
Start-up costs	
Labor	
General Stakeholder Engagement and Project Management	Contracting, budgeting, work planning, reporting, administration, stakeholder outreach, buy-in meetings, communication, travel
Software Development	CommCare agreement negotiation, software coding, software testing, software development meetings and communication, content translation and approval
Mobile Services	Landscaping, device and data plan negotiations, phone specifications
Training	Pilot (training protocol development, health worker training, feedback collection and analysis)
Other Direct	Network charges, server hosting, registration (for period before start of program)
Indirect	Rent, office supplies, vehicle, gas, utilities, and other overhead
Recurrent costs	
Labor	
General Stakeholder and Management	Contracting, budgeting, work planning, reporting, administration, stakeholder outreach, buy-in meetings, communication, travel
Software Support	Device and data plan negotiations, software coding, redesign, and debugging
Monitoring	HSA troubleshooting, tech support
Other Direct	Network charges, server hosting, registration (after start of program)
Indirect	Rent, office supplies, vehicle, gas, utilities, and other overhead

Expense item	Activities
HSA-level costs	
Labor	
Training (International Support)	Labor for support to training
Training (Local Support)	Per diem, accommodation, transportation, training materials (staff costs for training not included)
Other Direct	
Phone purchase	Mobile device procurement

2.2.1 General Stakeholder Engagement and Project Management

General stakeholder engagement and project management includes the start-up cost of planning, administration, communication, and stakeholder meetings and buy-in. The project set-up and pilot stages required intensive meetings among D-tree staff, partners and stakeholders. Much of this early project management included gaining buy-in on the mobile iCCM tool from national and local stakeholders. However, stakeholder meetings, administrative support, and general project management are necessary over the project's entire life cycle. Some resources for continued planning, administration, and stakeholder engagement are thus considered to be recurrent costs.

2.2.2 Software Development and Support

Software development is an intensive, initial development phase of the mobile decision support tool followed by ongoing testing and refinement. Tool development included the translation of iCCM content into a digital format. The D-tree mobile decision-making tool was built upon an existing "CommCare" platform, which required significant modification to support the mobile decision-making tool. Early software development and testing included D-tree staff and clinicians. Throughout the tool's pilot, roll-out, and eventual scale-up, costs are incurred to modify the tool and, eventually, add new functions. For this reason, software development includes both capital and recurrent costs, reflecting the initial development of the software and continued technical support to update and troubleshoot the software.

2.2.3 Mobile Services

Mobile services include the process of landscaping phone companies and networks, as well as determining phone specifications. It also includes mobile device and data plan negotiations with providers. Even though these contracts are impacted by the number of phones procured, and thus the number of HSAs, these costs are largely national costs negotiated and incurred during start-up.

2.2.4 Training

In preparation for the pilot, D-tree negotiated device prices and data plans with vendors and developed a health worker training protocol. The pilot included six HSAs and meetings with users every two weeks to learn about their experiences and problems with the application. Finally, these six HSAs tested mobile decision support tool on patients and provided feedback to D-tree on its issues, challenges, and benefits. Costs incurred to develop the training protocols and pilot the tool are considered start-up costs, because they are incurred only once.

2.2.5 Other Direct Costs

Network charges, server hosting, and registration occurred both in preparation for the program (for period before start of program, considered to be start-up costs) and on a routine basis throughout the life of the program, and are considered recurrent costs. However, these costs are fixed costs, in that they are incurred no matter how many HSAs are using the mHealth iCCM application.

2.2.6 Indirect Costs

Indirect costs include office rent, utilities, transportation, and other overhead incurred to support staff and activities associated with other activities. Indirect costs are calculated as a percentage of the cost of labor, based on the implementing partners' specific accounting rules. Indirect costs incurred before the training of the initial HSAs on the mHealth application are considered start-up costs.

2.2.7 Monitoring

Unlike training costs, monitoring costs are considered to be national, recurrent costs, because HSAs are in regular need of troubleshooting and technical support. A specified number of staff must always be on call to address technical or nontechnical issues, irrespective of the exact number of HSAs trained and utilizing the mobile devices. This is particularly the case as the functionality of a mobile device expands.

2.2.8 HSA Costs

HSA costs are costs associated with each HSA when the tool is disseminated and utilized by a large number of HSAs across the country. These costs cover the costs of training HSAs, including the associated support, per diems, accommodation, transportation, and training materials. Staff salaries paid to the trainers or training recipients during training not included. They also include the cost of procuring phones for the HSAs to use, and their maintenance over time.

3. DATA AND METHODOLOGY

3.1 Data

3.1.1 Costs

Cost data on the iCCM mobile tool were collected for the period October 2010 through March 2013 from three secondary sources: D-tree, the developer of the mobile decision support tool; CRS, the implementer of the iCCM program; and Dedza Health Commission (DHC), which trained HSAs on the mobile tool.

Because the mobile tool supplements but does not replace the existing paper-based system, the only cost data collected relate to the design, pilot, and roll-out of the mobile tool. Cost data were not collected or used for the existing paper-based system. For instance, HSAs using the mobile application received the same iCCM face-to-face training as those who only use and fill out the paper-based system. As such the cost of this training was not considered in the study.

Moreover, due to the fact that cost data could not be collected from all local NGO partners, data were collected only from DHC and used as a proxy for all other eight partners. To calculate total NGO partner costs, DHC costs were scaled up for 50 HSAs. Cost data also likely contain some measurement error, because certain costs (e.g., labor) were estimated retrospectively by D-tree, CRS, and DHC. The effect of such error is discussed in Section 3.3.

Costs are calculated in two ways. First, costs for both roll-out to 50 HSAs and the scale-up to 1,000 HSAs are presented as incurred during the actual program. These costs are both unadjusted (raw) and adjusted for inflation, and presented in 2013 U.S. dollars. For the latter group, costs incurred by D-tree and CRS are adjusted using the inflation rate in the United States, since costs for these partners are budgeted and incurred directly in U.S. dollars. Costs for DHC were adjusted for inflation using the applicable inflation rates from Malawi. International Monetary Fund GDP deflators were used to calculate inflation (IMF 2015).

Second, for the cost-effectiveness analysis, we calculate the annual equivalent costs of the program. For this calculation, only costs incurred by D-tree and Malawi's government are considered, even during the initial 50 HSA roll-out phase. Moreover, the costs of start-up activities and durable goods (including mobile phones and training of HSAs) are amortized over their assumed useful life. We use a discount rate of 3 percent to calculate the annual equivalent costs, per WHO guidelines (Baltussen et al. 2003).

3.1.2 Scale-up Costs

The main analyses of this study present the actual and inflation-adjusted costs, based on D-tree's experience through 2013. Since that time, D-tree has scaled up the program to reach 1,000 HSAS. These scale-up experiences are presented in Table 2 and are organized into two groups: cost sources and cost categories. While the three primary cost sources in this study were D-tree, CRS, and DHC, these sources and their respective roles changed considerably during scale-up.

After establishing offices in country, it was decided that either D-tree or its partner (in this case CRS) would stay on in country to scale up the tool while the other would stop contributing. In the case of the mobile decision support tool, CRS's role in project management, training, and monitoring was no longer needed, and thus no scale-up costs were incurred by CRS. D-tree has handed over most of the roles and responsibilities for scale-up to Malawi's government. As such, the government has been responsible for training new HSAS, purchasing phones, and paying existing staff. D-tree has taken on the role of advisor to the government, whereby it assists in supervision and training HSAS when needed. For this reason, DHC and other local NGOs, whose original role was to train HSAS on the mobile decision support tool, have also no longer been needed during scale-up.

TABLE 2: SCALE-UP EXPERIENCES

Overview of Roles	Government assumes responsibility of scale-up; Only one implementing partner needed to assist government (D-tree), while all others (CRS, DHC) drop off
Source of Costs	1. *D-tree*: Labor costs for content/programming/mobile services fall to zero during scale-up; labor costs for monitoring, stakeholder engagement, management, and training become minimal 2. *CRS:* Cost of labor, travel, supplies, phones, and rent fall to zero during scale-up 3. *DHC:* Cost of labor, travel, and supplies fall to zero during scale-up 4. *Government:* No role during design phase, but takes over labor costs (salaries), training supplies, and phones
Scale-up Cost Categories	1. *Government* a. Labor: Existing salaries, and thus no additional costs incurred b. Training: i. Per diem/accommodation: 1.5 days per training session, 2 trainers per session, 20 HSAs per session; $50 per HSA and $5 per HSA (for trainers) per training session. ii. Transportation: Costs include trainers and HSAs; $17 per HSA per training session iii. Supplies: $2 per HSA for training materials c. Phones: No economies of scale; $76 per phone per HSA; $8 per airtime per HAS 2. *D-tree* a. Labor: i. Stakeholder relations/management/supervision: Costs by district rather than number of HSAs; D-tree is last point of contact and only addresses software issues; $11 per HAS ii. Training: One staff member per five HSA training sessions over two days; $2 per HSA

Cost categories during scale-up have been broken down by the two sources of funding active during the scale-up: D-tree and Malawi's government. The only costs incurred by D-tree after the initial 50 HSA roll-out are those for labor – specifically, general stakeholder relations, management, technical support, and training. For stakeholder outreach and management, D-tree has incurred costs according to the number of districts rather than number of HSAs.

D-tree staff is working across these districts on program development, staff supervision, training, and financial management. For supervision, the existing model in Malawi is such that HSAs must first rely on government employees to troubleshoot issues with the mobile tool, followed by district health IMCI supervisors. Only problems requiring software changes are addressed by D-tree staff, who act as the third backstop for supervision and oversight. Management, outreach, and supervision have required roughly one D-tree staff member working at half time for every 1,000 HSAs, the equivalent of $11 per HSA. D-tree staff are also expected to oversee five training sessions at a time, whereby each training session includes 20 HSAs and lasts for two days. Thus, the cost for D-tree staff of training has been roughly $2 per HSA.

CRS and DHC costs have fallen to zero during scale-up, as neither organization incurred costs after the initial design, pilot, and roll-out to 50 HSAs. Malawi's government has incurred costs for salaries, training, and phones. Labor costs attributed to mobile tool have been zero, because training and monitoring costs are already covered by the government's salaried responsibilities. Data are not available on the time cost or productivity loss associated with these changing roles.

D-tree has not witnessed economies of scale in the bulk purchasing of phones, because D-tree's experience has been that these are offset by increased functionality and costs as successive phones are purchased. The cost of training has been broken into three components: per diems/accommodation, transportation, and materials. The cost per HSA for per diems and accommodation of a typical 1.5 day training session has been $50, while the per diem and accommodation costs for a trainer to train one HSA (two trainers are required for a 20 HSA training session) has been $5. This totals $55 per has for training logistics. Transportation per HSA, accounting for both trainers and the HSAs, has been $17. Training materials equate to $2 per HSA. Across both D-tree and Malawi's government, the total cost per HSA during scale-up to date has been $172. As discussed in Section 3.1.1, costs for training and phone procurement are annualized for the cost-effectiveness analysis.

3.1.3 Effects

Effect data were collected from a D-tree study conducted between March 2011 and March 2013. Based on a convenience sample of HSAs, 50 HSAs went through training on IMCI and the iCCM mobile decision support tool. These 50 HSAs were non-randomly selected from different village health posts across three districts (Lilongwe, Zomba, and Ntcheu) in Malawi, where 25 HSAs treated children using the mobile tool, while the other 25 HSAs treated children using only paper registries. Over the two-year period, a random sample of 625 patient records for children under five years of age was taken from each group (i.e., 1,250 child cases in total).

As such, the total sample size in this study was 1,250 patients, 625 of whom were diagnosed and treated with the mobile tool and 625 of whom received care from HSAs using only the paper-based registries. For each patient-level observation, HSAs recorded data on patient symptoms and diagnoses (fever, diarrhea, fast breathing, and red eye), patient clinical severity, treatments provided by health providers (per iCCM protocol) for those conditions, whether patients with more severe illness were referred, reasons why providers failed to administer appropriate treatments, as well as patient and village health post characteristics. With regards to referrals, all HSAs have the option to refer patients to health facilities for more complex and serious clinical conditions.

For the mobile group, HSAs were prompted and required to ask diagnostic questions to patients based on the symptoms and diagnosis; they were also required to confirm this behavior and record the patients' response to these questions in the mobile tool. Subsequent questions were presented to HSAs (which are then asked to patients), which eventually led to a recommended treatment. This was done as an app running on the phone. The data from each encounter were electronically uploaded to a central server for further use as a medical record.

For the group using the paper-based system, HSAs were provided an identical list of instructions and questions based on a patient's condition. They were asked to independently follow the instructions and fill out the paper registries during each patient visit. In addition to the fact that this information is recorded on a paper registry instead of a mobile phone, two other differences exist. First, unlike users of the mobile tool, HSAs are not obligated to record data or information into the registries. Second, unlike the mobile tool, the paper registries do not provide clinical treatment guidelines based on a given diagnosis. D-tree staff collected the paper registries from the HSAs' records, cleaned the data, and provided both datasets (mobile and paper) to HFG for analysis.

3.2 Evaluation Methods

The purpose of the evaluation was to assess whether the presence of the mobile decision support tool was associated with (a) a greater probability of HSAs asking follow-up diagnostic questions, (b) a greater probability of HSAs providing the correct treatment for a given medical condition, and (c) a greater probability of HSAs providing the correct medication dosage for a given treatment. To evaluate these three objectives, the study applied a range of statistical models including Fisher's exact test, bi-variate regressions, and multivariate regressions. Multi-variate analyses were conducted using logit models, because the dependent variables were all binary. Co-variates included case-mix (clinical severity) and other patient-level characteristics, as shown in Figure 2. These equations are as follows:

FIGURE 2: MULTIVARIATE EQUATIONS

1. Logit (Diagnostic Questions = 1) = Mobile Tool + Gender + Age + Symptom
2. Logit (Correct Treatment = 1) = Mobile Tool + Gender + Age + Symptom + Clinical Severity
3. Logit (Correct Dosage = 1) = Mobile Tool + Gender + Age + Symptom + Clinical Severity + Treatment

Symptom is measured as the presence of diarrhea, fever, fast breathing, red eye, and cough individually (as recorded by the HSAs). Clinical severity is measured as whether there was one symptom present or multiple symptoms, and treatment is measured as whether only one symptom was given a treatment or multiple symptoms were treated.

The absence of data on other co-variates, such as provider-level characteristics, availability of medical supplies, and drugs, was expected to artificially inflate the relationship between the mobile tool's use and the study's three variables of interest. Several factors were likely to create biases. First, the absence of randomization at the HSA level and potential impact of unobserved/unrecorded variables may have led to selection bias. For example, HSAs may have been selected to implement the mHealth tool based on their perceived performance (good or bad), and thus their performance may differ from the comparison HSAs (for better or worse) without the mHealth intervention. Second, the lack of oversight for HSAs using the mobile tool and paper registries likely led to measurement error. The effects and implications were threefold.

1. An assumption had to be made that HSAs correctly diagnosed their patients for broad clinical conditions, such as diarrhea, red eye, fever, or fast breathing. Without observers in place to monitor those HSAs, it was not possible to know if these decisions were accurate. However, the outcome variables used in these analyses are conditional upon the broadly defined clinical condition. For example, HSAs should ask the relevant follow-up questions, provide treatment, and provide the correct dosage of treatment for diarrhea regardless of whether the child was

correctly diagnosed for diarrhea. On the other hand, if HSAs tended to not diagnose broad categories that are 'harder' to follow-up and treat (e.g., involve more questions or assessment) this assumption may bias results if HSAs in one treatment arm were more likely to misdiagnose than HSAs in the other treatment arm.

2. Data were missing for some observations. We observe that the paper-based group was more likely to have missing data, although missing data for the outcome variables was always less than 5 percent. While unlikely, this could bias the findings.
3. It is feasible that HSAs using the paper-based registries may have incorrectly recorded data by misinterpreting instructions. Under such a scenario, HSAs using the paper tool could have diagnosed or treated patients correctly, but the results would suggest otherwise (or vice versa). While the mobile tool and the paper registries have identical instructions, the mobile interface helps HSAs record data correctly. Thus, recording error may potentially bias findings.

To assess the potential impact of erroneously recorded data, we conducted a sensitivity analysis on the data from the HSAs using the paper-based system. This sensitivity analysis makes arbitrary, but potentially valid, adjustments to the data to measure the degree to which erroneously recorded data may have influenced the results. Specifically, the assumption is made that HSAs were recording (i) the type of blister pack given for lumafenitrine artemether (LA) instead of the number of pills (i.e., a record of "1" indicates the HSA gave a 1x6 blister pack, with 6 pills instead of 1, and a record of "2" indicates the HSA gave a 2x6 blister pack, with 12 pills instead of 2), and (ii) for cotrimoxazole, zinc, and paracetamol, it was assumed that paper data recorded number of pills per day instead of the total number of pills).

3.3 Incremental Cost-effectiveness Model

This study examined the mobile tool's incremental cost-effectiveness, relative to the standard paper-based system, by measuring the cost per HSA per percent change in children correctly diagnosed and treated. For "correct diagnosis and treatment" to be achieved, this study required that the following conditions be met: (a) all appropriate follow-up questions for a given condition were asked; (b) the appropriate treatment/medication for that condition was delivered; and (c) the correct dosage for that treatment/medication was administered. In other words, if the mobile tool improves diagnostic and treatment accuracy, the above incremental cost-effectiveness ratio would be interpreted as "the cost of an HSA improving their diagnosis and treatment accuracy by 1 percent, above and beyond the existing paper-based system."

The percent of correctly diagnosed and treated patients was recorded for the 625 sample cases being treated by mobile users as well as the 625 sample cases being treated by paper users. This approach was taken after risk adjusting for patient case mix (clinical conditions included diarrhea, fever, fast breathing, and red eye). The cost used in this model was the cost per HSA of designing and implementing D-tree's mobile decision support tool in Malawi.

The incremental cost-effectiveness ratio above was derived using the following logic model.

1. $$\frac{\textit{Cost per HSA Mobile Tool}}{\textit{\% of Mobile Cases Correctly Diagnosed \& Treated} - \textit{\% of Paper Cases Correctly Diagnosed \& Treated}}$$

For the numerator, the change in cost per HSA is simply the total cost per HSA of the mobile tool, since the costs of the paper-based were incurred by both groups. For the denominator, the percent of cases (out of 625) correctly diagnosed and treated for HSAs using the paper-based system was subtracted from the percent of cases (out of 625) for HSAs using the mobile tool.

$$1 \; \frac{Change\ in\ Cost\ per\ HSA}{Change\ in\ \%\ of\ Cases\ Correctly\ Diagnosed\ \&\ Treated}$$

This leads to the change in cost per HSA (e.g., the cost per HSA of the mobile tool) over the percent change in the number of cases correctly diagnosed and treated.

$$2. \quad \frac{Cost\ per\ HSA}{1\ \%\ of\ Paper\ Cases\ Correctly\ Diagnosed\ \&\ Treated}$$

This ratio can be broken down further, thus giving the cost per HSA per percent change in cases correctly diagnosed and treated when the mobile tool is used in lieu of the existing paper-based system. Because the mobile tool supplements the existing paper-based system, one would expect the cost (numerator) to be positive. However, depending on whether the mobile or existing paper-based systems lead to a greater percent of cases correctly diagnosed and treated (denominator), the incremental cost-effectiveness ratio may be positive or negative.

3.4 Incremental Cost-effectiveness Assumptions

The following assumptions were made for the study's cost-effectiveness analyses, which include (a) the cost-effectiveness of designing, piloting, and rolling it out to 50 HSAs and (b) the incremental cost-effectiveness of scaling up the mobile tool to 5,000 HSAs:

1. A commonly applied practice in cost-effectiveness analyses is to choose an analysis perspective, such as that of society, the government, health care providers, donors, or implementers. This study takes the perspective of both implementers and governments. For implementers, this study provides the cost to them of designing, piloting, and rolling out a mobile decision support tool to a small number of HSAs. During scale-up, the costs in this study include the government perspective, because D-tree handed off most of the responsibility for the mobile decision support tool's scale-up to the Malawian government, as well as international technical support from D-tree.
2. While actual (raw) data are separately presented for those costs incurred by D-tree, CRS, and DHC, the cost-effectiveness section of the study uses inflation adjusted, annualized costs.
3. Incremental cost-effectiveness ratios are presented at different levels of program scale, up to 5,000 HSAs. As of 2009, there were 10,055 HSAs in Malawi, though it is unlikely that every one of them would receive a mobile tool (because not all HSAs implement iCCM). This figure was chosen to show how the cost-effectiveness of the mobile decision support tool would change as it is gradually scaled up to half of all HSAs in Malawi. To derive the cost-effectiveness of scaling up the mobile decision support tool, it is assumed that the cost structure presented in Section 3.1, which represents costs incurred during D-tree's scale-up to 1,000 HSAs, would remain the same when scaling up to 5,000 HSAs. Moreover, it is assumed that mobile phones will need to be replaced every two years and HSAs given refresher training courses every five years.

4. RESULTS

We present first the costs as incurred by the program and its three implementing partners. These costs include those for start-up, design of the mobile tool, a pilot, and roll-out to 50 HSAs, as well as the existing scale-up to 1,000 HSAs. These results are intended to inform other programs considering the implementation of similar programs as to the amounts of financial resources needed. Evaluation results are then presented showing where and to what extent differences in diagnoses and treatments exist between mobile and paper groups. The costs and effects are combined to report the incremental cost-effectiveness of the program as observed. Finally, findings from the study's cost and incremental cost-effectiveness analysis are modelled and presented for the mobile tool's national scale-up to 5,000 HSAs.

4.1 Costs

4.1.1 Design, Pilot, and Roll-Out

In Sections 4.1.1.1 through 4.1.1.3, costs are presented for each of the primary stakeholders involved in the design, implementation, and roll-out of the iCCM tool to 50 HSAs in Malawi, by expense category, and finally by time period. Costs were collected from the period October 2010 to March 2013. The former marks the study inception when the mobile tool was being designed in Malawi; the end date marks the final month of "effect" data collected by the HSAs. Total inflation-adjusted costs over this period were $175,678 ($172,483 without adjusting for inflation). Unadjusted costs were broken down by quarter for each implementing partner (Annexes A-C). This time interval was chosen because it offered the best combination of data granularity, availability, and quality.

4.1.1.1 D-tree Costs

D-tree incurred $149,649 (inflation-adjusted) over four years to start the program, representing 85 percent of all the costs incurred (Annex A and Table 3). About 77 percent of D-tree costs were incurred for labor. About 46 percent of a full-time equivalent (FTE) person working on the program in 2011 and 2012; smaller proportions of an FTE were incurred in 2010 and 2013 because the program was not implemented for the full year. Labor costs include D-tree staff, fringe benefits, and consultants. Labor is broken down by general stakeholder and management, iCCM content and programming, mobile services, training, and monitoring. iCCM content and programming represented 39 percent of total labor costs for the iCCM project, monitoring costs represented 23 percent of costs, and training represented 20 percent of costs; the other labor categories together constituted under 20 percent of costs. Other direct costs and indirect costs constituted the remainder of D-tree costs.

TABLE 3: COST OF PROGRAMS TO REACH 50 HSAS (2013 US$)

Category	2010		2011		2012		2013		Percentage of Total
	FTE	Salary	FTE	Salary	FTE	Salary	FTE	Salary	
D-tree									
Labor									
General Stakeholder and Management	1%	$730	7%	$7,435	5%	$4,237	1%	$579	7%
ICCM Content and Programming	4%	$2,433	23%	$35,675	5%	$6,653	1%	$629	26%
Mobile Services	1%	$487	5%	$4,958	2%	$2,118	1%	$290	4%
Training	1%	$730	7%	$7,435	23%	$13,615	6%	$869	13%
Monitoring	1%	$487	5%	$4,958	11%	$18,159	3%	$3,280	15%
Sub-total, labor	8%	*$4,867*	46%	*$60,460*	46%	*$44,782*	13%	*$5,647*	66%
Other Direct	NA	$2,639	NA	$13,254	NA	$4,948	NA	$2,618	13%
Indirect	0%	$0	3%	$2,203	14%	$6,740	4%	$1,311	6%
Total D-tree Costs		**$7,506**		**$75,917**		**$56,471**		**$9,576**	**85%**
CRS									
Labor			10%	$3,157	29%	$9,301			7%
Travel			NA	$468	NA	$1,378			1%
Office Supplies			NA	$363	NA	$1,068			1%
Phones			NA	$938	NA	$2,762			2%
Rent			NA	$325	NA	$957			1%
Other			NA	$0	NA	$0			0%
Total CRS Costs				**$5,250**		**$15,466**			**12%**
DHC									
Training Costs									
Labor			NA	$96	NA	$196			0.2%
Travel			NA	$25	NA	$245			0.2%
Training Supplies			NA	$449	NA	$4,481			3%
Total DHC Costs				**$570**		**$4,922**			**3%**
Total Costs of iCCM Program		**$7,506**		**$81,737**		**$76,859**		**$9,576**	

NA: Not applicable; FTE: Full-time equivalent

4.1.1.2 Catholic Relief Services Costs

After D-tree, CRS incurred the second most costs for the program at $20,717 (inflation-adjusted), which represented 12 percent of the cost of the entire program (Annex B and Table 3). About 60 percent of CRS costs were for labor, with 18 percent of costs for phone procurement. Travel, supplies, and rent constitute the remainder of CRS costs.

4.1.1.3 Dedza Health Commission Costs

The DHC supported the training of HSAs on the mHealth tool (Annex C and Table 3). The DHC incurred $5,492 (inflation-adjusted) in 2011-2012 in support of the program (3 percent of all costs), with 90 percent of costs incurred relating to training supplies.

4.2 Effects

In the following sections, findings are presented from calculations identified in Section 3.3. It is again critical to note that the absence of HSA observers led to two limitations/assumptions: (a) the study assumed that health providers were able to correctly diagnose patients into the following conditions: diarrhea, fever, rapid breathing, or red eye; (b) HSAs using the paper registries may not have recorded data or instead recorded data incorrectly. As such, the magnitude of these effects may be inflated.

4.2.1 Diagnosis Questions to Assess Clinical Severity

This section presents results on whether providers were more likely to follow government-approved and evidence-based protocols and asked the required follow-up questions for each illness once a patient was diagnosed with that particular condition. As shown in Table 4, patients/caretakers were asked the appropriate follow-up question 99 percent of the time for patients diagnosed with diarrhea, fever, cough, fast breathing, and red eye among health providers using both the mobile phone and the existing paper-based system. Multivariate findings indicated that use of the mobile tool was associated with 2.19 times greater odds of asking follow-up questions, but the association is not statistically significant ($p = 0.28$).

TABLE 4: FOLLOW-UP QUESTIONS BY ILLNESS TYPE

Illness	Diagnosis	Mobile	Paper	Unadjusted P-Value
Diarrhea	Asked # of days of diarrhea	100%	100%	n/a
	Asked if blood in stool	100%	100%	n/a
Fever	Asked # of days of fever	100%	100%	n/a
Cough	Counted breaths per minute	97%	98%	0.56
Fast Breathing	Asked # of days of cough	100%	99%	0.13
	Looked for chest in-drawing	100%	100%	n/a
Red Eye	Asked # of days of red eye	100%	100%	n/a
	Asked # of days difficulty	100%	100%	n/a
Total		**99%**	**99%**	***0.67***
Adjusted Odds Ratio			**2.19**	***0.28***

Diagnostic questions with * and ** represent those significant at the $p<.10$ and $p<0.05$ levels, respectively

4.2.2 Treatment

For each medical condition, guidelines stipulate certain treatments: oral rehydration solutions (ORS) and zinc for diarrhea, LA and paracetamol for fever, oral antibiotics (cotrimoxazole) for respiratory infections, and tetracycline eye ointment (an antibiotic) for red eye. In adjusted terms, HSAs employing the existing paper-based system were associated with more accurate treatment patterns for illness types (Table 5). They were more likely than mobile users to prescribe zinc for diarrhea ($p = 0.002$), and were more likely to prescribe paracetamol for fever ($p = 0.01$). Mobile users, on the other hand, were more likely to prescribe LA for fever ($p<0.001$). Overall, mobile users prescribed the appropriate medication for the diagnoses of patients 65 percent of the time, compared with 77 percent of the time for the users of the existing paper-based system ($p = 0.02$). In multivariate analysis, the mobile tool was associated with 0.57 times lower odds of prescribing the correct treatment, but the association is not statistically significant ($p = 0.28$).

Mobile users recorded the lowest prescription accuracy for paracetamol among patients with fever and antibiotics for red eye among patients that were referred. As discussed later, mobile users reported high stock-out rates for paracetamol (see Table 8). Users of the existing paper-based also had the lowest percent of correct prescriptions for paracetamol among patients with fever.

TABLE 5: TREATMENT PATTERNS BY ILLNESS TYPE

Illness	Treatment	Mobile	Paper	Unadjusted P-Value
Diarrhea	Prescribed ORS (Village posts)	100%	99%	0.50
	Prescribed zinc (Village posts)	89%	99%	0.002**
	Prescribed ORS (Refer)	94%	100%	0.99
Fever	Prescribed LA (Village posts)	100%	96%	<0.001**
	Prescribed paracetamol (Village posts)	57%	66%	0.01**
	Prescribed LA (Refer)	90%	75%	0.27
Respiratory infection	Prescribed oral antibiotics (Village posts)	99%	97%	0.06
	Prescribed oral antibiotics (Refer)	95%	100%	0.99
Red Eye	Prescribed antibiotic treatment (Village posts)	100%	86%	0.23
	Prescribed antibiotic treatment (Refer)	13%	n/a	n/a
Total		***65%***	***77%***	***0.02*****
Adjusted Odds Ratio			***0.57***	***0.28***

Treatments with * and ** represent those significant at the p<.10 and p<0.05 levels, respectively

The mobile tool was, on average, associated with significantly greater odds of prescribing the clinically recommended dosage given for those treatments ($p<0.001$) in bivariate and multivariate analyses (Table 6). While mobile users gave the correct dosage 95 percent of the time, based on the data as recorded in the registers, users of the existing paper-based system gave the correct dosage 5 percent of the time. The only category of patients given the correct dosage of treatment among users of the existing paper-based system were for LA among children aged up to five months presenting with fever, for which the correct dosage is none (because these children are too young to take the pills). On the other hand, mobile users prescribed the correct dosage over 90 percent of the time across all diagnoses and age groups. Note that Table 6 does not present dosage for ointments (red eye) or ORS (diarrhea), as there were no clinically defined dosage for these treatments (patients are rather given packets of ORS or tubes of ointment).

Given the absence of HSA oversight, it is conceivable that HSAs using the paper-based system incorrectly recorded their prescribed dosage for a given treatment, because they misinterpreted the instructions. For instance, in the above example, 268 of the 470 paper users who prescribed LA recorded a "1," which might represent a single LA tablet. But, as noted in Section 3.2 above, "1" might also mean one pack of six tablets, and thus HSAs actually provided the correct dosage. However, it should once again be noted that HSAs received identical instructions for the mobile tool and paper registries. Moreover, rather than speculate how HSAs interpreted the paper-based forms, this study merely presents findings based on the data and acknowledges this potential limitation. To assess the potential impact of erroneously recorded data, the study applied a sensitivity analysis on the data from the HSAs using the paper-based system, as outlined in Section 3.2. Findings from this analysis, which suggest less significant differences in dosage accuracy, are presented in Annex D. These results suggest that HSAs employing the existing paper-based system gave the correct dosage 91 percent of the time (which is statistically significantly lower than mobile tool users in an unadjusted comparison, but not in the adjusted comparison).

TABLE 6: DOSAGE BY TREATMENT AND ILLNESS TYPE

Illness	Treatment	Mobile			Paper			Unadjusted P-Value
		# Given Any Dose	# Given Correct Dose	Percent Given Correct Dose	# Given Any Dose	# Given Correct Dose	Percent Given Correct Dose	
Diarrhea	Zinc (2-5 months)	1	1	100%	7	0	0%	0.13
	Zinc (6-59 months)	91	88	97%	118	0	0%	<0.001**
Fever	LA (up to 5 months)	103	103	100%	143	141	99%	0.51
	LA (5-35 months)	255	250	98%	248	0	0%	<0.001**
	LA (36- 59 months)	132	122	92%	168	0	0%	<0.001**
	Paracetamol (2-35 months)	161	159	99%	147	0	0%	<0.001**
	Paracetamol (36-59 months)	69	63	91%	85	0	0%	<0.001**
Fast Breathing	Oral antibiotic (2-11 months)	41	39	95%	45	0	0%	<0.001**
	Oral antibiotic (12-59 months)	134	132	99%	181	0	0%	<0.001**
Total		***498***	***473***	***95%***	***567***	***28***	***5%***	***<0.001****
Adjusted Odds Ratio							***10,808***	***<0.001****

Treatments with * and ** represent those significant at the p<.10 and p<0.05 levels, respectively

4.2.3 Clinical Decision Making

Table 7 provides data on the number of patients experiencing "danger signs" for given medical conditions as well as the percent of those patients who were referred, broken down by mobile users and paper users. For most medical conditions, there appeared to be no difference in the referral rate among providers who used the mobile tool and those who used the existing paper-based system; however, sample size was not large enough to demonstrate statistical significance.

TABLE 7: REFERRAL PATTERNS BY CONDITION

	Mobile			Paper		
	# Identified	# Referred	Percent Referred	# Identified	# Referred	Percent Referred
Cough for 21 days or more	2	1	50%	0	0	n/a
Diarrhea 14 days or more	0	0	n/a	0	0	n/a
Blood in stool	6	6	100%	3	3	100%
Fever for last 7 days	1	1	100%	1	1	100%
Convulsions	4	4	100%	2	2	100%
Not able to drink or feed anything	5	5	100%	1	1	100%
Vomits everyday	8	8	100%	1	1	100%
Red eye for 4 days or more	3	3	100%	1	1	100%
Red eye with visual problem	4	4	100%	0	0	n/a
Chest in-drawing	13	12	92%	0	0	n/a
Very sleepy or unconscious	2	2	100%	1	1	100%
Palmar pallor	3	3	100%	0	0	n/a
Red on MUAC tape	0	0	n/a	2	0	0%
Swelling of both feet	4	3	75%	0	0	n/a

**Diagnoses in bold represent those significant at the $p<0.05$ level

4.2.4 Quantity and Quality of Data Collected

Beyond improving clinical quality of care (i.e., diagnoses and treatments), future versions of the mobile tool aim to increase the quantity and improve the quality of data collected by health providers. While not a primary function of this iCCM platform, additional analyses were done describing, for each medical condition, reasons why providers did not prescribe a particular treatment (see Table 8).

Across all clinical conditions and treatments, there was an overall absence of data from providers that used the existing paper-based system. Specifically, nearly 100 percent of paper users failed to explain why their patients were not treated with a particular medication. It is impossible to assess why providers did not treat patients with a particular medication and therefore difficult for policymakers to develop solutions for improving the quality of and access to key health services. Among providers who used the mobile tool, however, most indicated that they could not prescribe ORS, zinc, LA, paracetamol, or oral antibiotics, because they were stocked out of medications. For instance, when dealing with cases of fever, 198 of the 201 providers who did not prescribe paracetamol indicated that they could not prescribe the drug because it was out of stock.

TABLE 8: REASONS FOR NOT GIVING TREATMENT

Tool	Treatment	Sample	Reason for not giving treatment		
			No Reason Given	Out of Medication	Other Reason
Diagnosis: diarrhea					
Mobile	ORS	7	2	4	1
	Zinc	18	0	18	0
Paper	ORS	2	2	0	0
	Zinc	2	2	0	0
Diagnosis: Fever					
Mobile	LA	25	8	14	3
	Paracetamol	201	1	198	2
Paper	LA	19	19	0	0
	Paracetamol	122	121	0	1
Diagnosis: Fast breathing					
Mobile	Oral antibiotic	6	0	6	0
Paper	Oral antibiotic	0	0	0	0

4.3 Cost-effectiveness

The first part of this section explores the incremental cost-effectiveness ratio (ICER) of the program as observed for the first 50 HSAs trained. The annual inflation-adjusted costs for the program are presented, and then the overall effectiveness. These data are combined to calculate the ICER. Next, we present the costs of the program if it were implemented at scales of 50, 500, 1,000, and 5,000 HSAs (based on the methodology defined in Section 3.1) as well as the ICERs for each scale of implementation. Note that it is assumed that treatment effectiveness does not change with the scale of the intervention. That is, we assume the same effectiveness in the change in the percentage of children correctly treated found amongst 50 HSAs will also apply to 500, 1,000, and 5,000 HSAs.

4.3.1 Annualized Cost of the Mobile Intervention

The total, annualized cost of the mobile application is estimated to be $47,857, or $957 per HSA (see Table 9). The majority (65 percent) of costs are incurred as national-level (or program management level) recurrent costs, 19 percent of costs are considered start-up costs, and 16 percent of costs are incurred at the HSA level (for training, phone purchase, and airtime). These costs are less than the costs reported in Table 3 due to amortization of start-up and capital costs.

TABLE 9: TOTAL ANNUAL COSTS OF OBSERVED PROGRAM (2013 US$)

Expense Item	50 HSAs (observed)
National-level costs	
Start-up costs, amortized	
Labor	
General Stakeholder Engagement and Project Management	$2,352
Software Development	$4,372
Mobile Services	$824
Training	$86
Sub-total, labor	*$7,634*
Other Direct	$534
Indirect	$698
Sub-total, start-up costs	$8,867
Recurrent costs, per year	
Labor	
General Stakeholder Engagement and Project Management	$2,316
Software Support	$2,516
Monitoring	$13,120
Sub-total, labor	*$17,952*
Other Direct	$10,472
Indirect	$2,872
Sub-total, recurrent costs	$31,296

Expense Item	50 HSAs (observed)
HSA-level costs	
Technical Support (D-tree)	$0
Training (international, annualized)	$3,378
Training (local, annualized)	$1,221
Mobile Services (international support and airtime)	$1,160
Phone purchase (annualized)	$1,934
Sub-total, annual HSA-level cost	$7,693
Total annual equivalent costs	**$47,857**
Cost per HSA	$957

4.3.2 Percentage of Children Correctly Treated and Incremental Cost-effectiveness Ratio

To calculate the percentage of children correctly treated, we combined the data for the number asked the appropriate follow-up questions, the number given the correct prescription, and the number given the correct dosage. Failure to meet any one of these criteria indicates that a child was not correctly treated. For the HSAs employing the paper-based system, 548 children had complete data across the three categories of data, and 14 were correctly treated (2.6 percent). Complete data were available for 493 children treated by HSAs using the mobile tool, of whom 304 (61.7 percent) were correctly treated. The difference between the two groups is statistically significant ($p<0.001$) for both the unadjusted and adjusted comparisons, with an unadjusted difference of 59.1 percent between HSAs using the mobile tool and HSAs using the paper-based system only. After adjusting for case mix, an estimated 3.2 percent of children treated by HSAs using only the paper-based system would have been correctly treated (had they seen the same cases as was seen, on average, across the two groups of HSAs), while HSAs using the mobile tool would have correctly treated 94.9 percent of cases.

Thus, the cost per HSA for the mHealth intervention was $957 per HSA per year, and the mHealth intervention was associated with a 91.2 percent increase in the proportion of children correctly treated. These results suggest that the intervention incurred $10.43 per 1 percent increase in the proportion of children treated correctly (Table 10). The “Direction of Change,” column in Table 10 indicated that, compared with the existing paper-based system, the mobile tool cost more but also had a positive effect. As such, the cost-effectiveness ratio in Table 10 can be interpreted as, “Compared with the existing paper-based system, the mobile tool costs an additional $10.43 for an HSA to improve his/her diagnostic and treatment accuracy by 1 percent.”

TABLE 10: COST PER HSA PER % CHANGE IN CASES CORRECTLY DIAGNOSED AND TREATED

	Mobile	Paper	Mobile - Paper	ICER	Direction of Change
Cost per HSA	$ 957	$ -	$ 957	$10.43 per %	Positive
Effect	94.9%	3.2%	91.2%		

In the base sensitivity analysis, the mobile tool was not associated with an increase in the percentage of children correctly treated, and thus would both cost more and be less effective than the existing paper-based tool. This finding is the result of the existing paper-based tool HSAs doing better at prescribing the correct drug given diagnosis. However, as noted above, the poorer performance of mobile users on this metric is likely due to drug stock-outs, and not to the mobile tool. Excluding the 'correct prescription given the diagnosis' metric from the sensitivity analysis suggests that mobile HSAs correctly treat 1.6 percent more children than the existing paper-based HSAs (p = 0.24). Excluding this step, but including more generous assumptions about correct dosage, results in an ICER of $583 per 1 percent increase in the proportion of children treated correctly (although the results would not be considered statistically significant).

Under the scale-up scenarios, national-level start-up costs remain the same as observed in the program (Table 11). However, most national-level recurrent costs are assumed by the government, and were not available for our analysis. These costs, which were the majority of costs in the observed program, are not included in our scale-up scenarios. This results in an underestimation of the level of effort needed to run the program. Further, costs of training under the government program were less, per HSA trained, than they were under the observed CRS/DHC model for 50 HSAs. Thus, the costs of the program for 50 HSAs under the scale-up assumptions is $24,035 (compared to $47,857 as observed); some of these lower costs reflect genuine savings from more efficient implementation and some reflect missing costs for program management (although from a government perspective many of these costs would reflect shifting resources to the mHealth intervention, and not additional indemnities incurred). Under the various scenarios presented, the cost of the mHealth program would be about $66,000, $115,000, and $490,000 per year for 500, 1,000, and 5,000 HSA implementing the program.

TABLE 11: INCREMENTAL COSTS AND COST-EFFECTIVENESS RATIOS OF DIFFERENT SCALE-UP SCENARIOS (2013 US$)

Expense Item	Cost Assumptions for Scale-up	Scale-up Scenarios			
		50 HSAs (modelled)	500 HSAs	1,000 HSAs	5,000 HSAs
National-level Costs					
Start-up costs, amortized	**Total per year**				
Labor					
General Stakeholder Engagement and Project Management	$2,352	$2,352	$2,352	$2,352	$2,352
Software development	$4,372	$4,372	$4,372	$4,372	$4,372
Mobile Services	$824	$824	$824	$824	$824

Expense Item	Cost Assumptions for Scale-up	Scale-up Scenarios			
		50 HSAs (modelled)	500 HSAs	1,000 HSAs	5,000 HSAs
Training	$86	$86	$86	$86	$86
Sub-total, labor	*$7,634*	*$7,634*	*$7,634*	*$7,634*	*$7,634*
Other Direct	$534	$534	$534	$534	$534
Indirect	$698	$698	$698	$698	$698
Sub-total, start-up costs	**$8,867**	**$8,867**	**$8,867**	**$8,867**	**$8,867**
Recurrent costs, per year	**Total per year**				
Labor					
General Stakeholder Engagement and Project Management	$0	$0	$0	$0	$0
Software support	$0	$0	$0	$0	$0
Monitoring	$0	$0	$0	$0	$0
Sub-total, labor	*$0*	*$0*	*$0*	*$0*	*$0*
Other Direct	$10,472	$10,472	$10,472	$10,472	$10,472
Indirect	$0	$0	$0	$0	$0
Sub-total, recurrent costs	**$10,472**	**$10,472**	**$10,472**	**$10,472**	**$10,472**
HSA-level costs					
	Per HSA per year				
Technical support (D-tree)	$11	$550	$5,500	$11,000	$55,000
Training (international, annualized)	$0.44	$22	$218	$437	$2,184
Training (local, annualized)	$14	$690	$6,898	$13,796	$68,980
Mobile Services (international support and airtime)	$31	$1,560	$15,600	$31,200	$156,000
Phone purchase (annualized)	$37	$1,874	$18,741	$37,481	$187,406
Sub-total, annual HSA-level cost	$94	$4,696	$46,957	$93,914	$469,569
Total annual equivalent costs		**$24,035**	**$66,296**	**$113,253**	**$488,908**
Cost per HSA		$481	$133	$113	$98
Incremental cost-effectiveness ratio		**$5.24**	**$1.45**	**$1.23**	**$1.07**

As a consequence of spreading fixed costs (program management and start-up costs) over a greater number of HSAs, the cost per HSA is lower for scenarios with more HSAs. At 5,000 HSAs, this represents an incremental cost of $98 per HSA. Thus, the cost per 1 percent increase in the proportion of children treated correctly also is lower for scenarios with more HSAs (see final row of Table 11). With 50 HSAs enrolled in the program, it costs an estimated $5.24 per 1 percent increase in the proportion of children treated correctly, while in the scenario with 5,000 HSAs, it costs an estimated $1.07 per 1 percent increase in the proportion of children treated correctly (this latter figure is estimated at $59.52 in sensitivity analysis).

5. DISCUSSION

The primary purpose of this study was to develop an approach for estimating and scaling up costs of an iCCM mobile tool in Malawi, as well as evaluating the effectiveness of this tool. A secondary objective was to contribute evidence on the cost-effectiveness of D-tree's mobile decision support tool. It was expected that findings could inform policymakers in Malawi and other developing countries on whether and under what conditions mHealth applications, such as D-tree's mobile decision support tool, could be implemented and scaled up. Results from this study were also intended to guide policymakers and donors toward investing in mHealth applications that offer the greatest value for money. The following section summarizes key findings from this study and addresses these issues.

5.1 Design, Pilot, Roll-out, and Scale-up Costs

During the initial design, pilot, and roll-out phase to 50 HSAs, data from D-tree, CRS, and DHC suggest that labor costs accounted for the greatest share of costs (73 percent) in designing and implementing the iCCM mobile decision support tool. Of these, about 90 percent came from D-tree, the tool's developer. When broken down by category, 40 percent of D-tree's labor costs stemmed from the development iCCM content and programming, while another 43 percent went to monitoring and training. Other costs components included other direct costs (13 percent of total costs), indirect costs (7 percent of costs), training costs not including labor (4 percent of costs), and mobile phones (2 percent of costs).

For policymakers looking to design and implement similar mHealth applications, cost data, particularly the scale-up from 50 to 1,000 HSAs, provides two key lessons. First, while labor costs represent a significant portion of total costs during the design, piloting, and roll-out to 50 HSAs, these costs are a function of the wages needed to hire staff, the quality of that staff, and the total quantity of staff needed. For developing countries aiming to develop mHealth tools domestically, wages will be much lower than those incurred by D-tree, though finding qualified staff to design and oversee the roll-out of such a tool would be challenging in some settings. Second, additional cost savings could be realized during the design stage if the mobile tool were produced domestically, because significant travel and start-up costs, which were incurred by D-tree in the early stages of the tools' development, would be greatly reduced. These costs would decline substantially (a) if the organization (e.g., D-tree) already has a presence in country during the design phase and (b) the government or a local private organization were to spearhead development and roll-out of the mobile tool.

5.2 Modelled Annual Costs and Scale-up Costs

During the modelled scale-up from 50 to 5,000 HSAs, total annual costs rose in absolute terms from about $24,000 to about $490,000. While the total costs, as expected, increase as more HSAs are enrolled in the program, the cost per HSA is expected to decline by roughly 80 percent, from $481 to $98 per HSA. Results from the mobile tool's scale-up highlight several key takeaways for policymakers. During scale-up, mobile phone costs will increase as a proportion of total costs (from 8 percent to 40 percent). These findings assume that when governments take over responsibility for rolling out mobile decision support tools to the health workforce, the training and monitoring functions are inherently covered by salaried supervisors.

5.3 Diagnosis Follow-up

Findings indicated that HSAs are recording answers to follow-up questions to patients at a very high level (99 percent of the time) for both HSAs using the mobile tool and using the existing paper-based system. Given the high levels of follow-up questions in the HSAs using the existing paper-based system, it is unlikely that the mobile tool would increase this metric in Malawi.

An assumption was made that health providers correctly diagnosed their patients for broad clinical conditions, such as diarrhea, red eye, fever, or fast breathing. Without individuals in place to monitor those providers, it was not possible to know if these decisions were accurate. For example, previous research in Malawi suggested that HSAs correctly classify simple illnesses in children correctly about 68 percent of the time (Gilroy et al. 2013).

5.4 Treatment and Referral Decisions

Findings indicated that the mobile tool had a mixed impact on general treatment patterns; specifically, HSAs prescribed the correct medication for a given illness 71 percent of the time regardless whether the mobile was used. This is higher than previous studies done at the beginning of the iCCM program, which found 62 percent of HSAs gave the correct medication (Gilroy et al. 2013). While HSAs using the existing paper-based system gave the correct treatment more often than HSAs using the mobile tool, this may be due to drug stock-outs and not the tool used.

There were, however, dramatic differences in dosage patterns for those treatments. Excluding patients given ointment and ORS, for which dosage was not measured, on average, 95 percent of cases treated by HSAs using the mobile tool received the correct medication dosage compared with 5 percent of the cases treated by the paper group. Given the absence of HSA oversight, it is conceivable that HSAs using the paper-based system incorrectly recorded their prescribed dosage for a given treatment. Findings from a sensitivity analysis outline the impact if this were true. However, even if differences were less significant than those presented in this report, results suggest that the mobile tool still results in greater dosage accuracy and dramatically improve the quality of data recorded.

It should be noted that this analyses treats all decisions and actions as equal. Thus, for example, the decision to treat fever with paracetamol (an analgesic drug) is given the same weight as the decision to treat fever with LA (an antimalarial drug), and giving the correct dosage of paracetamol is treated the same as giving the correct dosage of LA. However, it is likely that the medical implications of these decisions and actions are not equal. Further refinement of the measure of effectiveness giving due attention to the medical implications of the decisions and actions would help to give more accurate information on the health implications of the mobile tool.

5.5 Cost-effectiveness

For the HSAs employing the paper-based system, 548 children had complete data across the three categories of data, and 14 were correctly treated (2.6 percent). Complete data were available for 493 children treated by HSAs using the mobile tool, of which 304 (61.7 percent) were correctly treated. In other words, the mobile tool was associated with significantly better quality of care than the existing paper-based system, as defined by greater clinical accuracy and adherence to protocols.

When only the cost of designing, piloting, and roll-out of the tool to 50 HSAs is considered, results from this study's cost-effectiveness analyses suggest that, compared with the existing paper-based system, the mobile tool costs $10.43 per annum for an HSA to improve his/her diagnostic and treatment accuracy by 1 percent. This means that the mobile tool is associated with an improvement in diagnoses and treatment accuracy relative to paper registries, but this improvement comes at a cost. Previous studies have estimated the cost per case (among children under five years of age) to be about $2.15 or about $575 per HSA per year (Collins et al. 2014). This indicates that a small-scale program would increase cost per HSA by about 166 percent, whereas a large-scale program would increase the cost per HSA per year by 17 percent.

Assuming that the relative effect difference does not change over time or the number of HSAs in the program, the tool's cost-effectiveness improves substantially as it is scaled up nationally. This is due to the significant drop in the tool's annual cost per HSA, which falls by roughly 80 percent when scaled up from 50 HSAs to 5,000 HSAs. The improvement in the tool's incremental cost-effectiveness ($5.24 vs. $1.07) suggests that policymakers are more likely to witness greater returns on investment if the tool is scaled up and maintained over time.

5.6 Health System Performance

While data collection was not yet a primary function of the mobile tool during this study period, it proved a useful mechanism for collecting high-quality data on patient health conditions and clinical severity, provider diagnostic and treatment patterns, as well as reasons for clinical decision making. This data are often not available with the current paper-based system.

Among these benefits, the mobile tool requires that health providers indicate reasons for not administering medical treatments when patients present their respective clinical conditions. In this study, providers using the mobile tool nearly always cited drug availability as the reason for not treating patients. The absence of data for this issue among paper users presents two challenges for policymakers looking to improve access to and quality of medical care in Malawi.

First, the lack of information makes it impossible to discern reasons why providers failed to administer correct medical treatments. Is this decision due to poor medical knowledge and quality of care by health providers, a lack of drugs, patient decisions not to receive medications, or other factors? Second, by knowing that incorrect treatment decisions were, for mobile users, due to drug stock-outs, policymakers can learn which facilities are out of medications, examine why they are out of stock, and ensure that the supply of medications is replenished.

5.7 Limitations

While this study offers an approach for estimating and projecting costs of mHealth interventions, as well as evaluating the effectiveness and cost-effectiveness of a mobile decision support tool in Malawi, several limitations should be noted. This study was conceived and designed when evaluation funding became available, after the initial implementing partners had closed the project. Cost data were derived based on staff estimates post facto, including estimates for NGO partners who were not contacted. Moreover, costs in this study did not include some costs, such as additional time spent and possible loss in productivity by HSAs who use the mobile tool. This led to findings that likely underestimated costs and inflated the incremental cost-effectiveness of the mobile tool. Limited effect data and oversight of health providers also made it impossible to assess the accuracy of diagnosing patient medical conditions, such as referral rates for severe health conditions. It also raises the possibility of error in dosage accuracy data.

Second, it is critical to note that findings from this study offer limited generalizability, and results will likely vary across different countries, health systems, and populations. For the cost and cost-effectiveness of various scale-up scenarios, results will be highly contingent on assumptions made in this study. Costs will also depend on which public agencies/private organizations are the developers and implementers of the mobile decision support tools, because they will all differ in their capacity, size, level of resources, and ultimately cost structures. Similarly, one should expect variation in effect results due to differences in health provider training, patient case mix, and broader health system characteristics. However this study offers value in its methodology for conducting a mHealth cost-effectiveness analysis, which is highly generalizable across different settings.

5.8 Conclusions

This study compared the costs and differences in correct diagnosis and treatment between a mobile decision support tool and control group using paper forms. Both paper and mobile based groups accurately assessed children for the presence of cough, fever, diarrhea, as well as assessing for danger signs, but mobile showed significantly improvement in correct medication dose. The primary contribution of this study is the documentation of a systematic methodology and study design for evaluating the cost effectiveness of a mHealth application. The estimated cost of $1.07 per health worker at scale provides a benchmark, or a reference case, for comparison with other interventions.

5.8.1 Implications for mHealth investment in Malawi:

The findings of this study are insufficient on their own to guide decisions about the relative value for money of the mobile application. The question is "more cost effective than what?" For Malawi policymakers to determine investment trade-offs, additional information would be needed with regard to the following:

- **Costs and effects of alternative interventions to improve quality of care**: The quality of care provided by health workers (measured in this case by adherence to recommended protocol) is influenced by numerous factors: recruitment criteria, intensity of in-service and refresher training, level of supportive supervision, peer support mechanisms, quality of job aids, as well as motivational factors including increased pay or performance based incentives. The lack of economic evaluations in the literature assessing the costs and benefits of two alternative interventions limits the comparability of our findings.
- **Broader health system context:** In order to define the acceptability of the cost for a unit of gain, analysis of epidemiological, budgetary, medical and other factors is needed. Cost effectiveness will be highest when the baseline quality is low for the process targeted, in this case iCCM. Considerations about appropriateness of investment in this mobile tool would depend upon the intensity, maturity and total budget expenditures for iCCM in Malawi, as well as utilization rates of treatments prescribed.

5.8.2 Implications of integrated mHealth applications on cost effectiveness

The mobile application evaluated in this study was a first generation single function job aid, designed solely to improve health worker fidelity to recommended diagnosis and treatment. However, processes related to diagnosis and treatment are dependent on other health system components with symbiotic effects on treatment efforts. Consistent with mHealth trends toward more integrated multi-function platforms, D-tree's mobile application has long since been superseded by later stage versions which include multiple functions within the same platform, including training reinforcement messages, patient tracking capability, and reporting of service delivery data.

These modular additions increase potential cost-effectiveness by leveraging the investment in devices, training and support with modest additional costs for software development and data use. Future studies to evaluate integrated mHealth applications will require methodologies which unpack discrete effects on health care services stemming from shared platform costs. Within this more holistic approach, two mobile-enabled functions are of particular relevance to health system efficiency, access and improved quality of care.

- **Patient utilization and adherence to treatment prescribed:** Unless beneficiaries correctly and consistently use treatments provided, provider prescriptions will not have their intended effect. Barriers such as lack of knowledge, traditional practices, and cultural norms can be reduced through mobile interventions that strengthen the bond between beneficiaries and providers, and reinforce messages on medication adherence. Consumer satisfaction and trust in treatment recommendations may be positively influenced by increased system responsiveness such as automated follow-up messages and mobile prompts to avoid missed appointments, built into the decision-support applications.
- **Linking supplies to utilization data:** The present study highlights the critical issue of a reliable supply chain, with the mobile application documenting stock-outs of essential medicines and supplies. Correct diagnosis and treatment decisions will not improve health outcomes unless the processes are in place to ensure medications and equipment are available to act on the decisions. Software applications linked to decision-support algorithms have been created to separately report commodity consumption and inventory data, automate resupply, and notify workers of shipments ready for pick up. Key elements include ensuring the people receiving the data have systems in place to ensure the continuous supply of products to the point of care.

5.8.3 Recommendations for future mhealth cost effectiveness studies

As set forth in the in Limitations section, this study presents a basic methodology for generating cost effectiveness data, but there were numerous challenges presented by the design. Below are some considerations for future studies:

- **Data quality standards:** The present study relied on post facto effects data collected prior to the authors' analysis, and there was limited access to partners and personnel involved in the implementation of the intervention. For example we did not measure or verify whether dose data was correctly entered or explore reasons why paper forms were not completely filled in. An improved study would include data quality assurance measures such as direct observation of health worker consultations with sick children, caretaker exit interviews, and/or re-examinations of children to confirm diagnoses. A mixed method evaluation would permit more nuanced examination of the ways in which the mobile tool facilitated or failed to improve diagnosis and treatment.
- **Cost data assumptions and analysis:** The mobile application evaluated in this study was conceived as a replacement for paper job aids and record keeping. During its introduction throughout the study period, however, the paper registers were retained and used in parallel with the mobile tools, so no savings were calculated for eliminating paper-based data collection. As digitization allows duplicative paper-based records to be phased out, future studies should capture the direct and indirect costs avoided for paper-based record keeping and refine the cost effectiveness ratios accordingly. This study also assumed no added costs to government iCCM trainings due to the addition of a mobile intervention. Further examination is needed to assess how the introduction of mobile affects the total training time and quality relative to the status quo.

Finally, the lens of this study focused only on costs to governments and partners with no assessment of non-tangible costs and benefits to health workers. Cost implications may include alterations in the quantity of services provided, provider demand for equipment and medication, and reductions in treatments deferred and waste.

- **Linking diagnosis and treatment to health outcomes**. As noted, this study did not conduct analyses needed to model the relationship between improved process inputs (e.g., correct dose) with health outcomes such as QALYs, DALYs, or lives saved. The link between intermediate outcomes such as provider adherence to protocol to population health is tenuous. Additional analyses would be required with regard to the diagnostic and prescribing patterns of providers, provider productivity, availability of stocks, and treatment effectiveness. Adjustments to the coverage assumptions for iCCM based on probability of correct application may not produce detectable effects on health in environments where many health interventions are underway. The measurable value of mhealth is likely to be demonstrated primarily in documenting lower recurring costs per unit of service delivery.

ANNEX A: D-TREE ICCM COSTS (UNADJUSTED)

Category	Oct - Dec 10		Jan - Mar 11		Apr - Jun 11		Jul - Sep 11		Oct - Dec 11		Jan - Mar 12		Apr - Jun 12		Jul - Sep 12		Oct - Dec 12		Jan - Mar 13		Total
	FTE	Cost	FTE	Cost	FTE	Cost	FTE	Cost	FTE	Cost	FTE	Cost	FTE	Cost	FTE	Cost	FTE	Cost	FTE	Cost	
Labor																					
General Stakeholder and Management	5%	$691	5%	$1,096	8%	$1,690	8%	$2,424	8%	$1,973	5%	$1,521	5%	$1,581	3%	$520	5%	$547	5%	$579	$12,622
ICCM Content and Programming	17%	$2,303	17%	$4,882	25%	$10,867	25%	$10,207	25%	$8,512	5%	$1,323	5%	$2,121	3%	$1,020	5%	$2,082	5%	$629	$43,946
Mobile Services	3%	$461	3%	$731	5%	$1,127	5%	$1,616	5%	$1,316	3%	$760	3%	$791	2%	$260	3%	$273	3%	$290	$7,625
Training	5%	$691	5%	$1,096	8%	$1,690	8%	$2,424	8%	$1,973	25%	$7,604	25%	$2,372	17%	$2,601	25%	$820	25%	$869	$22,140
Monitoring	3%	$461	3%	$731	5%	$1,127	5%	$1,616	5%	$1,316	13%	$3,802	13%	$9,486	8%	$1,300	13%	$3,280	13%	$3,280	$26,399
Sub-total, labor	33%	*$4,607*	33%	*$8,536*	50%	*$16,501*	50%	*$18,287*	50%	*$15,090*	50%	*$15,010*	50%	*$16,351*	33%	*$5,701*	50%	*$7,002*	50%	*$5,647*	*$112,732*
Other Direct	NA	$2,498	NA	$2,124	NA	$4,359	NA	$5,316	NA	$1,007	NA	$2,405	NA	$2,093	NA	$177	NA	$194	NA	$2,618	$22,791
Indirect	0%	$0	0%	$0	0%	$0	0%	$0	13%	$2,128	13%	$2,302	13%	$2,438	13%	$777	16%	$1,115	16%	$1,311	$10,071
Total ICCM Costs		$7,105		$10,661		$20,860		$23,602		$18,225		$19,718		$20,881		$6,655		$8,311		$9,576	$145,594

FTE: Full time equivalent; NA: Not applicable

ANNEX B: CRS ICCM COSTS (UNADJUSTED)

Category	Oct - Dec 11	Jan - Mar 12	Apr - Jun 12	Jul - Sep 12
Labor	$3,050	$3,050	$3,050	$3,050
Travel	$452	$452	$452	$452
Office Supplies	$350	$350	$350	$350
Phones	$906	$906	$906	$906
Rent	$314	$314	$314	$314
Other	$0	$0	$0	$0
Total Expense	$5,073	$5,073	$5,073	$5,073

ANNEX C: DEDZA HEALTH COMMISSION ICCM COSTS (UNADJUSTED)

	Jul - Sep 11	Oct - Dec 11	Jan - Mar 12	Apr - Jun 12	Jul - Sep 12
HSAs Trained	3	3	12	12	20
Expense					
Labor	$76	$76	$76	$76	$76
Travel	$19	$19	$77	$77	$129
Training Supplies	$354	$354	$1,416	$1,416	$2,359
Meeting Supplies	$0	$0	$0	$0	$0
Monitoring Supplies	$0	$0	$0	$0	$0
Other	$0	$0	$0	$0	$0
Total Expense	$396	$396	$1,584	$1,584	$2,639

ANNEX D: SENSITIVITY ANALYSIS OF DOSAGE ACCURACY

Illness	Treatment	Mobile			Paper			Unadjusted P-Value
		# given any dose	# given correct dose	percent given correct dose	# given any dose	# given correct dose	percent given correct dose	
Diarrhea	Zinc (2-5 months)	1	1	100%	7	7	100%	n/a
	Zinc (6-59 months)	91	88	97%	118	99	84%	0.003**
Fever	LA (up to 5 months)	103	103	100%	143	141	99%	0.51
	LA (5-35 months)	255	250	98%	248	242	98%	0.77
	LA (36- 59 months)	132	122	92%	168	158	95%	0.48
	Paracetamol (2-35 months)	161	159	99%	147	147	100%	0.50
	Paracetamol (36-59 months)	69	63	91%	85	80	94%	0.54
Fast Breathing	Oral antibiotic (2-11 months)	41	39	95%	45	42	93%	0.99
	Oral antibiotic (12-59 months)	134	132	99%	181	170	94%	0.04*
Total		***498***	***473***	***95%***	***567***	***517***	***91%***	***0.01*****
Adjusted Odds Ratio							*1.89*	*0.16*

Treatments with * and ** represent those significant at the p<.10 and p<0.05 levels, respectively

ANNEX E: REFERENCES

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