USING ELECTRONIC DECISION SUPPORT TO ENHANCE PROVIDER-CARETAKER COMMUNICATION FOR TREATMENT OF CHILDREN UNDER FIVE IN TANZANIA

by

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ABSTRACT

One out of every six children in sub-Saharan Africa dies from treatable diseases before reaching age 5. Millions of these deaths could be averted if health care providers followed evidence-based protocols, such as the Integrated Management of Childhood Illnesses (IMCI), to provide care. IMCI assists providers to diagnose and treat problems for children under 5, and specifies key information for the provider to teach to the child's caretaker. While IMCI has been adopted as official policy throughout Tanzania, the protocol has been neither universally used nor consistently followed.

An innovative IMCI-based protocol that runs on a mobile phone, called eIMCI, was designed for this study using user-centered design (UCD) principles to assist provider navigation of the protocol and improve provider-caretaker communication of key information points, including the problem and treatment of the child, and when to return to the clinic. The electronic protocol, eIMCI, was compared to an equivalent paper-based protocol, pIMCI.

This study was based on the mHealth Communications Theoretical Framework. The aims of the study were to (1) utilize UCD design principles to develop eIMCI and evaluate its usability, and (2) evaluate the effect of protocol delivery platform on (a) provider communication and (b) caretaker recall of key information points. A randomized cluster trial was conducted in which health care clinics in Tanzania were randomized to implement each platform.

Results suggested that electronic protocol use led to improved provider-caretaker communication. Providers who used eIMCI were more likely to give counseling that covered the key information points specified, and caretakers in the eIMCI arm recalled more of these key information points overall. The implications of this work suggested that the eIMCI mobile protocol may lead to improved provider-caretaker communication, which may result in a greater ability for caretakers to carry out treatment plans in the home. When utilizing mobile devices to deliver such interventions, the structure, clarity, and direction enabled by the electronic platform are suggested to promote adoption of the complete sphere of high-quality clinical care. As such adoption is continued, understanding of key health information may become firmly rooted in caretaker health literacy levels.

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GLOSSARY

Communication – The imparting or interchange of thoughts, opinions, or information by speech, writing, or signs. Communication is a generic concept that implies understanding of the intended meaning. Each exchange of information includes a sender, a message, and a receiver. The term "communication" was primarily used in this dissertation research to encompass information verbalized by a healthcare provider to a child's caretaker, and the caretaker's subsequent recall of the information provided.

Information and Communications Technology (ICT) – The technical infrastructure that merges information management and communication support, including computer hardware, software, networking, and telecommunications equipment, including telephone lines, wireless signals, and cellular telephones.

Information Exchange – A process that serves as a measureable proxy for communication.

Integrated Management of Childhood Illnesses (IMCI) – A standardized protocol for child health care developed by the World Health Organization, which contains a series of assessments and recommendations for treatable childhood illnesses common to low- and middle-income countries.

pIMCI – The paper algorithm that was developed to make the recommendation of the IMCI protocol explicit; utilized as a tool for providers to support IMCI protocol navigation and use.

eIMCI – The mobile application that was developed for this study based on the pIMCI algorithm; utilized as a tool for providers to support IMCI protocol navigation and use.

Key Information Points (as used in this study) – Information that is explicitly specified in the IMCI protocol which providers are supposed to tell to caretakers during the visit. Specifically, these key information points are 1) the child's problem or medical diagnosis, 2) when to return including symptoms that indicate worsening of the problem, and 3) teaching about treatments (type, dose, and when to take).

mHealth – Mobile computing, medical sensor, and communications technologies for health care.

Protocol – A tool that provides a standardized approach to making clinical decisions; intended to promote consistency in quality of provider care. A protocol is, essentially, a plan. An algorithm is developed from a protocol to enable the plan to be implemented. The terms are often used interchangeably, however. In this paper, the term protocol will be used for both protocols and algorithms.

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CHAPTER 1

INTRODUCTION

Background

One out of every six children in sub-Saharan Africa dies before reaching the age of five from treatable diseases such as malaria, pneumonia, diarrhea, and malnutrition (Childinfo.org, 2010). Millions of these deaths could be averted each year with appropriate diagnosis and treatment. A recent study in Tanzania suggested that incomplete clinical assessments in inpatient and outpatient facilities may be a greater contributor to elevated child-under-5 mortality rates than inadequate availability of basic treatment provisions (Reyburn et al., 2008).

This problem is not unique to Tanzania. The World Health Organization (WHO) notes that worldwide, many sick children are not properly assessed and treated, and caretakers are often poorly advised (WHO, 2010). To address the issue, the WHO and the United Nations Children's Fund (UNICEF) created the Integrated Management of Childhood Illnesses (IMCI), a protocol representing a standardized series of assessments for treatable childhood illnesses common to low- and middle-income countries. IMCI enables providers to appropriately diagnose or classify illnesses, and recommends treatment and caretaker instructions based on results of the assessments (WHO, 2007). Rigorous and consistent use of protocols such as IMCI has been shown to prevent a significant number of childhood deaths (Bryce et al., 2004, 2005a; Walter et al., 2009).

Statement of the Problem

Unacceptably high rates of child mortality continue to prevail in sub-Saharan Africa as the delivery of adequate health care remains an unmet objective. In many health facilities in low-income countries, the availability of diagnostic services and equipment are minimal or nonexistent. Providers must therefore rely on illness history and presenting signs and symptoms of an illness to determine a course of management that makes the best use of available resources. In Tanzania, the location of this study, government health authorities have adopted IMCI as an official national clinical protocol (Tanzania MOH, 2007). However, it has been suggested that providers in Tanzania, like providers in many low-income countries that officially endorse IMCI use, do not consistently adhere to the IMCI protocol (Bryce et al., 2005b; Walter et al., 2009). Poor protocol adherence is attributed to many factors, including inadequate training, overburdening workload, lack of supervision, and a deficiency of resources to effectively provide patient care (Bryce et al., 2004). Further, the IMCI handbook is lengthy at approximately 163 pages (WHO, 2005) and may be cumbersome for providers to follow at the point of care.

To compound these challenges, the WHO notes that caretakers are often poorly advised (WHO, 2010). Cultural norms and poor health literacy rates may contribute to a lack of communication between providers and caretakers, resulting in a caretaker's inability to fulfill treatment plans. Even when effective interventions are available, insufficient counseling at the point of care has compounded critically deficient levels of health literacy among the low-resource populace. This may have consequently produced a large body of disadvantaged individuals who may be unable to fully leverage the

already scarce resources that are available in African countries such as Tanzania. Communication between front-line health workers (providers) and the caretakers who bring a sick child to the health facility provides an opportunity to promote child health. Advice for home care is an integral part of the IMCI protocol; with specific instructions (key information points) embedded throughout the protocol (WHO, 2010). However, when the protocol is not followed, it is likely that the key information points will also not be communicated.

Proposed Solution

Building upon previous studies that demonstrated improved pediatric health service delivery by using the IMCI protocol (Bryce et al., 2004, 2005a; Walter et al., 2009), the proposed solution evaluated in this study was to use mobile technology to support use of the IMCI protocol, and thus to support health care provider communication and caretaker recall of key information provided during a child's clinic visit.

The IMCI protocol was originally published in 1995 (WHO, 2008) and was thereafter adopted in Tanzania (Tanzania MOH, 2007). Subsequently, a study was conducted in Tanzania in which an electronic version of IMCI that was deployed on a mobile phone was developed. Evidence from that study suggested that using the electronic platform to deliver the IMCI protocol increased adherence by assisting providers to properly navigate through the algorithm (DeRenzi et al., 2008). Information and communications technology (ICT) such as mobile devices are becoming ubiquitous and present an opportunity to provide electronic support to health care decision-making (Greenes, 2006). In addition to providing a means to deliver core decision algorithms,

features of mobile phones such as display of video clips may be utilized to further enhance communication and education at the point of care. Providing multimedia educational material has been suggested to be more effective than simple didactic instruction (Schüler et al., 2011). The World Health Organization (WHO) recommends that usability processes become part of the mHealth strategic plan in order to ensure success of such implementations (McCurdie et al., 2012). The resources and barriers to implementation, usefulness, and effectiveness of ICT projects must therefore be rigorously evaluated and shared among both public and private sectors (Maru et al., 2009).

Study Purpose and Aims

This dissertation study was conducted as a time-limited substudy within a larger randomized controlled trial (RCT) that evaluated a new ICT-reliant IMCI-based software application containing enhanced communications and deployed on a mobile phone (henceforth referred to as eIMCI), compared to a paper version of the same IMCI-based protocol (henceforth referred to as pIMCI). The pIMCI protocol was newly developed for this study; however, a great deal of its content was adapted from the original IMCI protocol. The eIMCI mobile application was likewise a de novo development for this study. The foci of the overarching RCT were (1) to test the medical safety of the new IMCI-based protocol, and (2) to the test the influence of protocol delivery method (pIMCI or eIMCI) on overall provider adherence to the protocol. Urban and rural clinics were randomized and evaluated in two phases. This dissertation study was conducted within the first phase of the RCT (urban sample).

The iterative development and usability of the eIMCI software was examined in this dissertation study in order to observe WHO recommendations for newly developed ICT interventions. In addition, the effect of protocol delivery method on communication between providers and caretakers of children under 5 was compared in order to examine the extent to which previous findings on the benefits of the mobile platform extend to communication aspects of the clinical encounter. Specifically examined were what the provider said during the visit, and what the caretaker recalled about what the provider said, regarding key points of information specified in the protocol. The study aims were:

Aim 1. Utilize UCD principles to develop the eIMCI mobile application and to evaluate its usability, specifically:

1.1. To develop a multimedia eIMCI application prototype.

1.2. To conduct knowledge base verification testing to assess the fidelity of the conversion of the decision rules from paper protocol (pIMCI) to electronic protocol (eIMCI).

1.3. To complete formative testing to evaluate specified aspects of usability, specifically: satisfaction and perceived usefulness, learnability and ease of learning the navigation, perceived efficiency, effectiveness, and accessibility/fit with clinical workflow, from a user perspective.

1.4. To conduct summative testing to assess effectiveness and accessibility/fit with clinical workflow from the perspective of users in a mock clinical environment.

Aim 2. Evaluate the effect of method of protocol delivery (pIMCI or eIMCI) on (a) provider communication and (b) caretaker recall of health information related to:

2.1. The child's medical diagnosis or health problem.

2.2. When to return to the health clinic.

2.3. Treatment (medications).

It was hypothesized for Aim 1 that using UCD processes would result in a user-friendly application that required minimal provider training and that fit with clinic workflow. It was hypothesized for Aim 2 that the electronic protocol delivery method would result in improved communication between providers and caretakers, as indicated by increased provider communication on key information points specified by the IMCI protocol, and increased caretaker recall of the same key information points.

Significance

This study will inform subsequent research evaluating the role of communication and education in pediatric care in low-income countries where resources are limited, with the ultimate goal of enabling sustainable and consistent evidence-based care for children. Providing access to adequate health services in low-income regions has traditionally consisted of multiple unique and highly challenging elements that require creative and efficient interventions. The use of mHealth solutions, which combine computing and communications technologies specifically for health care, is one such creative intervention. A momentous outpouring of interest from philanthropic and government agencies has recently surfaced in the use of information and communications technology (ICT) to develop mHealth interventions due to the sudden ubiquity of mobile technology

even in developing countries (Blaya, Fraser, & Holt, 2009). Such solutions may present vital support toward achieving targeted goals for reducing child mortality rates and may make a significant impact in improving public health (Masanja et al., 2008). Interventions that seek to elevate health systems through empowerment, novel development, and change (such as mHealth interventions) may provide a more successful investment over interventions that simply seek to strengthen currently existing structures and processes (Lucas, 2008).

The electronic IMCI-based mHealth application in this study (eIMCI) was an innovative, ICT-based intervention. The paper protocol (pIMCI) contained identical assessment and treatment rules and all of the same educational content in written format. The core clinical content of the protocols contained guidance for provider assessments and treatments for common illnesses in children under 5, and specified instructions to be communicated to the child's caretaker. The WHO recommends adapting the IMCI to fit local needs (WHO, 2007). The primary adaptations to the clinical content of IMCI for this study were 1) the rational use of drugs to respond to growing antibiotic resistance, and 2) incorporating the use of inexpensive diagnostic tests to diagnose malaria, instead of the sole presence of fever.

Three components were added to the eIMCI version to enhance the provider's delivery of health education to the caretaker: 1) an educational video to be displayed on the mobile phone at the onset of the clinical visit, 2) explicit, individualized communication prompts embedded at key points throughout the protocol, and 3) a customized screen presented at the conclusion of the protocol that summarized previously given information prompts to reiterate and consolidate the teaching. Using this

multilayered approach, the eIMCI software was intended to support correct navigation of the protocol, and to support the delivery of key information to caretakers they should possess upon the completion of an interaction with their child's provider.

Theoretical Framework

Advances in communications technology have enabled prolific and multifarious innovation in the field of mHealth, or "mobile computing, medical sensor, and communications technologies for health care" (Istepanian, Jovanov, & Zhang, 2004, p. 405). A theoretical framework was developed for this study by adapting the Staggers Health Human-Computer Interaction Framework (Staggers, 2014) for use in the context of mHealth and pediatric care.

The Staggers framework stems from the study of human factors. Human-computer interaction, ergonomics, and system usability are foundational components of human factors research (Staggers, 2014). Specifically, the Staggers Health Human-Computer Interaction Framework examines the influence of data representation, information, and knowledge on health care decision-making (Staggers, 2001).

To adapt the Staggers framework for this study, the element of *Computer* was renamed as *Communications Support, Caretaker* replaced *Patient*, and *Outcomes* of the information exchange task were added. Fundamental communication elements were identified, and the adapted framework was renamed the mHealth Communications Framework (Figure 1.1).

The computer in the Staggers framework is a type of technology. Technology, while commonly interpreted in terms of electronic devices, can have a broader definition meaning any type of tool used by humans to accomplish a task (Merriam-Webster, 2012).

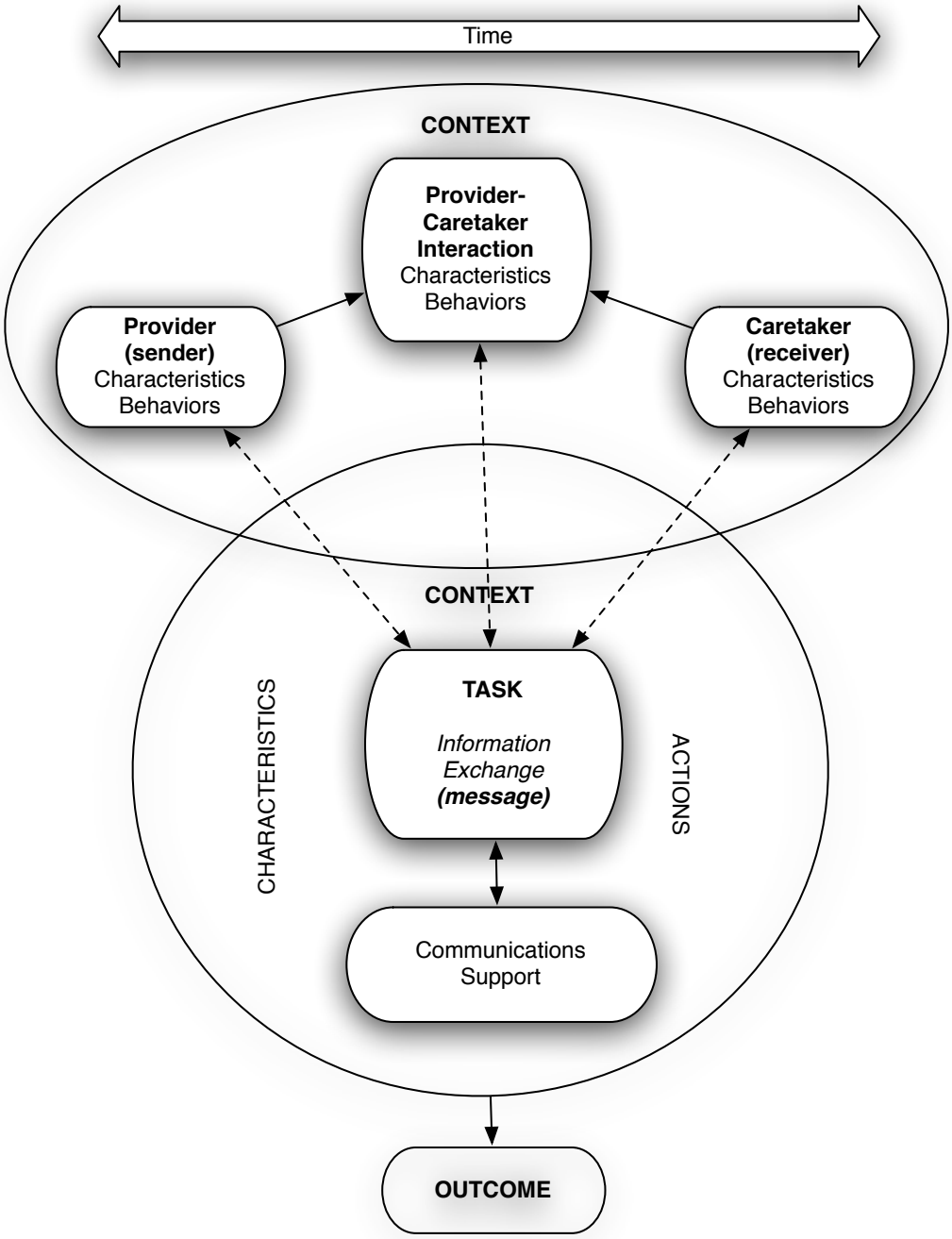


Figure 1.1
mHealth Communications Framework

Communications Support in the mHealth Communications Framework represented the clinical tools that facilitated communication, or information exchange, between provider and caretaker. The technology also influences health care decision-making, thus it is a means of clinical decision support (CDS). Although CDS systems are often electronic, CDS tools may also be paper-based (Greenes, 2006). The CDS in this study was delivered by 2 platforms, paper (pIMCI) and electronic (eIMCI).

Replacing Patient with Caretaker acknowledged that the caretaker was the receiver of the provider's communications related to diagnosis and treatment for children under 5, and was the person who would carry out treatment plans. The addition of Outcome represents the result of the interaction between each element in the model. The framework was also enhanced to show the focus on communication. Classic simple communication models consist of a *sender* who transmits a *message* to a *receiver.* In this study, the provider was the sender, the key information points specified by the IMCI-based protocol were the messages (each message being an *information exchange task*), and the caretaker was the message receiver. As early as the 1940s Shannon noted that a fundamental concern of communication is that the person receiving the message can reproduce, exactly or as a reasonable approximation, the message transmitted by the sender (Shannon, 1948). This remains a concern today; therefore, Aim 2 in this study examined the extent to which caretakers could reproduce a reasonable approximation of the information points verbalized by the provider.

Each element of the mHealth Communications Framework has characteristics (preexisting features) and behaviors (actions). The *provider* was the clinician who examined a child and prescribed treatment. Provider characteristics measured in this

study include provider type (typical Tanzanian designations include medical officer, assistant medical officer, or clinical officer), age, and gender. Other characteristics could be added, such as level of experience as a provider, training in pIMCI and eIMCI, experience using mobile phones, and attitude toward technology.

The *caretaker* was the person accompanying the child to the health facility, usually but not always a parent. Caretaker characteristics measured in this study include age, gender, relationship to the patient, and level of education. Other characteristics could be added, such as health literacy or experience seeking pediatric care.

The *provider-caretaker interaction* is the event representing a clinic visit, which is a health encounter between a provider treating children under 5 who are being seen for acute illnesses in a Tanzanian health clinic, and the child's caretaker. Characteristics of the provider-caretaker interaction include the time of day at which the visit occurred, the length of time the visit took, and interruptions during the visit. The provider-caretaker interaction is mutually influenced by all other elements in the system.

The *Information Exchange Task* in the framework represented information exchanged between provider and caretaker. A clinic visit involves diagnosing the child's problem, generating a treatment plan, and delivering health education to the caretaker; thus, for each provider-caretaker interaction, there were multiple information exchange tasks. This study was focused primarily on the communication tasks related to health education. The IMCI protocol includes prompts at key points in the algorithm, to provide specific health education related to the child's problem or diagnosis, when to return to clinic, and the treatment plan. Each message, or *key information point,* was considered a separate information exchange task.

Both the paper and electronic protocols were forms of *Communications Support* technology for this study. The characteristics of the Communications Support included the decision-making algorithm (CDS knowledge base) and the content of the messages. The electronic and paper methods of Communications Support contained identical decision-making and communication message content. However, the eIMCI intervention was further enhanced with features made possible by use of the mobile phone, including the display of a health information video prior to the provider-caretaker interaction, individualized medication dosage calculations based on weight or age of the child, and a summary screen that compiled all results and prompted the provider to reinforce teaching at the completion of the clinic visit. The usability of the mobile phone interface was a crucial characteristic of this intervention mode; the user-centered design process and usability evaluations were the focus of Aim 1 in this study.

The *context* in the framework represents the environment. This was the unique aspects of each clinic, such as number of providers, number of patients seen each day, and resources available at the clinic. The *time* element represents the manner in which the elements may change over time. This study focused on the duration of a single clinical encounter. Although the time element was not measured in this study, time was retained in the framework to represent that the overall interaction could change across time, as providers become more experienced using the tools, a caretaker has multiple experiences with a particular type of problem, or key health information is reinforced for both groups. In each of these cases, the quality and quantity of information exchange tasks may change.

The *outcome* element was added to the model to represent the results of the information exchange tasks. Outcomes of provider usability perceptions of eIMCI were evaluated in Aim 1. Aim 2 provider outcomes included level of adherence to embedded eIMCI and pIMCI communication prompts, operationalized as key information points verbalized during direct observation of the encounter. Caretaker outcomes were recall of the key information points, operationalized as caretaker responses to interview questions at the completion of the encounter.

The mHealth Communications Theoretical Framework described the process and elements of the provider-caretaker interaction that are needed to accomplish the communications specified by the IMCI protocol. This study examined the extent to which the communications support delivery mode (paper or electronic) influenced communications between providers and caretakers.

CHAPTER 2

REVIEW OF THE LITERATURE

This literature review begins with childhood mortality rates in sub-Saharan Africa to underscore the impetus for conducting this research. This problem is then framed via the influence of health literacy and the quality of provider-caretaker communication. Next, a description of the IMCI protocol provides context for the study interventions. The IMCI protocol reflects standardized, evidence-based practice; therefore, literature describing the influence of standardized protocols is additionally examined. The use of mHealth interventions to facilitate the use of standardized protocols is described. ICT and mHealth are additionally examined as emerging foci in nursing informatics. Finally, usability and user-centered design are examined as approaches for evaluating the electronic IMCI protocol.

Childhood Mortality, Health Literacy, and Communication

Child mortality rate reflects the number of children in a given population who die before their 5th birthday. In 2010, the global childhood mortality rate was 93 deaths per 1,000 children under 5, the majority of which took place in developing countries (MGD 2010; World Bank, 2010c). The United Nations (UN) adopted the Millennium Development Goals (MDG), an assemblage of eight goals with 21 targets to be reached by the year 2015, toward improving the quality of life for inhabitants of impoverished nations (MDG, 2012). MDG number 4 is aimed at significantly decreasing global child

mortality rates by two-thirds, to 31 deaths per 1,000 children under 5 by 2015 (MGD, 2010). Demographically, child mortality rates are highest in sub-Saharan Africa at 166 per 1000 children in 2005, a small improvement from 185 per 1000 in 1990 (MDG, 2010). Childhood mortality in Tanzania in 2005 was 102.8; rates improved to 75.8 in 2010 (World Bank, 2010b), but remains at more than double the targeted MGD goal. Thus, while some progress has been made, the rate of improvement suggests that without action, it is improbable that targeted mortality reductions will be met (MDG, 2012).

Deaths in children under 5 years old are largely preventable with the provision of basic child health services. Child mortality rates have been most successfully reduced in recent years in communities that are located in wealthier demographics, or where mothers or caretakers have been provided with child-related health education (Oxfam International, 2008)

Children require their caretakers to act as intermediaries on their behalf to interpret health information during clinical visits and deliver care as instructed after the child returns home (Gentles, Lokker, & McKibbon, 2010). Caretakers must comprehend, recall, and implement prescribed treatments for a clinical encounter to be successfully completed. In order to accomplish this task, caretakers must possess at least a minimum baseline of health literacy.

Health literacy is the ability to read or hear, understand, and act on basic health information (Lanning & Doyle, 2010). Health literacy includes an individual's level of ability to seek services needed and to make appropriate health decisions (Nielsen-Bohlman, Panzer, & Kindig, 2004). The considerable contribution that inadequate health literacy makes toward health disparities was outlined in an international collaborative

research agenda on health literacy (Protherore et al., 2009).

Developing interventions aimed at educating caretakers may be the most effective strategy to improve child health outcomes, particularly in resource poor communities where options for clinical care are limited (Sanders et al., 2009). Pediatric primary care providers may further be in the most advantageous position to provide health education (van Olmen et al., 2010). Improving the provision of health information in resource-limited settings is thus a critical factor of effective health promotion and current empowerment strategies (Wallerstein, 2006).

In addition to improved clinical assessment and treatment planning, successful reduction of child mortality rates must include the effective transfer of specific actionable knowledge to caretakers who will carry out treatment plans (UNICEF, 2012). Enhancing the communication skills of child health professionals may improve caretaker health literacy, and thus child health outcomes (Sanders et al., 2009). Effective communication between providers and caretakers must occur in order for this to take place (Lanning & Doyle, 2010).

Integrated Management of Childhood Illnesses (IMCI)

Encouraging the use of the Integrated Management of Childhood Illnesses (IMCI) protocol to enhance clinical practice is a significant element of the collaborative nursing network strategy to improve global children's health (Harrison et al., 2008). IMCI is a clinical decision support protocol developed by the World Health Organization (WHO) and United Nations Children's Fund (UNICEF) in the mid-1990s. Many common and potentially serious childhood illnesses present with overlapping signs and symptoms, so making a definitive diagnosis can be difficult, particularly in low-resource areas where

examinations involve few instruments and little or no laboratory testing (Chopra et al., 2012). The protocol guides users to classify common childhood illnesses based on history of illness and presenting symptoms, recommends treatment and care, and identifies cases where for referral is needed for severely ill children. In addition, the protocol contains caretaker counseling that outlines when to seek care and how to correctly implement prescribed treatment plans (WHO, 2010).

The IMCI protocol, when properly followed, has been demonstrated to effectively enable providers to consistently administer high-quality care (Bryce et al., 2004). Its effectiveness in improving care delivery is similar between providers, regardless of type of health worker or duration of pre-IMCI training (Huicho et al., 2008). The value of correct and consistent use of IMCI in Tanzania cannot therefore be overemphasized, as the largest distribution of Tanzanian health problems per capita affect children under 5, and IMCI applies to 27.2 % of the causes of these illnesses (Tanzania MOH, 2006).

The IMCI protocol was designed for use in outpatient settings with limited resources such as diagnostic tools and treatments. Its handbook specifically states that it provides generic recommendations and may be adapted for the context in which it is to be used. Technical adaptations suggested include method of delivery, meaning that the material may be presented in forms other than paper, and the material may be divided into subsets. Recommended adaptations include modifying the content to focus on illnesses typically seen in an area, maintaining consistency with local policies, and to consider available resources and "the rational, effective, and affordable use of drugs" in order to enable feasibility to implement the guideline in local health care systems (WHO, 2005, p. 3).

While IMCI has been shown to improve child survival in Tanzania, it has been suggested that providers do not consistently adhere to the IMCI protocol (Bryce et al., 2005b; Walter et al., 2009). The use of IMCI is limited due to lack of sufficient supervision, and the time and effort required to follow the lengthy IMCI chart booklet. Further, insufficient training contributes to this problem; the duration of the recommended training program is 11 days. Efficient methods to encourage greater uptake of IMCI principles at the point of care are needed (Chopra et al., 2012). In addition, clinicians commonly demonstrate a tendency to adhere to protocols less rigorously over time, relying on memory rather than directly referring to the protocol (DeRenzi et al., 2008).

An electronic version of IMCI, called eIMCI, was developed to run on a personal digital assistant (PDA) or mobile phone, and guided child healthcare providers step by step through the protocol (DeRenzi et al., 2008). Evidence suggested that adherence to the protocol was improved through the electronic platform, and time spent implementing the protocol was acceptable to clinicians. It was further noted that clinicians often did not provide the advice or counseling to the mother that was recommended by IMCI, and the counseling was provided more frequently with eIMCI than with usual care (DeRenzi et al., 2008). Adaptation of the IMCI protocol to local needs may play an important role in long-term sustainability of the IMCI strategy (Chopra et al., 2012).

Adherence to Clinical Protocols

Protocols provide standardized instructions for making clinical decisions, in turn promoting consistency in quality of care (Morris, Hirshberg, & Sward, 2009). Protocol recommendations must be carried out by the provider if they are to produce any impact

on clinical outcomes. Protocol adherence is the level at which individual recommendations are followed. Issues with protocol adherence are not unique to any one demographic or sphere of application, and may occur at both institutional and individual levels. From the institutional level, organizational support (or interference) and consistency in supervision are key factors influencing protocol implementation. At the individual level, satisfactory usability, attitudes and perceptions regarding the protocol, and customary habits of providers may independently influence implementation success regardless of clinical environment or circumstances (Latoskek-Berendsen et al., 2010). Implementing protocols via electronic platforms may address some of these issues (Morris, Hirshberg, & Sward, 2009).

Although there is a growing body of research evaluating the use of electronic media to increase protocol adherence, most scientifically rigorous research has been conducted in developed countries with high-income demographics, and relevant studies that evaluated the impact of mHealth in low- and middle-income countries have been significantly lacking. Some of the factors that were identified in an evaluation of clinician compliance of protocols in developed settings included perceived prestige associated with the developers of the protocol, influence of peers and supervisors, and perceived value of content (Morris, 2003). In a white paper that reviewed studies that approached health care delivery using mobile phones with the purpose of enhancing treatment compliance, findings of the effectiveness of interventions were varied and largely depended on the purpose and domain of interventions (Mechael et al., 2010). However, overall satisfaction and acceptance of mobile technology were encouraging enough to recommend continued evaluation. In another review of studies that compared paper methods to electronic

methods of recording and reporting data, handheld computers overall performed better over paper-based methods in time and user preferences, as handheld computers were suggested to be quicker than paper-based methods, and were more often favored by participants (Lane et al., 2006).

ICT and mHealth

The electronic platform may enhance protocol adherence by serving as a tool to assist providers to navigate decision support algorithms, and provide consistent interpretation of protocol elements (Morris, Hirshberg, & Sward, 2009). Electronic tools are frequently implemented in health care via ICT. ICT is a merger of information and communication technologies, and may include computer hardware, software, networking, and telecommunications equipment such as telephone lines, wireless signals, or cellular telephones (International Telecommunication Union, 2009). For example, a smart phone, which contains multiple information and telecommunications technologies interfaced to produce a communication tool with numerous feature sets, is a commonly used ICT. ICT is increasingly used to facilitate communications in a variety of pediatric healthcare settings (Gentles, Lokker, & McKibbon, 2010). Now-ubiquitous communications infrastructure has enabled previously untapped development and innovation in the healthcare setting. According to the International Telecommunication Union (2009), mobile telephony has far surpassed fixed line use in the 21st century; mobile phone service subscription was three times greater than fixed line service worldwide in 2008. The highest growth rate of mobile phone subscription in the developing sector has taken place in Africa, with 28% penetration in 2008. In Tanzania, there were 47 mobile cellular subscriptions per 100 people in 2010 (World Bank, 2010a), and continued growth is still

expected. mHealth has retained momentum as an increasingly popular and viable mechanism to assist with health service delivery, as wireless communication technology has improved in quality and scope while continuing to decrease in cost (Istepanian et. al.,, 2004; Mlot 2012).

These developments have enabled access to previously unreachable communities. The rapid advancement of infrastructure and widespread adoption of mobile technology has enabled increasing development of point-of-care mobile interventions (Bukachi et al., 2007). Still, there are particular considerations associated with the costs and logistics of ICT development. The up-front costs of initiating electronic systems using handheld computers are typically higher than paper-based systems; however, eliminating or reducing the need to generate and distribute paper-based job materials may help over time to mitigate these costs (Seebregts et al., 2009).

As health workers are included in the general population reliant on mobile phones for communication, integrating ICT into systems development may prove to be a convenient and timely transition towards improved knowledge management (Bukachi et al., 2007). Utilizing a mobile phone to deliver protocols further adds concurrent benefits such as enabling remote supervision through use of automatically generated reports that can display the pathways followed through protocols, or reports of time users spent on communication prompts during each case (DeRenzi et al., 2008). Further, many moderately priced mobile phones have the capacity to support multimedia applications such as video display, making novel means for the delivery of the education modules of IMCI newly accessible.

Fit Between Nursing and ICT

A growing and increasingly influential facet of nursing science, nursing informatics (NI) "integrates nursing, its information and knowledge and their management with information and communication technologies to promote the health of people, families and communities worldwide" (Saranto & Casey, 2009, p. 14). The interface between nursing science and public health via the informatics domain has significant implications for improving disease management across cultural and demographic boundaries (ANA, 2008).

The rapidly advancing field of information and communication technologies for development (ICTD) entails the use of information and communication technology (ICT) in developing regions for the advancement of human welfare. ICTD research is likely to be a vital element in the domain of mHealth, and the NI community is well-prepared to contribute greater involvement in ICTD research. According to Perri (2010), projects in ICTD may particularly benefit from NI science, in which the translations of patient, provider, and community needs into ICT solutions are specifically emphasized. For example, many ICTD projects rely on field development and testing to achieve the best fit and use for the environment in which an application or device will be deployed. The common use of focus groups or socio-cultural factors to inform system development in NI science may assist to address unique and often times challenging human and environmental factors in the field. However, NI contributions toward ICTD research are significantly lacking.

The legacy of nursing contains a fundamental cornerstone of global and child health promotion in honor of the principles established by Florence Nightingale (Beck et al.,

2010). International nursing organizations have additionally established an imperative to partner with interdisciplinary teams to promote MDGs. For example, the Network for Nursing in Child Health, an international alliance of nurses collaborating towards the advancement of pediatric nursing care, has emphasized the use of evidence-based practice and IMCI to improve communication to improve children's health (Harrison et al., 2008). Informatics nurses are thus strongly recommended to apply the foundational tenets of NI science towards developing and implementing technologies to support global public health.

Usability and User-Centered Design

Interventions implementing mHealth solutions may contribute to efforts in global health. In order to observe the WHO recommendation to incorporate usability processes in the mHealth strategic plan (McCurdie et al., 2012), the resources and barriers to implementation of ICT projects must be evaluated and distributed among both public and private sectors ((Maru et al., 2009). Many approaches in software development exist in which systematic approaches are emphasized, such as iteration, prototyping, and validation testing. The values of such methods were recognized even in early methods of software development. Examples of these foci are described as early as the 1970s (Royce, 1970), and continually on through the 80s, 90s, and beyond by many early software development experts (Boehm, 1988; Kan, 2002; Smith, 1991). Though often ignored or minimized, two critically valuable components of a comprehensive and rigorous ICT implementation strategy are usability, a subtopic in the field of human factors, and user-centered design (UCD), an application of usability principles. While no literature was found during the writing of this dissertation that explores usability and UCD in mobile

applications relating to products intended for use by health care providers in low-resource settings, the research conducted herein will provide important insight that may inform the rapidly growing efforts in this arena.

Human factors is the term used for "the scientific study of the interaction between people, machines, and their work environments," (Staggers, 2003, p. 311). Simply put, human factors studies how design informs the way people use objects. A universally applicable tenet threaded through human factors concepts is that objects should ideally be designed as straightforward and simply as possible. Design should promote intuitiveness, consistency, and fit (Staggers, 2014).

Within the science of human factors are three subcategories: ergonomics, human-computer interaction (HCI), and of particular note for this study, usability. *Ergonomics*, as the term is used in the U.S., refers to the physical characteristics of equipment and tools as they relate to accessibility, comfort, and safety (Staggers, 2014). For example, when applied to computers, ergonomics may be concerned with where a monitor is placed, if a user must turn their head to see the monitor, or if equipment is situated to reduce body strain. For a mobile device, ergonomics could describe how phone buttons, screen size, or the weight of the device influences use. While the term *ergonomics* may be used interchangeably with *human-computer interaction* (HCI) internationally, ergonomics is distinguished independently in the U.S (Staggers, 2014).

HCI is the study of the interaction between people and computers within a given environment. HCI areas of study include computer design, human usage, and performance of tasks (Staggers, 2014). HCI may be examined on a spectrum from the

individual to entire societies, and draws upon theory and evidence from diverse fields of study, such as psychology, informatics, and cognitive science (Staggers, 2014).

Usability is a subset of HCI that specifically examines human usage of computers, and addresses task performance within a specific context. The primary goal of usability is to make a product optimally usable and useful across any spectrum of diverse users within a given environment (Schneiderman & Plaisant, 2010). The International Standards Organization (ISO) formally defines usability as "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use" (Jokela, Iivari, Matero, & Karukka, 2003). Steve Krug (2006) unassumingly states that "usability really just means making sure that something works well: that a person of average (or even below average) ability and experience can use the thing – whether it's intended for a website, a fighter jet, or a revolving door – for its intended purpose without getting hopelessly frustrated" (p. 5). The Usability Professionals' Association (UPA) describes usability as the level of fit and of ease of use of a product ("Resources: About Usability," 2010). The UPA further adds measures of quality, efficiency, effectiveness, and satisfaction to the characteristics of usability, and includes usability as the kind of techniques used to develop anything with the aim of being more usable. There are three essential constituents across these definitions that are explicitly identified by Tullis and Albert (2008): 1) a user, or any kind of consumer of a product, 2) the act of doing something, and 3) a product or thing that enables the user to perform the act of doing.

Usability affects all objects and the interactions with those objects. In its most extreme consequence, usability can "mean the difference between life and death," as

noted by Tullis and Albert (2008, p. 5). Lesser extremes of poor usability can still result in frustration and decreased user productivity or utilization of a product. Alternatively, successful and efficient usability can produce an affirmative mindset of triumph and proficiency in users. When usability is achieved well, the user interface may even become nearly invisible and promote optimum performance (Shneiderman & Plaisant, 2010). In all cases, usability becomes increasingly vital as products become more complicated, are used by more kinds of users, and as IT and ICTs advance. As the complexity of product tasks and purposes grow, usability metrics and utilizing UCD become a flagship of product quality (Tullis & Albert, 2008).

The goals of usability may be thought of in terms of effectiveness, efficiency, and satisfaction (Staggers, 2014). *Effectiveness* is the usefulness and safety of a product; it is the ability to successfully perform a relevant task using a product. If effectiveness is hindered due to design usability issues, it is expected that the product will fail (Tullis & Albert, 2008). *Efficiency* concerns resource management, including time and energy needed to complete tasks, error frequency, and learnability or the ease of learning how to use a system (Staggers, 2014). *Satisfaction* is more of a subjective metric – it is a user's self-reported description of a number of perceptions, such as ease of use, benefits, level of appeal, intuitiveness, trustworthiness, or usefulness of using a product (Tullis & Albert, 2008).

User-Centered Design

User-centered design (UCD) is an approach to systems development focused specifically and intentionally on usability (Smith, Thorp, & Henry, 2004). In the UCD approach, user context, environment, and requirements are closely examined during all

stages of product design and evaluation ("Resources: About Usability," 2010; Schneiderman & Plaisant, 2010; Bevan, 2006). Rubin, a distinguished expert in the UCD field, summarized UCD as "the techniques, processes, methods, and procedures for designing usable products and systems, but just as important, the philosophy that places the user at the center of the process," (1994, p. 10). A spectrum of methods may be used to involve users in product design, from limited requirements analysis and product testing, to active and detailed participatory design processes. However, all methods that employ the UCD approach are based on intentional user involvement (Abras, Maloney-Krichmar, & Preece, 2004).

While there are many variations in specific UCD procedures, the basic principles and techniques are the same. UCD is guided by three distinguishing principles or axioms stemming from usability foundations (Smith, Thorp & Henry, 2004; Staggers, 2014; Taylor, Bray, Staggers, & Olson, 2003). First, early focus on users and their tasks is emphasized. This implies a deep understanding of users, their tasks, perceptions, and the context of their work. Iterative design incorporating user feedback is the second principle; this is the process in which a product is designed, modified, and tested repeatedly. The third principle is empirical measurement or observation of user interactions, which may range from formal research methods to informal observations of user interaction (Staggers, 2014). In UCD, these principles guide design decisions, processes, and all phases of the software development lifecycle, from initial needs assessment through iterative prototyping, formative and summative evaluation, and into implementation (see Table 2.1).

Table 2.1
Traditional Software Development Alignment with UCD/Usability Testing

Systems Development Lifecycle Phase	UCD Phase	Usability Testing
Planning and analysis	Needs assessment	Exploratory Testing (Rubin & Chisnell) Requirements Gathering (Hebda & Czar) CTA (Crandall et al.)
Design & development	Iterative prototyping	Formative Testing (Tullis & Albert) Assessment Testing (Rubin & Chisnell)
Implementation & evaluation	Preparing for implementation	Summative Testing (Tullis & Albert) Validation and Verification testing (Dix et al., Rubin & Chisnell) Comparison Testing (Rubin & Chisnell)

Needs Assessment

The first axiom of UCD, early focus on users and their tasks, is implemented during initial stages of software development. Goals of this phase include understanding users needs and requirements, evaluating the context in which a system will be used, and developing an initial list of product specifications (Staggers, 2014). Further objectives may include hypothesizing how the product should interact with a user to assist performance, and understanding the users' workflow.

This may be referred to as a *needs assessment* or *requirements gathering* phase (Hebda & Czar, 2009), also called *exploratory usability evaluation* by Rubin and Chisnell (2008). Needs assessments are conducted at the onset of development in order to observe and assess the needs and deficits of users in their environment, in relation to the tasks a

product is aimed to achieve (Hebda & Czar, 2009). This assessment of user requirements and needs is highly recommended early in the design process, as modifications become increasingly difficult to achieve as development progresses (Dix, Finlay, Abowd, & Beale, 2003).

One family of techniques that can inform a needs assessment is cognitive task analysis (CTA) (Crandall, Klein, & Hoffman, 2006). CTA is "the activities of perceiving and attending to issues that underlie performance of tasks, the cognitive skills and strategies needed to respond adeptly to complex situations, and the purposes, goals, and motivations for cognitive work" (Crandall, Klein, & Hoffman, 2006, p. 3). CTA and exploratory techniques emphasize the identification of a user and the examination of factors surrounding task performance. Factors that drive performance of a task are identified, and design goals may be created to respond to those factors. Designers and users must thus have direct contact in order to achieve these objectives (Staggers, 2014). Many software features such as navigational representation, i.e., vertical or horizontal, may be decided once some foundational understanding of the goals of the product is achieved (Hebda & Czar, 2009).

Iterative Prototyping

The second axiom of UCD is *iterative design*, wherein user feedback is incorporated into design decisions (Staggers, 2014). Rubin's *exploratory testing* stage takes place during iterative design. Once an initial design is developed, a prototype is built and tested with users (Dix, Finlay, Abowd, & Beale, 2003). Iterative design, the process of repeatedly cycling through testing and redesigning, is used to modify and refine the prototype until a satisfactory product results. Prototypes may be developed

using any of three approaches: 1) throw-away, wherein one or more prototypes are built for testing (sometimes including low fidelity prototypes, drawings, or mock-ups) with final fully functional software construction later in the design process; 2) incremental, in which smaller segments are created to be released sequentially but built towards an overall product or system; and 3) evolutionary, describing a process wherein an initial prototype begins as a simplified version that is continually modified and refined, until an ultimate product results (Dix, Finlay, Abowd, & Beale, 2003).

User Interface Design

The user interface, or data display, is the primary mechanism by which most users interact with a software application and is the primary interface feature that users perceive. This may be increasingly refined during iterations of the design process.

User interface design should be guided by a set of high-level guidelines, which may become increasingly refined through the development process (Rubin & Chisnell, 2008). Smith and Mosier (1986) suggested five principles by which to organize displays: consistency, efficiency of information assimilation, minimizing memory load, formatting data entry and data display to be compatible, and user options for data display. *Consistency* in design means to use the same standards for each instance of a design feature. This applies to all facets of the display, such as terminology, language standards, and formatting. *Efficiency of information assimilation* is to format the display to be easy, familiar, and relevant to the user. Text should be easy to read by comfortably spacing text and columns, simplifying dialogue, and using consistent labeling. *Minimizing user memory load* is aimed at ensuring that when navigating from screen to screen, the user is not required to memorize information. Tasks and navigation should be arranged in such a

way that natural workflow is observed. Labeling should further orient new users to their navigational point within the software. *Compatibility of data display with data entry* is to match the format of displayed information with that of user-entered information. And last, allowing *user options for data display* may enhance the user experience by providing flexibility for preference and task, determined by users as needed.

Shneiderman and Plaisant (2010) suggest the preservation of simplicity and learnability in data display is to be emphasized through menu and dialogue design. The small screen of a mobile application places an especially critical need for the use of tick-boxes, brief information fields, and simplification of text and labeling wherever possible. Grouping displays and data entry and text by similarity, workflow, and ease of learning may also enhance user satisfaction. To the contrary, cluttered, overfilled, or disorganized displays can incite frustration, boredom, and decreased productivity (Shneiderman & Plaisant, 2010). Aims of elegance, consistency, and simplicity should ultimately underlie all design decisions.

Formative Testing

Empirical measurement and observation of users is the third axiom of UCD. During the iterative design phase, empirical measurement is often categorized as *formative testing* because test results inform the design of subsequent iterations. Through a multitude of testing methods, the formative approach seeks to offer insight on how usability affects performance, what characteristics of a product impact user satisfaction, what kinds of errors are possible or common, and what issues and features are or are not eligible for design modification (Tullis & Albert, 2008).

Rubin's *assessment testing* corresponds to formative testing stages. Exercises to examine how users actually interact with a product are conducted during this stage. Assessment testing is conduced once an initial prototype is developed, likely in the early to middle-development cycle. Findings of exploratory testing may be further developed during assessment testing in order to fill in and refine development (Rubin & Chisnell, 2008).

Summative Testing

The principle of empirical measurement and observation of users is also applied when the software is ready for implementation. At this phase, *summative testing* occurs. Summative usability testing is described by Tullis and Albert (2008) as being appropriately conducted when a final prototype has been developed and is either entering implementation or after rollout. The aim of summative testing is an assurance of quality, to assess the ability of a product to assist a user to accomplish the tasks that it is intended to support. Usability targets that have been previously established and the improvements made through protocol iteration may be evaluated.

Once a software application is developed, it must be further assured that it fits with customer needs, and accurately maintains fidelity to source materials. This may be achieved through validation and verification testing. While Rubin and Chisnell (2008) uses the term *validation* interchangeably with the term *verification*, Dix, Finlay, Gregory, and Russell (1993) and others distinguish between the two. According to Dix et al. (1993), verification testing focuses on the methods of the development process; internal fidelity to source materials or other standards upon which the product is built are objectively evaluated herein. Validation testing focuses on actual user need, examining if

the product fulfills its purpose against a predetermined standard or benchmark when placed in its intended environment.

Another application of summative testing is to compare multiple versions, or multiple products, with one another. This is referred to as *comparison testing* by Rubin and Chisnell (2008). The objective of comparison testing is to evaluate multiple design decisions against one another. Product performance and user satisfaction are the foci of comparison, with results being increasingly significant as differences in tested features increase.

Usability Testing Preparation

At the onset of usability inquiry, decisions to be made involve 1) the types and numbers of participants to include, and 2) the kind of usability data needed to answer research questions (Tullis & Albert, 2008). Participants for inclusion for a usability study must be carefully selected (Tullis & Albert, 2008). Different types of users may be better suited for assessing different types of tasks. For example, when evaluating the user interface, novice users may be recruited to uncover basic usability issues of the interface and workflow design. However, if evaluating complex decision rules of a decision support system, experts who are able to overlook any usability problems and focus on complex product content would be more appropriate participants.

Sample size is an additional consideration for conducting a usability study, and is one that lacks a single definitive standard. Lazar, Feng, and Hochheiser (2010) propose that more participants are always better to optimize user representation, and if including a smaller sample, the chance of including users who may not complete tasks in a typical manner (e.g., do so more quickly or slowly, or draw more or less on personal expertise) is

a risk. Tullis and Albert (2008) state that the ideal sample size depends on the kind of usability testing being conducted. For many, the inclusion of "five participants *per significantly different class of user"* (Tullis & Albert, 2008, p. 119) will typically uncover the majority of issues, and further explain that more participants included in an individual usability test typically do not yield substantial new results. This may not apply, however, if the scope of the product or evaluation is rather expansive, or the user base is undefined or underrepresented. Further, the most significant issues may be discovered by a smaller group of participants early in the design process, and as design progresses towards finality, a greater number of participants may be required to detect remaining problems or to assess different facets of usability. Despite these recommendations, recruiting a large sample for usability testing may be problematic or outright impossible in some instances. Utilizing in-depth examinations through key informants (Clemmensen, 2011) or case studies (Lazar, Feng, & Hochheiser, 2010) that include even just one user may still produce highly valuable results, when more participants may not be accessed.

Determining the kind of data needed to effectively evaluate how a product will influence the completion of tasks is another primary concern when designing a usability study (Tullis & Albert, 2008). Metrics, or "a way of measuring or evaluating a particular phenomenon or thing" (Tullis & Albert, 2008, p. 7), provide the measurable elements that may be evaluated to answer this question. Metrics may include elements such as learnability, task completion time, error rate, knowledge retention, and satisfaction (Shneiderman & Plaisant, 2010; Tullis & Albert, 2008). These metrics may be framed and evaluated using numerous data collection methods.

Data Collection Methods Used in Usability Evaluations

Four ways to collect data, identified by Crandall, Klein, and Hoffman (2006) and reviewed herein, include interview data, self-reports, observation, and automated collection of behavioral data. These data collection methods may be used at any point of usability testing or UCD phases.

Interview Data

Collecting data through interviewing is a highly popular usability testing method. While careful participant selection is crucial for interview studies to yield useful data, interviews may offer advantage over other methods. Crandall et al. (2006) note that by conducting interviews, insight into specific workflow, goals, or other dynamics may be easily captured that otherwise may be overlooked. Further, interview data may drive underlying theories and ideas that may serve any stages of design and iteration. At times, interview data may be considered to be more exploratory than conclusive, and findings from interviews may be complimented and validated by additional interviewing or with other testing methods. Methods of interviewing are additionally highly flexible to suit the needs of a particular usability study, and may range in convention from formal, structured interviews to informal discussions with experts or other users. Accessibility of interview participants may be limited, thus interview studies often include a smaller sample; however, this may not be a serious limitation due to the richness of data the method may yield. Key informants may be exceptionally valuable for interviews in cross-cultural settings of usability testing (Clemmensen, 2011), or situations when large sample sizes are inaccessible. Problems may be identified or recommendations for design and iteration may result from the interviewing process (Shneiderman & Plaisant, 2010).

Self-Reported Data

Self-reported data are data that are independently produced by participants. This may be achieved through a variety of formats, such as formal reviews, surveys, or informal record-keeping logs (Crandall, Klein, & Hoffman, 2006; Tullis & Albert, 2008). By formatting self-report forms appropriately, metrics may be extracted from data and used for definitive usability analyses (Tullis & Albert, 2008). Advantages of self-reported data are that participants can freely submit data while using a product without interference of researchers, thus allowing for easy data collection opportunities and flexibility. This may also serve as a disadvantage, however, as participants must be internally motivated to participate without advertent supervision (Crandall, Klein, & Hoffman, 2006). However, because self-reported data are gleaned directly from users expressing their perceptions, if it can be generated then may provide highly valuable information for researchers (Tullis & Albert, 2008).

Observation Data

Whenever possible, user performance and on-site observations are highly recommended in order to gain insight into specific workflow, user interactions, and actual performance expectations (Crandall, Klein, & Hoffman, 2006; Shneiderman & Plaisant, 2010). Shneiderman and Plaisant describe user-interface designers as a unique subset of ethnographers, who must not only have a deep understanding of their subjects, but they must also be able to mobilize that knowledge to improve their designs in order to best serve their clients. Ethnographic interface designers as observers may familiarize themselves with work environments, establish relationship with their users, and collect and analyze observation data in order to inform product design. When a full

understanding of these elements is established at the onset of design, developers can use that knowledge to drive display and flow design success. Some examples of observation methods include walk-throughs, think-aloud, and test case scenarios.

Walk-throughs may be a component of a needs assessment, during which developers are physically guided through a work site, observing relevant roles and tasks that may inform product development. During a walk-through, a designer typically records workflow, interactions, and task completion, as an actual user would do with a product (Rubin & Chisnell, 2008). This information can then be used to determine product task sequence, features, or other adaptations to respond to user needs.

A think-aloud exercise is a technique used to observe what users are thinking while using a product. A user is asked to verbalize a running explanation of their thoughts, actions, perceptions, and expectations of the software to perform a task during actual use. Rubin and Chisnell (2008) observes that while the think-aloud technique offers the advantage of potentially directly capturing an array of performance and satisfaction feedback, the method also may contain limitations. By relying on a participant's ability to perform and verbalize a task, and to be willing to provide relevant information, the method may not yield productive results. Rubin recommends that the technique should be adapted, or an alternative testing method used, if the participant is unable to effectively perform the think-aloud activity.

Test case scenarios may be used to assess task success by observing user navigation processes of actual work that is performed using a product (Tullis & Albert, 2008). Scenarios are ideally generated for this exercise that span most, if not all, of a product's coverage. Response data may be compared to expected data in order to evaluate

performance. Data generated using test case scenarios may illuminate task completion time, problems with logic or pathways if a user is unable to correctly navigate to a desired outcome due to design flaws, frequency and severity of errors, etc. Rubin and Chisnell (2008) declare that five qualities of test case scenarios should be 1) realistic, 2) accurate in sequential task order, 3) matching user experience with scenario tasks, 4) free of jargon, and 5) all-inclusive of performance tasks.

When conducting any of these or other usability testing exercises, designers should pay particular attention to observing verbal and nonverbal behaviors. Verbal behaviors may be examined by categorizing comments as positive, negative, or neutral for comparison (Tullis & Albert, 2008). Nonverbal behaviors may be recorded as well, particularly to gauge participant satisfaction, or dissatisfaction, with a product. These observations "may be particularly useful if the product has some physical, perceptual, or cognitive demands," (Tullis & Albert, 2008, p. 117).

Automated Data Capture

Data capture may be automated by incorporating computers to collect data as users perform tasks using a product (Crandall, Klein, & Hoffman, 2006). A product must be programmed to establish this option; however, once done, it can be run with minimal supervision by developers. While this method potentially lacks personal interaction that strengthens other types of usability testing, certain kinds of data are good candidates for automation. For example, tracking user navigation may assist developers to assess whether the intended navigation pathways are utilized to accomplish a task, or if workarounds are being generated.

Summary of Literature Review

Child mortality rates may be significantly improved through standardized practice and improved communication among providers and caretakers of children. A strategy developed by the World Health Organization, IMCI, has been shown to enable the delivery of evidence-based clinical practice regarding the diagnosis and treatment of illnesses for children under 5. In addition, it provides guidance for clinicians in key elements to be taught to caretakers of children. The IMCI protocol, if widely implemented, could significantly improve child mortality rates and assist to achieve Millennium Development Goals. However, IMCI has not been used to its fullest effect, and adherence to the protocol is hampered by lack of supervision, lack of resources and training, and usability problems. Electronic methods can support adherence to clinical guidelines. ICT and mHealth applications could provide a means to support better protocol adherence in low-income countries.

Although the provision of health education and communication are vital components of improving health literacy and clinical outcomes, little literature was found that examines the influence of communication on the ability of caretakers of children in low-income regions to carry out treatment plans. In addition, little scientifically rigorous research has been conducted on the measureable effectiveness of ICT systems and their utility as an instrument to improve provider/caretaker communication and caretaker comprehension, recall, and adherence to prescribed treatment plans. Research related to IMCI, mHealth applications, and communication is needed to enable the development of effective interventions that may improve child health outcomes and assist with reaching projected MDG goals.

Utilizing usability evaluations and UCD methods may ameliorate usability deficits of the paper IMCI protocol. Cultivating a deep understanding of users (providers), the environment, and the tasks for electronic protocol development may effectively assist providers to perform the tasks established by the protocol. A strength of UCD and usability testing is that the great body of literature available describing the aforementioned constructs and methods may be applied to a wide variety of products and environments. Although the recent literature reviewed here mainly comes from applications of a human-computer or web-based design context, these concepts are highly suited for the mobile ICT platform.

CHAPTER 3

STUDY OVERVIEW

Study Design Overview

This section provides an overview of the study design (Figure 3.1) and human subject protections. The eIMCI protocol included enhanced communications support. User-centered design (UCD) is a software development approach in which users are the central focus, analogous to patient-centered approaches in health care. Aim 1 described the UCD methods and usability testing that guided application development (Figure 3.1). Initial evaluations (Aim 1.1) focused on understanding the users and context of use (1.1.1) and the video that would be shown to caretakers before the visit (1.1.2). The decision support was examined during knowledge base verification testing (Aim 1.2). The user interface was the focus of formative testing in a mock clinical environment for Aim 1.3, and Aim 1.4 consisted of summative testing also in a mock clinical environment.

The ultimate purpose of this study was to evaluate the effect of protocol delivery method (pIMCI or eIMCI) on provider-caretaker communication during clinical encounters for children under 5. Specifically, the study examined the health education that is represented in the IMCI protocol as key information points (Aim 2) related to the child's problem (Aim 2.1), the treatment (Aim 2.2) and when to return to clinic (Aim 2.3). Both the provider verbalization of information and the caretaker's recall of what the provider verbalized were examined.

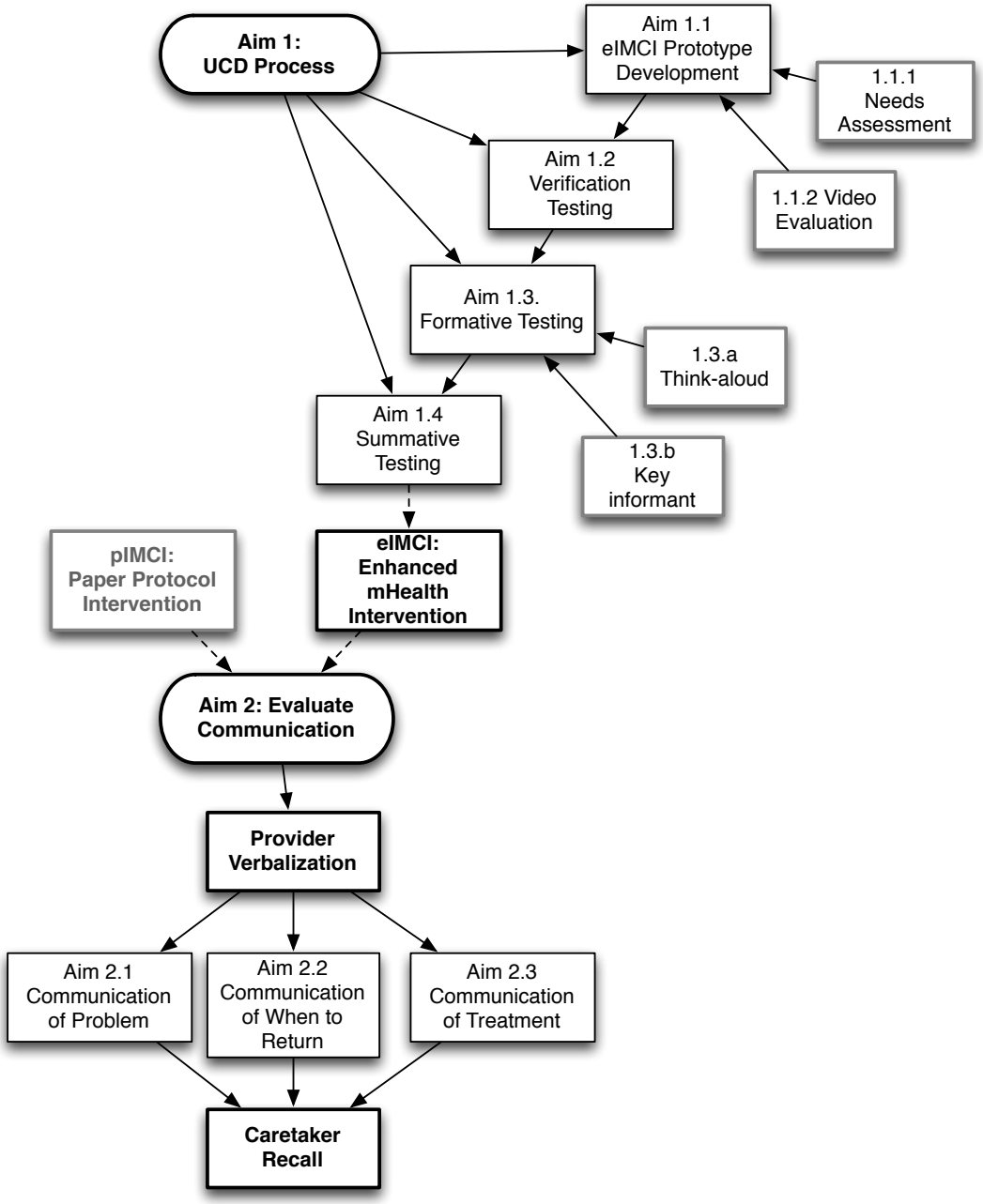


Figure 3.1
Overview of Study Elements

Human Subjects Protections

As a global health research project, this study contained unique aspects to human subjects protection. To ensure appropriate protections for the participants and the community, three independent academic and scientific research institutions provided human subjects oversight and granted approval for both aims of this minimal-risk study. Oversight was provided in the United States by the Harvard School of Public Health (HSPH) Institutional Review Board (IRB). In most cases, the University of Utah IRB oversees student dissertation research. The HSPH IRB already had international agreements in place with the Tanzanian government and was serving as the primary IRB for the overarching study; therefore, the Utah IRB allowed HSPH to serve as the IRB of record for this dissertation. Oversight was provided in Tanzania by the National Institute of Medical Research (NIMR) IRB, a government agency that must approve all research taking place in Tanzania, and local/community oversight was provided by the Ifakara Health Institute (IHI) IRB.

The Belmont Report observes three universally applicable cardinal principles of ethical conduct in research: respect for persons, beneficence, and justice ("Belmont Report," 1979). Respect for persons acknowledges two fundamental principles: 1) to acknowledge autonomy, and 2) to protect individuals with diminished autonomy. In observation of the principle of autonomy, informed consent was obtained by all providers and caretakers participating in the study. As children comprise of a population with diminished autonomy, caretakers were given detailed information about the study. Those who chose to participate provided permission for the paper and electronic protocols to be available for provider use to guide care for their children. Providers were able to choose

whether or not to participate in all aspects of the study; each participated in e-IMCI development activities and provided feedback without coercion or compensation, and could choose whether or not to adhere to the IMCI-based protocol for an individual child. Usual care was given if the provider chose not to adhere to the protocol. Caretakers were able to choose whether or not to participate in all aspects of the study as well, including video evaluation of the development (Aim 1) aspect of the study, and the communication evaluation (Aim 2) aspects of the study.

Beneficence (nonmaleficence) is the obligation to maximize benefits and do no harm ("Belmont Report," 1979). Potential direct benefits to providers for participation in the development phase included the educational classes that accompanied protocol training sessions, and receiving the benefit of improving their provision of care through the assistance of learning to use standardized protocols, best practice communication, and learning the importance of these. Indirect benefits of participant contribution to e-IMCI development activities included adding to e-IMCI's usability and utility, assisting to develop the contextual relevance of the application, achieving a sense of ownership in the final product, and contributing to the body of knowledge of mobile protocols and the UCD process. Child and caretaker participants potentially experienced direct benefits in instances when children received improved clinical care through the standardized protocols and communication of key information points as a result of provider adherence. It is likely that children participating in the study could have improved chances of recovery due to receiving treatment using standardized care, and caretakers would be better able to implement treatment plans in the home as a result of improved communications.

In observation of the principle of nonmaleficence and minimizing possible harm, no significant medical or psychosocial risks to participant safety, comfort, or convenience were anticipated or encountered during the development of the e-IMCI protocol (Aim 1). Nor was any medical or psychosocial risk anticipated or encountered for the providers, caretakers, or children involved due to the implementation or data collection components of e-IMCI and p-IMCI (Aim 2). The IMCI protocol, which the protocols used in this study were based from, is considered the standard of care for children under age 5 in Tanzania. In addition, a separate "safety study" was conducted prior to this dissertation study, in which the decision content of the protocols that were utilized in this study was confirmed to be safe and effective. Measures were taken to ensure that research data collection did not interfere with or slow down the care of ill children. If the provider felt that any instructions provided by the protocol were incorrect or insufficient to address the child's problem, they were encouraged to use their personal expertise towards administering final provisions for the child. Caretakers were interviewed following the clinical encounter, which did require additional time. However, long waits are common when seeking health services in the Tanzanian context and time for the interview was not considered an additionally burdensome inconvenience. The possibility did exist that the phones could break, making the eIMCI protocol unavailable; however, there were backup phones and a backup paper copy of the IMCI-based protocol in each facility, as well as IT support personnel readily available by phone or already present in the clinic. Providers in the e-IMCI arm signed an agreement not to leave the phones unattended or loan out the phones.

The principle of justice addresses fairness in distribution of study benefits and risks, attends to responsible targeting of vulnerable subjects, and intentionally includes subjects who may benefit from participating in the research ("Belmont Report," 1979). While no foreseeable risks were anticipated, distributive justice was observed by the provision of clinical supplies, including malaria rapid diagnostic tests (mRDTs), urinary dipsticks for the detection of urinary tract infections (UTIs), and a variety of medications for widespread use for pediatric patients in participating clinics (not only for children enrolled in the study) during the study period. All eligible children suffering from acute illnesses in the actual clinical settings were given the opportunity to participate in the study, and those who were ineligible were still given access to the medications and testing supplies, which are frequently unavailable in Tanzanian municipal health facilities.

Privacy and confidentiality were rigorously protected during all study procedures. An observer was present in the room to record elements of the clinical encounter; however, in Tanzania, additional personnel present during the examination of a young child is common and the observer was only present if the caretaker consented to participate; therefore, having the observer present was not considered a significant risk to patient privacy. No identifying information was collected during e-IMCI development activities taking place with nonstaff participants. Data security risk for the development portion of this study was low because only fabricated scenarios were used (no real patient data). No problems were encountered in maintaining data confidentiality, which was stored on an encrypted, password-protected laptop belonging to the study PI. No problems were anticipated or encountered in maintaining confidentiality of clinical

observation and interview data. All paper data collection forms were secured in locked clinic supervisor's offices until they were collected weekly and taken to the city council medical office for storage and where data were entered into a secure, password-protected computer. Data stored on the phones were uploaded daily to a secure, password-protected central server in which only a small group of approved personnel had access. All data were fully de-identified prior to analysis.

Additional Considerations and Risks in International Research

As a global health research project, additional protective measures must also be extended to surround the researcher traveling internationally. When abroad, it is the personal responsibility and obligation for the traveling researcher to develop a working understanding of cultural norms. This includes being accountable to observe local customs by dressing appropriately, observing gender roles, speaking formally to elders and superiors with appropriate titles and greetings, and abstaining from critical political commentary if possible. Any issue that does arise in conflict with the researcher's own belief system, which is invariably likely to occur, should be discussed with supervisors and trusted local contacts. Observing such measures will contribute to the personal safety of foreign researchers and preserve professional relationships among partners.

Personal safety may be a considerable risk to the researcher in some settings abroad. Taking measures to protect one's health from potentially fatal illnesses that are not endemic to a researcher's native land is paramount, such as obtaining appropriate vaccinations, and using any appropriate protective equipment such as mosquito nets or safety goggles. In addition, researchers should maintain personal safety by observing common sense safety rules and keeping high-risk theft items such as laptops, mobile

phones, and cash out of sight in public. However, even when observing common sense safety measures, incidents still occur. It is essential to have laptops protected with high-level encryption and password protection in the event of a theft in order to rigorously protect participant confidentiality. Finally, any incidents that may occur should be immediately reported to supervisors both abroad in the study setting and in the researcher's academic institution, as well as any relevant local or international authorities.

Study Contribution

The study team made additional contributions to the participating sites in the form of education and clinical supply provisions. As described above, medications and testing supplies were provided for all children under 5 seeking acute care health services, regardless of study enrollment. Another contribution was classes held for participating providers during protocol trainings. During these classes, members of this study team lectured providers from all sites on the role of caretaker health literacy and the linkage between provider-caretaker communication and child health outcomes. Partnering researchers additionally updated participating providers on best practice for administering antibiotics and the serious dangers of overuse. In addition, this study team left the phones in the clinics for providers to use the electronic protocols at the conclusion of data collection at the request of clinic supervisors. Local partners in Tanzania, D-Tree International, continually provide light technical support for eIMCI use in these clinics.

CHAPTER 4

AIM 1. USER-CENTERED DESIGN

Aims and Hypotheses

Aim 1 of this study was to utilize user-centered design (UCD) principles to iteratively develop the eIMCI mobile application and to evaluate its usability. The primary component of the mHealth Communications Framework examined was the Communications Support, operationalized as the eIMCI mobile application. Communications Support was represented by both the pIMCI and eIMCI platforms; the sole focus of Aim 1 was the eIMCI application. The software context of use, characteristics, and actions assist with and influence the Information Exchange task, which is the transfer of the message from the sender (provider) to the receiver (caretaker of a child). Outcomes of the communication task were evaluated in Aim 2. Specifically, Aim 1 subaims were as follows:

Aim 1.1: To develop a multimedia eIMCI application prototype

- 1.1.1 To conduct a needs assessment in order to understand the context of eIMCI use, including 1) users (providers), 2) the clinical environment, and 3) in-clinic resources.
- 1.1.2 To create communication enhancement educational videos and conduct comparison testing to determine the most effective video.

Aim 1.2: Conduct knowledge base verification testing to assess the fidelity of the conversion of the decision rules from paper protocol (pIMCI) to electronic protocol (eIMCI).

Aim 1.3: Conduct formative testing to evaluate specified aspects of usability, specifically: satisfaction and perceived usefulness, learnability and ease of learning the navigation, perceived efficiency, effectiveness, and accessibility/fit with clinical workflow, from a user perspective. To achieve this, two types of formative testing were conducted: a) think-aloud evaluation and b) key informant feedback

Aim 1.4: Conduct summative testing to assess effectiveness and accessibility/fit with clinical workflow from the perspective of users in a mock clinical environment.

Each of the subaims required individual methods, samples, and analyses to implement, which together resulted in the final eIMCI prototype. Detailed narratives of each aim and subaim follow in corresponding sections. Because the course of eIMCI prototype creation was an iterative development process, characteristic study designs for each component of the process were not applicable. The focus on primary axioms of usability foundations, including 1) early focus on users and their tasks, 2) iterative design, and 3) empirical measurement of users (Smith, Thorp & Henry, 2004; Staggers, 2014; Taylor, Bray, Staggers, & Olson, 2003), drove development and testing processes of the eIMCI mobile application (see Figure 4.1).

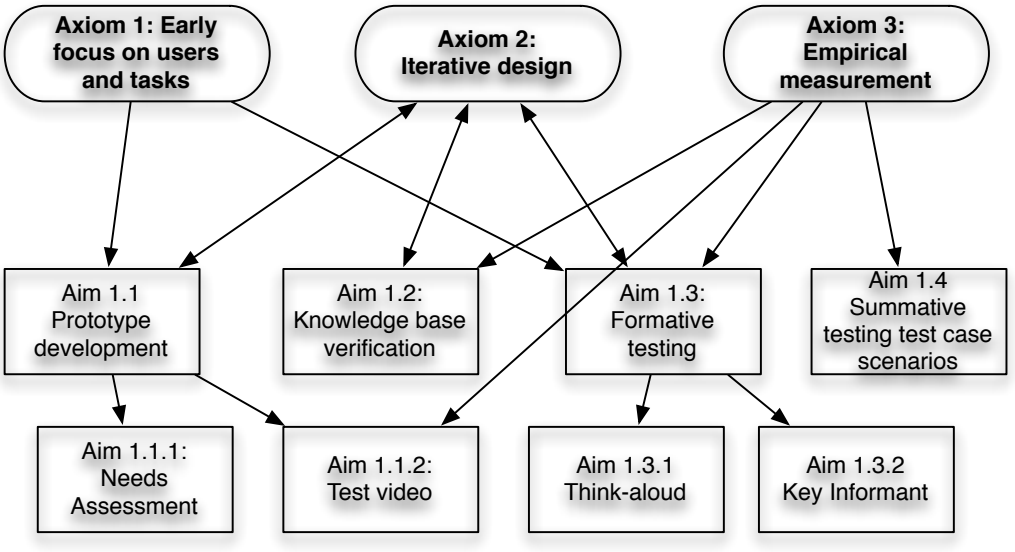


Figure 4.1
Usability Axioms Implemented through UCD Development

Aim 1.1 Initial eIMCI Application Prototype Development

The primary deliverable of this aim was an initial eIMCI prototype that could be used as a foundational application, on which usability testing and iteration would be later conducted. The eIMCI application was to contain the same problem classification, treatment, and communication prompt pathways as the pIMCI protocol, with the addition of an educational video to be played on the mobile phone for the participating caretaker of the child, and a summary screen at the conclusion of the encounter to condense all teaching points given during the evaluation. The pIMCI and eIMCI protocols were designed to support isolated, first-time clinical encounters for treatment of children suffering from generalized acute illnesses. Aim 1.1 included a needs assessment (Aim 1.1.1) and development of communications videos (Aim 1.1.2).

Aim 1.1.1 Needs Assessment

The initial eIMCI software design began with an onsite needs assessment and walk-through. This was conducted before initiating the application prototype development in order to fully understand the actual context in which the eIMCI protocol was to be deployed.

Sample

One clinic supervisor accompanied researchers through the clinic to conduct a walk-through for the needs assessment. The supervisor was a highly experienced medical officer (the Tanzanian equivalent to a medical doctor), and spoke fluent English as a second language.

Setting

The developers of the eIMCI application and conductors of the needs assessment were the PI for this dissertation study (a nursing informatics doctoral student) and an experienced software designer. Both were residing in Dar es Salaam, Tanzania throughout the course of the development process, the majority of which took place over the course of 10 months (June 2010-March 2011).

The needs assessment walk-through evaluation took place in one of the study participating municipal clinics (see Aim 2 for description of clinic sample selection). Procedures and environments of municipal clinics in Dar es Salaam were highly similar, and it was deemed by local authorities from the Dar es Salaam City Council Medical Office to be sufficient to limit assessment activities to one clinic. All study participating clinics were visited in preparation for the study at various times; only one was

specifically examined for the needs assessment walk-through. During the needs assessment, a workflow analysis was conducted, and researchers tracked processes from the perspectives of providers and patients.

Procedure

Approval for clinic access was obtained from clinic supervisors, the facility in-charge, and the Dar es Salaam City Council Medical Office. Letters of approval were obtained from the Dar es Salaam City Council Medical Office to conduct visits to the clinic, and were delivered to the facility in-charge upon arrival. Visits were scheduled for specific days and times, indicated within the approval letters.

The clinic supervisor accompanied researchers to conduct a clinic walk-through, during which the processes and procedures related to a clinic visit were explained in detail. All relevant departments involved in pediatric acute care were visited. Researchers documented provider workflow, as well as physically moved through the clinic in the order that a patient would go through a clinic visit. This began with the patient queuing area, followed by the provider visit rooms, lab areas, and pharmacies.

Results

Following the walk-through, developers discussed findings that could influence the implementation and use of the eIMCI application. These findings were labeled as *evaluation elements* and *influential elements*. Responses to the influential elements were then generated as *design goals*. These design goals informed the subsequent *design activities*, which ultimately resulted the initial prototype (Figure 4.2).

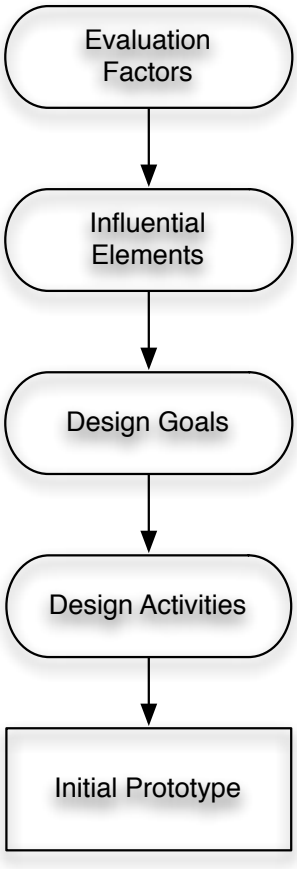


Figure 4.2
Needs Assessment Flow

Evaluation Factors and Influential Elements

A picture of the dynamic interaction between each evaluation factor emerged from the needs assessment (Figure 4.3). The evaluation factors focused the identification of influential elements, to which responses were generated in the form of design goals, which then informed design activities. Three categories of *evaluation factors* were relevant to eIMCI application implementation, including 1) users (providers), 2) the clinical environment, and 3) in-clinic resources. Influential elements were characteristics of the evaluation factors that could influence eIMCI implementation.

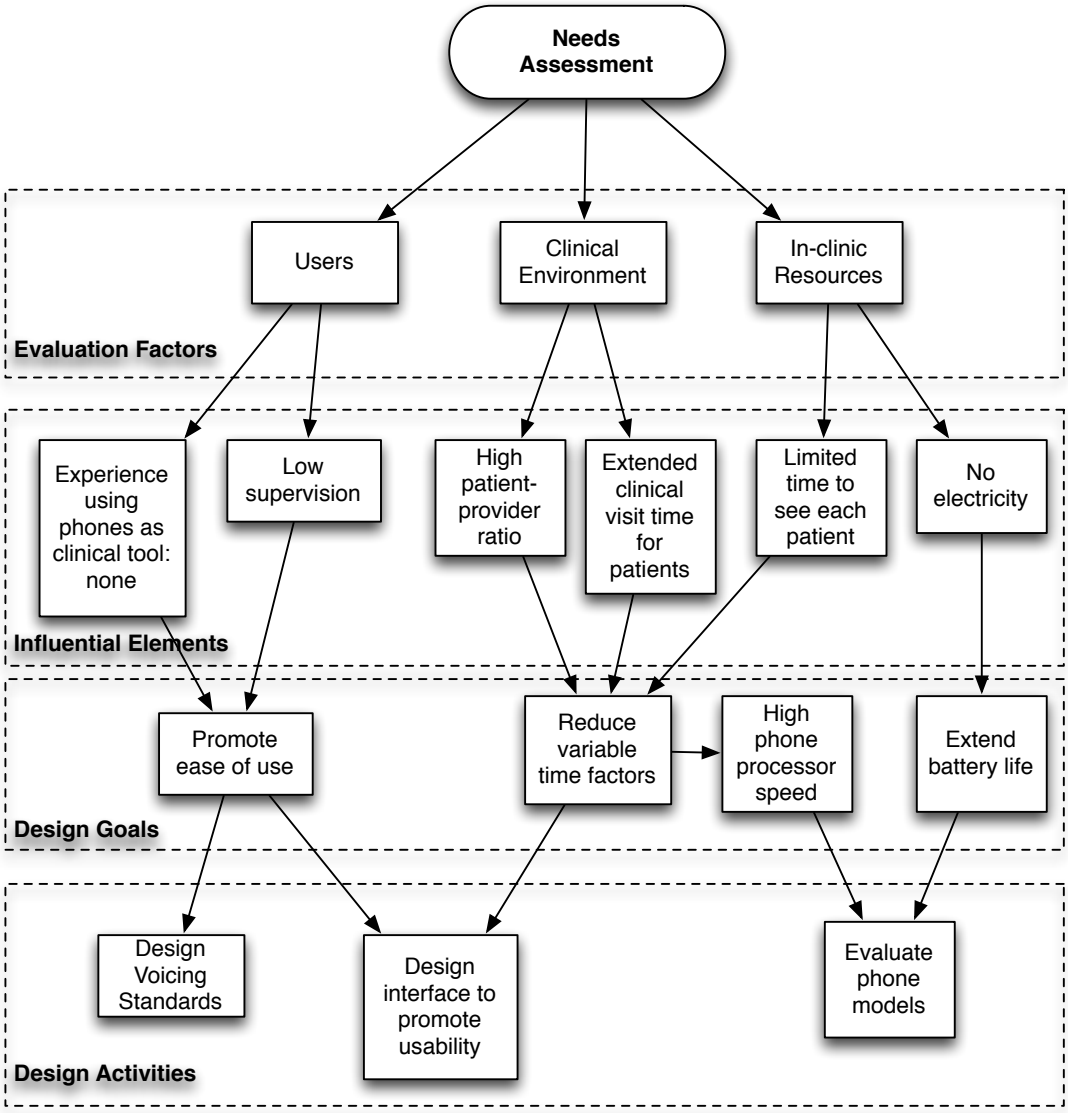


Figure 4.3.
Needs Assessment Overview

Users. The target users of eIMCI were providers who attended acutely ill children under 5 in municipal outpatient department (OPD) clinics, and could possess varying clinical degrees. Use of the eIMCI application did not require any specific previous experience or education beyond being able to read and understand basic medical terminology and treatment recommendations. Two concerning *influential elements* were identified in the user evaluation. First, the clinic had never incorporated any mHealth interventions into practice in any capacity in the clinic, thus no providers had experience using the phones as clinical tools. Second, low levels of supervision were common in the clinic as well. Therefore, it was anticipated that difficulties in implementing the eIMCI application might be encountered. The lack of supervision was a particular concern when combined with providers' lack of mHealth intervention experience.

Clinical environment. Concerning influential elements emerging from the clinical environment evaluation were the high patient flow and extended time that was required for patients to move through a clinical encounter. Elevated outpatient department (OPD) patient volume and insufficient staffing resulted in a high patient-provider ratio. On a typical day, 3 to 5 OPD providers in each facility saw approximately 200-400 patients (these included all types of patients seeking acute care, of which approximately 10 were children eligible to participate in the study). Patients typically arrived by 8:00am and formed a queue outside the providers' offices, and were seen in the order they arrived. Individuals seeking care were frequently obliged to queue for 2 to 4 hours before being seen by a provider. While providers generally spent around 5 minutes per clinical interaction, caretakers commonly spent upwards of 5 hours seeking care for their children

between each component of the visit, particularly if lab tests or treatments were required for the child.

The eIMCI application was intended to correspond with the patient flow and sequence of provider activities in the clinical environment, which was a municipal OPD clinic. Clinical workflow, including patient flow, provider activities, and documentation in clinic records and the child's health passport (a government-issued personal health record retained by caretakers and recorded in by providers during clinical encounters) were documented and modeled (Figure 4.4). The child and their caretaker were considered a single unit for the workflow analysis. No follow-up care plans were recorded in the health passport or government register unless the child was registered in the national HIV management program.

In-clinic resources. In-clinic resources were assets or supplies, or lack thereof, that could influence eIMCI implementation. Only resources that were relevant to the deployment of the eIMCI application were documented. For example, none of the clinics were equipped with indoor running water. However, this did not influence eIMCI deployment, thus was not considered in the resource evaluation.

The two primary in-clinic resources that were determined to hold potential influence over the implementation of the eIMCI application were 1) limited time was available for providers to treat patients due to the high patient-provider ratios identified in the clinical environment findings, and 2) no electricity was available in the visit rooms. This was due to a lack of electric wiring in provider rooms and high frequency of power shortages that affected the entire facilities. It was determined through working with clinic supervisors that phones could be charged at night in the in-charge's office, and then used

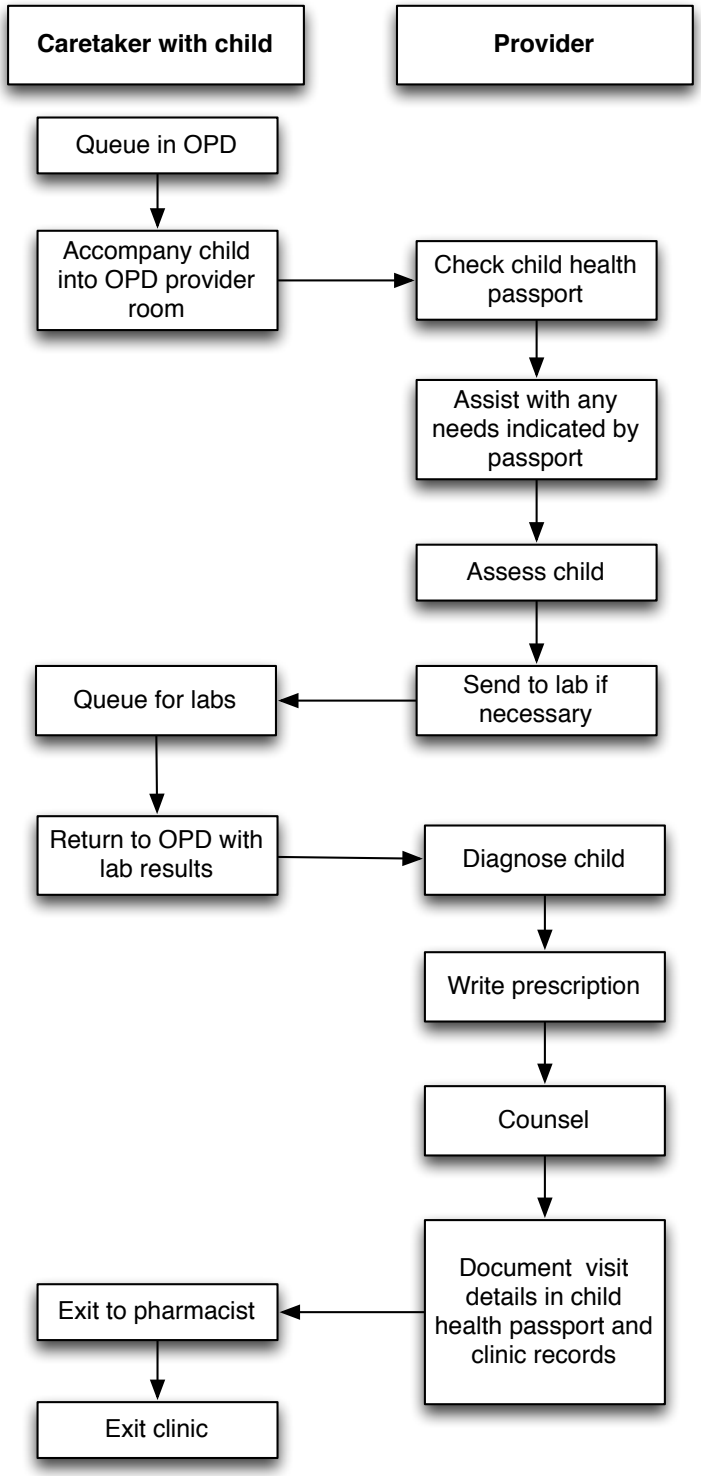


Figure 4.4.
Clinical Flow Map

the next day in the clinic; however, there would likely be no opportunity to recharge until the following night when phones were collected and locked in the in-charge's office. This solution provided the additional benefit of increasing supervisors' role and involvement in the study, which contributed to the essential need to actively include local leadership and staff in the project (Fraser & Blaya, 2010; Marcelo, Adejumo, & Luna, 2011). However, design support was still needed to provide assistance for these issues.

Design Goals

Team discussions led to the identification of design goals to address influential elements identified from the needs assessment. The design goal created in response to the lack of provider experience using mobile phones as clinical tools and the low levels of clinical supervision was to designate priority status to promoting ease of use to the application. This would be later emphasized through usability testing; however, simplification was needed for the initial prototype as well.

The second design goal was to reduce factors influencing the length of time required to complete a case using the eIMCI application in response to high patient-provider ratios, extended clinical visit time that was required to move a patient through the facility when seeking care, and the limited time providers had for each patient encounter. Because the clinical environment could not be altered, the onus was upon the developers to achieve time reduction for case encounters to the best of their ability within the eIMCI application. The most directly influential opportunity to achieve this was to use a phone that had high processor speed, as slower models were discovered to take upwards of 2 minutes to load a new case, save a case, or retrieve existing cases. When combined among multiple cases each day, the cumulative effect of this load time could

destroy the chance of eIMCI success, particularly when it was known that providers spend only around 5 minutes per case when giving usual care. Finally, the lack of electricity in the visit rooms was another nonchangeable factor. Solar chargers were not an option due to inaccessibility and high cost. This issue could only be addressed by selecting a phone with long battery life.

Design Activities

The design goals were implemented through design activities. Nomenclature and voicing were identified as primary design features that could enhance the usability and ease of use of the initial eIMCI prototype. The application language, voicing, and imperative nomenclature were based on informal standards, which were established to provide consistency, simplicity, and accuracy. Simplicity was particularly emphasized. Informal standards are an accepted practice in UCD when appropriate formal standards are not available or have not been established (Abras et al., 2004), as was the case in Tanzania. Imperatives were utilized for the voicing throughout the application in order to 1) enhance the simplicity and ease of use of the application, and 2) orient users to their navigational point within the application. Imperatives included register, assess, ask, look, test, classify, treat in clinic, treat at home, and instruct caretaker now (Figure 4.5). Enhancing interface design to promote usability and ease of use was the second major design activity. The software underwent iterative cycles of usability evaluation and prototype refinement (see Aim 1.2). The need to promote ease of use, reduce load time, and extend battery life led the development team to examine phone models for processor speed, combined multimedia capability, battery life, and cost in order to select the optimal device model. Because the development team partnered with a local non-

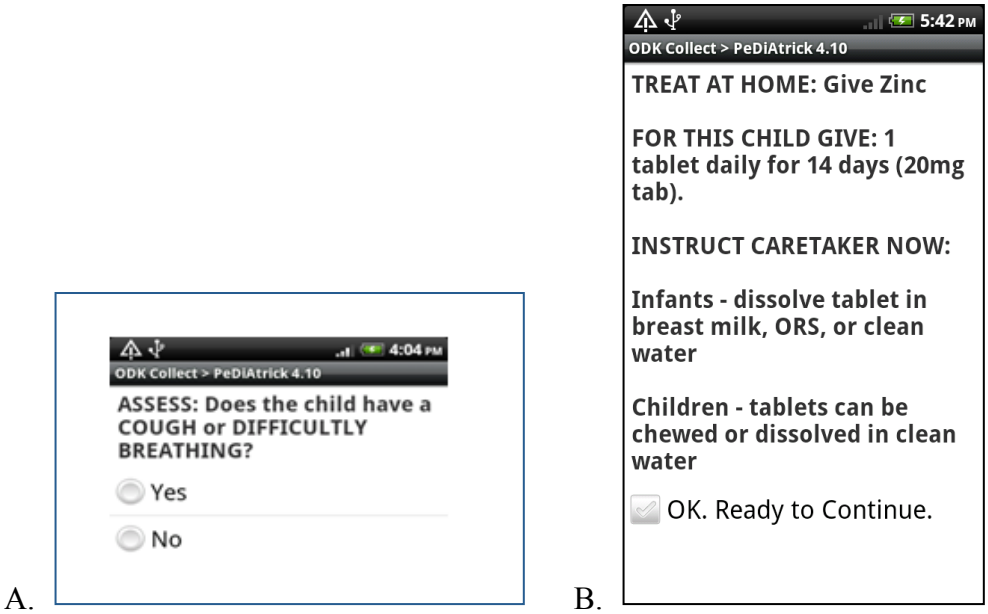


Figure 4.5
Assessment (A) and Treatment Teaching Screen (B) Imperatives

governmental organization, D-Tree International, who championed mHealth development extensively throughout Tanzania, four mobile phone models were evaluated with D-Tree International for deploying the eIMCI application. These models were the Google Nexus, Huawi Ideos, HTC Wildfire, and HTC Desire. The mobile phones were evaluated by examining specs and cost of each model, and by installing early versions of the application and conducting testing to evaluate load time, screen quality, and case saving and retrieval time.

The phone model ultimately selected by the developers for use in the study was the HTC Desire. Because the developers alone possessed thorough familiarity of the various phone models, other research team members and users did not contribute to the selection process. The HTC Desire model was selected based on the combined advantages of its processor speed, multimedia capability, screen size, battery life, and cost. Furthermore, this phone model supported the software development platforms,

which included XForms, Open Data Kit (ODK), and AndroidOpenMRS. These software development platforms were preselected based on the available resources and recommendations provided by the project's development partners. Feature sets of these combined software platforms were adequate to fulfill the requirements identified across the needs assessment. These features included case saving and case retrieval to accommodate patient flow needs, case sharing to promote provider collaboration and ease of use, user login access to observe security and privacy measures, and data upload to a central database for study requirements. Administrator feature sets that further assisted research procedures and data collection included central database interfacing to enable hierarchical access control, aggregate reporting, and user surveillance and supervision.

Aim 1.1.2 Video Prototype

Intervention

One of the communication enhancements for the eIMCI application was a didactic-style health information video to be displayed to the caretaker from the eIMCI mobile phone application. The video was intended to inform the caretaker that they should know three key information points by the conclusion of the clinical visit: 1) the child's problem, 2) when to return to the clinic, and 3) the treatment plan. Comparison testing was conducted to discover the most effective video to teach caretakers to repeat these three points.

The video was to be displayed on the phone screen by the provider at the initiation of a clinical encounter. This strategy was intended to address two goals: 1) to remind the provider to adhere to communication prompts embedded within the algorithm,

and 2) to prime caretakers to pay attention to these fundamental information points during the course of the clinical encounter.

Setting

The video production team consisted of the PI for this dissertation study and a volunteer assistant from the United States who was spending a summer in Dar es Salaam working for the study team. Two actors were featured in the videos. One actor was a Tanzanian nurse who worked in IT for a local partner of the study team. The second actor was the housekeeper at one of the study offices who volunteered to act in the videos. The PI and the volunteer assistant filmed the videos in two locations in Dar es Salaam including: 1) in a local neighborhood, and 2) at the study team central office.

Sample

Consenting caretakers who agreed to evaluate the videos were taken from a convenience sample in a municipal health clinic participating in the study. Eligibility criteria included presently seeking care for an acutely ill child under 5, and willingness to view one video and repeat the key information points outlined in the video, or watch the video repeatedly until they were able to repeat the key information points. Demographic data were not collected in this sample; however, all participants were caretakers of children under 5 seeking health services. No compensation was given for participation in the evaluation.

Video Development Procedure

The production team filmed four videos for comparison. Table 4.1 displays themes and settings for each video filmed. Based on time constraints identified in the

Table 4.1
Description of Videos Filmed for Evaluation and Potential eIMCI Inclusion

Video #	Tone	Scene	Setting
1	Casual	Two neighbors discussing key points of information to know for an upcoming clinical visit for a child.	Local neighborhood
2	Formal	A clinical nurse directly instructing the viewer on the key information points to know following the clinical visit.	Staged clinic visit room
3	Formal	A "doctor" (played by same clinical nurse as video #2) directly instructing the viewer of the key information points following the clinical visit.	Staged clinic visit room
4	Formal	A clinical nurse directly instructing the viewer on the key information points to know following the clinical visit (same dialogue and role as video #2)	Outside setting

needs assessment, it was determined that the video must be under 30 seconds in length. Developers evaluated each video recorded to determine if the display, sound, and acting quality was suitable for editing and potential inclusion in the mobile application. Those selected were prepared for on-site testing at one participating study clinic with actual caretakers seeking care for their children. Videos were uploaded to a mobile phone and displayed on the phone screen for the testing procedure in order to correspond with the video delivery method to be used in the study.

Video Evaluation Procedure

Approval letters from the Dar es Salaam City Council Medical Office were obtained for video testing, and informed consent was obtained from caretakers. Research team members approached queuing caretakers of children under 5 who were seeking care at the participating facility and explained the evaluation to them. Each participating caretaker viewed one video (video #1 n=12, video #2 n=12). The number of times the

video needed to be repeated for each caretaker to be able to repeat all three key information points was recorded and averaged. The video with the lowest number of averaged repeats would be selected to embed in the eIMCI application.

Results

After video composition and editing, it was determined that only two of the videos filmed were suitable for user evaluation. Those appropriate for use included the casual neighbor video #1, and the formal nurse in clinical setting video #2. The sound quality of the other two was insufficient for use, as a highly disruptive echo was present in the formal doctor video #3 that could not be removed, and the sound of birds surrounding the outdoor filming area in video #4 was so cacophonous that none of the dialogue could be heard. Of the two remaining, the formal video #2 required an average of 1.33 views per caretaker to recite the three information points, compared to an average of 2.92 views per caretaker for the informal neighbor video #1. The formal video #2, with instructions given by a nurse directly to the viewer, was therefore selected for use in the eIMCI application.

Aim 1.2 Knowledge Base Verification

The next stage of eIMCI prototype development was knowledge base verification. The knowledge base is the set of rules and actions, and the navigation between those rules and actions, in a decision support tool (Greenes, 2006). The pIMCI protocol document served as both the source document and human readable text for development of the eIMCI application. The pIMCI protocol was developed and evaluated by a team of medical experts and was determined to reflect evidence-based practice. Therefore, it was assumed that the content of the eIMCI application also reflected evidence-based practice

if its fidelity to the content of pIMCI was maintained. Knowledge base verification testing was completed to evaluate the extent to which the content of the eIMCI application contained an exact representation of the content of the source document.

Sample and Setting

The two developers of the eIMCI application conducted the majority of the verification testing. A third evaluator joined the research team toward the end of initial prototype development and contributed to later stages of verification, to respond to ongoing iterations of the application. The first tester was the PI for this dissertation study (a nursing informatics graduate student) who initially began the process with limited field and verification testing experience. The second tester was an expert software engineer who had worked as a developer on multiple decision-support mHealth projects. The third tester also had a background in IT, but who also began with limited field and verification testing experience. Testing was conducted in an office setting in Dar es Salaam, and each tester conducted independent evaluations.

Procedure

The three developers conducted verification testing of eIMCI prototype using a detailed, multistep process. The paper-electronic fidelity of the logic (rules) and navigation through the logic was verified using manual systematic pathway navigation. During this process, the application was installed on phones, and all possible pathways in the pIMCI document were manually followed using the eIMCI application to conduct an end-to-end evaluation. A detailed record of problems, changes, and processes was

documented in a web-based repository to enable real-time access to test results and changes made during prototype iterations.

Verification testing was repeated throughout all stages of development to respond to paper protocol changes and to software iterations that were triggered by usability evaluations. After the initial comprehensive verification of the entire application, all iterations thereafter were verified by manually navigating changed pathways.

Results

The benchmark goal of the verification testing was 100% fidelity to the source rules and pathways. Hundreds of hours were spent between the three developers over the course of development to saturate 100% content coverage across all possible rules and navigation pathways. Results and feedback from the verification testing were iteratively assimilated and retested. It was determined with reasonable certainty that the goal of 100% accuracy and fidelity to the paper source document was achieved at the final development stage, prior to deployment. Because of the complexity of the branching logic in the algorithm, conducting an end-to-end evaluation of all possible pathways was crucial in order to confirm the reliability of the application and to ensure that it was appropriate for the provision of pediatric care. Multiple "bugs" were detected and resolved using this system that may otherwise have remained undiscovered.

Aim 1.3 Formative Usability Testing

The objective of the formative testing for the eIMCI application was to evaluate specified aspects of usability from the perspective of users in a mock clinical environment, using fabricated scenarios. Usability aspects of interest were: user

perceptions related to the satisfaction and perceived usefulness, learnability and ease of learning the navigation, perceived efficiency, effectiveness, and accessibility/fit with clinical workflow from a user perspective.

Secondary goals were to determine the ease of which eIMCI could be used as a clinical tool, and the training time required to initiate a new user to be able to use the application to attend to children in the clinical setting.

Aim 1.3.a Think-aloud Evaluation

As a well-established means to gather usability data (Rubin & Chisnell, 2008), the goal of the think-aloud evaluation was to evaluate the satisfaction and perceived usefulness, learnability and ease of learning the navigation, perceived efficiency, effectiveness, and accessibility/fit with clinical workflow of the eIMCI application, from a user perspective during actual use.

Sample and Setting

The sample included three provider users who participated in independent evaluation sessions. Each was selected by convenience through study activities. Inclusion criteria included consent to participate, ability to speak and read English, and designation as a clinical provider. All participants were familiar with the background and rationale for the protocol. None of the participants had prior experience using the eIMCI application or mobile phones in any capacity as tools in the clinical setting. All participants had been trained in the use of the original WHO version of the IMCI protocol in years past, spoke fluent English as a second language, and had completed their clinical training in English, which reflects current standard practice for health workers in Tanzania.

The first participant was an experienced pediatrician who initially worked with the study team by testing the IMCI-adapted pIMCI protocol in a clinic. The provider had thus far seen hundreds of pediatric using the paper algorithm at the time of think-aloud testing. Thus, this provider was highly familiar with the protocol and was expected to offer particularly valuable advice on the usability of the electronic platform. The second participant was a newly practicing clinical officer who attended pediatric and adult OPD clients in a different clinic; the provider was also hired by the research team to conduct initial clinical protocol (pIMCI) testing. This provider had received complete training on the pIMCI protocol and had practiced using it in a clinical setting. The third participant was an experienced clinical officer who typically attended OPD clients in an urban setting, and who was recruited for formative testing of the eIMCI protocol during eIMCI training sessions. This participant received one full day of pIMCI training before formative eIMCI testing commenced, but had not yet conducted actual clinical use of the pIMCI protocol.

Materials

The developers created a list of 49 test case scenarios for the purpose of standardizing materials to guide the think-aloud evaluation (and summative evaluation, described in Aim 1.4) (see Appendix A). All possible main symptoms and problem classifications in the IMCI-based protocol were listed in a table column, including febrile and nonfebrile versions of each illness. Corresponding signs, symptoms, and vital signs that would be required to be entered to result in correlating problems were then listed in a column adjacent to each problem, and ages and genders were randomly assigned to each case. The master list table contained columns for the case number, the scenario with the

information that was provided for the participant, and the expected outcome. A test version of the table was also created in which the outcomes were omitted, with the outcomes column left blank for the tester participant to fill in, for the summative testing portion.

Procedure

Training time was unconfirmed prior to the think-aloud test, as no actual users had thus far used the eIMCI application. Therefore, a training assessment was incorporated into the think-aloud exercise encounter; test case scenario material (Appendix A) was prepared beforehand and approximately 30 minutes of training time was anticipated to be sufficient. Each participant thereafter performed the think-aloud evaluation in a single session lasting approximately 30-40 minutes.

Training for the think-aloud evaluation occurred immediately prior to the session. At the onset of the think-aloud evaluation, each participant was oriented to the phone and application and a demonstration was provided on how to login, play the video, initiate, save, and retrieve cases, and send data to a central server. Following a formal training orientation, participants were instructed in English to begin the think-aloud assessment from the login start and to navigate through a given test case scenario (see Appendix A) that was provided to them by the researcher. They were asked to verbalize their navigational processes by stating out-loud what they were doing, how they were doing it, and where they were at in the application (e.g., "I am beginning a new case by selecting "New Patient" in the menu…I will now swipe to the next screen and enter the patient id number as it is asking for this. I see by the imperative that I am registering a child now,").

The participants were additionally encouraged to comment on their usability impressions, i.e., what does or does not make sense about the content, workflow, and interface of the application while they navigated through the test case. Comments and actions of the participants were recorded in typed notes in real time by the researcher.

Results

Each participant was able to successfully complete the tasks of the test case scenarios and provided commentary on their perspective of the quality of the protocol itself. When verbalizing perceptions about the application, the impressions expressed by all three participants were consistently positive and contained praise, for example "This tool will make our assessments for children much easier," and "This will guide all of our care for children patients. This will help us a lot." No participants expressed suggestions for improvement or noted anything that did not make sense. When asked to provide specific feedback on how the content, workflow, and interface of the application might be improved or to state what was experienced as difficult about using the application, no participants were willing to state anything that could be characterized as anything other than general, unspecified praise. Though the researcher witnessed errors and what could be interpreted as frustration (based on facial expression and body language) at specific, consistent points in the application, including logging in, saving, and sending data, each participant remained firm in their praise of the application and no neutral or negative verbal feedback was gleaned. Errors were captured for training redesign to increase time spent learning these tasks.

Further challenges were encountered during the think-aloud assessment. While participants did successfully navigate through the protocol, the attempt to gather

comment on users' navigational actions was for the most part unsuccessful. None of the users verbalized their actual navigation processes. All three participants, in their independent sessions, stated only feedback that related to perceptions of the application. Multiple attempts were made to clarify and restate the instructions; however, no progress was achieved in getting the users to verbalize their navigation steps or what they were attempting to do when navigating the program.

Aim 1.3.b Key Informant Feedback

As recommended by Tullis and Albert (2008), actual users are ideal candidates to participate in usability testing procedures. In circumstances that present unique cross-cultural and resource challenges, such as those faced by the eIMCI development team, use of a key informant may provide unique and valuable insight within available means (Clemmensen, 2011). The involvement of such participants may provide access to highly valuable, in-depth, and rich data to aid successful development.

Sample and Setting

During the months following the think-aloud evaluation, a provider who was hired by the research team to conduct pIMCI testing unexpectedly emerged as a key informant for eIMCI development. Of Tremblay's 5 optimal characteristics of a key informant (Marshall, 1996), this pediatrician contained 4. Regarding her *role in the community*, the provider gained a great deal of experience in the formal role of working with the research team as a pIMCI user. The provider's *knowledge* gained by this experience allowed easy recognition of the congruence of the flow and fit between the two platforms. Additionally, as an experienced provider in a local government hospital, the key informant possessed a frame of medical and clinical reference for the objectives

of the eIMCI application. As familiarity and use of the eIMCI application increased with use to provide care for actual patients, the provider further became *willing* to provide feedback and suggest improvements. Finally, *communicability* was demonstrated in the provider's ability able to provide feedback to the developers in an effective manner. The fifth characteristic, *impartiality*, was not considered to be an optimal characteristic because 1) the provider could have been somewhat influenced by her status as a paid implementer of the protocols, and 2) may have reflected some continued demand characteristics biases (see Chapter 6).

Procedure

The key informant tested the eIMCI mobile application in a health clinic to care for actual children-under-5 patients over the course of approximately 4 months. Researchers were typically present in the clinic to provide technical support for the application, to review data collection forms being developed for the RCT study, and to discuss cases and procedures; almost daily interaction between the provider and research team commenced, which supported the development of trust and open communication between the key informant and the research team. The key informant's method of reporting feedback occurred verbally in three ways: 1) during informal interviews consisting of daily encounters and discussions regarding the content and quality of the day's work, 2) during weekly meetings in which all members of the research team discussed ongoing study issues; semistructured interviews were conducted with the key informant during these meetings in which specific performance issues were reported, and 3) verbally via other team members to whom the key informant additionally reported.

Comments and suggestions were discussed between the developers, and occasionally the entire research team if a proposed change warranted further consultation.

Results

Comments and suggestions were recorded as they were received and all proposed changes were documented in a central online repository. Feedback was grouped into the categories of text/dialogue, clinical flow, formatting, and user experience. Feedback received by the key informant and corresponding development responses follow in Table 4.2. If feasible and approved by developers, changes suggested by the key informant were implemented in the software application, which was then updated on the key informant's phone. Follow-up feedback was also elicited to determine if changes had achieved the expected result, or if further iteration was necessary. The average time to complete a clinical encounter after the key informant became accustomed to using eIMCI was approximately 15 minutes, with additional time needed if outside lab tests were necessary. This was deemed by the study team to be acceptable; however, compared to a typical setting clinical encounter time (approximately 5 minutes), the protocol would require further modification to decrease case time in a larger scale-up.

Aim 1.4 Summative Testing

The objective of the summative testing was to attain a quantitative measure of user navigational behaviors towards the completion of development by using clinical test case scenarios (Appendix A). Herein, the *effectiveness* of the application, defined as users navigating to the correct problem and advice for a given test scenario, was evaluated. The application was expected to perform accurately (specific inputs consistently resulting in specific outputs) without any outside support to assist a user, including pIMCI guidance

Table 4.2
Key Informant Feedback

Feature Category	Original Feature	Key Informant Feedback	Changed/Not Changed	Redesign
Text/ dialogue	Application text in English language only	Requested to have English and Kiswahili text	Changed, not implemented	Programmed Kiswahili option, however not used during study
	Medication dosages written in decimal form, for example 0.75 tablet	Requested to change dosage to fraction.	Changed	All tablet medications changed representation to ¾, ½, ¼, etc.
Clinical flow	Direct navigation through protocol with saving at the end and no case retrieval	Needed to be able to save and retrieve patient cases after lab tests; in order to see new patients while waiting for lab results.	Changed	Created saving option and daily patient list in main menu.
	Laboratory test prompts followed paper algorithm flow	Providers were prompted to send patients to the lab repeatedly as they navigated the protocol	Changed	Assessment, lab test, problem classifications, and treatment recommendations placed together in groups
Formatting	Contents and size of "Today's Patient" menu	Contents of list on screen difficult to read	Changed	Increased row height and font size of patient list.
User input	Some screens not mandatory to select response	Errors when users skipped critical decision points	Changed	All critical decision point screens made user response mandatory
	Saving feature reached by selecting back arrow on phone hardware. Multiple exit options	Providers could exit without saving	Not changed	Constraints within pre-determined platform prohibited modifications of menu contents – incorporated into training

or clinical background knowledge. The summative testing was intended to mimic the arrangement and type of information that a provider would have access to in a typical clinical environment, such as vital signs, presenting symptoms, and the history of illness of a child.

Sample and Setting

The original intention of the summative testing was to enlist nonclinicians to conduct the exercise in order to reduce the potential influence of clinical knowledge and experience that a provider may unknowingly exercise when navigating. However, again due to personnel and resource constraints, researchers were unable to access nonclinical personnel. The main summative testing was completed during the eIMCI application training seminars for providers participating in the study. The exercise ultimately served two purposes: 1) to enable developers to identify remaining navigation problems given the type of information a provider would have access to in a real clinical setting, and 2) to assist trainees to learn how to use the eIMCI application. Forty-one provider participants attended the eIMCI arm training (detailed description of this participant sample follows in Chapter 4). Provider inclusion criteria were the ability to read English, those who attended children under 5 during regular clinic duties, willingness to have an observer present during their clinical encounters, and ability to be present to attend training sessions and clinic days during data collection. Each provider was given the opportunity to decline participation. No compensation was offered for provider participation other than training workshop provisions, including transportation fees and a national standard rate per diem for the training day (supervisors in each clinic were however compensated with a small monetary provision, approximately $65/month USD over the course of data

collection for the added responsibilities of storing phones and supervising provider participation).

Procedure

The previously generated master list of 49 test case scenarios that contained symptoms and vital signs that lead to a single specific problem or diagnosis (Appendix A) was utilized for the summative testing procedure. During the eIMCI training, provider participants were given an overview of the application. Sample test case scenarios were navigated together as a group practice to teach the exercise to the group. Following the group practice, participants divided into groups of two to three. The list of test case scenarios was given to the participants; each group was verbally assigned five scenarios from the list. Participants were expected to use the information given in the scenarios to arrive at an outcome (a medical diagnosis or problem, and a treatment recommendation). It was anticipated that the participants would arrive at the desired outcome if the specific key elements given in the scenario were correctly entered into the eIMCI application. For example, a case with a child with a temperature of 38.1 C, and ear pain with drainage would always be expected to result in a problem categorization of "acute ear problem," and a custom dose of paracetamol would be provided by the application. Researchers compared expected outcome from the master list with the outcomes filled in on the tester list by participants. The benchmark goal was 100% accuracy.

Results

Test case scenario forms were collected from participants and examined for accuracy by the PI. Participants were able to navigate to the expected outcome using the

eIMCI application in 100% of cases tested. No new problems with the eIMCI application were discovered by the participants, who were new users and unfamiliar with the protocol. The benchmark goal of 100% accuracy was met and the eIMCI application was deemed to be effective for purposes of the study.

CHAPTER 5

AIM 2: COMMUNICATION EVALUATION

Aims and Hypotheses

Communication involves a sender (the provider), a receiver (the caretaker), and a message. Aim 2 evaluated the effect of protocol delivery method (pIMCI or eIMCI) on (a) provider verbalization (what the provider said during the visit) and (b) caretaker recall (of what they were told by the provider) related to key health information points specified by the IMCI protocol (Figure 5.1). Specifically, the subaims were **to evaluate the effect of method of protocol delivery (pIMCI or eIMCI) on communication of** the following messages:

Aim 2.1: The child's problem

Aim 2.2: When to return to the health clinic

2.2.1 Nonimprovement after a specified number of days

2.2.2 Symptoms that could indicate the child's problem is worsening

Aim 2.3: Treatments (medication)

2.3.1 The name or type of medication

2.3.2 The number of times/ day to administer the medication (frequency)

2.3.3 The number of days to administer the medication (duration)

For each of the subaims, the hypothesis was that there would be no difference in communication between the pIMCI arm and the eIMCI arm.

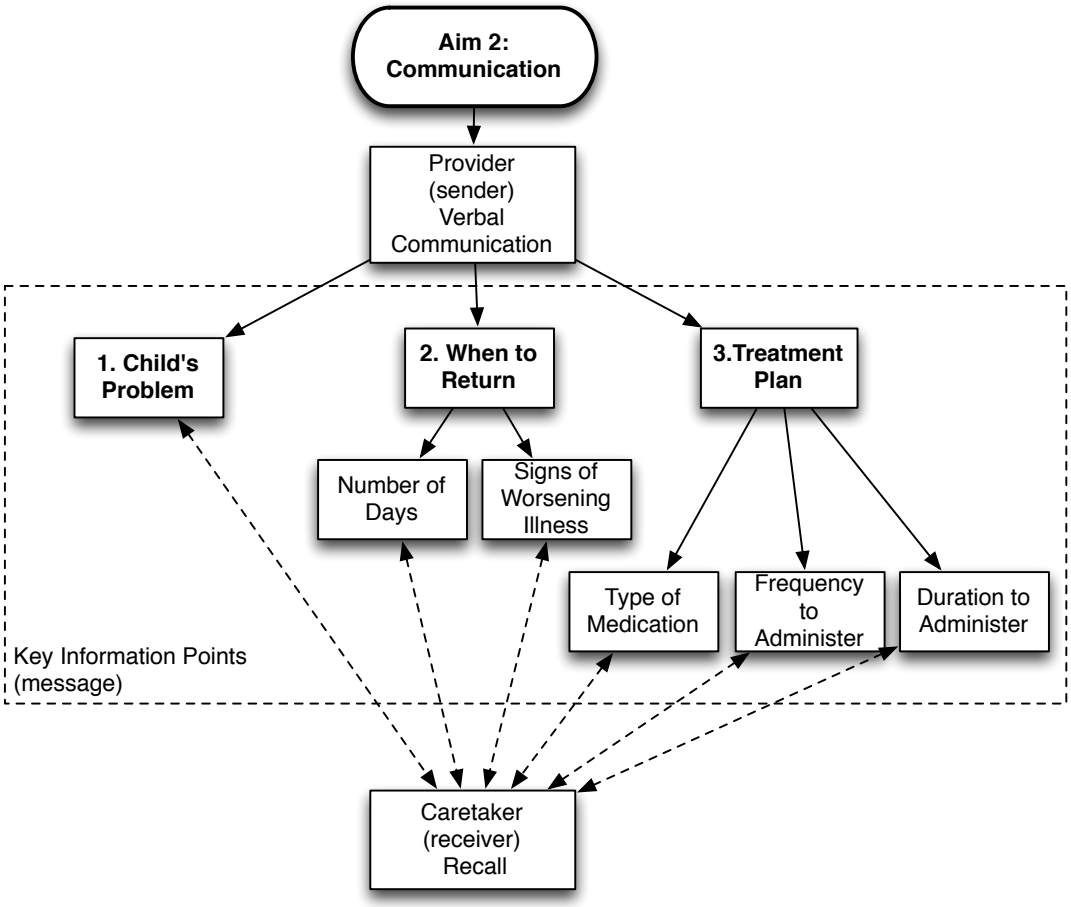
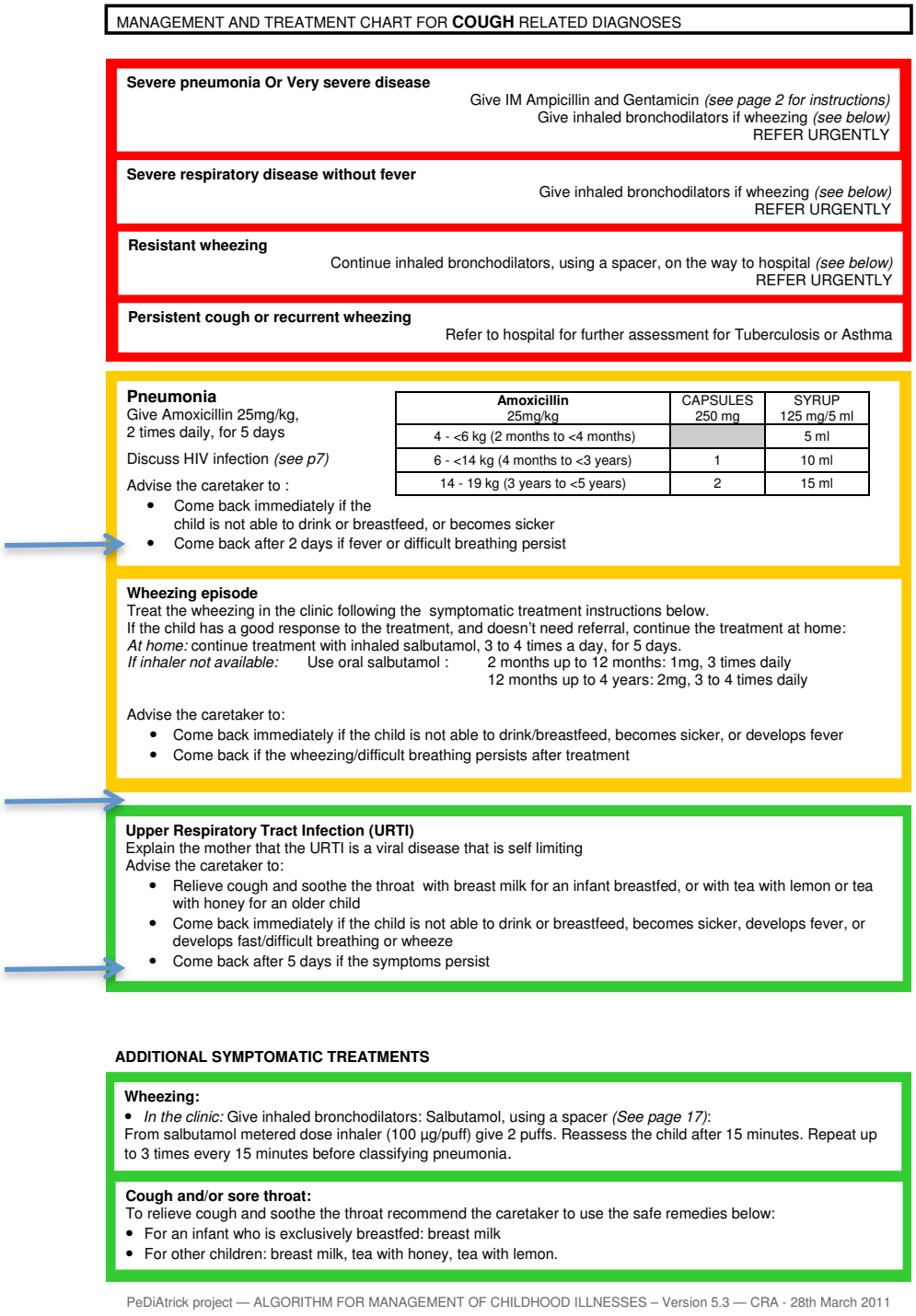


Figure 5.1
Key Information Points Specified in
the IMCI-based Protocol

Intervention

The pIMCI and eIMCI protocols contained identical health education and communication prompts. The pIMCI protocol was designed like the WHO protocol, with prompts provided via message boxes throughout the protocol (Figure 5.2). The eIMCI application used identical content; however, it was organized through three mechanisms. The first mechanism was an educational video that was displayed for caretakers at the onset of the visit to inform them of the key points of information to listen for during the



MANAGEMENT AND TREATMENT CHART FOR **COUGH** RELATED DIAGNOSES

Severe pneumonia Or Very severe disease

Give IM Ampicillin and Gentamicin *(see page 2 for instructions)*
Give inhaled bronchodilators if wheezing *(see below)*
REFER URGENTLY

Severe respiratory disease without fever

Give inhaled bronchodilators if wheezing *(see below)*
REFER URGENTLY

Resistant wheezing

Continue inhaled bronchodilators, using a spacer, on the way to hospital *(see below)*
REFER URGENTLY

Persistent cough or recurrent wheezing

Refer to hospital for further assessment for Tuberculosis or Asthma

Pneumonia
Give Amoxicillin 25mg/kg,
2 times daily, for 5 days

Discuss HIV infection *(see p7)*

Advise the caretaker to :

- Come back immediately if the child is not able to drink or breastfeed, or becomes sicker
- Come back after 2 days if fever or difficult breathing persist

Amoxicillin 25mg/kg	CAPSULES 250 mg	SYRUP 125 mg/5 ml
4 - <6 kg (2 months to <4 months)		5 ml
6 - <14 kg (4 months to <3 years)	1	10 ml
14 - 19 kg (3 years to <5 years)	2	15 ml

Wheezing episode
Treat the wheezing in the clinic following the symptomatic treatment instructions below.
If the child has a good response to the treatment, and doesn't need referral, continue the treatment at home:
At home: continue treatment with inhaled salbutamol, 3 to 4 times a day, for 5 days.
If inhaler not available: Use oral salbutamol : 2 months up to 12 months: 1mg, 3 times daily
12 months up to 4 years: 2mg, 3 to 4 times daily

Advise the caretaker to:

- Come back immediately if the child is not able to drink/breastfeed, becomes sicker, or develops fever
- Come back if the wheezing/difficult breathing persists after treatment

Upper Respiratory Tract Infection (URTI)
Explain the mother that the URTI is a viral disease that is self limiting
Advise the caretaker to:

- Relieve cough and soothe the throat with breast milk for an infant breastfed, or with tea with lemon or tea with honey for an older child
- Come back immediately if the child is not able to drink or breastfeed, becomes sicker, develops fever, or develops fast/difficult breathing or wheeze
- Come back after 5 days if the symptoms persist

ADDITIONAL SYMPTOMATIC TREATMENTS

Wheezing:

- *In the clinic:* Give inhaled bronchodilators: Salbutamol, using a spacer *(See page 17)*:

From salbutamol metered dose inhaler (100 µg/puff) give 2 puffs. Reassess the child after 15 minutes. Repeat up to 3 times every 15 minutes before classifying pneumonia.

Cough and/or sore throat:
To relieve cough and soothe the throat recommend the caretaker to use the safe remedies below:

- For an infant who is exclusively breastfed: breast milk
- For other children: breast milk, tea with honey, tea with lemon.

PeDiAtrick project — ALGORITHM FOR MANAGEMENT OF CHILDHOOD ILLNESSES – Version 5.3 — CRA - 28th March 2011

Figure 5.2
pIMCI Treatment Section with Key Information Communication Prompts

visit. The second mechanism was communication prompts embedded throughout the protocol. For example, when the provider navigated to a point in the protocol where the child's problem was known, the provider was explicitly instructed to tell the caretaker the child's problem. The third communication mechanism was a summary screen that appeared at the conclusion of the visit. The summary screen compiled the diagnosis and treatment information along with specific symptoms that could indicate that the child's problem is worsening and therefore need immediate medical care. The provider was prompted via imperative voicing ("Say xxx") to deliver the summary information to the caretaker (see Figure 5.3). Communication prompts were customized to each case based on the provider's input into the software. As described in Aim 1, all verbiage emphasized simplicity in diction to encourage both provider adherence and caretaker retention.

The Tanzanian providers were fluent in English and Swahili. Because the text of both pIMCI and eIMCI was delivered in English, the provider translated the key information points into Swahili in real time when talking with the caretaker.

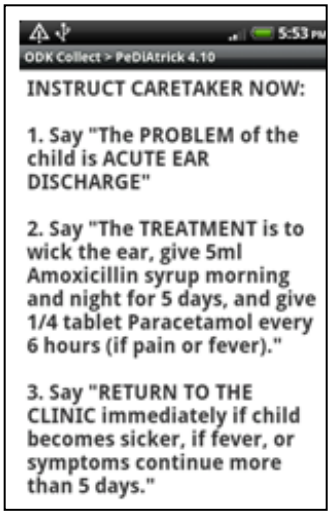


Figure 5.3
eIMCI Summary Screen Example
Communication Prompts

Study Design

Institutional Review Board (IRB) approval was obtained in the United States through the Harvard School of Public Health, and in Tanzania through the National Institute of Medical Research (NIMR). Data included in this dissertation study were collected in Tanzania from September-November 2011.

This study was conducted as part of a large randomized controlled trial (RCT); therefore, the design of this study was constrained by the RCT randomized cluster design. In cluster designs, social units (clusters) are allocated to intervention groups, rather than assigning individual participants to interventions. Specifically, a *stratified* cluster design was used, in which homogeneous strata were identified, and then clusters randomly allocated within the strata (Wojdyla, 2005). Clinics were randomly selected from government census reports, and then within each strata, clinics were randomly assigned to a study arm (pIMCI or eIMCI).

Sample and Setting

Participants for the study were 1) consenting providers who worked in the outpatient department of study-participating government clinics, and 2) caretakers of children under 5 who sought medical care at the participating government clinics. Provider inclusion criteria were the ability to read English, attended children under 5 during regular clinic duties, willingness to have an observer present during their clinical encounters, and ability to be present to attend training sessions and clinic days during data collection. There were no exclusion criteria for providers.

Caretaker inclusion criteria included seeking care for a child under 5 suffering from an acute illness, willingness to have their children treated using the respective

protocols, willingness to have an observer present in the room during the clinical encounter, and willingness to be interviewed immediately following the visit. If the child exhibited obvious severe illness or danger signs, the caretaker was excluded so that the child could be treated immediately.

Provider Recruitment and Training

After participating clinics were randomly allocated to arms, providers were formally invited by clinic supervisors to participate in the study. Each provider was given the opportunity to decline participation. All providers were trained over two sessions. The first session was a 2-day group workshop. For the first 1.5 days, both arms received information about the rationale for updating the IMCI protocol and overview of the updated protocol. Participants in the pIMCI and eIMCI arms were divided for the remaining half-day to focus on learning how to deliver the protocol using their respective platforms. A second session consisted of face-to-face training that took place immediately prior to data collection, to serve as a refresher. No compensation was offered for participation other than transportation fees and a national standard rate per diem for the training workshop.

Caretaker Recruitment

Research field staff recruited and consented caretaker participants when caretakers arrived at the clinic and began the queuing process at the start of morning clinic hours. Caretakers who were accompanying children who appeared to be under the age of 5 were approached for screening. Field staff determined if children and their caretakers were eligible to be in the study, and if eligible, described the study and its processes to them. A consent document written in Swahili was signed once understanding

and agreement was established. No compensation was offered to caretakers for participation in the study.

Sample Description

Six municipal health clinics were randomly assigned to intervention arm for this study, implementing the pIMCI protocol (provider *n*=25) or the eIMCI protocol (provider *n*=41). The sample included 352 caretakers seeking care for children aged 2-59 months at the clinics (pIMCI arm *n*=180, eIMCI arm *n*=172). Table 5.1 summarizes the participant demographic characteristics. Providers varied in gender and age, with the pIMCI arm clinics having more females, who also tended to be about 5 years older than providers in the eIMCI arm. All other demographic characteristics were essentially equivalent. The education level for the majority of *caretakers* in both arms was primary school or less.

Table 5.1
Participant Demographic Summary

Provider Characteristic	eIMCI *n*=41	pIMCI *n*=25	*p* value
Mean Age	37.65 (SD 9.5)	42.16 (SD 5.0)	<0.001
Provider Type = Clinical Officer	100%	99.4%	0.331
Provider Gender = Female	55.6%	76.7%	0.001
Caretaker Characteristic	**eIMCI *n*=172**	**pIMCI *n*=180**	***p* value**
Mean Age	27.58 (SD 6.4)	28.06 (SD 6.6)	0.493
Gender = Female	94.2%	95.6%	0.817
Relationship to Child:			
Parent	91.3%	94.4%	0.363
Other	8.7%	5.6%	
Highest Education Level:			
Primary School Not Completed	11.6%	10.0%	0.660
Primary School Completed	69.8%	66.7%	
Form 4 Completed	14.5%	19.4%	
Form 6 Completed	1.2%	1.1%	
University	0.6%	1.7%	

Data Collection Methods

Data Collection Forms

Two data collection forms were used for this study. A research team observer used a *provider observer form* to record communication points verbalized by the provider (see Appendix B). The observer impartially recorded provider statements during the clinical encounter without attempting to assess the *correctness* of the statements. A study team interviewer used a *caretaker interview form* to interview caretakers immediately following the clinical visit to determine what the caretaker recalled about what the provider verbalized. Data collection forms were written and recorded in Swahili.

Procedures

Study identification numbers were assigned to each case. Research staff recorded the number on the provider observer form and the caretaker interview form to link forms for a clinical encounter. The flow of study activities was designed to correspond to the usual clinic workflow (Figure 5.4). At the beginning of a clinical encounter in the eIMCI arm, providers displayed the educational video to caretakers, followed by assessment and treatment of the child. In the pIMCI arm, providers began the visit with assessment and treatment. An observer who was stationed in the visit room recorded the provider's verbalization of key information points. Immediately following the clinical encounter, an additional research staff member accompanied caretaker subjects to a separate area for the caretaker interview. Caretaker interviews were conducted in a closed area to ensure privacy. After interviews were completed, caretakers and their children exited the facility.

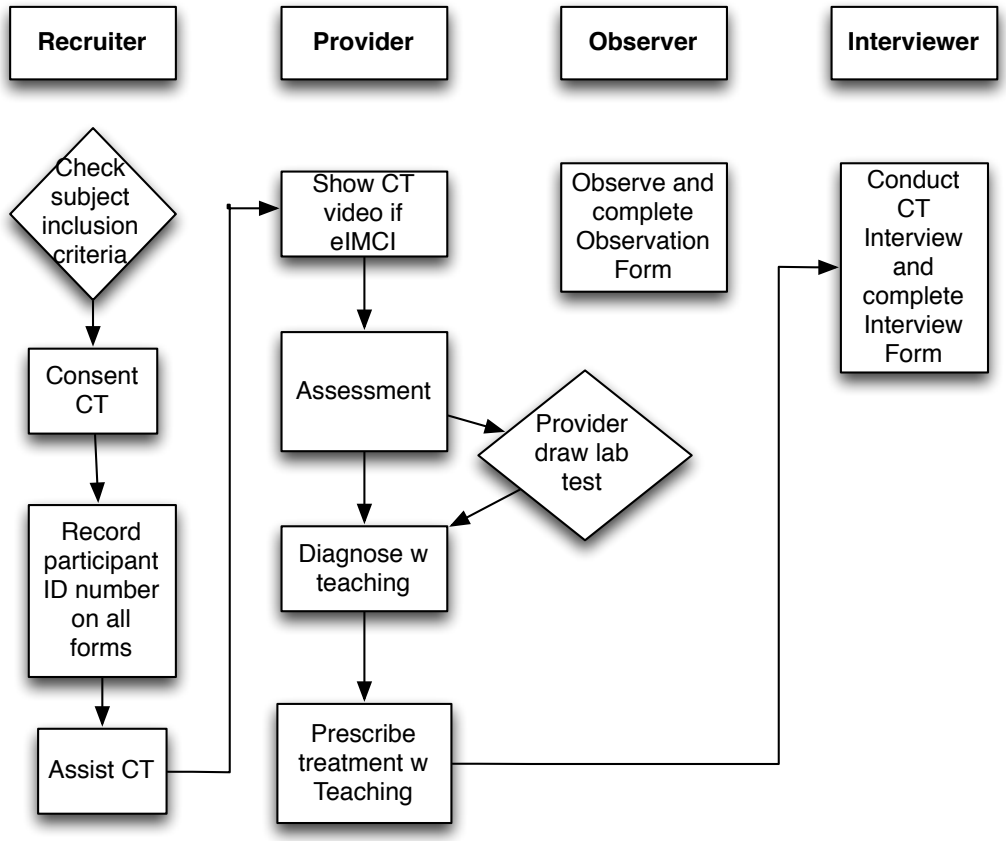


Figure 5.4
Study Workflow

Data Preparation

All data were entered into a central database (EpiInfo v3.5.1). Data were exported to Excel files for cleaning and preparation for analysis. Analyses were conducted using IBM SPSS Statistical Analysis Software v20.1. Two graduate students, 1 native Swahili speaker and fluent in English, and 1 native English speaker, manually translated free text data entries into English and verified each other's translation. After translation, items were coded for analysis. Cases with incomplete data (12 cases missing provider information) were omitted from the analysis.

Approach to Data Analysis

This dissertation study was a subset of the larger RCT, focused on a single stratification (urban clinics). Data analysis was approached as a pilot study. The analysis was limited to simple statistics to facilitate clinical interpretation of the findings. A Chi-square test for two independent samples was conducted for each key information point. Delivery platform (pIMCI or eIMCI) was the independent variable. The dependent variables were each key information point. All dependent variables were categorical. The null hypothesis (Ho) for each analysis was that the levels of the dependent variable would not differ based on delivery platform.

Aim 2.1 The Child's Problem

Methods

The communication related to the child's diagnosis or problem that took place during clinic visits was evaluated in this analysis. Medical diagnoses were not differentiated from problems and will be collectively referred to as *problem*. Because of the screening criteria for study recruitment, it was assumed that each case would contain at least one problem, the provider would verbalize that problem to the caretaker, and the caretaker could recall and restate the problem verbalized by the provider.

Aim 2.1.a Problems Verbalized by the Provider

Analytic Methods

Given that the clinics served similar patients, it was expected that there would be no difference between arms in the number of problems verbalized by the provider. The number of problems verbalized per case was counted; cases existed where no problems, one problem, two problems, or three problems were verbalized (three was the maximum

number of problems verbalized in any encounter). A Chi-square test for two independent samples was conducted to evaluate whether method of protocol delivery was associated with number of problems verbalized. The dependent variable, number of problems verbalized, contained four levels (0, 1, 2, 3). The number of problems verbalized was treated as categorical rather than ordinal because the number of problems the child actually had was not included as part of the analysis.

Results

The providers using the eIMCI application verbalized greater number of problems to caretakers, Chi-square (3, N=352) = 52.361, p<0.001 (see Table 5.2). Providers in the eIMCI arm verbalized on average 1.7 problems per child, whereas providers in the pIMCI arm verbalized 1.34 problems per child on average. Providers in the eIMCI arm were more likely to verbalize at least 1 problem for each case (98.8% of cases had at least 1 problem verbalized in the eIMCI arm, versus 77.8% of cases in the pIMCI arm).

Table 5.2
Number of Child Problems Verbalized by the Provider

Number of Problems Verbalized	eIMCI (172)	pIMCI (180)	Total (352)
3 Verbalized	17 (9.9%)	9 (5.0%)	26 (7.4%)
2 Verbalized	89(51.7%)	47(26.1%)	136(38.6%)
1 Verbalized	64(37.2%)	84(46.7%)	148(42.0%)
0 Verbalized	2(1.2%)	40(22.2%)	42(11.9%)
Total Cases	170(98.8%)	140(77.8%)	310(88.1%)
Total Problems Verbalized	293	205	499
Pearson Chi-Square	Value 52.361	*df* 3	*p* value <0.001

Aim 2.1.b Caretaker Recall of the Child's Problem

Analytic Methods

This subaim examined the extent to which caretakers were able to recall the child's problem(s), when the provider verbalized a problem. Cases were excluded from this analysis if the provider verbalized no problems.

The IMCI-based protocols in this study used moderately informal terminology to describe problems, such as *acute ear infection* rather than *otitis media*. Caretakers described problems using a variety of colloquial terms, reflective of social patterns in this community. For example, for a child with otitis media, caretakers reported terms such as *ear pain* or *ear problems.* In order to compare the problem stated by providers and the colloquial terms stated by caretakers, the problems stated by providers and caretakers were translated into English, then manually coded into categories (see Table 5.3).

Cases were compared by problem category code to determine if problems verbalized by the provider were the same as those recalled by the caretaker. Each case was summarized into one of three possible degrees of matching: all problems verbalized by the provider were reported by the caretaker (full match), some of the problems verbalized by the provider were reported by the caretaker (partial match), or none of the problems verbalized by the provider were reported by the caretaker (no match). For example, suppose a child was seen who had ear infection and impetigo, and the caretaker recalled "ear problem" and "skin problem" as the child's problems; that case would be categorized as full match. If the caretaker only recalled "ear problem," the case would be categorized as partial match.

Table 5.3
Diagnosis and Problem Codes Assigned for Analysis

Problem Code	IMCI Diagnosis or Problem Term
1 – Respiratory system related	• Pneumonia • Wheezing • Upper respiratory tract infection
2 – Diarrhea related	• Acute diarrhea with dehydration • Acute diarrhea without dehydration • Persistent diarrhea (> 2 weeks) • Dysentery
3 – Ear related	• Acute ear discharge • Persistent ear discharge • Acute ear infection
4 – Measles related	• Measles with eye or mouth complications • Measles without eye or mouth complications
5 – Skin related	• Impetigo • Infected skin lesion
6 – Urinary tract infection	• Urinary tract infection
7 – Bacterial intestinal	• Bacterial intestinal infection
8 – Malaria positive	• Malaria (positive RDT)
9 – Viral infection	• Viral infection
10 –Malaria negative	• No malaria (negative RDT) **
11 – Helminthes	• Helminthes*
12 – Eye infection	• Eye infection
13 – Other	• Other (not in protocol)
14 – Malnutrition	• Malnutrition
15 – Fever	• Fever

*Helminth infection was not covered in the protocols, but was included in data analysis due to saturation of instances, and the problem being verbalized by both providers and caretakers.
** Positive and negative malaria tests were separately reported

A Chi-square test for two independent samples was conducted to evaluate whether method of protocol delivery was associated with match between problems verbalized by the provider and problems recalled by the caretaker. The dependent variable, problem recall, contained three levels (full match, partial match, no match).

Results

Caretaker problem recall in the eIMCI group was significantly better than recall in the pIMCI group, Chi-square (2, *N*=352) = 10.727, *p*=0.005 (see Table 5.4). Most notably, more caretakers in the pIMCI arm were unable to correctly recall any problems verbalized by the provider than the eIMCI arm (31.4% versus 15.9%, respectively).

Aim 2.2 When to Return to the Clinic

Methods

In the IMCI-based protocols, instructions are given for when a caretaker should return to the clinic for follow up. For each problem, this includes: 1) a time frame (number of days) to return if the child's condition does not improve (listed in

Table 5.4
Caretaker Problem Recall Match

Problem Recall		eIMCI (170)	pIMCI (140)	Total (310)
Full Match	*n*(%)	70 (41.2%)	50(35.7%)	120(38.7%)
Partial Match	*n*(%)	73(42.9%)	46(32.9%)	119(38.4%)
No Match	*n*(%)	27(15.9%)	44(31.4%)	71(22.9%)
Total Any Match	*n*(%)	143(84.1%)	96(68.5%)	239(77.0%)
Pearson Chi-Square		Value	*df*	*p* value
		10.727	2	0.005

Appendix D), and 2) signs that would indicate the child's condition is worsening and needs further investigation (listed in Appendix E). Seven possible signs of worsening condition are addressed in the protocol: 1) unable to drink, 2) child drinks poorly, 3) child becomes sicker, 4) child develops fever, 5) child develops fast breathing, 6) child develops difficult breathing, and 7) child develops blood in stool. It was assumed that each case would include advice about when to return to the clinic. All cases in both arms were included in this portion of the analysis.

Aim 2.2.1.a Number of Days – Provider Verbalization

Analytic Methods

Although each problem in the IMCI protocol was associated with instructions for when to return to clinic (for example, "return in 3 days if the child does not improve"), providers did not always verbalize a number of days in which a child was to be brought back to the clinic for re-examination. Cases where the provider told the caretaker a specific number of days to return were categorized as "number of days verbalized" and cases where the provider did not verbalize a specific number of days were categorized as "number of days not verbalized."

A Chi-square test for two independent samples was conducted to evaluate whether method of protocol delivery was associated with provider verbalization of number of days to return to the clinic. The dependent variable contained two levels (number of days verbalized, number of days not verbalized).

Results

The providers using the eIMCI protocol verbalized a specific number of days to return to the clinic for nonimprovement for more cases than providers using the pIMCI protocol, Chi-square (1, N=352) =16.118, p<0.001 (see Table 5.5). No advice was verbalized regarding when to return for 55.0% of the cases in the pIMCI arm, and no advice was given for 33.7% of the eIMCI arm.

Aim 2.2.1.b Number of Days – Caretaker Recall

Analytic Methods

Only cases where providers verbalized a number of days to return were included in this analysis. When the caretaker reported the same number of days as the provider stated, the case was coded as *match*; caretaker reports that differed from provider advice were coded as *no match*. If the provider stated a number of days but the caretaker could not remember any number, the case was also coded as *no match*. A Chi-square test for two independent samples was conducted to evaluate whether method of protocol delivery was associated with caretaker recall of days to return to the clinic. The dependent variable, match in number of days recalled, contained two levels (match, no match).

Table 5.5
Provider Verbalized Number of Days to Return

Provider Number of Days to Return Advice Given	eIMCI (172)	pIMCI (180)	Total (352)
Verbalized *n*(%)	114(66.3%)	81(45.0%)	195(55.4%)
Not Verbalized *n*(%)	58(33.7%)	99(55.0%)	157(44.6%)
Pearson Chi-Square	Value	*df*	*p* value
	16.118	1	<0.001

Results

More caretakers in the eIMCI group correctly recalled the number of days to return to the clinic for nonimprovement, Chi-square (1, *N*=195) =6.685, *p*=0.010 (Table 5.6). Overall, both arms did rather poorly on this indicator with an overall rate of 74.4% incorrect responses. In the pIMCI arm, 84% of caretakers did not recall the number of days verbalized by the provider, whereas in the eIMCI arm, 67.5% did not recall the number of days verbalized by the provider.

Aim 2.2.2.a Signs of Worsening Problem – Provider Communication

Analytic Methods

The protocol contained advice on signs that would indicate the child's problem was worsening. It was assumed that each case would contain at least 1 sign, and up to 7 signs could have been verbalized by the provider. A Chi-square test for two independent samples was conducted to evaluate whether method of protocol delivery was associated with number of signs of worsening problems verbalized by the provider. To achieve at least 5 cases per cell, number of signs verbalized was collapsed into 3 levels (4 to 7 signs, 1 to 3 signs, no signs verbalized).

Table 5.6
Caretaker Recall of Number of Days to Return

Number of Days Match		eIMCI (114)	pIMCI (81)	Total (195)
Match	*n*(%)	37(32.5%)	13(16.0%)	50(25.6%)
No Match (incorrect)	*n*(%)	77(67.5%)	68(84.0%)	145(74.4%)
Pearson Chi-Square		Value	*df*	*p* value
		6.685	1	0.010

Results

The providers using the eIMCI protocol verbalized more signs of worsening problems than providers using the pIMCI protocol, Chi-square (2, *N*=352) = 98.78, $p<0.001$ (Table 5.7). Approximately twice as many providers in the pIMCI arm gave no advice regarding worsening condition. Most providers (76.7%) in the eIMCI arm gave advice regarding 4 or more signs.

Aim 2.2.2.b Signs of Worsening Problem – Caretaker Recall

Analytic Methods

This analysis examined caretaker recall of signs indicating worsening problems. Only cases where providers verbalized signs of worsening problems were included in this analysis. Each case could have a different number of signs verbalized by the provider, so to enable comparison across cases, the number of signs correctly recalled by the caretaker divided by the number of signs verbalized by the provider was computed to yield a percent match between caretaker and provider (Table 5.7).

Table 5.7
Provider Verbalized Signs of Worsening Problem

Signs of worsening problem		eIMCI (172)	pIMCI (180)	Total (352)
4-7 signs	*n*(%)	132(76.7%)	43(23.9%)	175(49.7%)
1-3 signs	*n*(%)	34(19.8%)	123(68.3%)	157(44.6%)
None given	*n*(%)	6(3.5%)	14(7.8%)	20(5.7%)
Total Cases Any Verbalized	*n*(%)	166(96.5%)	166(92.2%)	332(94.3%)
Pearson Chi-Square		Value 98.78	*df* 2	*p* value <0.001

Percent match was then collapsed into groups to achieve at least 5 cases per cell (0%=No match, 1-25%, 26-50%, 51-75%, and 76-100% match). A Chi-square test for two independent samples was conducted to evaluate whether method of protocol delivery was associated with caretaker recall of signs of a worsening problem. The dependent variable, recall of signs of worsening problems, contained five levels.

Results

Caretakers in the eIMCI group recalled significantly more signs of worsening problems than caretakers in the pIMCI group, Chi-square (4, N=332) =29.50, p<0.001 (Table 5.8). More than 3/4 of caretakers were able to recall at least some signs verbalized by the provider in the eIMCI arm (77.1%) versus only half of the caretakers in the pIMCI arm (50.0%).

Table 5.8
Caretaker Recall Signs of Worsening Problem

% Match Signs of Worsening Problem		eIMCI (166)	pIMCI (166)	Total (332)
76-100% Match	*n*(%)	10(6.0%)	12(7.2%)	22(6.6%)
51-75% Match	*n*(%)	36(21.7%)	24(14.5%)	60(18.1%)
26-50% Match	*n*(%)	57(34.3%)	36(21.7%)	93(28.0%)
1-25% Match	*n*(%)	25(15.1%)	11(6.6%)	36(10.8%)
No Match	*n*(%)	38(22.9%)	83(50%)	121(36.4%)
Pearson Chi-Square		Value 29.50	*df* 4	*p* value <0.001

Aim 2.3 Treatment (Medications)

Methods

The focus of this analysis was to examine the communication patterns of providers and caretakers regarding treatments prescribed, primarily medications. Some other prescribed treatments, such as lemon tea, were counted as medications for this analysis. If treatments were prescribed, three components were evaluated. These were the type or name of medication, the number of times per day to give the medication (frequency), and the number of days to give the medication (duration). Because caretakers used colloquial terms rather than actual medication names (for example, Paracetamol was often called "a tablet for body heat"), caretaker statements and provider verbalizations were coded into categories.

It was assumed that medication prescriptions would be given only for some cases; therefore, only cases in which at least one medicine was prescribed were included in this analysis. Cases were first categorized as any medication prescribed or no medication prescribed. While there was a slightly larger percentage of cases with medications prescribed in the eIMCI arm, the difference was not statistically significant, Chi-square (4, N=352) =4.769, p=0.312 (Table 5.9).

Table 5.9
Medications Prescribed by Provider

Medications - number of cases	eIMCI (172)	pIMCI (180)	Total (352)
Any Medication Prescribed *n*(%)	168(51.7%)	167(26.1%)	335(38.6%)
No Medication Prescribed *n*(%)	4(2.3%)	13(7.2%)	17(4.8%)
Pearson Chi-Square	Value	*df*	*p* value
	4.769	4	0.312

Aim 2.3.1.a Medication Type – Provider Verbalization

Analytic Methods

All cases where medications were prescribed were included in the analysis to evaluate the extent to which the provider verbalized the key information point (explained) the name of the medication being prescribed. Cases were grouped into categories based on number of medications prescribed. A Chi-square test for 2 independent samples was conducted to evaluate whether method of protocol delivery was associated with provider verbalization about types of medications. The dependent variable contained three levels.

Results

The providers using the eIMCI protocol verbalized greater number of medications per case, Chi-square (2, N=298) = 25.105, p<0.001) (see Table 5.10). At least 1 type of medication was verbalized by providers for 97% of cases for which medications were prescribed in the eIMCI arm; at least 1 type of medication was verbalized by providers for 80.8% of cases for which medications were prescribed in the pIMCI arm. Conversely, prescribed treatment was not verbalized for 19.2% of cases in the pIMCI arm versus 3% of cases in the eIMCI arm.

Table 5.10
Provider Verbalized Treatment Type

Treatment Type Explained		eIMCI (168)	pIMCI (167)	Total (335)
3 or More Rx Explained	*n*(%)	38(22.6%)	21(12.6%)	59(17.6%)
1-2 Rx Explained	*n*(%)	125(74.4%)	114(68.3%)	239(71.3%)
No Rx Explained	*n*(%)	5(3.0%)	32(19.2%)	37(11.0%)
Pearson Chi-Square		Value	*df*	*p* value
		25.105	2	<0.001

Aim 2.3.1.b Medication Type – Caretaker Recall

Analytic Methods

The focus of this aim was to examine the extent to which caretakers were able to recall the type or name of the medication prescribed. Only cases where the provider verbalized at least one type of medication were included in the analysis. Cases where the caretaker reported the same medication as the provider stated were coded as a "match" and caretaker reports that differed from provider statements were coded as "no match" for that medication. Because multiple medications were typically prescribed for a child, cases were then aggregated across all medications. If all prescribed medications were correctly recalled, the case was termed "full match," if some but not all medications were correctly recalled, the case was termed "partial match", and "no match" was assigned if no medications were correctly recalled. A Chi-square test for two independent samples was conducted to evaluate the extent to which protocol delivery method was associated with caretaker recall about medication types. The dependent variable contained three levels (full match, partial match, no match).

Results

More caretakers in the eIMCI group recalled medication types than caretakers in the pIMCI group, Chi-square (2, N=298) = 29.50, p=0.001 (see Table 5.11). Caretakers in the eIMCI arm recalled all medications correctly in 41.1% of cases, whereas only 28.9% of caretakers in the pIMCI arm correctly recalled all medications. Of note, 42.2% of caretakers in the pIMCI arm were unable to recall any medication that was verbalized by providers (versus 21.5% in the eIMCI arm).

Table 5.11
Caretaker Recall Medication Type

Match between caretaker and provider		eIMCI (163)	pIMCI (135)	Total (298)
Full Match	*n*(%)	67(41.1%)	39(28.9%)	106(35.6%)
Partial Match	*n*(%)	61(37.4%)	39(28.9%)	100(33.6%)
No Match	*n*(%)	35(21.5%)	57(42.2%)	92(30.9%)
Pearson Chi-Square		Value 14.999	*df* 2	*p* value 0.001

Aim 2.3.2 Treatment Frequency and Duration

Methods

Medications were grouped into two categories to evaluate communication regarding how to administer medications (Table 5.12). Group 1 included medications for which the protocol provided instructions regarding frequency and duration. For example, Amoxicillin tablets are to be administered twice per day (frequency) for 5 days (duration). Group 2 contained medications with frequency indications only, e.g., to be given until symptoms subsided. For example, Paracetamol tablets are to be given 3 times per day (frequency) until the child improves (no specific duration). Treatments that did not contain instructions for duration or frequency (for example, lemon tea to soothe the throat) were eliminated from this analysis.

A Chi-square test for two independent samples was conducted to evaluate whether method of protocol delivery was associated with number of prescriptions. No difference was found between arms for Group 1 medications, Chi-square (3, N=115) = 1.889, p=0.596, nor was a difference found between arms for Group 2 medications, Chi-square (2, N=268) = 3.256, p=0.196 (see Table 5.13).

Table 5.12

List of Treatment Groups 1 & 2

Group 1: Frequency and Duration	Group 2: Frequency Only
Amoxicillin	Paracetamol
Salbutamol	Tetracycline
Alu	Gentian Violet
Ciprofloxacin	Iron Tablets (single dose)
Cloxacillin	
Zinc	
Quinolone drops	

Table 5.13
Treatment Groups 1 & 2 Prescribed by Provider

Group 1 Medications Prescribed		eIMCI (168)	pIMCI (167)	Total (335)
3 Rx	*n*(%)	0(0%)	1(0.06%)	1(0.03%)
2 Rx	*n*(%)	4(2.4%)	3(1.8%)	7(2.1%)
1 Rx	*n*(%)	50(29.8%)	57(34.1%)	107(31.9%)
0 Rx	*n*(%)	114(67.9%)	106(63.5%)	220(67.5%)
Total *Cases* Group 1 Prescribed	*n*(%)	54(32.4%)	61(36.5%)	115(34.3%)
Total *Count* Group 1 Prescribed	*n*	58	63	121
Pearson Chi-Square		Value 1.889	*df* 3	*p* value 0.596
Group 2 Medications Prescribed		eIMCI (168)	pIMCI (167)	Total (335)
2 Rx	*n*(%)	1(0.06%)	1(0.06%)	2(0.06%)
1 Rx	*n*(%)	140(83.3%)	126(75.4%)	266(79.4%)
0 Rx	*n*(%)	27(16.1%)	40(24.0%)	67(20.0%)
Total *Cases* Group 2 Rx Prescribed	*n*(%)	141(83.9%)	127(76.0%)	268(80%)
Total *Count* Group 2 Prescribed	*n*	142	128	
Pearson Chi-Square		Value 3.256	*df* 2	*p* value 0.196

Aim 2.3.2.a Treatment Frequency – Provider Verbalization

Analytic Methods

Both Group 1 and Group 2 medications had specific information points for how many times per day to give (frequency) and were analyzed together. A Chi-square test for two independent samples was conducted to evaluate whether method of protocol delivery was associated with provider verbalization of medication administration frequency. The dependent variable contained four levels (frequency explained for three, two, one, or no applicable medications).

Results

Providers in the eIMCI arm verbalized the frequency to administer medications more often than providers in the pIMCI arm, Chi-square (3, *N*=292) = 16.140, *p*=0.001 (see Table 5.14). More providers in the eIMCI arm explained at least one treatment frequency to caretakers (eIMCI = 93.2% and pIMCI = 79.1%).

Table 5.14
Provider Verbalized Treatment Frequency

Frequency Explained		eIMCI (148)	pIMCI (144)	Total (292)
3 Rx	*n*(%)	2(1.4%)	3(2.1%)	5(1.7%)
2 Rx	*n*(%)	33(22.3%)	39(27.1%%)	72(24.7%)
1 Rx	*n*(%)	103(69.6%)	72(50.0%)	175(59.9%)
Did Not Explain	*n*(%)	10(6.8%)	30(20.8%)	40(13.7%)
Total Cases Frequency Explained	*n*(%)	138(93.2%)	114(79.1%)	252(86.3%)

Pearson Chi-Square	Value	*df*	*p* value
	16.140	3	0.001

Aim 2.3.2.b Treatment Frequency – Caretaker Recall

Analytic Methods

The focus for this analysis was to examine caretakers' ability to recall medication administration frequency. Cases where they did not prescribe medications or did not verbalize frequency to give medications were eliminated. Cases where the caretaker reported the correct frequency to give treatments were coded as "correct," caretaker reports that differed from provider advice were coded as "incorrect."

A Chi-square test for two independent samples was conducted to evaluate whether eIMCI use was associated with greater caretaker recall of frequency to administer treatments. The dependent variable, frequency to administer treatment, contained three levels (two correct, one correct, incorrect).

Results

Caretakers in the eIMCI group correctly recalled significantly more medication frequency instructions than caretakers in the pIMCI group, Chi-square (2, N=252) = 13.529, p=0. 001 (see Table 5.15). The error rate remained notable. Caretakers in the pIMCI arm

Table 5.15
Caretaker Treatment Frequency Recall Match

Caretaker Recall Frequency		eIMCI (138)	pIMCI (114)	Total (252)
2 Correct	*n*(%)	10(7.2%)	8(7.0%)	55(16.5%)
1 Correct	*n*(%)	78(56.5%	39(34.2%	117(46.4%)
Incorrect	*n*(%)	50(36.2%)	67(58.8%)	117(46.4)
Pearson Chi-Square		Value	*df*	*p* value
		13.529	2	0.001

incorrectly reported the frequency of medication administration in 58.8% of cases, compared to 36.2% of cases reported incorrectly in the eIMCI arm.

Aim 2.3.3.a Medication Duration – Provider Verbalization

Analytic Methods

Only Group 1 medication had messages in the IMCI protocol for duration to administer (number of days to give the medication); therefore, only cases where Group 1 medications were prescribed were included in this analysis. A Chi-square test for two independent samples was conducted to evaluate whether method of protocol delivery was associated with provider verbalization of medication duration. The maximum number of Group 1 medications that any child received in this study was two. The dependent variable contained three levels (two, one, or no Group 1 medications had duration explained).

Results

No difference was found between providers using the eIMCI protocol or the pIMCI protocol regarding communication of medication duration, Chi-square (2, N=103) =2.717, p=0.257 (see Table 5.16). Providers verbalized duration for most of the cases in which a relevant medication was prescribed (eIMCI = 93.0% and pIMCI = 86.9%).

Aim 2.3.2.b Medication Duration – Caretaker Recall

Analytic Methods

It was expected that there would be no difference in caretaker ability to recall duration to give relevant medications (from Group 1 only) between arms. Cases where

Table 5.16
Provider Verbalized Treatment Duration

Duration Explained		eIMCI (54)	pIMCI (61)	Total (115)
2 Medications	*n*(%)	1(1.9%)	4(6.6%)	5(4.3%)
1 Medication	*n*(%)	49(90.7%)	49(80.3%)	98(85.2%)
None Explained	*n*(%)	4(7.4%)	8(13.1%)	12(10.4%)
Total Cases	*n*(%	50(93.0%)	53(86.9%)	103(89.6%)
Pearson Chi-Square		Value	*df*	*p* value
		2.717	2	.257

providers did not prescribe Group 1 medications or did not verbalize duration to give the medication were excluded from the analysis. Cases where the caretaker reported the correct duration to give treatments were coded as "correct," caretaker reports that differed from provider advice were coded as "incorrect." A Chi-square test for two independent samples was conducted to evaluate whether method of protocol delivery was associated with caretaker recall of treatment duration. The dependent variable contained two levels (correct, incorrect).

Results

No significant difference was found in caretaker recall of the correct duration to administer medications, Chi-square (1, N=103) = 0.735, p=0.391 (see Table 5.17). The maximum number of correct matches in any case was one. Many caretakers in both eIMCI and pIMCI arms reported an incorrect number of days to administer medications (72.0% and 79.2% incorrect, respectively).

Table 5.17
Caretaker Treatment Duration Recall Match

Caretaker Recall Duration		eIMCI	pIMCI	Total
1 Match	*n*(%)	14(28.0%)	11(20.8%)	25(24.3%)
No Match	*n*(%)	36(72.0%)	42(79.2%)	78(75.7%)
Pearson Chi-Square		Value	*df*	*p* value
		0.735	1	0.391

Aim 2 Results Summary

The mHealth Communications Framework communication guided the design and analysis of Aim 2. The act of *communication* encompassed both sending a message about a key information point (provider verbalization), and receiving the message (caretaker recall). In general, the eIMCI mobile application demonstrated improved communication, compared to the pIMCI protocol. Overall, providers communicated key points of information more often and more thoroughly when providing care using the electronic platform, and caretakers recalled more information at the completion of the visit when the electronic platform was used. Of the 12 communication aspects examined in Aim 2, ten were found to be statistically in favor of the eIMCI application (Table 5.18). This pilot study suggested that the electronic protocol delivery method could promote enhanced communication between providers and the caretakers of children under 5.

Table 5.18
Aim 2 Results Summary

Provider Verbalized	pIMCI	eIMCI	Not Sig.	*P* value
Child's problem		*		<0.001
When to Return Days		*		<0.001
Signs of Worsening Condition		*		<0.001
Medication: Type		*		<0.001
Medication: Frequency		*		0.001
Medication: Duration			*	0.257
Caretaker Recalled				
Child's problem		*		0.005
When to Return Days		*		0.010
Signs of Worsening Condition		*		<0.001
Medication: Type		*		0.001
Medication: Frequency		*		0.036
Medication: Duration			*	0.478

* arm favored by the statistical test

Communication Gaps Between Arms

Provider Verbalization of Key Information Points

Wide gaps between eIMCI and pIMCI arms were seen regarding problem verbalized (98.8% vs. 77.8%), number of days to return (66.3% vs. 45.0%), signs of worsening condition, medication type (97.0% vs. 80.8%), and mediation frequency (93.2% vs. 79.2%); however, most providers verbalized at least one sign of worsening condition (96.5% and 92.2%). The smallest gap was information regarding medication duration (the number of days to take the medication), with no statistical difference between arms. In both arms, mediation duration was verbalized frequently for Group 1 medications (92.6% eIMCI and 86.9% pIMCI; p=0.257). Figure 5.5 displays the provider verbalization of communication prompts.

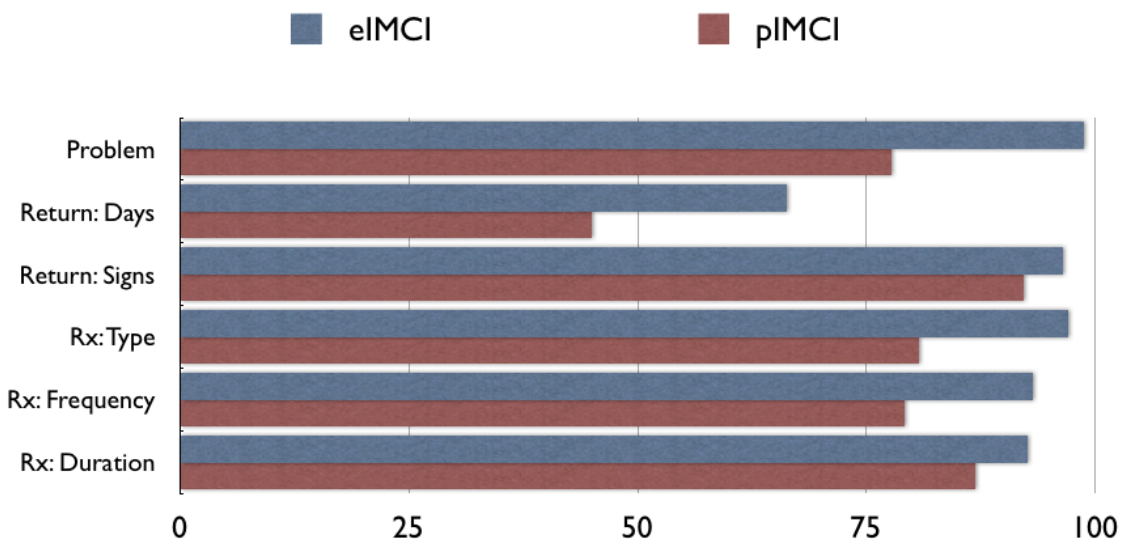


Figure 5.5
Provider Verbalization of Key Information Points

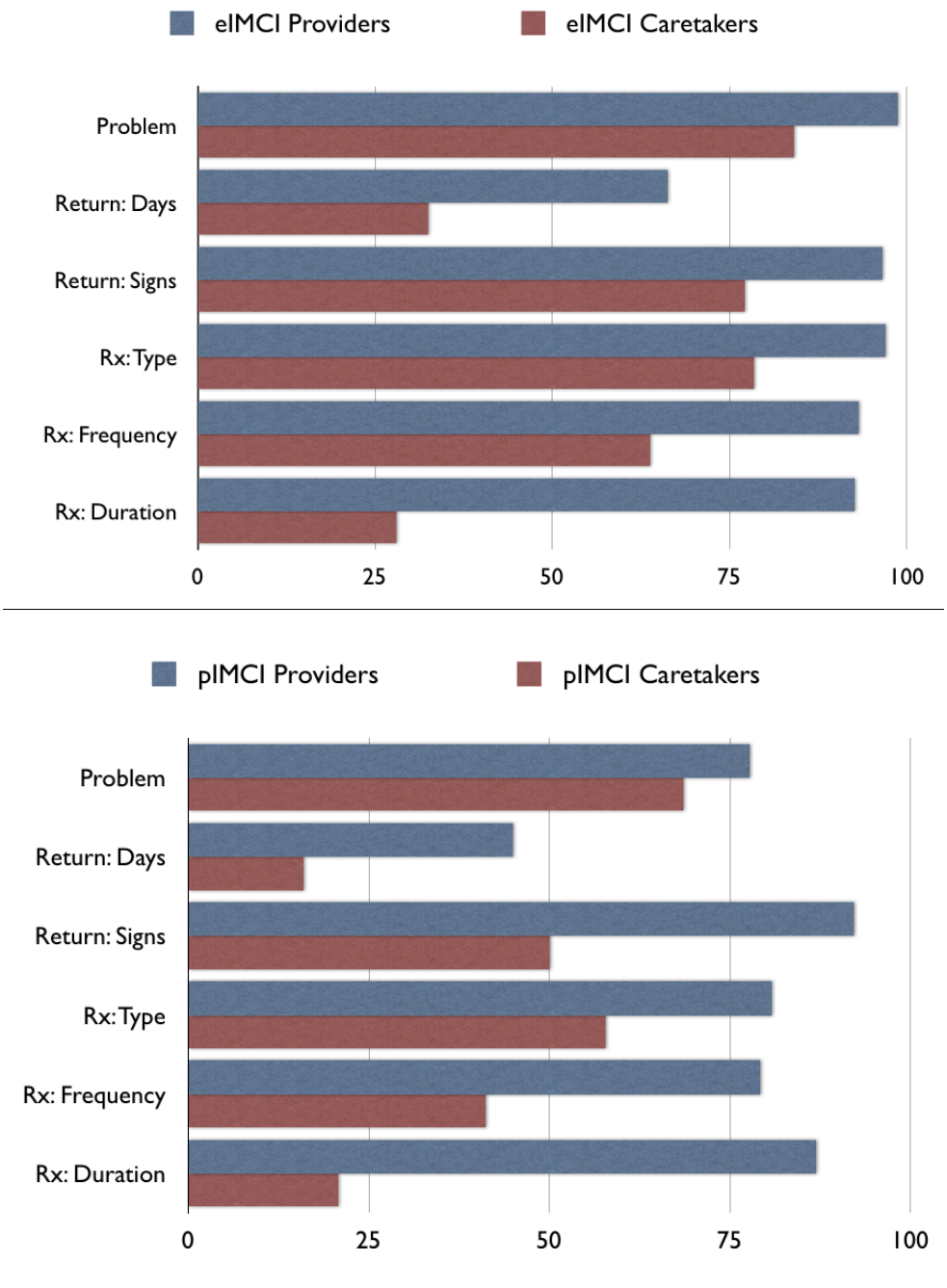
Providers in the pIMCI arm did not verbalize the child's problem in 22.2% of cases (approximately 1% of providers failed to communicate this in the eIMCI arm). Providers in the pIMCI arm did not verbalize any signs of worsening condition in 7.8% of cases (but only 3.5% of cases in the eIMCI arm). Providers in the pIMCI arm were more likely to fail to verbalize when to return to the clinic (number of days), although both groups failed to verbalize this information for more than one third of the children. Providers in the pIMCI arm did not verbalize the medication name in 19.2% of cases, medication frequency was not explained in 20.8% of cases, and mediation duration was not explained in 13.1% of cases. Far fewer eIMCI arm providers failed to communicate the medication name (3.0% of cases), 6.8% did not verbalize medication frequency, and 7.4% did not verbalize medication duration.

Caretaker Recall of Key Information Points

Within each study arm, caretaker recall largely mirrored provider verbalization of the key information points, with the exception of medication duration (see Figure 5.6). Significant deficits in caretaker recall were found in both arms; however, the most severe were in the pIMCI arm (see Figure 5.7).

Caretakers in the eIMCI arm did not know the child's problem in 15.9% of cases, while those in pIMCI could not recall this information approximately 1/3 of the time (31.4%). There were large deficits in recall of when to return to the clinic (see Figure 5.7 Return: Days and Return: Signs). Caretakers frequently did not know the number of days to return, with 67.5% of eIMCI cases and 84.0% of pIMCI cases failing to recall this information correctly. Fully 1/2 (50%) of caretakers in the pIMCI arm and 22.9% of cases in the eIMCI arm were unable to correctly recall any signs of worsening condition (p=< 0.001).

Recall about medication instructions was also poor (see Figure 5.7 Rx: Type, Rx: Frequency, and Rx: Duration). Caretakers in the eIMCI arm did not know any medications in 21.5% of cases, and for 42.2% of pIMCI cases (p=0.001). More than half (58.8%) of caretakers in the pIMCI arm did not recall how often to give the medication (versus 36.2% in the eIMCI arm), and 79.2% did not correctly recall how many days to give the medication (72.0% in the eIMCI arm). A smaller gap in caretaker recall among arms was found in the duration to administer treatment, but that may have been because few caretakers in either arm correctly reporting medication duration (28.0% vs. 20.8% correct, respectively), and no caretaker correctly recalled this information for more than one medication.



Note: Top half shows eIMCI arm and bottom half shows pIMCI arm

Figure 5.6
Provider-Caretaker Communication within each Arm

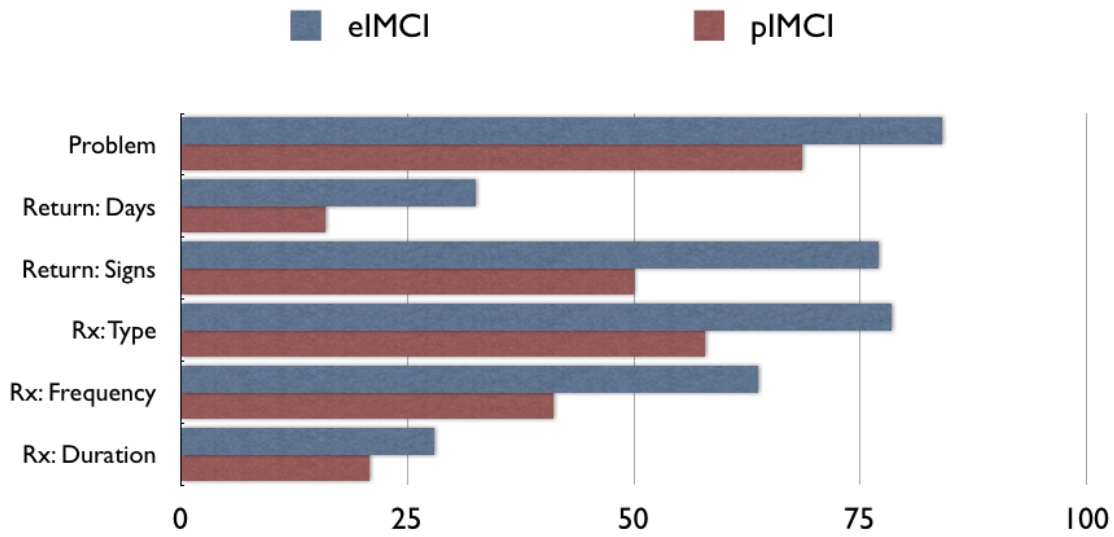


Figure 5.7

Caretaker Recall of Key Information Points

CHAPTER 6

DISCUSSION AND CONCLUSIONS

Summary and Discussion

Aim 1 Summary and Discussion

User-Centered Design

Aim 1 of this study was to utilize User-Centered Design (UCD) principles to develop the eIMCI mobile application and evaluate its usability. Three fundamental axioms of UCD guided Aim 1. Employing the first axiom of UCD, early focus on users and their tasks (Staggers, 2014), the needs assessment (Aim 1.1.1) and creation of the educational video (Aim 1.1.2) provided information that was essential for creating a product that fit the clinical environment and the needs of providers and caretakers.

Several issues that could have otherwise been overlooked were identified. The greatest difficulties encountered were in the nonadaptable features of the application, including logging in, saving, and sending data. However, interaction with the protocol screens and verbiage were never met with any observable resistance, confusion, or difficulty. Directive simplicity enabled this to occur. The primary task for the users of the eIMCI protocol was related to the diagnosis and treatment of an ill child under age 5. The eIMCI decision-making algorithm (knowledge base) was evaluated for fidelity, defined as the ability to guide the clinician to exactly the same diagnosis and treatment plan that was provided by the paper protocol.

The second axiom of UCD, iterative design (Staggers, 2014), was illustrated in the prototype development, particularly the design of the eIMCI application interface and navigation (Aim 1.3). Feedback that provided information for iterative design was obtained throughout the development process. Formative evaluation is conducted in early design phases to discover insights into user behaviors and shape the design direction (Tullis & Albert, 2008), and in middle to later phases to refine development (Rubin & Chisnell, 2008). Formative evaluation was conducted through a think-aloud session and through key informant feedback. Iterative improvements to the eIMCI application were based on the formative testing. The application was localized to a greater extent than would have been possible without this feedback. Key informant feedback (Aim 1.3.b) identified issues and qualitatively evaluated perceptions about the user interface.

Empirical measurement, the third axiom of UCD, was demonstrated through summative testing. Summative usability evaluation is conducted to measure or validate the current usability of an interface, through observable metrics such as task times, completion rates, and satisfaction scores. Usability was measured in terms of application learnability (Aim 1.3.a) and satisfactory time to complete a clinical encounter (Aim 1.3.b.).

Because the use of mHealth interventions are relatively new and many of the participating clinicians were using smart phones in their work for the first time during this project, adaptations made during iterative development were essential to encourage phone use and improve provider adherence. Further, responding to user feedback enabled vital modifications to the eIMCI application that led to greater fit with clinical workflow and congruence with standards Tanzanian providers were accustomed to.

Think-aloud Exercise

Among all of the Aim 1 components, the most unforeseen was the response to the think-aloud exercise. The think-aloud exercise was intended to observe the user cognizing about the protocol, and confirm if the imperatives and content were understood. The think-aloud exercise was also used to assess the learnability of the application, and the training strategy. The think-aloud method can work well to attain deeper understanding of cognitive processes, elicit feedback on user experience, and gain suggestions for improvement (Anderson, Gifford, Avery, Fortnum, Murphy, Krska, & Bond, 2012; Britto, Jimison, Munafo, Wissman, Rogers, & Hersh, 2009; Fonda, Paulsen, Perkins, Kedziora, Rodbard, & Bursell, 2008; George, 2008; Munger, 2003). However, the empirical strength of the think-aloud method may be uncertain (van den Haak, De Jong, & Schellens, 2003). The technique relies on a participant's ability to perform as they would in the absence of observation, which may be difficult to assess; and users may have difficulty verbalizing what they are thinking (Rubin & Chisnell, 2008).

Some portions of the think-aloud exercise were successful. Based on observation of users during this exercise, it was deduced that clinicians could use the protocol effectively (i.e., could navigate the protocol to arrive at a correct decision, without additional assistance from the researcher), and the training was confirmed to be sufficient for successful protocol use.

However, little meaningful verbal feedback was gleaned from this exercise related to user cognition of the navigation process. Despite thorough training and practice sessions, the researcher was unable to elicit any verbalization about the navigational processes from any of the participants. Each user simply navigated through the test case

scenarios without comment. The researcher postulated several potential reasons for the failure to produce verbalization about what the users were thinking and feeling. One factor may have been because the method was unfamiliar to the users. The instructions may not have been clear enough to withstand language and cultural barriers. Alternatively, it is possible that the process may have been interpreted to be a test and the participants were avoiding being seen as making a mistake (which could be culturally feasible in this setting) despite the researcher's emphasis that the product, not the user, was being evaluated. A third postulation was that the application navigation was so straightforward that the exercise may have seemed meaningless to the participants.

Understanding of eIMCI satisfaction and perceived usefulness, perceived efficiency, effectiveness, or accessibility/fit with clinical workflow from the user perspective was also attempted via the think-aloud exercise. However, full understanding of how the user understood the meaning of the imperatives and context of the protocol was not achieved. Feedback about the software was exclusively positive and non-specific despite strong encouragement to describe any confusing, unfavorable, or challenging experiences using the application. While the navigation of the application was very straightforward, the actions of logging in, saving, and sending data required considerably more time to master, and resulted in more typing and selection errors. However, no participants acknowledged any concern. The researcher witnessed the application crashing several times during one of the tests; however, the participant verbalized no negative feedback, frustration, or dissatisfaction with this, although the participant’s body language appeared to indicate confusion.

Cross-cultural Usability Testing

The failure of the think-aloud method to yield a deeper understanding of user perspectives provided a valuable lesson in cross-cultural usability testing. The overwhelmingly positive responses may have been a reflection of demand characteristics bias, a phenomenon in which participants alter their behavior or feedback to accommodate what they believe is the researcher's expectations (Rosenthal & Rosnow, 2009). Dell et al., (2012), reported a demand characteristics bias that may occur in international research when researchers are perceived as having a greater social status than their subjects. Participants in Dell's study were asked to evaluate videos displayed on a small video player and state their preference for one or another. One experiment displayed two videos that were exactly the same, and another displayed a high-quality video against a clearly degraded video. Giving detailed and enthusiastic feedback, participants were overwhelmingly more likely to verbalize a perceived superiority of whichever video was associated with a foreign researcher. Similarly to the present study, demand characteristics biases in the Dell study were suggested to significantly influence participant responses in a human-computer interaction (HCI) system evaluation in a developing world context, where a significant demographic or stature difference existed between researchers and participants (Dell et al., 2012).

The extent to which this phenomenon would affect this study was unanticipated. The "lesson learned" from this experience is that demand characteristic biases are critical to consider in research that occurs in any cross-cultural setting, particularly those cultures in which discrepancies may be perceived between the social status of subjects and researchers.

While this type of bias cannot reasonably be eliminated from international research, investigators must consider the effect and attempt to diminish or alter its effect in whatever manner is feasible (Dell et al., 2012). Rubin and Chisnell (2008) advise usability testers to abandon the think-aloud method if it appears to yield unproductive or inauthentic results. In this study, the method was abandoned.

Steps to mitigate the risk for demand characteristics bias in future projects might include employing a native speaker who is in a trusted position related to the participant to administer the exercise, and allowing extra time to complete each component so that the exercise does not feel like a test. Providing participants with choices to compare or ranking exercises may be more successful to evaluate satisfaction and other metrics than eliciting open-ended qualitative feedback. No existing literature describing the use of the think-aloud method in similar environments to that of this study was found; therefore, additional research is recommended to further explore cultural adaptations needed for successful use of the think-aloud method.

Aim 2 Summary and Discussion

The act of *communication* in the context of this study represented both the imparting of information and the recall of that information. Results of this study suggested that 1) overall, providers communicated key points of information significantly more often and more thoroughly when using the electronic platform of the eIMCI protocol, and 2) caretakers retained more information at the completion of the visit when the eIMCI protocol was used. The electronic intervention was therefore considered to be effective by both measures of provider and caretaker components of the communication

encounter. A significant innovation was hence achieved in the domain of mHealth by the use of ICT and mobile phones toward the promotion of clinical health communication.

Remaining Deficits

While significant improvements were observed from eIMCI use, deficits in provider verbalization of key information points and caretaker recall of information verbalized still remained, indicating a need for further improvement in provider-caretaker communication. Long standing societal patterns likely influenced these deficits, as it has been a well-established norm for providers to abstain from teaching this information, and for caretakers to accept an insufficient level of communication and health-related teaching.

Organizational supervision and feedback have been identified in multiple studies as key influences of provider motivation (Franco, Bennet, & Kanfer, 2002; Mbindyo, Gilson, Blaauw, & English, 2009). At the same time, healthcare providers typically receive little feedback on the work they are doing (Manongi, Marchant, & Bygbjerg, 2006). Mobile electronic standardized protocols have been shown to lead to more consistency in arriving at correct diagnoses and treatments compared to paper protocols (DeRenzi, 2008). The mobile platform has the potential to influence provider motivation through added supervision and feedback; the provider's correct and consistent use of the protocol is recorded as a case file in the eIMCI application. As mHealth interventions are continually developed to respond to the unique low-resource environment, the assets provided by the electronic platform may be leveraged.

In addition, the lack of caretaker recall of certain key information points was noteworthy. The lowest caretaker recall was for the duration to administer treatments.

Because most providers in both arms did verbalize this key information point, two postulations were made. Caretakers may have focused on what they perceived as the most important component of the treatments, the frequency to give the medication. Caretakers could simply stop when there was no medication left if they were giving it the correct number of times per day; therefore, the duration information may have seemed irrelevant. Alternatively, the duration of medication administration was sequentially the last of six key information points potentially received by the caretaker *per problem*. Many children received more than one treatment per problem. As the human brain possesses limitations in its ability to process and retain information, this information may have simply been outside of the scope of immediate recall of short-term memory for caretakers. Caretakers in the eIMCI arm did recall the medication name/type more often than caretakers in the pIMCI arm. It is possible that the enhancements to the eIMCI application, particularly the educational video reminding the caretakers to attend to certain information, contributed to overall better communication in this arm

Health Literacy

The deficits in caretaker recall of the key information points may be a product of the limited maternal health literacy, and may correlate with the globally relatively high child mortality rate of Tanzania (low education level was observed, although actual health literacy level was not empirically measured). As far back as 1979, child survival has been linked to maternal educational level (Caldwell, 1979). Caldwell identified factors associated with greater maternal education as a transference from traditional, passive acceptance of health disparities and outcomes, into realization of basic health literacy; a greater ability to navigate contemporary paradigms, such as confidant

interaction with healthcare providers; and a more empowered stature in the family model, which may lead to educated women having more influence in health decisions for their children (Hobcraft, 1993). The great need for improvement in health literacy via caretaker education and empowerment is illustrated herein, as health literacy may impact caretaker's ability to navigate the clinical encounter, expectation to receive high quality care, and ability to implement care plans in the home. While there is a great deal of improvement and continued effort needed to rectify this startling deficit, using the electronic protocol was demonstrated to promote enhanced communication between participating providers and caretakers. It is imperative that the continual development of interventions such as the eIMCI mobile application may be further explored as a mechanism to improve provider-caretaker communication, and ultimately increase caretaker knowledge and child health outcomes.

Theoretical Framework Applications

The mHealth Communications Framework was adapted from the Staggers Health Human-Computer Interaction Framework (2003). The mHealth Communications Framework extended the fundamental concepts of the Staggers framework to the realm of mHealth. The mHealth Communications Framework was designed to illustrate the elements and processes that inform communication patterns within provider-caretaker interactions, supported by a communications support tool.

This study focused on the extent to which communications support tool delivery mode (paper or electronic) influenced communication. The mHealth Communications Framework described the components that influenced and supported communication between providers and caretakers of children under five. The novel Communications

Support intervention, the eIMCI mobile application, was developed and evaluated as guided by the model components.

Study Strengths, Limitations, and Issues

Generalizability

This study had several strengths, but also had limitations and issues. A significant strength was that the study utilized a Randomized Controlled Trial design, considered by many as providing the highest level of empirical evidence. However, results of this dissertation study should be considered as preliminary findings and may not be widely generalizable, as the sample was a subset of a larger RCT and was limited to urban centers in Tanzania. The use of a single key informant may also reduce generalizability, although no evidence was encountered to suggest that the opinions of the key informant were isolated. Additionally, the unexpected emergence of the key informant lacked the structure of a highly formal process, in which a deliberate study design could further enhance the focus and content of the feedback. These challenges were nevertheless unavoidable, and the feedback from the key informant produced significant contribution to the development process. Using this approach, satisfactory contribution was made toward the primary objective of the formative testing phase, though by alternative means than originally intended.

Study Design and Statistical Analysis

The simple analysis used in this study was limited in that it ignored possible bias associated with randomized cluster sampling. The randomized cluster sampling was mandated by the needs of the overarching study. Reasons for cluster randomization include minimizing intervention contamination (individuals in one intervention group

receiving information intended for the other group) and feasibility considerations (training can occur for all clinic staff at one time, with all staff in a clinic using the same protocol delivery method). The design has been used to reduce threats to study validity such as variable adherence to a protocol or differences in provider skill levels (Glynn et al., 2007). Cluster randomized designs, however, are perceived to have an inherently greater risk of bias (Puffer, Torgerson, & Watson, 2003), in that members in the same clinic could be influenced by factors inherent in the clinic, rather than as an effect of an intervention, statistically referred to as intraclass correlation (Wojdlyla, 2005). Chance imbalances in covariates may be more likely with cluster randomized designs (Glynn et al., 2007). It is also possible that effect sizes may be smaller with a cluster randomized design (Glynn et al., 2007).

Large sample sizes can help mitigate the perceived risks of the randomized cluster design (Glynn et al., 2007). In this study, all eligible providers who agreed to participate were enrolled, and a large number of caretakers were enrolled at each clinic. Other measures that can mitigate the perceived risk are stratified clustering with relatively homogeneous strata (Glynn et al., 2007). In studies that include both providers and patients, chance differences in provider group characteristics can be partially mitigated by similarities in patient characteristics across the groups (Glynn et al., 2007). The provider sample in this study was not homogeneous across arms; the eIMCI arm contained younger providers on average by approximately 5 years, and there were more females in the pIMCI arm. There is no current evidence that suggests differences in mobile application or paper protocol use based on gender. The age difference was not a concern, as the average age for eIMCI and pIMCI users was 37 and 42, respectively, neither of

which would indicate a large enough gap or being very young or very old that might perform differently with each platform. The providers' years of experience as a provider and the years of experience using IMCI was not collected for this study, which was a limitation; however, all providers in Tanzania do receive IMCI training by mandate, although it is known that the protocol has not been consistently used (Bryce, 2005b).

Mixed-method statistical analyses can account for the effect of intraclass correlations and chance differences between participant groups (Glynn et al., 2007; Wojdlyla, 2005). Subsequent analyses of this data, and analysis of the data from the overarching RCT, should include evaluation of the effect of clustering (Glynn et al., 2007), by using mixed-model or general estimating equation analyses.

Provider Motivation and Compensation

An influence on provider performance in this study may have revolved around provider motivation and compensation. The question of provider compensation was not easy for researchers to address when weighing various options. Provider salaries may typically be quite meager in sub-Saharan Africa and may become only barely adequate with supplementation from outside sources such as patient side payments or foreign development projects.

One study implementing a results-based payment system revealed that formal salary and feedback incentives were a critical component of motivation to provide high-quality care, according to provider interviews (Songstad, Lindkvist, Moland, Chimhutu, & Blystad, 2012). Another study, however, found that informal payments, or those paid outside of normal salary provisions (often by patients), did not motivate providers to

exert greater effort towards their patients, and there was less consistency and quality in the overall care that providers receiving external payments gave (Lindkvist, 2012).

The researchers of this study faced a dilemma in considering payment for providers for their participation in the study and to use the interventions in the clinics. Not wanting to influence adherence by paying the providers, researchers ultimately abstained from offering providers compensation, but did pay a small fee to supervisors in all clinics (paper and electronic) in order to compensate them for the small amount of extra supervising they were requested to perform. However, a critical influential factor may have thus resulted from this decision in that it was possible that fewer gains could be acquired in the absence of any provider payment system. Despite the research teams' intentions to reduce the likelihood of persuasion to adhere by not offering financial incentive, it is possible that the decision may have actually negatively influenced adherence to the intervention. However, providers did not receive compensation in either arm; therefore, it may be inferred that the effect would be equal in both arms.

Potential Sources of Bias

The potential influence of demand characteristics bias on the think-aloud evaluation has been discussed earlier in this chapter. Another potential influence source of bias was via the presence of an observer during the clinical encounter, possibly initiating an observer effect and altering the performance of providers participating in the study. Although the presence of an observer has been found to positively affect performance in some studies (Alvero et al., 2008), this was not considered to be a significant influence, as any effect may be assumed to distribute equally across participants in both arms.

Language Barriers

A final limitation of this study was the language deficit the PI of this dissertation research possessed, having learned functional but clinically limited Swahili while in the country. While all indigenous study team and staff members spoke English as a second language, language barriers within the team remained a concern. Several instances occurred in which understanding about data collection methods and study coordination was taken for granted by all research team members and had to be restated or clarified to ensure cohesion.

Conducting Dissertation Research as a Component of a Larger Study

Data for this study were collected during a large, multisite, and dual institutional international research project that accommodated numerous facets of scientific exploration. There were numerous benefits and challenges of conducting this dissertation research as a component of a larger overarching study. Because each institution involved was awarded a specific amount of grant funds to carry out their respective projects, together each was able to conduct a larger study with more provisions and a larger sample. In addition, the talents and knowledge of the interdisciplinary team enhanced the quality and depth of scientific exploration. Because of the wide breadth of relevant disciplines involved in the overall project, results will be relevant to a broad audience of nursing, information technology, medical, and public health audiences.

However, there were also many decision-makers influencing the study design that required some degree of effort to accommodate. There was less flexibility to negotiate the dissertation study design than would have occurred with an isolated study. Components

that were under the sole provisions of the PI of this study, such as usability testing, could only be conducted during specific time frames, using specific resources and personnel, in order to accommodate all study partner needs and the overall study structure. The researcher wholeheartedly endorses dual institutional research partnerships, and emphasizes the importance of establishing detailed and explicit understanding and written agreement covering all research questions, responsibilities, publications, and monetary accountabilities prior to commencement.

Future Research

Many ICT researchers have found difficulty in demonstrating the impact of technology in low-resource regions due to limited breadth of research metrics, and a commonly favored evaluation framework of a-priori outcomes rather than actual field observation or experience (Kleine, 2009). Expanding both of these limits is necessary to accurately evaluate the impact of ICT. In order to achieve deep understanding of the motivations of health workers and influences of their performance levels, comprehensive qualitative studies to determine providers' *values* and perceived *barriers* to the provision of quality care would provide future developers with the needed insight to develop mechanisms to overcoming such barriers. Future research may explore potential relationships between provider's perceived barriers to communication and performance to determine how these perceptions influence the greater outcome.

Because the potential influence of mobile technology on provider motivation has been hypothesized but is yet to be understood, an implementation study on the use of ICT to enhance provider motivation and performance may be of great value. Using data that are automatically generated from the eIMCI protocol, quantifiable performance feedback

may be given to providers and their supervisors. This strategy draws from "gamification" technique, which is the integration of game theory and methods such as achievement rewards and competition, into nongame environments to incentivize practice of specific behaviors (Frey, 2012). Though using a recognition system is not a new concept to promote motivation and performance, doing so via ICT may effectively and inexpensively enable health workers to engage in their work and shift from an inadequate, externally based rewards system to becoming internally motivated to perform. While many industries are leveraging this concept to influence desired behavior, little has been done to use this strategy in healthcare. This approach may produce a significant impact on the challenging problems of provider motivation and performance.

Formal postimplementation research utilizing multiple key informants and stakeholders should also be commenced in order to re-evaluate fit and workflow of the intervention, as well as perceived usefulness and utility within the deployment environment. Complex cultural considerations were outside the scope of this study, as this study primarily focused on the immediate intervention effect. Evaluation of the presence of technology, as it influences provider and patient perceptions of the clinical encounter through use of qualitative interviewing and ethnographic techniques, is recommended. Evaluating the cost and resource demand for scaling and wide implementation is also necessary.

Baseline caretaker knowledge, without any standardized care intervention, must also be explored in order to fully understand the scope of health literacy deficiencies in Tanzania, and the true impact of ICT interventions aimed at improving such deficits.

In terms of improving caretaker key information point knowledge, several measures may be taken in future research. The communication of the last key information point, the duration to administer medications, may be considered for redesign in future versions of eIMCI. Mechanisms to further condense or strip away information may be built into the information delivery in order to accommodate potential limits in short-term memory load. Building in provider prompts to ask caretakers to repeat back key information points during and at the conclusion of the clinical encounter may yield increased caretaker recall. It is also recommended to conduct qualitative research on the educational video to further hone the delivery of the information that caretakers should know upon the completion of the visit. Incorporating the use of culturally appropriate pictographs may be another strategy to improve caretaker recall rather than videos.

Significance

Clinical Significance

Studying the effects of enhanced provider-caretaker communication provides an essential basis to establish foundational knowledge towards ending unnecessary child mortality in low-resource contexts. The next logical course of action will be to examine the implications on actual child health outcomes following similar intervention measures. Determining what influence use of the mobile platform in the clinical context has on actual implementation of care plans in the home, if any, is necessary. Such research may then lend powerful evidence regarding policy implications of the results.

Finally, widely disseminating findings at local and international levels of what knowledge has been discovered, and what does and does not work towards

implementation, is of the most paramount value for the all stakeholders in the global health community.

Recommendations for Future mHealth Projects

Many ICT projects in sub-Saharan Africa are viewed by locals as transitory (and are in fact so) (*Mobile technology for community health in Ghana*, 2012), thus it is imperative to determine a long-term plan for the intervention that is supported at both clinic and government levels, as well as clearly identified benefits to stakeholders at all levels in order to be taken seriously and maximize success. While this project conducted ongoing logic-driven, organized evaluation of the ICT system being implemented, limited gains could be achieved using any system in the absence of such measures (Kaufman, Roberts, Merrill, Lai, & Bakken, 2006). Formally conducting requirements analyses to enhance initial prototype design, followed by onsite rapid iteration, is essential (Fraser & Blaya, 2010). Taking the utmost care to fit the product with the clinical workflow, rather than expecting providers to adapt to an application workflow, is further critical. Likewise, accommodating a wide range of user ability is needed. The usability testing conducted during Aim 1 development further heightened the efficacy and reliability of the eIMCI intervention, and is highly recommended for future projects.

Many development projects in low-income settings are constrained by limited resources. For projects with limited means to access sufficient personnel or time, an absolute minimum of a walkthrough or some kind of exposure to actual use environments is vital. While this is not always possible due to development occurring in countries other than those which an intervention is to be deployed, a "virtual walkthrough" may be another option that weighs in as a distant second for initial prototyping. If neither is

possible, allowing sufficient time before deployment for iteration once the product reaches its use environment may be a last resort. In addition, power supply for an electronic system may be a challenging factor to navigate in low-resource settings. Ideally, unpredictable power supplies and electrical surges may be addressed by use of generators, solar chargers, and surge protectors if resources permit (Fraser & Blaya, 2010), though none of these solutions were within reach of this study. However, the low cost and power requirements of mobile phones compared to computers or laptops allow the mobile platform to be a more feasible mechanism to develop electronic systems in sub-Saharan Africa and other low-resource regions (Marcelo, Adejumo, & Luna, 2011). Further, it is recommended to "code-in-country" whenever possible as well to maximize use of local resources in all possible capacities to promote sustainability and contribution to the environment.

While it was established that training time was sufficient for learning the mechanical actions of how to use the application and understanding its purpose, the time allotted was not sufficient to achieve adoption. Perhaps the most significant, and rather obvious, lesson learned is how imperative it is to follow up with a strong presence in the clinic immediately following training to reinforce training and allow newly trained providers the opportunity to practice their freshly acquired knowledge and skills. There was a significant delay (4 months) between the time of training and data collection for the sample described in this study. While it was hoped that the providers would use the protocols in the interim, neither paper nor electronic delivery methods were practiced with. One of the contributors to this problem in the electronic arms may have been that while researchers were relieved to be able to charge and secure the phones in supervisor's

offices at night, at times, supervisors were not always present in the clinics. Therefore, providers were disallowed from consistently being able to access the phones when the person with the key or the research team was not in the clinic collecting data. This not only presented a physical barrier to using the protocol tools, but also may have sent a message that enforced a belief that the intervention was transitory and thus not critical to adopt. The aforementioned points illustrate the essential need to establish actionable buy-in and support from clinic in-charges and supervisors, as well as establish a feasible plan for access to participate in the intervention.

In consideration of caretaker health literacy and the ability to carry out treatment plans at home, far too few interventions focus sufficient attention towards the end product of intervention deployment. The researcher greatly emphasizes the need for end-to-end evaluation of an intervention, not solely focusing on clinical interventions, but also the implications and barriers to final achievements of such intervention *in the home* once clinical stages are completed. As stated in the significance section of this study, while improved clinical care is often the focus of sub-Saharan African child-under-5 research and development, little may be fully leveraged without caretaker inclusion to finalize the realization of such measures.

When nonindigenous researchers are heading research and development projects in low-resource regions, two of the most crucial actions to successfully implement electronic systems are to formally involve local leadership, and actively recruit support from local staff members (Fraser & Blaya, 2010; Marcelo, Adejumo, & Luna, 2011). Such partnership and collaboration is culturally essential, and such arrangement provides the knowledge and experience of all groups involved (Marcelo, Adejumo, & Luna, 2011).

Whatever effort is necessary to secure strong, positive relationships among local and foreign stakeholders, even from the onset of idea initiation, is of vital importance for the entire lifespan of the project. In terms of achieving scalable and sustainable ICT implementation, three essential elements may promote long-term success of electronic system development in low-resource regions: 1) partnership and collaboration with local leaders, 2) implementing interoperability standards in order to enable sustained maintenance and growth, and 3) utilizing the mobile platform for implementation (Marcelo, Adejumo, & Luna, 2011). This study implemented each of these recommendations.

On a final and most essential note, compared to the ubiquity of non African developers and researchers in Africa, a critical dearth of indigenously originated research currently exists in ICT development, and has resulted in an alarming lack of local influence in project development, implementation, and policy (Gitau, Plantinga, Diga, Hutchful, 2011). Ironically, it is these individuals from which the most relevant ideas, contribution, and leverage come. While this study partnered heavily with local authorities and associates, there is yet need for a great deal more local research than is currently being produced in Africa. Gitau, Plantinga, Diga, and Hutchfield (2011) recommend two strategies to address this problem. First, greater local government and donor accountability to promote and incentivize research that is designed, implemented, and disseminated by indigenous researchers is needed. Second, distinguishing greater credibility and merit to projects that do demonstrate diversity and firmly established inclusion of indigenous researchers, as well as diversifying publication methods in order to widen the dissemination of such research, is needed. These strategies will require a

multilayered and committed approach to widen and shift development priorities. However, such measures are not only ethically called for, they are entirely necessary to produce sound and effective solutions to the unique problems facing the developing world. Foreign researchers may promote this agenda by prioritizing indigenous inclusion and authorships in all research conducted abroad.

Implications

An extensive body of literature exists that confirms that UCD is an effective tactic to achieve maximum usability and effectiveness of a product. The World Health Organization recommends that usability processes become part of the mHealth strategic plan in order to improve success of such implementations (McCurdie et al., 2012). However, despite that it has been known for years that UCD works, these techniques often remain ignored. In this study, Aim 1 exhibited multiple ways that UCD processes can be incorporated into the design and development of an mHealth intervention implemented in a low-resource region. While noting that adaptations may be needed when using traditional UCD methods in order to overcome potential cultural barriers that may exist between the researcher and participants, Aim 1 of this study demonstrated that not only is UCD mandatory to comply with recent WHO recommendations, the approach is entirely feasible in cross-cultural settings, even in projects with limited resources.

Aim 2 of this study indicated that both the delivery and recall of key information points were improved overall with the use of eIMCI. In cases where the provider adhered to the communication prompts embedded within the protocol, the caretaker more often recalled these points than when the clinical encounter was guided by the paper protocol. As caretakers possess this knowledge, it may be given that an improved ability to fulfill

treatment plans indicated by the child's provider will follow. Through regular practice of the communication exchange between the provider and caretaker, health literacy may rise and child mortality rates may improve.

Conclusions

Few formal usability evaluations and UCD processes have been published in the domain of global health thus far. UCD and usability evaluation are uncommon in low-resource settings compared to the vast emergence of mHealth projects in the developing world. However, the UCD process is not only critical to maximize product efficacy, it is also inherently well suited to respond to unknown user and field conditions needing site-specific customization. Some degree of UCD is feasible in any project. The more unfamiliar developers are with the use environment, the more critical it is to adopt, and specifically so when developers are not innate members of the user group (Moore, Bias, Prentice, Fletcher, & Vaughn, 2009). Many of the practical issues encountered when deploying electronic health systems in low-resource settings can be identified and solved during the beginning stages of project development (Fraser & Blaya, 2010). The final result of this development process was a product that was customized to respond to the users, clinical environment, and available resources in the deployment setting.

In addition, little has been previously studied about caretaker health literacy and provider-caretaker communication patterns in Tanzania. Using the multifaceted approach deployed in this study, the eIMCI mobile application supported correct navigation of the protocol for providers, and supported the delivery of key information points to caretakers necessary to optimize their ability to implement care once home. This study will inform subsequent research evaluating communication in pediatric care in low-resource regions,

and the development of interventions that seek to promote its improvement in order to contribute to the development of sustainable, evidence-based care for children. The multiple unique and challenging elements surrounding child health such as health literacy, female empowerment, and strained resources will require a great deal of knowledge and a fundamental paradigm shift to address. By providing access to interventions possessing innovation, creativity, and customized site-specific adaptation, such as those potentially offered via the mobile platform, such paradigm shift may be fostered (Lucas, 2008).

APPENDIX A

TEST CASE SCENARIOS

Case #	Scenario	Outcome
1	A 3-year-old child is brought to the clinic. The mother reports the child has been lethargic but has no symptoms of cough or diarrhea. The child's weight is well below normal on the RCH chart. T=35.3, RR=49.	Malnutrition
2	A 5-year-old child is brought to the clinic with diarrhea that has been ongoing for the past 3 weeks. While the mother reports that the child has not been unusually irritable, you offer the child some water and notice that he drinks it eagerly. RR=42, T=37.5, skin pinch is normal, eyes appear normal.	Persistent diarrhea without dehydration
3	A 4-month-old child is brought to the clinic who has had diarrhea for 3 days. The child appears extremely lethargic and is unable to drink. T=38.1	Acute diarrhea with severe dehydration
4	A 3-year-old child is brought to the clinic who has had a cough for the past 4 days. No stridor is heard, nor is the child wheezing. RR are 48 the first time measured and 50 the second time.	Upper respiratory tract infection
5	A 1-year-old child is brought to the clinic. Her mother reports that she has had a cough for 2 months and has had intermittent diarrhea for the past 6 months. She is able to breathe and no wheezing or stridor is heard upon auscultation. T=36.4, RR=40. The child's weight for age is very low when the RCH card is checked.	Symptomatic HIV infection unlikely
6	A 16-month-old child is brought to the clinic for diarrhea which has been ongoing for the past 4 days. The mother reports that the child has been very irritable. You assess the abdominal skin pinch and the response is slow. RR =43, T=37.8	Acute diarrhea with some dehydration
7	A 3-year-old child is brought to the clinic with a fever. The mother reports that the child has no cough or other symptoms but has been very irritable. You observe abdominal tenderness. RR =43, T=37.8	Possible intestinal bacterial disease
8	A 2-year-old child is brought to the clinic. His mother reports that he has diarrhea with blood in it for the past 2 days. The child takes a drink of water when offered. T=37.9, RR=40.	Dysentery
9	A 6-month-old child is brought to the clinic with a cough. The mother reports that the child has been coughing for the past week but hasn't seemed to have any difficult breathing. You listen to the breath sounds and cannot hear any stridor or wheezing. T=38.9, RR=52 on the first measurement and R=53 on the second measurement.	Pneumonia

Appendix A continued

Case #	Scenario	Outcome
10	An 18-month-old child is brought to the clinic who is and has difficulty breathing. T=38.0 he child has not had any diarrhea. The mother reports that the child has been very tired but is eating and drinking adequately. You administer one cycle of inhaled bronchodilators and the child's breathing improves.	No respiratory distress
11	A 5-month-old child is brought to the clinic. Her mother reports that she has had diarrhea for the past month, however her disposition has been normal and she is drinking normally. You check her abdominal skin pinch, which is also normal. T=37.6, RR=44.	Persistent diarrhea
12	A 3-year-old child is brought to the clinic with a cough. The mother reports that the child has been coughing for the 3 days week but hasn't seemed to have any difficulty breathing. You listen to the breath sounds and cannot hear any stridor or wheezing. T=36.9, RR=52 on the first measurement and R=49 on the second measurement.	Upper respiratory tract infection
13	A 4-year-old child is brought to the clinic who has been coughing for 2 weeks and is currently having difficulty breathing. Stridor can be heard upon auscultation. RR=51, T=37.9.	Severe pneumonia or very severe disease
14	A 2-year-old child is brought to the clinic who is crying inconsolably and is clutching her left ear. Upon examination, you see that the ear is swollen and slightly reddened. Her grandmother who has brought her to the clinic states that she has not had any cough, diarrhea, or other symptoms, but has been worried because the child has been so distressed. T=38.1, RR=40.	Mastoiditis
15	An 18-month-old child is brought to the clinic. Her mother reports that she has been crying and has a slight ear discharge for the past 8 days. No other symptoms are present. T=37.8, RR=43.	Acute ear discharge
16	A 3-year-old child is brought to the clinic. The mother reports that he has been restless and irritable and has been vomiting for the past 2 days. When you offer the child some water, he hardly drinks any of it. T=37.1, RR=40.	Very severe disease
17	A 13-month-old child is brought to the clinic with a cough. Upon examination you find a rash on her back and the front of her legs. No other symptoms are present. T=37.9, RR=44.	Measles
18	A 4-year-old child is brought to the clinic with a rash on his arms and legs. Upon examination you notice his eyes are red and find an ulcer at the right corner of his mouth. No other symptoms are present. T=37.8, RR=44.	Measles with mouth complication

Appendix A continued

Case #	Scenario	Outcome
19	A 30-month-old child is brought to the clinic crying and holding on to her right ear. Her mother reports she has not had any ear discharge or any cough. Upon examination, no swelling can be found. T=37.7, RR=42.	Acute ear infection
20	A 7-month-old child is brought to the clinic with a cough. Her mother reports that she had a fever 2 days ago and has been restless since then. No stridor is heard but the child is wheezing. You administer 2 cycles of bronchodilators and the child's breathing does not improve. T=37.8, RR=42.	Respiratory distress
21	A 3-year-old child is brought to the clinic with a cough. The grandmother shows you a rash that has developed on his chest and back but no skin abscess is observed. Upon examination, you observe abdominal tenderness in the child. T=37.9, RR=46.	Possible intestinal bacterial disease
22	A 25-month-old child is brought to the clinic. The mother reports that the child has had diarrhea for the past 3 days. Upon examination, the abdominal skin pinch is slow and when you offer the child water, she drinks it eagerly. T=37.9, RR=41.	Acute diarrhea with some dehydration
23	A 9-month-old child is brought to the clinic crying. His mother reports slight fluid draining from his left ear for the past 2 days but no cough or fever. T=37.3, RR=43.	Acute ear discharge
24	A 21-month-old child is brought to the clinic with a cough. Her mother reports no fever or diarrhea. Her disposition is normal and she is drinking normally. Her weight is normal when compared to the RCH chart but she has some palmar pallor. T=37.0, RR=42.	Anemia
25	A 2-year-old child is brought to the clinic. His mother reports that he had a fever 2 days ago but he has not had a cough or diarrhea. The child weighs 8kg. T=37.2, RR=45.	Malnutrition
26	A 28-month-old child is brought to the clinic with a fever. His mother reports he has had a cough for the past 2 weeks. The child's respiratory rate is measured at 53 the first time and 51 the second time. No other symptoms are present. T=37.8.	Pneumonia
27	A 7-month-old child is brought to the clinic. Her mother reports she has been coughing for a week. Upon auscultation, no stridor or wheezing are heard. T=37.1, RR=43.	Upper respiratory tract infection
28	A 10-month-old child is brought to the clinic crying. Her mother reports that she has had slight pus draining from the ear for the past 2 weeks and has been especially restless for the past 3 days. The mother also mentions that the child has not had a cough during this time. T=37.7, RR=43.	Chronic ear discharge

Appendix A continued

Case #	Scenario	Outcome
29	A 7-month-old child is brought to the clinic. The mother reports she has been coughing for the past 8 days but has not had a fever. She is drinking adequately but has been very tired. Upon auscultation, wheezing is heard. The wheezing persists after 3 administrations of a bronchodilator. T=37.2, RR=47.	Severe pneumonia or very severe disease
30	A 19-month-old child is brought to the clinic. The mother reports she has had a cough for the past month. Upon examination, no stridor or wheezing can be heard. T=37.6, RR=45.	Persistent cough
31	A 5-year-old child is brought to the clinic with a fever, T=37.8. His grandmother reports that he has had a cough for a week with intermittent fevers, and mentions that the child's older brother has TB. Respiratory rate is 55 on the first measurement and 53 on the second measurement. The child's weight for age is very low when the RCH card is checked.	Suspected symptomatic HIV infection
32	A 6-month-old child is brought to the clinic. His mother reports diarrhea for the past 5 days. The child appears restless. The abdominal skin pinch is slow. T=37.9, RR=44.	Acute diarrhea with some dehydration
33	An 18-month-old child is brought to the clinic with a cough. His mother reports that he has had intermittent diarrhea for the past month. The child's disposition is normal as is his abdominal skin pinch. T=37.3, RR=40.	Persistent diarrhea
34	A 1-year-old child is brought to the clinic with a fever. The mother reports no cough or diarrhea. The child's disposition is normal and no other symptoms are present. T=37.9, RR=42.	Perform mRDT
35	A 33-month-old child is brought to the clinic. Her mother reports that she has had slight ear discharge for the past 10 days but has not had a cough or fever. Upon examination, the child's neck and armpit glands are enlarged. No other symptoms are present. T=37.2, RR=45.	Check HIV status of child
36	A 3-month-old child is brought to the clinic crying. Her mother reports a fever for the past 2 days but no cough or diarrhea. Upon examination, the child's right ear appears slightly reddened. T=37.7, RR=41.	Mastoiditis
37	A 14-month-old child is brought to the clinic. His mother reports the child has had a rash for the past 3 days on his arms and thighs. Upon examination, the child's eyes are red and his cornea's are clouded. T=37.8, RR=44.	Severe complicated measles
38	A 27-month-old is brought to the clinic. Her mother reports she has not been able to get the child to drink over the last couple of hours. Upon examination, the abdominal skin pinch is very slow. T=37.7, RR=40.	Severe dehydration

Appendix A continued

Case #	Scenario	Outcome
39	A 5-year-old child is brought to the clinic with a cough. Upon auscultation, stridor but no wheezing can be heard. T=37.9, RR=51.	Severe pneumonia
40	A 3-year-old child is brought to the clinic crying incessantly. The worried mother reports she has had a fever but no other symptoms. Upon examination, you observe a slight fluid discharge from the right ear. T=38.0, RR=43.	Acute ear discharge
41	A 5-month-old child is brought to the clinic. Her mother reports a fever over the past week and a mild cough. T=37.8, RR=41.	Persistent fever
42	An 11-month-old child is brought to the clinic with a cough. No other symptoms are found. A urine dipstick tests positive for nitriles. T=37.9, RR=46.	Urinary tract infection
43	A 22-month-old child is brought to the clinic. The mother reports he has had intermittent diarrhea for the past 3 weeks but reports no changes to his disposition. Upon examination, you check his skin pinch which is normal. T=37.7, RR=41.	Persistent diarrhea
44	A 2-year-old child is brought to the clinic. The mother reports an intermittent fever for the past 10 days and a cough. No other symptoms are reported. T=38.0, RR=41.	Persistent fever
45	A 15-month-old child is brought to the clinic crying. Her mother reports no coughing, diarrhea or rash but the child has been irritable for the past 2 days. Upon examination, you observe abcesses along the child's arm. T=38.0, RR=43.	Bacterial infection
46	A 5-year-old child is brought to the clinic. Her mother reports that she complains of difficulty breathing for the past 2 days. Upon auscultation, wheezing but no stridor is heard. You administer a bronchodilator, but the wheezing subsides only after the second dosage. T=37.4, RR=47.	No respiratory distress
47	A 14-month-old child is brought to the clinic. His mother reports diarrhea for the past 2 days and has found blood in the child's stool. No other symptoms are present. T=35.3, RR=44.	Dysentery
48	A 29-month-old child is brought to the clinic. Her mother reports she has been unusually lethargic but has no cough, diarrhea or fever. The child's weight is normal when compared to the RCH chart. You are able to test for Hemoglobin and the child's level returns as Hb = 3g/dl. T=37.1, RR=45.	Anemia
49	A 4-year-old child is brought to the clinic with a cough and a runny nose. His mother reports a fever over the past few days and a decrease in urination. A urine dipstick tests negative for both leukocytes and nitriles. T=37.9, RR=42.	No urinary tract infection

APPENDIX B

PROVIDER OBSERVATION FORM:

COMMUNICATION COMPONENTS

<table>
<tr><td>1.</td><td colspan="3">What <u>diagnosis (es)</u> or classification(s) does the health worker tell the CT as the problem(s) of the child?</td></tr>
<tr><td></td><td colspan="3">1) |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|
2) |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|
3) |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|
|__| N/A Health worker did not tell the CT ANY problem of the child</td></tr>
<tr><td>2.</td><td>Does the HW ask the CT if s/he understood the health problem of the child</td><td>Yes</td><td>No</td></tr>
<tr><td>3.</td><td>Does the HW ask the CT to repeat information for the child's problems</td><td>Yes</td><td>No</td></tr>
<tr><td>4.</td><td>Does HW explain to CT how to administer this treatment at home?</td><td>Yes</td><td>No</td></tr>
<tr><td>a.</td><td colspan="3">If yes, for which drugs? a. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| b. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| c. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|</td></tr>
<tr><td>5.</td><td>Does HW ask CT to repeat instructions how to administer this treatment at home?</td><td>Yes</td><td>No</td></tr>
<tr><td>a.</td><td colspan="3">If yes, for which drugs? a. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| b. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| c. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|</td></tr>
<tr><td>6.</td><td>Is CT able to correctly repeat instructions how to administer this treatment at home?</td><td>Yes</td><td>No</td></tr>
<tr><td>a.</td><td colspan="3">If yes, for which drugs? a. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| b. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| c. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|</td></tr>
<tr><td>7.</td><td>Is the first dose of this medication given at the facility?</td><td>Yes</td><td>No</td></tr>
<tr><td>a.</td><td colspan="3">If yes, for which drugs? a. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| b. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| c. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|</td></tr>
<tr><td>8.</td><td>Does the HW ask the CT if s/he has any questions about this treatment?</td><td>Yes</td><td>No</td></tr>
<tr><td>a.</td><td colspan="3">If yes, for which drugs? a. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| b. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| c. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|</td></tr>
<tr><td>9.</td><td>Did HW advise the CT on the use of ITN?</td><td>Yes</td><td>No</td></tr>
<tr><td>10.</td><td>Did HW advise the CT on feeding?</td><td>Yes</td><td>No</td></tr>
<tr><td>11.</td><td>Does the HW tell the CT when to return to the clinic?
If Yes:</td><td>Yes
Number of days |__|__|</td><td>No</td></tr>
<tr><td>12.</td><td colspan="3">Does the HW explain to the CT to return if the child:</td></tr>
<tr><td></td><td>a. Is not able to drink or breastfeed</td><td>Yes</td><td>No</td></tr>
<tr><td></td><td>b. Becomes sicker</td><td>Yes</td><td>No</td></tr>
<tr><td></td><td>c. Develops fever</td><td>Yes</td><td>No</td></tr>
<tr><td></td><td>d. Develops fast breathing</td><td>Yes</td><td>No</td></tr>
<tr><td></td><td>e. Develops difficult breathing</td><td>Yes</td><td>No</td></tr>
<tr><td></td><td>f. Develops blood in stool</td><td>Yes</td><td>No</td></tr>
<tr><td></td><td>g. Drinks poorly</td><td>Yes</td><td>No</td></tr>
<tr><td></td><td>h. If symptoms persist</td><td>Yes</td><td>No</td></tr>
<tr><td>13.</td><td>Does the HW ask CT to repeat the information on when to return immediately?</td><td>Yes</td><td>No</td></tr>
<tr><td>14.</td><td>Did the HW ask the CT if s/he had any questions during the consultation?</td><td>Yes</td><td>No</td></tr>
<tr><td>15.</td><td colspan="3">If yes in item 88, what was/were the question(s) asked by CT?
a. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|
b. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|
c. |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|</td></tr>
<tr><td>16.</td><td colspan="3">What was/were the response(s) from the HW to the question(s) asked by the CT in item 79 above?</td></tr>
</table>

APPENDIX C

CARETAKER INTERVIEW FORM

Ningependa kukuliza maswali machache kuhusu tatizo na matibabu ulipata kwa mtoto leo

1.	Daktari alikuambia mtoto alikuwa na shida/ugonjwa/tatizo gani leo?		
	1).|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|		
	2) |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|		
	3) |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|		
	|__| **N/A** Daktari **hakuniambia** matatizo yeyoye za mtoto gani leo		
2.	Ni DALILI zipi/gani za hatari ambazo daktari alikuambia ukiziona umrudishe mtoto zahanati/katika kituo cha afya haraka? (*Weka vema(√) dalili zote zilizotajwa na mzazi/mlezi na usimsomee kipengele chochote)*		
	a. Mtoto akiwa hawezi kunywa au kunyonya	|__| Imetajwa	|__| Haikutajwa
	b. Mtoto akiwa mgonjwa zaidi (akizidiwa)	|__| Imetajwa	|__| Haikutajwa
	c. Mtoto akipata homa	|__| Imetajwa	|__| Haikutajwa
	d. Kupumua haraka	|__| Imetajwa	|__| Haikutajwa
	e. Kupumua kwa shida	|__| Imetajwa	|__| Haikutajwa
	f. Damu katika haja kubwa	|__| Imetajwa	|__| Haikutajwa
	g. Mtoto akiwa anakunywa kwa shida	|__| Imetajwa	|__| Haikutajwa
	h. Dalili zinaendelea	|__| Imetajwa	|__| Haikutajwa
3.	a. Daktari alikuambia umrudishe mtoto kituoni baada ya siku kadhaa ikiwa hapati nafuu?	|__| Ndio	|__|Hapana
	b. Kama ndio, daktari alikuambia umrudishe baada ya siku ngapi ikiwa mtoto hapati nafuu? |__|__| siku |__| Siku yoyote |__| Hafahamu		
4.	Je, ulishauriwa mtoto huyu apewe rufaa/apelekwe katika hospitali kubwa zaidi kwa matibabu zaidi siku ya kwanza ulipomleta hapa kituoni?	|__| Ndio	|__|Hapana
5.	Ikiwa ndio, andika matokeo ya rufaa hiyo:_____ _____ _____		
6.	Je, dawa zote alizoandikiwa mtoto huyu na daktari siku ya kwanza hapa kituoni ulizipata?	|__| Ndio	|__|Hapana
7.	Ni dawa gani alizoandikiwa mtoto huyu lakini hazikupatikana hapa kituoni?(*linganisha katika daftari*) a.|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| b.|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| c.|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__| d.|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|		
8.	Ulifanya nini kuhusu hizo dawa alizoandikiwa mtoto ila hazikupatikana hapa kituoni?		

<table>
<tr><td></td><td colspan="3">____
____</td></tr>
<tr><td>9.</td><td>Je, unaamini kuwa uliweza kumpa mtoto dawa zote alizoandikiwa na wataalamu wetu kama ulivyoelekezwa bila matatizo yoyote?</td><td>|__| Ndio</td><td>|__|Hapana</td></tr>
<tr><td>10.</td><td colspan="3">Ulimpaje mtoto dawa alizoandikiwa na daktari wetu katika kituo hiki?
a. Dawa
|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|
b. Kiasi cha dawa kila mara (dose)
|__|__|__|___|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|
c. Mara ngapi kwa siku |__|__| d. Jumla ya siku ulizotakiwa kumpa mtoto dawa hii |__|</td></tr>
<tr><td>11.</td><td colspan="3">Ulimpaje mtoto dawa alizoandikiwa na daktari wetu katika kituo hiki?
a. Dawa
|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|
b. Kiasi cha dawa kila mara (dose)
|__|__|__|___|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|
c. Mara ngapi kwa siku |__|__| d. Jumla ya siku ulizotakiwa kumpa mtoto dawa hii |__|__|</td></tr>
<tr><td>12.</td><td colspan="3">Ulimpaje mtoto dawa alizoandikiwa na daktari wetu katika kituo hiki?
a. Dawa
|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|
b. Kiasi cha dawa kila mara (dose)
|__|__|__|___|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|
c. Mara ngapi kwa siku |__|__| d. Jumla ya siku ulizotakiwa kumpa mtoto dawa hii |__|__|</td></tr>
</table>

APPENDIX D

SPECIFIED DAYS TO RETURN FOR NONIMPROVEMENT OF PROBLEM

Problem Specified	Number of Days to Return
Pneumonia	2
Upper Respiratory Tract Infection (URTI)	5
Malaria	2
Urinary Tract Infection (UTI)	2
Possible Intestinal Bacterial Disease	2
Acute Diarrhea with Some Dehydration	5
Persistent Diarrhea	5
Dysentery	2
Acute Diarrhea Without Dehydration	5
Chronic Ear Discharge/Nonfebrile Ear Discharge	5
Acute Ear Infection	3
Measles with Eye or Mouth Complication	2
Soft Tissue Infection or Folliculitis	1
Impetigo or Minor Abscess	2
Some Malnutrition or at Risk of Malnutrition	5
Anemia	14

APPENDIX E

SIGNS OF WORSENING CONDITION

CORRESPONDING TO PROBLEM

Problem Specified	Signs of Worsening Condition
Pneumonia	• Unable to drink/Drinks Poorly • Becomes Sicker
Upper Respiratory Tract Infection (URTI)	• Unable to drink/Drinks Poorly • Becomes Sicker • Develops Fever • Develops Fast Breathing • Develops Difficult Breathing
Malaria	• Unable to drink/Drinks Poorly • Becomes Sicker
Urinary Tract Infection (UTI)	• Unable to drink/Drinks Poorly • Becomes Sicker
Possible Intestinal Bacterial Disease	• Unable to drink/Drinks Poorly • Becomes Sicker
Acute Diarrhea with Some Dehydration	• Unable to drink/Drinks Poorly • Becomes Sicker • Develops Fever • Develops Blood in Stool
Persistent Diarrhea	• Unable to drink/Drinks Poorly • Becomes Sicker • Develops Fever • Develops Blood in Stool
Dysentery	• Unable to drink/Drinks Poorly • Becomes Sicker • Develops Fever
Acute Diarrhea Without Dehydration	• Unable to drink/Drinks Poorly • Becomes Sicker • Develops Fever • Develops Blood in Stool

Appendix E continued

Problem Specified	Signs of Worsening Condition
Chronic Ear Discharge/Nonfebrile Ear Discharge	• Unable to drink/Drinks Poorly • Becomes Sicker
Acute Ear Infection	• Unable to drink/Drinks Poorly • Becomes Sicker • Develops Fever
Measles with Eye or Mouth Complication	• Unable to drink/Drinks Poorly • Becomes Sicker • Develops Fever
Soft Tissue Infection or Folliculitis	• Unable to drink/Drinks Poorly • Becomes Sicker
Impetigo or Minor Abscess	• Unable to drink/Drinks Poorly • Becomes Sicker • Develops Fever
Some Malnutrition or at Risk of Malnutrition	• Unable to drink/Drinks Poorly • Becomes Sicker
Anemia	• Unable to drink/Drinks Poorly • Becomes Sicker • Develops Fast Breathing • Develops Fever

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