**The application of a mobile phone-based system
for seeking healthcare and infectious disease
surveillance in Ghana: users' experiences**

SYNOPSIS OF

A user-centred evaluation of a mobile phone-based interactive voice response system to support infectious disease surveillance and access to healthcare for sick children in Ghana: users' experiences, challenges and opportunities for large-scale application

Part of a concept and pilot study for a mobile phone-based Electronic Health Information and Surveillance System (eHISS) for Africa

A thesis submitted by

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Contents

Acknowledgments

Publications that Form the Basis of this Thesis

1. **Brinkel J**, Krämer A, Krumkamp R, May J, Fobil JN. Mobile Phone-Based mHealth Approaches for Public Health Surveillance in Sub-Saharan Africa: A Systematic Review. International Journal of Environmental Research and Public Health 2014, 11(11):11559-82. *Impact factor 2.145 (2017).*

2. **Brinkel J**, Dako-Gyeke P, Krämer A, May J, Fobil JN. An investigation of users' attitudes, requirements and willingness to use mobile phone-based interactive voice response systems for seeking healthcare in Ghana: A qualitative study. Public Health 2017; 144:125-33. *Impact factor 1.441 (2017).*

3. **Brinkel J**, May J, Krumkamp R, Lamshöft M, Kreuels B, Owusu-Dabo E, Mohammed A, Bonačić Marinović A, Dako-Gyeke P, Krämer A, Fobil JN. A Mobile Phone-based Interactive Voice Response Algorithm to Support Guardians Caring for Diseased Children in Ghana – an Evaluation of User Experiences. Tropical Medicine and International Health 2017; 22(5):622-30. *Impact factor 2.541 (2017).*

4. Franke K, Krumkamp R, Mohammed A, Sarpong N, Owusu-Dabo E, **Brinkel J**, Fobil JN, Bonačić Marinović A, Asihene P, Boots M, May J, Kreuels B. A mobile phone based tool to identify symptoms of common childhood diseases in Ghana: development and evaluation of the integrated clinical algorithm in a cross-sectional study. BMC Medical Informatics and Decision Making 2018; 18(1):23. *Impact factor 2.134 (2017).*

Further Publications Related to the eHISS Research Project

5. Mohammed A, Franke K, Okyere PB, **Brinkel J**, Bonacic Marinovic A, Kreuels B, Krumkamp R, Fobil NJ, May J, Owusu-Dabo E. Feasibility of Electronic Health Information and Surveillance System (eHISS) for disease symptom monitoring: A Case of Rural Ghana. PLoS ONE 2018; 13(5):e0197756. *Impact Factor 2.78 (2017).*

6. Lamshöft M, Krumkamp K, **Brinkel J**, Kreuels B, Fobil JN, Owusu-Dabo E, Mohammed A, Bonacic Marinovic A, May J. How Health Information Systems Could Contribute to the Timely Surveillance of Infectious Diseases. Findings from a Pilot Study in Ghana. *To be submitted.*

List of Abbreviations and Acronyms

AGOO	Interactive mobile platform for health education, *UNICEF/Ghana*
BMBF	Federal Ministry of Education and Research (DE: Bundesministerium für Bildung und Forschung), *Germany*
BNITM	Bernhard Nocht Institute for Tropical Medicine, *Germany*
eHealth	Electronic Health
eHISS	A mobile-phone based Electronic Health Information and Surveillance System (eHISS) for Africa: concept and pilot study, *BNITM/Germany*
EVD	Ebola Virus Disease
FGD	Focus Group Discussion
GRADE	Grading of Recommendations Assessment, Development and Evaluation
GSPH	Ghana School of Public Health, *Ghana*
HCD	Human-Centered Design
ICT	Information and Communication Technology
IMCI	Integrated Management of Childhood Illness, *WHO*
ISO	International Organization for Standardization
IVR	Interactive Voice Response
KCCR	Kumasi Centre for Collaborative Research, *Ghana*
LMIC	Low- and middle-income countries
MDGs	Millennium Development Goals
mHealth	Mobile Health
MMS	Multimedia Message Service
PDA	Personal Digital Assistant
RCT	Randomized Controlled Trial
RIVM	National Institute for Public Health and the Environment (NL: Rijksinstituut voor Volksgezondheid en Milieu), *The Netherlands*
SDGs	Sustainable Development Goals
SMS	Short Messages Service
SUS	System Usability Scale
UKE	University Clinic Hamburg Eppendorf, *Germany*
UNICEF	United Nations Children's Fund
UTAUT	Unified Theory of Acceptance and Use of Technology
VRS	Vital Registration System
WHO	World Health Organization

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Introduction

Mobile health (mHealth), a sub-segment of digital and electronic health (eHealth), is defined as the application of mobile and wireless technology in the healthcare sector. Due to the rapid explosion of mobile technology in low- and middle-income countries in the last decades, mHealth has tremendous potential to change the face of health systems in those regions. In Ghana, where there are more mobile phones than inhabitants, mHealth offers significant solutions to meet two urgent needs of the health system at the same time, viz; (i) the crying need for nationwide access to life-saving health information, and (ii) the improvement of real-time data for improved surveillance of and response to infectious diseases. Although mHealth has become central to global health thinking, various implementation barriers still exist. One of the most significant is the process of user acceptance and adoption of the new technology, which still remains a neglected research area in sub-Saharan Africa. To minimize the risk of spending resources on interventions of questionable benefit, there is a strong need to include users in the design process of new mHealth interventions, and to carefully assess user needs and perceptions, as well as barriers to use and factors to enhance acceptance and adoption of the technology.

This synopsis is a synthesis of the findings of a three-year research study embedded within a larger research consortium that developed and piloted a mobile phone-based Electronic Health Information and Surveillance System for sub-Saharan Africa (eHISS). The synopsis is developed as a doctoral thesis, which focuses on system usability and acceptance among end-users of the system (caregivers of children) by soliciting their views on their experiences while using the system. The study followed a human-centred design (HCD) and applied the circle of research activities in accordance with the international standard. The HCD research circle was adapted to the developing-cycle of the eHISS project and consisted of the following research activities; (i) the assessment of the state of research, (ii) the innovative field test of a prototype of the eHISS system and an assessment of users' needs to drive the design, (iii) the evaluation of the clinical decision algorithm as backbone of the electronic system, and (iv) the evaluation of experiences with the system after a six-month pilot phase of the system. A manuscript was developed from each research activity for publication, thus making a total of four papers that form the empirical basis of this thesis.

The thesis has five chapters. The introductory chapter provides a background to mHealth in the global context with special focus on Ghana and highlights the importance of user perspectives and technology acceptance as key factors in implementing mobile health interventions. Furthermore, the importance of addressing user needs and engaging patients in the design process of mobile health interventions is discussed by providing insights into technology acceptance research, and an introduction of the approach of human-centred design is given. The methodology adopted in the introduction includes an overview of relevant publications and state of research on mHealth in Ghana. The chapter closes by highlighting main research

gaps and resulting research needs. Chapter two presents the objectives of the research activities and the four resulting published papers. In chapter three the eHISS research project, within which the thesis is embedded, is introduced. In addition, the human-centred design-developing circle, applied as conceptual framework for the research activities of the thesis, is presented. Chapter four summarizes the main results of the research activities. The chapter is organized in accordance with the human-centred design framework, namely: (i) understanding of the context and state of research (paper no. one), (ii) assessment of attitudes and user behaviour relating to the use of mobile technologies in the Ghanaian society and field test of the prototype of the mHealth interactive voice response (IVR) system (paper no. two), (iii) field test of the clinical decision algorithm as solution to identifying disease symptoms (paper no. three), and (iv) evaluation of users experiences after a six-month test phase of the IVR system (paper no. four). Chapter five summarises the workflow of the thesis, and critically reflects on its methodology. Furthermore, key statements derived from the doctoral project are presented and discussed, including the development of two possible future directions of the system. This chapter concludes the thesis with a summary of lessons learned from the eHISS project and the author's reflections/conclusions on the subject area.

1. Background and Public Health Significance

This chapter provides an introduction to mobile health in general, and the key role of end-users in implementing mHealth services in particular. First, an introduction to mHealth in the context of global public health, and a situation analysis of mHealth applications in Ghana is provided. Second, an overview of technology acceptance research models and human-centred design as methodological framework is given. Third, evidence gaps and research needs derived from the background to the subject matter are discussed.

1.1. Mobile Technology Innovations for Global Health

Health outcomes in low- and middle-income countries (LMICs) have been improved over the last several decades, and a remarkable achievement in global health has been made (1, 2). However, with the 2030 agenda for sustainable development in place, a new level of health needs and growing public expectations have arisen (3). Innovative and cost-effective solutions, responding to changing public needs and valued and trusted by the population are of highest priority to tackle global health challenges (4). Given its remarkable opportunities to provide economically viable and sustainable solutions, the use of mobile and wireless technologies for health, known as mobile health (mHealth), has experienced explosive interest in LMICs and is now central to global health thinking and in striving towards universal health coverage (5, 6). The potential of mHealth is driven by a powerful combination of factors including (i) the rapid developments in mobile technologies and applications, (ii) the continued growth in mobile cellular network coverage accompanied by an, (iii), explosive increase of cell phones usage rates and, (iv) growing investments of the private market due to possibilities for interoperability and integration in the existing digital health sector (7-9). In sub-Saharan Africa, mobile networks have reached far more people than any other advanced information and communication technology (ICT) in recent years, extending far beyond the reach of electrical grid and area-wide health infrastructure (10). As a result, the remarkable proliferation of mHealth has helped to address the challenges faced by health sectors in resource-limited countries in terms of quality and easily accessible health care at lower costs (11-13). For the last five decades not only various terms to define the dynamic and rapidly developing field of the application of information and communication technologies to the healthcare sector have been used, but also different definitions of mHealth (7, 14). Most recently, the term digital health has been introduced as an umbrella term including electronic health, telehealth and more (15). Furthermore, the World Health Organization (WHO) recently published a first approach towards a shared language to classify the different areas of technology-supported health interventions (16). For the purposes of this thesis, mHealth is conceived in accordance with the WHO definition as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices" (7). The landscape of mobile health programmes and policies, implemented

by a diversity of private and public stakeholders, can address various constraints of health systems, both in quality and coverage; solutions can help to overcome logistical, structural and geographical barriers to health services and play a vital role in promoting the Sustainable Development Goals (SDGs) and universal health coverage (8, 17). mHealth approaches can serve as an access point in national surveillance systems as well as registries and vital event tracking by streamlining data collection and reporting, and they can facilitate health care worker training through electronic learning and enhance diagnosis and treatment through electronic health records (14, 18) **(Table 1)**. mHealth interventions also offer the potential to beneficially influence gender relations and inequities (19-21). mHealth programmes use a variety of mobile phone functions and technologies to accomplish their goals. Examples include Short Message Service (SMS), Multimedia Message Service (MMS), Interactive Voice Response (IVR), Global Positioning Service (GPS), Vital Registration Systems (VRS), audio/video clips, mobile web (WAP/GPRS), stored information 'apps', digital forms, transfer of airtime minutes/mobile money transfer and voice communication (14).

Table 1: Main Purposes of Mobile Health Interventions

Area	Purpose	Examples of application
Extending geographic access	To overcome distance between physician and patient by replacing a traditional office visit	- Health call centres/ helplines - Mobile telehealth/ medicine
Facilitating patient communication	To facilitate communication between health workers/programmes and patients outside regular office visits. Subcategories include: • General health education • Encouraging patient compliance • Enabling emergency care • Protecting patient privacy	- Toll-free number for information (prevention/care) - Reminders to improve patient adherence - Helplines for sensitive health topics and advice
Improving diagnosis/treatment	To allow a health worker to improve clinical performance through real-time assistance with clinical decision-making and diagnosis	- Electronic health records - Disease diagnosis aids/ medical calculators
Improving data collection/data management	To enable remote data collection and enhance data transmission. Subcategories include: • Data collection • Data management and analysis	- Patient monitoring - Health surveys - Disease surveillance
Streamlining financial transactions	To expedite financial transactions by making it easier for patients to pay for their care/for the physician to receive the payment	- Mobile insurance payments - Vouchers over the phone
Preventing fraud and abuse	To prevent abuse by e.g. verifying a medical product/patent identity or tracking human resources/operations	- Text/pin codes to detect counterfeit drugs - Biometric data to confirm that a health worker has visited a patient

WHO 2011 (7), Lewis et al. 2012 (11), WHO 2018 (16)

1.2. Mobile Health in the Republic of Ghana

Ghana, with a total population of 28.8 million (22), is ranked 140th out of 187 on Human Development Index (HDI) countries, placing it in the category of medium human development countries (23). The country's progress towards the Millennium Development Goals (MDGs) has been mixed, with a relatively slow process relating to maternal and infant health remaining an on-going challenge (24, 25). Based on most recent data, the maternal mortality is 319 (per 100,000 live births), while the under-five mortality rate is 58.8 (per 1,000 live births) (23). Both indicators are still higher than the MDG's targets, and considerably far away from the SDGs' targets of a maternal mortality rate of less than 70 (per 100,000 live births) and an under-five mortality of 25 or less (per 1,000 live births) by 2030 (24, 26). Despite strong investments in health care service delivery and coverage, the health system continues to face challenges in public health surveillance as a basis for infectious disease outbreak investigation and a lack of early warning systems. Furthermore, the country has restrictions in providing access to high quality of care and suffers from its low ratio of health care providers (22, 23). In urban areas for instance, access to health care and new technologies remains highly dependent on income, status and geography (27), and with a physical density of 0.10, and a nurse- and midwife density of 0.93 per one thousand of its inhabitants respectively, a reliable health communication network to improve healthcare access is urgently needed (18, 23). In sharp contrast to the weaknesses in healthcare services delivery, the ICT infrastructure in Ghana is one of the leading in the West African region. Mobile phones have become ubiquitous in the country with a mobile subscription penetration of more than 136 percent in 2018, and with the one of region's highest levels of network coverage and a growing start-up scene, the ICT sector is one of the most active parts of Ghana's economy (28, 29). The country ranks 116th in the Information and Communication Technology Development Index (IDI) out of 167 countries examined, and had the highest relative improvement between 2010 and 2015 in the African region (28, 30, 31). Given those optimal ICT conditions, cellular phones have brought various opportunities to the country and the use of mobile devices in the health sector has proven to be a valuable tool to improve health service delivery (18, 32). Several mHealth projects in the country have been conducted so far for various purposes, although only a small minority has been scaled up nationally. Conducted projects focussed, for example, on the extension of geographical access to diagnosis and treatment or health information, improvement of communication between physicals, training and monitoring of health workers or medical supply chains and stock management **(Table 2)**.

Table 2: Overview of Mobile Health Approaches in Ghana (n=27 in total)[1]

Factors (multiple selection possible, depending on available information)	No. of publication/citation
1. Purpose of technology use	
Improving communication between physicians	(33), (7)
Improving diagnosis/treatment	(34), (35), (36), (37), (38), (39), (40), (41)
Mitigating fraud and abuse	(42)
Providing appointment/medical reminders	(43), (44), (45), (46)
Providing health information/advice for case management and referral	(37), (42), (43), (47), (39), (48), (49), (50), (51), (52), (40), (53)
Supporting medical supply chain/stock management	(54), (55), (56)
Improving public health surveillance	(48), (51)
Improving data collection/data management	(43), (57)
Improving staff training, support and monitoring	(38), (58)
2. Health focus	
Antenatal/maternal/infant health	(43), (47), (39), (52), (58), (45), (53)
Infectious diseases	(36), (37), (44), (49), (50), (51), (55), (57)
Non-infectious diseases	(34), (38), (56), (41)
Other/various purposes	(7), (33), (35), (42), (39), (54), (40)
3. Communication channel	
Directly with end-user	(42), (44), (47), (49), (50), (52), (45), (41), (46)
Via third party (e.g. community health worker)/ between health professionals only	(7), (33), (34), (35), (36), (37), (38), (43), (39), (48), (51), (54), (55), (56), (57), (58), (40), (53)
4. Design and health system level	
Pilot/feasibility project	(33), (34), (35), (36), (37), (38), (44), (47), (48), (49), (50), (51), (52), (55), (56), (57), (58), (40), (45), (41), (46), (53)
National scaled-up project	(7), (42), (43), (54), (39)
5. Type of device	
Basic mobile phone/smart phone	(7), (33), (37), (42), (43), (44), (47), (39), (49), (50), (51), (52), (54), (55), (56), (58), (45), (46), (53)
Smart phone	(34), (38), (56), (40), (41)
PDA/tablet/other	(35), (36), (48), (57), (41)
6. Use case employed/data transmission	
Voice call	(7), (33), (38), (42), (43), (39), (50), (51), (58)
IVR	(47), (52)
SMS/MMS	(7), (37), (42), (43), (44), (47), (49), (50), (52), (54), (55), (45), (58), (46), (53)
Technology platform/web-based interface	(36), (39), (48), (56), (57), (40), (41)
Camera (video/photo)	(34), (35), (38)

1 The table does not present a systematic review of mobile health in Ghana, but is rather an attempt to provide an overview of the diversity of applied mHealth approaches from a variety of sources. Five electronic databases (PubMed/MEDLINE, EMBASE, the Public Library of Science (PLoS), African Index Medicus (AIM), and the Institutional Repository for Information Sharing (iris.); the digital library of WHO's published material) were searched up to 30th April 2019 using pre-defined search terms (Telemedicine OR mHealth OR mobile health AND Ghana); the Medical Subject Headings (MeSH) were applied wherever possible. As the majority of mHealth approaches in Ghana are not published in peer-reviewed literature, the emphasis of the literature research was on grey information- and literature search, including open search on websites of reliable institutions and governments and personal contacts to experts/stakeholders/authors as well as snowballing to further publications.

1.3. Users' Acceptance and Behaviour as Key Factors for Successful Interventions

1.3.1. Theoretical Dimensions of Technology Acceptance

Despite their great potential for innovation, mHealth approaches in LMICs continue to run the risk of not realizing their full potential due to various barriers (17, 59, 60). One of the most important and crucial of these barriers is whether the intended end-users accept and manage to integrate the new technologies into their daily life (61). If users feel no motivation to use the new ICT or even perceive a risk in adopting it, the mobile application will have poor chances of success (62, 63); therefore user acceptance and experiences regarding usability are the key barriers to - or indicators for successful development and implementation of new ICTs (7). Complex dynamics of user-experiences and behavioural determinants affect the end-user acceptance of new technologies and applications. A number of ICT acceptance models and theories have been proposed and validated in different settings. Well-established theoretical approaches primarily focus on constructs favouring the acceptance of a certain technology, such as intrinsic and extrinsic motivation (64, 65), the constructs of perceived usefulness and ease of use of the technology (66), or attitude toward behaviour, subjective norm and perceived behavioural control (67). Other concepts tend to concentrate on factors which might discourage the acceptance of a certain technology and reflect on user-perceived risks and disadvantages as barriers to adoption (68). Those multi-faceted perceived risk constructs capture users' subjective fears of using the new mobile technology and cover, for example, the fear of spending too much money or time on the technology (69, 70). Due to the high relevance of the socioeconomic dimension in health research, constitutional factors such as age, sex and gender have also been found to be important determinants and been included in applied models (71, 72). In addition to the categories of factors which favour or disfavour ICT adoption, the importance of the effects of users' personally traits is also discussed (70). Those factors include the priori attitude towards the activity, i.e. the existing view on the ICT activity and not on the technology investigated (62, 70, 73). The attitude towards the activity is of particularly high importance in the ICT acceptance as applied to health care technologies. For instance, if a user does not see the need of health information on vaccination in general, this would also negatively affect their attitude toward the application of a mHealth vaccination reminder system (62). While the most suitable model to examine the acceptance of mHealth technology is still under discussion, one of the most prominent models to evaluate the acceptance of ICT within a given population is the Unified Theory of Acceptance and Use of Technology (UTAUT) (74, 75). UTAUT was formulated by Venkatesh et al. 2003 as a meta-theory based on eight main competing theoretical models of technology acceptance, namely the Theory of Reasoned Action (TRA), the Technology Acceptance Model (TAM), the Motivational Model (MM), the Theory of Planned Behaviour (TPB), the Model of PC Utilization (MPCU), the Innovation Diffusion Theory (IDT), and the Social Cognitive Theory (SCT). The authors assessed conceptual and empirical similarities of the existing eight models and integrated them into a newly developed and validated theory (74).

According to UTAUT, performance expectancy, social influence, effort expectancy and facilitating conditions have a positive influence on users' system acceptance whereas gender, age, experience and voluntariness of use are defined as moderator effects (**Figure 1**). UTAUT has been validated in a variety of health care settings and contexts (76).
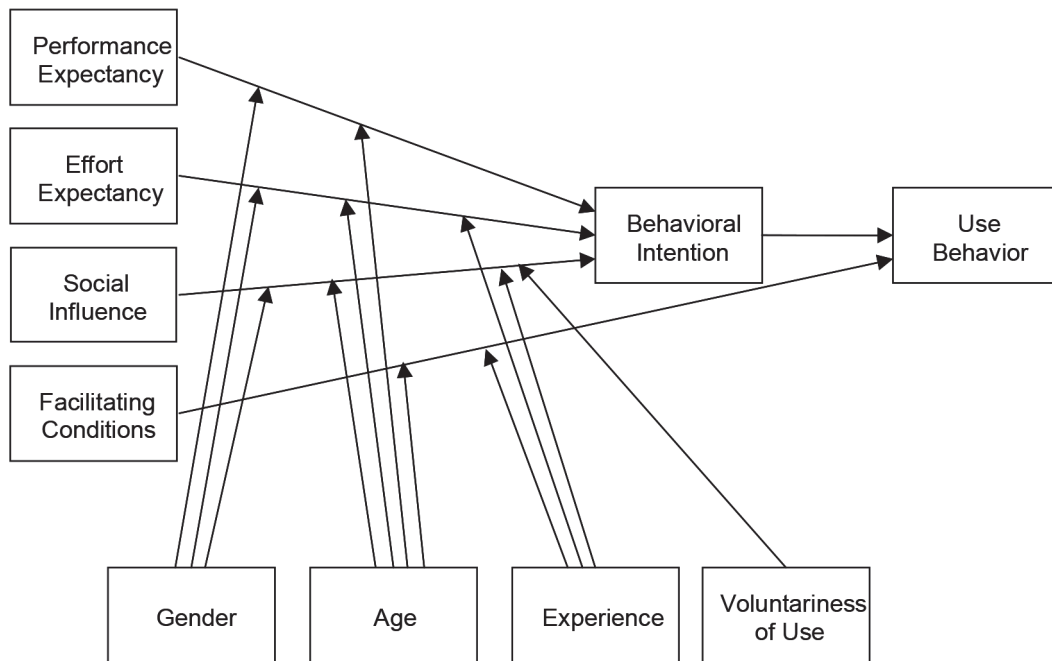
Figure 1: Research Model of the Unified Theory of Acceptance and Use of Technology (UTAUT); Venkatesh et al. 2003 (74)

1.3.2. Engaging Users in the Mobile Health Development Processes

Users' perspectives, experiences and insights with regard to new tools are of paramount importance when considering the use of mHealth in the highly sensitive setting of healthcare (62). To address this context, partnerships with and involvement of patients and potential users of ICT technologies are highly recommended by leading public health institutions such as the WHO, and are increasingly required by funding organizations (17). Researchers in the field have offered insights based on their experiences of how to involve users in the design process; however, there is a luck of best practice for research partnerships with end-users in the fast-developing and still somewhat uncoordinated discipline of mHealth. Therefore the question of how best to involve users in the design process of mobile interventions, not only as users but as valuable partners, is crucial to address (15). While not yet widely applied in the field of mHealth, approaches and solutions have been created which explicitly address the questions about how to develop interactive computer-based systems as tools for improving access to healthcare with close involvement of the end-user (77). One

longstanding and proven framework for the development of computer-based systems is the user-centred design (UCD) or human-centred design as a structured development approach that centrally focuses on the end-users throughout all stages of the design process (78).[2] It allows end-users to influence how a design takes shape in order to make sure that developed systems and information provided meet the needs of the user, are easy to operate and achieve best possible usability (79). HCD evidence suggests that the involvement of users is central to improving system quality and significantly increases effectiveness and sustainability of applications as a result of in-depth assessment of users' needs and higher levels of user acceptance (80). HCD design draws on multiple sources of knowledge and activities in order to involve users in the design process, including quantitative and qualitative methods to improve usability of the system and acceptance among end-users. What all approaches have in common is that they keep the focus on meeting users' needs and that they can be individually adapted according to particular contexts and user characteristics including culture, environment, and language (77). There is a substantial body of principles and formal standards available on how human-centred designs can be used to increase effectiveness and sustainability of systems that are newly introduced (77, 78, 81). One of the best-known examples might be the definitions of standards from the International Organization for Standardization (ISO). The ISO standard 9241-210:2010 is a description of best standard in HCD and can be considered as general reference in interactive systems developments. It describes an development circle following four human-centred design activities; (1) understanding and specifying the context of use, (2) specifying the user requirements in sufficient detail to drive the design, (3) producing design solutions that meet these requirements and (4) conducting user-centred evaluations of these design solutions and modifying the design to take into account the results (77, 82).

1.4. Evidence Gaps and Research Needs

Restrictions in real-time epidemiologic surveillance of infectious diseases as well as challenges in providing high quality health information in high-risk populations still pose enormous public health challenges in sub-Saharan African countries. These shortcomings are of particular significance in times of health emergencies such as during the most recent Ebola virus disease (EVD) outbreak in the Democratic Republic of Congo and West Africa (83, 84). Given the explosive growth of ICT infrastructures in the region, mHealth has the potential to contribute to both nationwide access to health information of sufficient quality to be effective and to real-time disease surveillance and -alert. In sub-Saharan Africa, despite various mHealth initiatives having been introduced, most interventions are small scale, fragmented, and with unidirectional flow of information. There is the urgent need for two-way communication methods in mHealth projects focussing on (i) access to the provision of health information for the civil society

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2 The term "human-centred design" rather than "user-centred design" emphasizes that this framework not only addresses persons typically considered as users of a technology but also impacts on a number of stakeholders. However, in practise, most often no difference is made between these terms [40].

while (ii) at the same time collecting real-time surveillance data to combat infectious diseases. However, as highlighted in previous chapters, new mHealth approaches continue to run the risk of not realizing their full potential due to various barriers, of which one of the most significant is the risk of low acceptance among the end-users. Existing mHealth approaches in sub-Saharan Africa suffer from a low rate of inclusion of users in development processes and/or it is rare to find information about the methods that were used to recruit users into the different stages of the design process (80). Therefore reasons for the success or failure of projects from a user's point of view remain largely unexplored and/or underreported. As a step to increase the success of the intervention, there is a need to go beyond existing quantitative assessment of user acceptance or usability, and include users at all stages of the development and implementation process of new interventions. The framework of HCD provides the exclusive opportunity to bring users into the centre of the design process of mHealth technologies, not only as study participants but as valued partners providing insights, perceptions and opinions. Although HCD is highly acclaimed as a key component to improve user acceptance of interactive application in other fields, it has not been widely used and communicated in digital health (80). HCD applies four principal activities which correspond to four evidence gaps in the field of mHealth solutions in sub-Saharan Africa, and will be assessed in the presented thesis: First, there is a lack of an overall picture of mobile phone-based projects in the field of public health surveillance conducted in sub-Saharan Africa (paper no. one). In particular, it remains unclear to what extent existing research has evaluated user acceptance and/or involved users in the design process of interventions. Second, in implementing new mHealth technologies there is the need to overcome the shortcomings of prevailing quantitative technology acceptance research by paying particular importance to the following components; an in-depth assessment of user needs, attitudes and willingness to use (paper no. two), followed by an adequate adaption of the mHealth system and evaluation of its reliability (paper no. three), and a final evaluation of user experiences after implementation of the mHealth system (paper no. four). Those research steps and the adequate communication of lessons learned are of high importance for researchers, stakeholders and funding agencies in order to build on existing evidence not only for future research but also for developing guidelines and standards for the field of mHealth in sub-Saharan Arica.

2. Study Objectives and Research Questions

The general aim of the research for which this thesis is produced was to assess users' needs and experiences with regard to the usability of a newly developed mobile phone-based interactive voice response system. To this end, target users were involved in the development process and pilot trial of the system at different stages. The study followed a human-centred design approach and consisted of four research components in accordance with ISO 924-210:2010 (82). The following chapter introduces the objectives of the four research components and published papers.

Paper no. one: Understanding the context and state of research
The first paper of the thesis provides a systematic overview of the available evidence of mobile phone-based approaches applied in the field of public health surveillance in sub-Saharan Africa.

Objectives:

To provide evidence of mHealth applied in sub-Saharan Africa via a systematic review of literature on mobile phone-based mHealth interventions for public health surveillance. Through identifying current practice, and by assessing the representativeness of studies included in the review, the paper aims to contribute to a better understanding of factors that determine successful (or failed) mHealth implementation and adoption in sub-Saharan Africa.

Research Questions:
- What type of mobile phone-based mHealth approaches (SMS-based, app-based, VRS-based, and telephony-based) have been conducted in the region?
- Which methodological characteristics do identified studies hold (specific focus, design, and hardware- and software format)?
- Is the identified evidence representative and of good quality?

Paper no. two: Situation awareness and specification of users' needs
The second paper aims to specify the requirements of caregivers of children when using IVR-based mobile technology for seeking healthcare.

Objectives:

To investigate mobile phone use behavior, attitude and experiences, and to test a prototype of the electronic system on site and monitor its performance in terms of subjective reported facilitators/challenges to use and suggestions for improvement.

Research Questions:
- What are the attitudes towards the use of mobile phones in general and in the field of health care in particular?
- Do participants have experience in using IVR for health services?
- What are the impulsive feedbacks of participants regarding the prototype of the system; what kind of facilitators and barriers exist or are encountered? What can be improved?

Paper no. three: Adaption and evaluation of the clinical decision algorithm

The third paper introduces the evaluation of the clinical decision algorithm as backbone of the developed mHealth system.

Objectives:

To introduce the development of the clinical decision algorithm as design solution for the mobile phone-based IVR System, and to evaluate the adapted algorithm.

Research Questions:

- Are guardians able to correctly assess their children's health status using the system?
- How can the algorithm performance in identifying disease symptoms be rated compared to examination by a physician?
- Is the algorithm able to give out appropriate health care recommendations?

Paper no. four: Evaluation of user experiences with the mobile health system

The fourth paper presents the evaluation of user experiences with the system during the six-month field phase in the Ashanti Region of Ghana.

Objectives:

To evaluate users' experiences with the IVR system by assessing self-reported adherence to and usability of the system and identifying participants' perceived opportunities and barriers.

Research Questions:

- How often did participants call the system? For what symptoms/diseases did participants need advice? What action did participants take after the call?
- How did participants rate the usability of the system based on the System Usability Scale (SUS)?
- What barriers to acceptance and which benefits in using the system did participants experience?

3. Conceptual Framework and Methods

This chapter first provides background information on the research project in which this thesis is embedded. In a second part, the human-centred design as central conceptual framework of the thesis is introduced, and in a third part applied methods are summarized.

3.1. Scope of the Study – the "eHISS" Research Consortium

This work is part of the research consortium "A mobile phone-based Electronic Health Information and Surveillance System for Africa: concept and pilot study (eHISS)". Principal investigators of the project were the Bernhard Nocht Institute for Tropical Medicine (BNITM) in Germany and the Kumasi Centre for Collaborative Research (KCCR) in Ghana. Further cooperation partners of the multi-disciplinary research project included the Ghana School of Public Health (GSPH) in Ghana, the University Clinic Hamburg Eppendorf (DE: Universitäts-klinikum Hamburg-Eppendorf, UKE) in Germany and the Dutch National Institute for Public Health and the Environment (NL: Rijksinstituut voor Volksgezondheid en Milieu, RIVM) in the Netherlands. A complete list of partner institutions and contact details can be found in the appendix **(Appendix 1)**. The consortium was supported by the German Federal Ministry of Education and Research (DE: Bundesministerium für Bildung und Forschung, BMBF) within the framework of the federal government's strategy for the internationalisation of science and research partnerships for sustainable solutions with sub-Saharan Africa. eHISS aimed to conceptualize and develop a mobile phone-based electronic information and surveillance system for sub-Saharan Africa, and to pilot the tool for a first evaluation in Ghana. The system had two major objectives: (i) to provide tailor-made health information for caregivers of sick children and at the same time (ii) to collect continuous spatio-temporal data of health parameters in order to display real-time syndrome-specific surveillance and serve as an early alerting system. The system relied on an IVR system provided via telephone hotline. Callers were asked to respond to a set of questions about symptoms of illnesses of diseased children, which were then grouped according to symptom complexes, based on the WHO's Integrated Management of Childhood Illness guidelines (IMCI) (85). Tailored feedback with specific health advice was provided at the end of each call. In addition, the reported disease symptoms along with location and time data were recorded electronically. Using an automated cluster analysis tool, all valid incoming calls were continuously evaluated for space-time associations between disease symptoms. An alert was triggered if more cases than expected were reported (**Figure 2**).
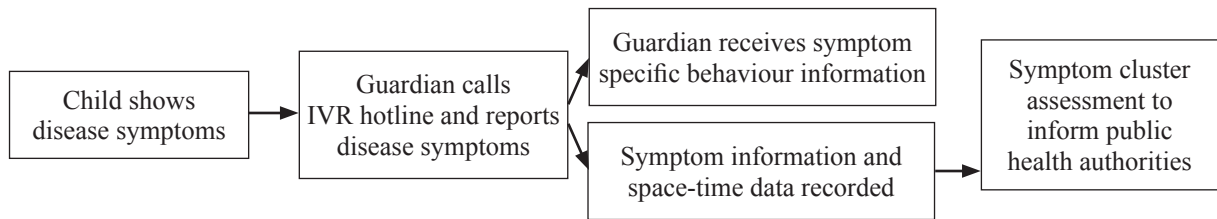
Figure 2: Structure of the IVR System to Support Guardians with Sick Children and to Collect Symptom Data for Automated Surveillance

eHISS was organized into the following work- and developing packages; (1) creation of the clinical decision algorithm to provide health content and advice, (2) translation of the algorithm into an IVR system for mobile phones, (3) detection of user behaviour of mobile technologies in the Ghanaian society with a focus on care takers of children, including adaption and evaluation of the clinical algorithm, (4) programming a database and automated analysis algorithm to identify time-spatial symptom accumulations, and (5) evaluation of user experiences with the system after a six-month field phase. The thesis applied the research and development work package numbers one, three and five.

3.2. Study Design and Conceptual Framework

In order to fulfil the explorative nature of the proof of concept period of the eHISS project a human-centred design based on the principles of the International Organization for Standardization was applied as conceptual framework for the thesis. We expected that the close cooperation with stakeholders and end-users of the system would support the identification of end-users' requirements crucial for technology adoption. The ISO "Ergonomics of human-system interaction - Part 2010: Human-centred design processes for interactive system" (ISO 9241-210:2010) is a description of best practice in user-centred design. It describes a development circle to involve users in the design process of interactive systems and provides required principles and guidance on activities to be performed. Accordingly, the research activities of the thesis were grouped into a research-circle adapting the four main activities described in ISO 9241-210:2010 to the eHISS context, namely (1) understanding and specification of the context of use, (2) specification of user requirements, (3) production and evaluation of an adequate technical solution and (4) evaluation of users' experienced usability of the system. The applied HCD circle for the presented thesis is visualized in **Figure 3.**
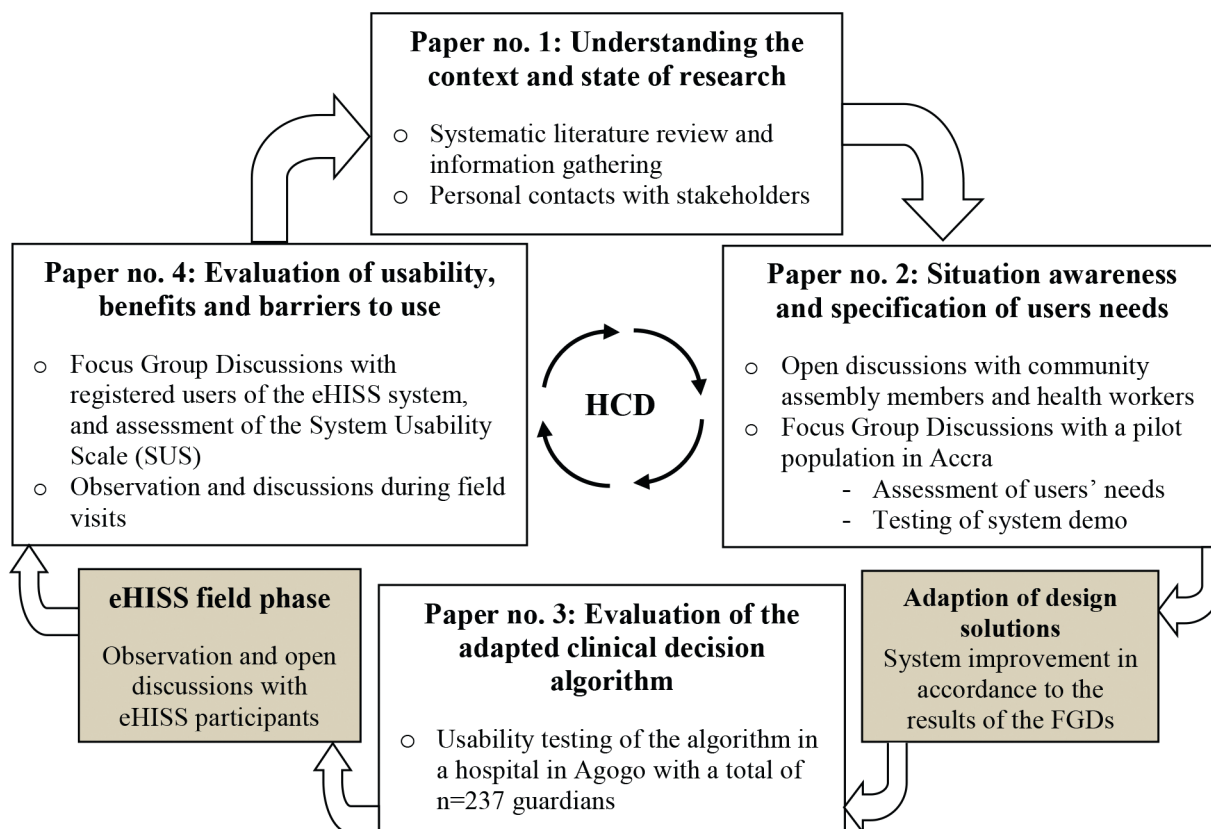
Figure 3: Conceptual Human-Centred Design (HCD)-Based Framework for the Thesis.[3]

Under consideration of method selection criteria in HCDs (86) the following methods and procedures were selected for the thesis:

Information gathering and literature overview

To understand the context and state of research, in-depth information gathering took place through (i) personal contact with stakeholders and (ii) a systematic literature review. Personal contacts included governmental agencies in Ghana, international organizations, and service providers in order to introduce the eHISS project and to gather and exchange experiences. Key contacts in Ghana included the School of Public Health at the University of Ghana, the Ministry of Health Ghana, the World Health Organization country office, the United Nations Development Programme country office, and Vodafone and MTN Ghana as mobile phone service providers. The systematic review applied a six-step research strategy and included electronic database search of peer-reviewed bibliographic as well as non-bibliographic databases and open search on websites of reliable institutions. The systematic literature search formed the empirical basis of the first paper of this thesis.

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3 Activities coloured indicate steps within the eHISS project which were not part of the thesis or/and steps which were not published.

Collection of primary data

Qualitative Approaches: The thesis focuses on users' perspectives of the eHISS project. Therefore "users" were defined in accordance with the target population of eHISS. Accordingly, when discussing the user perspective in this thesis, the target user, or end-user is a guardian caring for a diseased child in Ghana. Focus Group Discussions (FGDs) were applied at two different stages of the eHISS project in order to (i) assess attitudes toward mobile phone use and to specify user requirements, and to (ii) evaluate users' experiences with the IVR system after the field phase. Four qualitative semi-structured FGDs were conducted for data collection at each stage. Qualitative data were analysed using qualitative content analysis in accordance with Mayring (87). The FGDs conducted before and after the pilot phase of the IVR system formed the empirical basis of the second and fourth paper of this thesis. Additionally, open discussions with community assembly members and community health workers, as well as observations of and discussions with registered eHISS users during the field phase were applied to specify users' needs. Results were used to support the results of the FGDs and to provide additional insights as internal information for the eHISS project.

Quantitative Approach: After the assessment of user needs, the developed clinical decision algorithm of the IVR system was adapted based on the results of the FGDs, before the algorithm was evaluated. The field evaluation of the algorithm took place in the outpatient department of the Agogo Presbyterian Hospital in the Ashanti Region of Ghana, and compared diagnosis and advice of the algorithm to subsequent results from a consultation with a physician. The performance of the algorithm against the medical records was evaluated by statistic calculation of the inter-rater agreement using Cohen's Kappa Value. In addition, the sensitivity, specificity, as well as Positive Predictive Value (PPV) and Negative Predictive Value (NPV) were calculated. The evaluation of the algorithm formed the empirical basis of the third paper.

4. Results of Applied Human-Centred Design Activities

This section presents an overview of main results as contained in the published papers following the order of the papers presented in chapter three and according to the applied conceptual framework of HCD.

4.1. Understanding the Context and State of Research

As first step of the HCD, a systematic literature review of mobile health surveillance approaches in sub-Saharan African countries was conducted to reveal the state of research (paper no. one). The search ultimately identified nine studies that fully met the applied inclusion criteria. All studies focused on collection and transmission of disease information on a timely basis and aimed to bridge the health communication between district, community, and national levels. Identified approaches followed the same standard flow of information: Data were (i) collected either during standard routine data collection at the healthcare facilities or in the community by outreach personal, (ii) entered into the mobile device and forwarded to a central server located at district or national level, and (iii) analysed and shared with different stakeholders. Due to a lack of best practice criteria for mobile health approaches, we proposed a subjective metric in order to assess the representativeness of the studies reviewed. We focused on ten attributes in order to assess the methodological quality of studies. None of the included studies met all quality standards. However, all studies provided a two-way communication that had been identified as a major point of strength in programme implementation in previous studies. A major weakness of the studies included in the review was that all surveillance systems were based on information gathered through third parties such as community health workers, thus introducing a high risk of potential bias. A further major weakness was that none of the studies included in the review assessed end-user acceptance or included users in the design process of the mHealth intervention. The review concluded with implications for practice and research, and emphasized the significance of the involvement of users in the developing process of mHealth applications as well as the significance of prioritizing the still neglected research area of user acceptance in future.

4.2. Situation Awareness and Specification of User Needs

As second human-centred design step (i) user behaviour, perceptions and experiences of mobile phone use were assessed, and (ii) the performance of a prototype of the developed mHealth system was tested on site to identify facilitators and challenges to use of the IVR system as proxies for users' needs. A total of 40 participants were involved in the study, of which 21 were female and 19 were male. Results showed that participants had positive attitudes and feelings towards the use of mobile phones in general, and phones played a key role in their social life. Furthermore, caregivers of children were open and willing to use innovative IVR mobile health technologies for seeking healthcare in the future, although none of the participants had ever

used IVR for health care purposes before. In addition, most participants were familiar with the technology itself as IVR turned out to be a common tool used by mobile phone providers in Ghana for pre-paid and post-paid customers. Alongside a variety of reported advantages of using IVR to receive health information, identified hesitance to use included a set of infrastructural, technical and social factors such as concerns over power shortages (n=19; 47.5%) or lack of network availability (n=16; 40%), apprehension to learn using the technology/system (n=16; 40%) as well as the concern that health is too complex to be addressed by IVR technology (n=5; 12.5%) and the lack of human interaction (n=4; 10%). We discussed a variety of (i) suggestions how to improve the system, for example available languages (n=12; 30%) as well as (ii) recommendations to overcome social and technical barriers, for example the provision of training on device use (n=17; 42.5%) and the inclusion of community health workers (n=16; 40%) for system introduction. Finally, our study confirmed constructs influencing technology acceptance known from the UTAUT, indicating that the model may be used for predicting the intention to adopt IVR systems for seeking health care in the socio-economic environment of Ghana.

4.3. Adaption and Evaluation of the Clinical Decision Algorithm

Following the assessment of user needs, in a third step the prototype of the IVR clinical decision algorithm was adapted accordingly and evaluated. For example, medical terms that were found not to be easily understood by the FGD participants were replaced and crucial medical conditions, such as "stiff neck" were explained for general understanding. The challenge was to set up a system simple enough to be handled easily by users on the one hand; on the other hand, the system had to allow for the complexity of health requests from lay people. Therefore, the focus was rather to assess a condition's severity and guide caretakers to appropriate prevention and to initiate health-seeking behaviour, than to correctly diagnose diseases. The clinical decision algorithm was developed based on the WHO IMCI guidelines (85) to assess a child's condition using a three-level classification system of disease severity. As technical solution to be used by eHISS, the algorithm was translated into an IVR system. Symptoms to be identified were fever, cough, diarrhoea and vomiting. Disease severity was assessed and resulted in recommendations to either seek care (A) immediately, (B) within 24 hours or (C) to remain at home and treat and monitor symptoms. In addition, health advice was provided for the symptoms reported. Evaluation of the health care recommendations showed that the tool assessed the majority of patients as A (n=171, 72.2%), followed by B (n=55, 23.3%) and C (n=11, 4.6%), while the physicians ranked most of the children as B (n=175, 73.8%), followed by A (n=48, 20.3%) and C (n=14, 5.9%). Evaluation of the algorithm's reliability showed that symptom-detection was feasible and comparable to the physicians' findings for the symptoms of cough (percentage agreement 82.3%, kappa=0.64, $p<0.001$), fever (83.5%, kappa=0.59, $p<0.001$) and diarrhoea (84.4%, kappa=0.57, $p<0.001$), while vomiting showed reasonable agreement (76.4%, kappa=0.42, $p<0.001$). It was concluded that the system performed well in

identifying symptoms correctly, sufficiently assessed disease severity, and can provide basic health care recommendations without a medical health care professional nearby.

4.4. Evaluation of the Usability of the eHISS System

After a six-month field phase, in a fourth and closing HCD step, the usability of the eHISS system as experienced by users was evaluated. To this end, the usability was assessed with the SUS and barriers and facilitators to the use of the system were assessed in an explorative manner. A total of 37 women at ages ranging from 18 to 45 years (M=30.5 years; SD±6.8) participated in the study. Results suggested that the great majority of participants (n=34; 89.2%) followed the system's recommendations and either admitted their child to hospital (n=10; 27.0%), or provided home care (n=23; 62.2%) in accordance with received recommendations. Furthermore, ten categories of factors that facilitated the use of IVR mHealth interventions and a total of eight categories hindering the adoption and acceptance of the IVR mHealth system were identified. Important factors for the acceptance of the IVR system included the experience of improvement of individual child health (n=29; 78.4%), the use of the system for first aid (n=22; 59.5%), previous experiences with health education (n=18; 48.6%), ease of use (n=14; 37.8%), and empathy (n=14; 37.8%), the possibility of the system supporting the empowerment of women (n=14; 37.8%), availability in different languages (n=8; 21.6%), and reduced costs compared to the use of other health services (n=6; 16.2%). Barriers to the use of the IVR system included inter alia the lack of social integration of the system into the community (n=27; 73.0%), operational challenges in the use of system (n=12; 32.4%), lack of update of health information/pieces of advice provided (n=12; 32.4%) and lack of human interaction (n=11; 29.7%), complexity of health issues (n=9; 24.3%), limitation of symptoms addressed by the system (n=18; 48.6%) as well as limitations of short time intervention (n=15; 40.5%). The use of mobile telecommunication for seeking health care was perceived as an integral part of the community in that 73.0% of participants reported that community health workers and -leaders or other persons of respect in the community should play a key role in the introduction of and motivation to use the system. The evaluation showed that regular use of the mHealth system would only be acceptable to participants if the system provided not only standard health information but also additional value such as daily updated health news or nutrition advices.

5. Discussion and Implications

In this chapter, the main results of the thesis are summarized and methodological limitations as well as challenges are discussed.

5.1. Summary of Results and Work Flow

As indicated in previous chapters, the research is part of a larger interdisciplinary research consortium that aimed to develop and pilot a mobile phone-based IVR system for health information and public health surveillance in sub-Saharan Africa. The aspect of the research covered by this thesis represents one work package of the research consortium focussing on evaluation of user needs and experiences with the eHISS system. The context and state of research was comprehensively analysed through a systematic literature review (paper no. one). The review brought together evidence for the collection of health surveillance data by mobile phone-based mHealth applications in sub-Saharan Africa. In a second step, users' experience of mHealth, attitudes and needs were assessed and the demo of the mHealth system was tested with a pilot study population (paper no. two). Results were used to improve the demo of the system and for its evaluation (paper no. three). In a third step, an evaluation of the usability of the system as experienced by the users was carried out, and suggested improvements for future research were assessed after six-month field application and testing of the IVR system (paper no. four).

Based on the evidence of the four research activities of the published papers and the research objectives, the following key messages can be formulated:

1. The field of mobile health information and surveillance in sub-Saharan African countries faces fragmentation and lack of scale in evidence-based implementation guidelines and scientific reporting.
2. A profound evaluation of interventions, including in-depth assessment of user perceptions is an essential challenge to overcome if reasonable progress is to be made in the field of mHealth.
3. Caregivers were interested in new technologies but strategies to motivate sustained regular use are crucially needed. If caregivers can be motivated to regular use, systems have the potential to be applied for seeking healthcare and behaviour change in future.
4. In health crises with a high demand for disease data (e.g. cholera or EVD outbreaks) information could be delivered to and retrieved from even remote areas by a further development of the eHISS system.

5.2. Discussion of Resulted Key Messages

The following discussion will address each of the key messages stated in 5.1 under consideration of the theoretical background and state of research; finally implications for research, practice and policy will be examined.

5.2.1 Mobile health interventions in sub-Saharan African countries face a high degree of fragmentation and a lack of scale in evidence-based implementation guidelines and scientific reporting

In the past decades, rapid proliferation and innovation have been seen in the field of mobile health in sub-Saharan Africa, and a variety of studies and initiatives have been tested and implemented. However, despite the tremendous activity in the field, only few studies move forward to national scale-up and/or consumers do not continue to use the systems after a short period of initial use (88). Besides, there is a lack of rigorous evidence regarding the effectiveness and efficacy of interventions (89). For instance, in Ghana despite the fact that approximately 30 mHealth projects were tested **(Table 2),** the great majority did not move beyond the pilot phase and, to the best of our knowledge, only five were adapted countrywide. In the light of this lack of evidence, in the following some major conceptual and methodological challenges were observed and strategies to overcome them were discussed in paper one of the thesis. The review revealed that mHealth projects are highly fragmented, largely underreported and infrequently published. For this reason, we adapted our research strategy for the literature review (paper no. one) several times as evidence is disseminated in multiple forms including peer-reviewed literature, reports, websites, white papers and online blogs. Through personal information requests to authors as well as to stakeholders in Ghana, we also learned that a couple of pilot projects were never published. This might be due to the fact that a huge number of mHealth studies did not progress beyond the feasibility status, and general discussions about the usefulness of publishing pilot studies exist among researchers. In the field of mHealth this might be aggravated due to the interdisciplinary character of research consortia and diverging interests, motivation and expectations of partners. Moreover, evidence varied in terms of quality and completeness, i.e. information on infrastructure, intervention context, technology platform, intervention delivery, usability testing, and results of evaluation of user's feedback; thus making the comparison of interventions challenging. As this also applied to systematic literature reviews, an essay of Tomlinson and colleagues suggests organizing reviews of interventions according to specific targets, such as local cultural adoption or content-specific objectives (90). Beside these issues in reporting and communication of mHealth interventions, we faced a more unique challenge regarding the lack of scale and evidence-based practice and/or standards for implementation of interventions. Having the exhilarating opportunities of mobile technology in the health sector in mind, the lack of implementation guidelines and best practice strategies may stand in the way of deploying the technology in the field. After our study was implemented, in 2015 the World Health Organization published a mHealth Assessment and Planning for Scale (MAPS) Toolkit as a planning guide on how to scale up mobile health interventions and achieving long-term sustainability (91), as well as most recently guidelines to assess the appropriateness of technology options to make interventions as effective as possible (17).

5.2.2 A profound evaluation of interventions, including in-depth assessment of user perceptions is an essential challenge to overcome in the field of mHealth

Results of our literature review showed that a key challenge in the field of mHealth relates to adequate evaluation, including consideration of user experiences. We found that despite the variety of projects only very few were evaluated, and even more rarely were the evaluation methods adequately communicated. None of the identified studies included the user at all stages in the development process of the intervention, although the key role of the user in technology acceptance and the value of user-centred design are unequivocal (80, 82). These results support the strong need not only for better and more extensive evaluation of mHealth approaches, but also for improved knowledge on how to evaluate interventions (88). To combat this shortcoming, the WHO issued an mHealth Toolkit as a planning guide covering six areas of scaling up mHealth projects, which also highlights the importance of monitoring and evaluation (91). Randomized controlled trials (RCTs) are one element needed to provide more rigorous clinical evidence on mHealth applications in the region (92). However, discussions suggest that considering those kind of studies as the "gold standard" for system evaluation is too restrictive for the field of mHealth (88). Complex interventions such as mHealth applications require a more comprehensive definition of "evidence" like, for instance, the inclusion of qualitative approaches to assess not only the effectiveness, but also underlying reasons and required conditions for the success of interventions (93). Considering the high importance of user perceptions as important determinant for the success of interventions, and the complex underlying dynamics associated with technology acceptance, we support a complex evaluation of mHealth applications not exclusively but in addition to the existing need of RCTs. We argue that in the context of scarce resources, when mHealth interventions are implemented without testing systems with end-users under real-life conditions on the basis of theories of technology acceptance and behaviour change, these interventions are likely to result in failure to scale up projects and high levels of wastage of funds. Therefore interventions should be carefully evaluated against the socio-cultural background of the country of implementation, and theoretical approaches, such as instruments for measuring technology acceptance, may be adapted accordingly. Furthermore, mobile health is a fast-changing and developing field, and qualitative approaches should be included in evaluation strategies to be able to adapt to new developments and open questions still to be explored. For instance, results of our qualitative approach revealed that mHealth systems might contribute to the empowerment of mothers in sub-Saharan African settings. Women's empowerment through digital services and participation needs to be reflected in the context of social and cultural norms influencing gender relations and behaviours. We observed that the involvement of male community members was a crucial point in addressing social norms in the cultural context of Ghana, as men play a critical role in household and financial decision making and influence women's decisions in these areas. This is in line with research that examined the influence of measures of gender equality on the utilization of maternal and child health services in Africa (94). During the last years the WHO

has published resources to strengthen digital health evaluation, such as a practical guide for monitoring and evaluation (95), and most recently the first guideline on different ways to apply digital health intervention (17) as well as the global strategy on digital health 2020-2024 (15), which may lay the foundation to guide the development and evaluation of interventions based on a robust strategy.

5.2.3 Caregivers were interested in new technologies but motivation strategies for regular use are urgently needed. Systems overcoming this challenge have the potential to apply for seeking healthcare and behaviour change in future.

The users saw the eHISS system as a helpful tool to support the care for sick children, and were open and positive about its use (see paper no. 2 and no. 4). However, a major restriction identified was that the motivation to use the system regularly was low among users due to missing additional value after they had once heard the treatment recommendations from a non-human source. To overcome this essential and missing component, the results of our FGDs identified the possibility to talk to someone in person as an additional component, especially if disease symptoms are severe and/or might not be covered by the IVR algorithm. In addition, the results again revealed the opportunity to add regular updated health topics/news to the existing standard IVR algorithm. Besides, participants made frequent request for the inclusion of treatment advice into the IVR system during the discussions (see paper no. 2 and no. 4). Furthermore, it is known from research in the field of healthcare utilization that decisions of mothers to take their child to hospital are associated with a variety of independent factors, i.e. the travel distance to the next health facility, enrolment in the national health insurance scheme (96), and beliefs of older women and partners, particularly in rural settings (97, 98). The results of the evaluation of the eHISS system thus suggest that an IVR mobile health information hotline has the potential to overcome (i) distance and (ii) cost-associated challenges, and further (iii) bear the chance to empower women in decision making concerning treatment support of their children (see paper no. 4). Based on these results, we see potential to apply future systems for support of seeking healthcare and behaviour change. To address the missing motivational component that would make eHISS a frequently used hotline, the results of the FGDs are very important and suggest for a future system combining IVR elements with a health professional hotline that provides the opportunity to talk to someone in person. The IVR could support mothers' treatment decisions with "a second opinion" and serve as a first point of contact of seeking healthcare, but transfer the call to a call centre in case of emergencies (e.g. acute poisoning) or disease conditions that cannot be accurately assessed by the IVR algorithm. Even more promising for Ghana, the IVR system could be linked to an already existing hotline that was launched by the United Nations Children's Fund (UNICEF) during the course of the eHISS project. Accompanied by a vast publicity campaign, a multilingual telephone hotline called AGOO [the word 'Agoo' announces someone's presence when entering a house in Ghana] was launched in order to educate about cholera and EVD risk prevention, and accordingly prevent

outbreaks in future. The AGOO-hotline combines the services of a call centre with trained agents responding to callers with an IVR and also offers a Short Messaging Service. As part of the campaign, more than 200,000 students registered voluntarily to receive health information via SMS. In case of an EVD or cholera outbreak in future, the registered numbers will be used to distribute essential information to affected areas (50). If widely accepted, this hotline merely providing information may be continuously enhanced by advanced features for mothers and guardians of children, such as information weeks about prenatal care and safe delivery, child nutrition, and changing health topics of importance, as suggested by our study results. Thinking ahead, the system could be comprehensively developed for mobile phone-based healthcare seeking and support of behaviour change, and may even add the component of self-medication as treatment advice, which was identified as missing part of the IVR system during our study. Self-medication and treatment advice need to be critically reflected, but it should be considered that e.g. antimalarial medication and antibiotics are available as over-the-counter medication without prescription in the majority of countries in sub-Saharan Africa. If such a system is further developed, it could contribute to guidance on correct over-the-counter medication; this could lead not only to a greater interest and rising number of calls to the system, but could also help combat drug resistance in such countries.

5.2.4 In health crises with a high demand on disease data (e.g. during infectious disease outbreaks) information could be delivered to and retrieved from even remote areas by a further development of the eHISS system

When considering the eHISS evaluation with respect to surveillance and epidemic preparedness, we perceive great potential for a further development of the system to be applied as "standby system" during infectious disease outbreaks, such as EVD, cholera or Lassa fever. Considering that sub-Saharan Africa is the region with the fastest growing mobile health market in the world and a very high mobile phone penetration (9) mobile phone data have the potential to play an important role. Data could be used to facilitate epidemic surveillance through mapping population movements, indicating geographical areas to focus on or deploy preventive interventions and communication, and design surveillance and control of epidemics (99). The eHISS system could quickly be adapted during an outbreak to communicate important information even in remote areas, and to capture symptom data comprehensively and promptly, which could make it a highly important tool of disease surveillance and response in outbreak situations. Although interest of stakeholders and donors was quite low when the eHISS project started, we observed an increasing interest in the intervention in Ghana when the public health emergency of the EVD outbreak occurred in neighbouring West African countries. The epidemic (2014-2015) turned into the largest EVD outbreak in history, and spread on unprecedented scale, not only in terms of infected cases and number of deaths, but also in terms of geographical aspects and proportion of healthcare workers infected (100). In response to the outbreak, several approaches to control the disease through mHealth strategies became manifest. Mobile health mapping systems were

implemented to support surveillance of the epidemic (101), and mHealth-based education tools and public awareness campaigns supporting prevention and behaviour change whilst reducing the fear and stigma attached to the disease were applied as well as training tools for public health professionals (102). mHealth tools both for population mapping and for health education have successfully been applied for disease control and prevention of malaria and cholera outbreaks in Africa and Haiti (103, 104), as well as for zika virus risk communication (105). However, rethinking the 2014-2015 EVD epidemic in West Africa, and the great value of mHealth information hotlines that were established with weeks' or months' delay, one could imagine that the frequency of calls would have been sufficient for surveillance purposes and the course of the epidemic could have been followed better. We feel that through fast-tracking of mHealth technologies the field could have reacted much faster to the Ebola epidemic, but unfortunately quick adoption of mHealth systems during times of global public health emergencies remains challenging (101, 106). We advocate a further development of the eHISS system which may fill this gap in the provision of an existing "standby system" as it complies with all key requirements for usage in sub-Saharan Africa; the technology at hand has been tested against requirements and usability, the application is free of charge if adopted by national authorities, and due to the leading mobile phone market in the assessed area connectivity should not be a major restriction. Moreover, a system following eHISS could be easily adapted to local needs, target groups and specific diseases, and could be part of a more strategic emergency response in health crises. Referring to the example of the AGOO-hotline introduced previously, a further developed system could also be linked to such an already existing system supplementing the surveillance component. A space-time algorithm, signalling the presence of an abnormal trend to warrant further investigation would initiate control efforts by the Ministry of Health, such as mass drug administration or timely spraying in case of malaria peaks.

5.3. Methodological Considerations

5.3.1. Limitations of Study Design and Potential Bias

When interpreting the presented research results, limitations of the methodological framework and design of the eHISS study should be considered. First, the complete eHISS research project and therefore also the embedded thesis had pilot character. Accordingly, by the very nature of pilot studies, there are critical limitations to the scope of the work and interpretation of the results presented. For example, hypothesis testing was not possible within the thesis and therefore the efficacy of the IVR system was not evaluated. Furthermore, the study could only assess usability experienced by the users included in the study, and cannot necessarily be generalized beyond the inclusion and exclusion criteria of study participants. To pursue best practice criteria in the implementation of a human-centred design, we followed the principles and activities recommended by the International System of Standardization (ISO), ISO 9241-210:2010. Although ISO 9241-210:2010 provides a reasonable model of how to involve users in the design process of mHealth applications, some limitations should be considered, the most

important of which is that the HCD approach was applied only to the work package focussing on user's perspectives and not to the complete life cycle of the eHISS project. Therefore the HCD methods and principles were restricted; for instance results were used to improve the system, but the revised version was not iteratively tested with users before the field phase of the project started. Furthermore, although ISO 9241-210:2010 provides an overview of HCD activities, it does not provide detailed information on methods or techniques to be applied. The limitation of HCD methods applied in our study may be another restriction to be considered, as well as the fact that based on our definition of "users" we mainly focussed on end-users/the target population of the eHISS system. However, we assessed stakeholders' opinions with open discussions during the project phase and during a stakeholder meeting at the Ghana School of Public Health, the results of which were not published. These limitations are inherent in the pilot- and proof-of-concept character of the entire eHISS projects; therefore a more iterative design was beyond the scope of the project.

5.3.2. Restrictions of Applied Methods

Apart from restrictions in the study design, some limitations of the methods applied exist. The thesis involved two qualitative studies at different stages of the eHISS project. Both studies applied Focus Group Discussions for data collection in which participants were asked to critically reflect upon their experiences regarding the usability of the eHISS system. Discussions were conducted by a researcher who was (i) affiliated with the eHISS team and (ii) foreign to the country of Ghana. Accordingly it might have been the case that participants felt inhibited to share their points of criticism publicly in the presence of a member of the research team and/or were affected by ethno-cultural inhibitions, which is why results may be prone to interviewer bias. To limit this sensitivity, interviews were conducted in English with simultaneous translation into Twi [dialect of the Akan language spoken in southern and central Ghana] by a Ghanaian interviewer assistant. Another challenge was the loss of-follow up of participants during the six-month test phase of the project. To evaluate user experiences with the eHISS system (see paper no. four), we selected participants for our FGDs out of the database of registered users of the eHISS test phase. All registered users who had a diseased child during the six-month field phase and called the system for advice were potential FGDs candidates and were selected through an algorithm from the database. However, many users were no longer reachable under the registered contact details, and the lack of information about them may have biased our results. However, the very high response rate of the selected participants for our FGDs is a great strength of this study.

The empowerment of parents with children, focusing on giving more autonomy to manage children's health care and on providing access to health care resources, was one of the reasons for the establishment of eHISS. Due to cultural and social norms in rural areas of Ghana, the system was piloted during a six-month field phase with female participants only. One of the facilitating factors to the use the mobile health-based system identified during the study

was the potential to promote women's empowerment. This is in line with evidence revealing the positive effects of mHealth toward women's decision-making and economic gain (20). However, despite this evidence there is growing concern that mHealth initiatives that target female mobile phone users may exacerbate gender inequalities in developing countries. For example, mobile projects enhancing women's autonomy and decision-making ability may have harmful consequences within conjugal relationships and increase the risk of domestic abuse and/or men's monitoring of women's communication and behaviour (20, 107, 108). In order to promote relational equality and to address social and cultural norms, we involved men as critical gatekeepers in the research activities, following the recommendations for women and gender empowerment published by the mHealth Alliance (19). Therefore, the need assessment of test of a demo version of the eHISS system was assessed with male and female potential users (see paper no. two), and data were analysed giving consideration to differences in sex. However, it was decided to merge results for publication (see paper no. two). Husbands of registered women were furthermore encouraged to support the mothers in using the system in daily life, and invited to join the evaluation of the system. Although only one husband accepted the invitation and accompanied his wife to the discussion (he did not stay, but preferred to wait outside on the hospital campus where the discussion took place), male partners felt respected and appreciated to be informed and included in the idea of the project. However, the potential influence of the system on gender relations was not examined further, and more research is needed to address gender-related issues and implications. Although women are still less likely to own a mobile phone than men in developing countries (94), we could not find any so-called "gender digital divide" in our study. This might be due to the fact that Ghana has a mobile phone penetration of more than 100%, meaning the population even tend to own more than one mobile phone per person.

5.4. Implications for Research, Practice and Policy

A final reflection of the results of this thesis leads to implications and future directions in the field of mobile health addressing research, communication, practice and policy.

<u>Research and communication</u>
Based on the challenges we faced due to fragmentation of the sector, we support the call for a set of standards in the research field of mobile health. For decades there has been an urgent need for strategy guidelines or best practice checklists to be developed in order to standardize the quality of future research, as well as reporting and communication of intervention. Taking up the need, the development of a robust roadmap to improve measurement, monitoring and research has also become partial target of the strategy for digital health 2020-2024 recently published by the WHO (15). An improvement in reporting would greatly facilitate screening of emerging evidence and identification of research gaps, and therefore be a valuable contribution to support policy makers in decision-making. The value of standardized guidelines for scientific reporting is already accepted in different areas of public health. For instance, the system for

Grading of Recommendation, Assessment, Development and Evaluation (GRADE) developed by the GRADE working group and the approach of Confidence in the Evidence from Reviews of Qualitative Research (GRADE-CERQual) has been adopted by variety of organizations, such as the WHO and The Cochrane Collaboration (109). In the field of digital health, tools such as CONSORT-EHEALTH (110) or the mHealth evidence reporting and assessment (mERA) checklist released by the WHO mHealth Technical Evidence Review Group (111) are first line approaches providing guidance on reporting of specific mHealth interventions. Besides, the GRADE and GRADE-CerQual approaches have, among others, been part of the first-ever set of guidelines on digital health interventions released in April 2019 by the WHO (17). Concomitantly, the organization announced the newly established digital health department with the aim to develop further guidelines and advise member states on issues related to digital health (112). We strongly support the development the wide distribution and the adoption of guidelines as a first step in standardizing the quality of mHealth publications, and in order to indirectly improve the quality of evidence.

Practice and policy

To exploit the full potential of digital health in developing countries in support of the post-2015 developing agenda, we feel that a timely national refocusing of policies in the sector is required. Based on our experiences during the eHISS study, we support the call for more comprehensive frameworks and robust standards for mHealth in order to enable a better organization of necessary steps to implement interventions. Those standards should be integrated partially into the already existing mHealth strategies in sub-Saharan African countries and should be publicly available and free of charge, as well as adapted to the local context of specific country. We therefore highly support the most recently published first guidelines on digital health for health system strengthening by the WHO as leading public health institution (17), as well as the decision to launch a Department of Digital Health as part of 'wide-ranging' reforms of the organisation. We argue that the implementation of the existing recommendations and those further to be developed can greatly increase the power of mHealth and digital health by supporting countries to assess, integrate, manage and maximise the opportunities of digital public health interventions. We argue that strategies should define (or redefine) the user position within mobile health applications, should be guided by a theory of behaviour change and/or may include human-centred designs for the development of new interventions. Although so far only rarely used, the application of HCD to the development of medical technologies has the potential to greatly reduce errors and improve usability, along with improved user acceptance of interventions. A further recommendation from our study would be for programmes and policies in the field of child health to additionally focus on gender measures in mHealth programmes. Furthermore, we strongly support the sustainable development and integration of strategic online platforms such as the Global Digital Health Network (113) to share information and provide networking opportunities as well as leadership in digital health for global public health.

5.5. Lessons Learned from the eHISS Project

The PhD project was part of the eHISS research project; therefore in the following, a brief overview of the most important results not limited to the work package presented is provided:

i. It was originally planned to cooperate with mobile phone operators to obtain position information of incoming calls in order to be able to link position data with symptom data. For reasons of data protection this was not possible, despite readiness and interest signalled by the Ghanaian Ministry of Health and mobile operators. Therefore, eHISS was piloted with registered users only, meaning that we registered the mobile phone numbers in advance and could therefore link incoming calls to corresponding villages. The lack of precise location data challenged the evaluation of potential disease clusters. We therefore conclude that the use of geographic data is essential if the caller and the associated disease data is to be located. From a data protection point of view, it is generally possible to use position data; however, it should be discussed in advance of a project. An additional involvement of health authorities may help to ensure the state's consent for data collection. In addition, the identification of outbreak signals does not by itself constitute an efficient system for syndromic surveillance or outbreak detection, and should be accompanied by a verification process, decision-making and operational measures for epidemic control and outbreak management in order to be effective.

ii. For detection of abnormalities in reported disease symptoms, the 'surveillance' package of the statistic software *R* was used. It facilitated the visualization of data generated by incoming calls and provided adjustable algorithms for the statistical detection of aberrations. However, we faced major challenges in implementing eHISS as a routine surveillance tool due to the low number of incoming calls. Regular use of the system is a basic requirement for the calculation of geographic clustering of symptom data. Therefore, additional value in using the system should be provided for the participants to allow systems to become standard tools in case of childhood diseases.

iii. The lack of community health workers and medical staff, particularly in rural areas of sub-Saharan Africa, is a major public health challenge to overcome. Therefore, any developed mHealth systems should be able to be implemented without medical personnel, in order not to tie up the already limited capacity of the health system of the countries and thus weaken existing structures.

iv. Despite limitations to overcome, we believe eHISS experience offers great opportunities for future mHealth systems to significantly contribute to (i) health service delivery and/or (ii) early disease detection and response in this region. Apart from the direct benefit for the population, future systems could provide health authorities and health policy with reliable and easily accessible health data for remote areas and enable public health officials to respond timely, effectively and efficiently in the event of unexpected disease outbreaks. In addition, the system could be used for the recruitment of participants for future research, such as for clinical trials or long-term cohort studies.

5.6. Author's Conclusion

Following a user-centred design circle, we were able to include users at different stages in the development process of the eHISS project; we assessed users' needs prior to the pilot study, tested the precision of the clinical decision algorithm in a hospital setting, and evaluated the usability of the system as experienced by end-users after the six-month field phase. We have learned that users are generally open to mHealth and interested in new technologies, and gained comprehensive knowledge on critical factors favouring and disfavouring the integration of the system in the daily life of participants, and suggestions on how the system could be improved. The thesis thus confirmed and highlighted the key role of user experiences in the design process of new mHealth approaches, and provided insights on how to develop and evaluate mobile health approaches from the user perspective. Based on the results of the user evaluation, two possible directions for the future of eHISS have been developed and introduced in the discussion section of this thesis. We further conclude that a set of policy standards is needed in the field of mobile health to overcome existing barriers for implementation. Guidelines may be included in the partially already existing eHealth strategies of the countries. Based on the collective experiences of the eHISS project, we would like to summarize the following key requirements which we feel are crucially necessary for IVR-based mHealth projects for seeking healthcare and disease surveillance to be implemented in sub-Saharan Africa in future: (i) a high mobile penetration and coverage, (ii) consideration of users in the developing process not only as users but as partners, including needs assessment and consecutive evaluation of user experiences, (iii) a toll-free system, available 24/7 and easy to access via a short code, (iv) the possibility of obtaining location data (in cooperation with mobile phone companies, and if possible in cooperation with the national health as well as communication authorities), and (v) motivation strategies to support the integration of new systems in the daily life of participants.

Like all digital health interventions, the presented eHISS system is not a silver bullet and has significant limitations, but taking the discussed requirements into consideration we believe that systems developed based on the eHISS experiences in future can make a real impact on health service delivery and disease response.

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Affidavit

I hereby confirm that the thesis entitled „A user-centred evaluation of a mobile phone-based interactive voice response system to support infectious disease surveillance and access to healthcare for sick children in Ghana: users' experiences, challenges and opportunities for large-scale application" is the result of my own work. All passages quoted from publications or paraphrased from these sources are properly cited and attributed.

Furthermore, I declare that I am currently not in any other running doctoral procedure and no previous attemps have been taken.

Place, Date   Signature

Eidesstaatliche Erklärung

Hiermit erkläre ich an Eides statt, die Disseration mit dem Titel „A user-centred evaluation of a mobile phone-based interactive voice response system to support infectious disease surveillance and access to healthcare for sick children in Ghana: users' experiences, challenges and opportunities for large-scale application" eigenständig angefertigt zu haben und keine anderen als die von mir angegebenen Quellen und Hilfsmittel verwendet zu haben.

Ich erkläre außerdem, dass ich mich derzeit in keinem weiteren Promotionsverfahren befinde und auch keine vorausgegangenen Promotionsversuche unternommen habe.

Ort, Datum   Unterschrift

Appendix

Appendix 1: eHISS Project Partners and Institutions*

	African Principal Investigator	German Principal Investigator	Partner 1	Partner 2	Partner 3	Associated Partner
Ms./Mr..	Mr.	Mr.	Mr.	Mr.	Mr.	Ms.
Title	Prof. Dr.	Prof. Dr.	Prof. Dr.	Dr.	Prof. Dr.	Prof. Dr.
First name	Ellis	Jürgen	Julius	Benno	Christian G.	Mirjam
Family name	Owusu-Dabo	May	Fobil	Kreuels	Meyer	Kretzschmar
Institution	Kumasi Centre for Collaborative Research (KCCR)	Bernhard Nocht Institute for Tropical Medicine (BNITM)	Ghana School of Public Health (GSPH)	University of Hamburg (UKE)	Bernhard Nocht Institute for Tropical Medicine (BNITM)	National Institute for Public Health and the Environment (RIVM)
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*Affiliations refer to the time frame when the research project was conducted.