FUNDAÇÃO GETULIO VARGAS

ESCOLA DE ADMINISTRAÇÃO DE EMPRESAS DE SÃO PAULO

mHEALTH ENTREPRENEURSHIP: AN EXPLORATORY RESEARCH FOR A MANAGERIAL MODEL FOR mHEALTH START-UPS IN LOW- AND MIDDLE-INCOME COUNTRIES

REYMOUND YAW BUCKMAN

SÃO PAULO

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Knowledge Field: mHealth Entrepreneurship

Adviser: Prof. Dr. Edgard Barki

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Approval Date

____/____

Committee Members:

Prof. Dr. Edgard Barki, FGV-EAESP

Prof. Dr. Gilberto Safarti, FGV-EAESP

Prof. Dr. Marcelo Pedroso, FEA-USP

Letting computers do healthcare's more algorithmic work might allow us the time and emotional space to re-establish the Art of healing, to be more, well... human.

Blog post from Amanda Angelotti (2014)

Abstract

Since some years, mobile technologies in healthcare (mHealth) stand for the transformational force to improve health issues in low- and middle-income countries (LMICs). Although several studies have identified the prevailing issue of inconsistent evidence and new evaluation frameworks have been proposed, few have explored the role of entrepreneurship to create disruptive change in a traditionally conservative sector. I argue that improving the effectiveness of mHealth entrepreneurs might increase the adoption of mHealth solutions. Thus, this study aims at proposing a managerial model for the analysis of mHealth solutions from the entrepreneurial perspective in the context of LMICs.

I identified the Khoja–Durrani–Scott (KDS) framework as theoretical basis for the managerial model, due to its explicit focus on the context of LMICs. In the subsequent exploratory research I, first, used semi-structured interviews with five specialists in mHealth, local healthcare systems and investment to identify necessary adaptations to the model. The findings of the interviews proposed that especially the economic theme had to be clarified and an additional entrepreneurial theme was necessary. Additionally, an evaluation questionnaire was proposed.

In the second phase, I applied the questionnaire to five start-ups, operating in Brazil and Tanzania, and conducted semi-structured interviews with the entrepreneurs to gain practical insights for the theoretical development. Three of five entrepreneurs perceived that the results correlated with the entrepreneurs' expectations of the strengths and weaknesses of the start-ups. Main shortcomings of the model related to the ambiguity of some questions. In addition to the findings for the model, the results of the scores were analyzed. The analysis suggested that across the participating mHealth start-ups the 'behavioral and socio-technical' outcomes were the strongest and the 'policy' outcomes were the weakest themes.

The managerial model integrates several perspectives, structured around the entrepreneur. In order to validate the model, future research may link the development of a start-up with the evolution of the scores in longitudinal case studies or large-scale tests.

Key Words: health, mobile communication technology, entrepreneurship, low- and middleincome countries, start-ups.

Resumo

Tecnologias móveis na saúde (mHealth) representam há alguns anos a força de transformação para melhorar problemas de saúde em países de baixa e média renda (LMIC). Embora vários estudos tenham identificado evidências inconsistentes e novos quadros de avaliação tenham sido propostos, poucos trabalhos exploraram o papel do empreendedorismo para criar mudança disruptiva em um setor tradicionalmente conservador. Defendo que a melhoria da eficácia dos empresários mHealth pode aumentar a adoção de soluções mHealth. Assim, este estudo tem como objetivo propor um modelo de gestão para a análise de soluções mHealth do ponto de vista empresarial no contexto de LMIC.

Identifiquei o 'Khoja-Durrani-Scott (KDS) framework' como base teórica para o modelo de gestão, devido ao seu foco explícito no contexto de LMICs. Na pesquisa exploratória introduzida a seguir utilizei entrevistas semi-estruturadas com cinco especialistas em mHealth, os sistemas de saúde locais e de investimento para identificar as necessárias adaptações ao modelo. Os resultados das entrevistas propuseram que especialmente a questão econômica deveria ser clarificada, assim como a questão empresarial deveria ser adicionada. Além disso, foi proposto um questionário de avaliação.

Na segunda fase, apliquei o questionário a cinco *start-ups*, que operam no Brasil e na Tanzânia. Realizei entrevistas semi-estruturadas com os empresários para obter *insights* práticos para o desenvolvimento teórico. Três dos cinco empresários perceberam que os resultados correlacionavam com as expectativas dos pontos fortes e fracos das *start-ups*. As principais deficiências do modelo foram relacionadas com a ambigüidade de algumas questões. Além dos resultados para o modelo, os resultados das pontuações foram analisados. A análise sugeriu que entre os *start-ups* que participaram os resultados 'comportamentais e sócio-técnicos' foram os mais fortes e os resultados 'política' foram os mais fracos.

O modelo de gestão integra várias perspectivas, estruturadas em torno do empresário. A fim de validar o modelo, a pesquisa futura pode vincular o desenvolvimento de uma *start-up* com a evolução das pontuações em estudos de caso longitudinais ou testes em grande escala.

Palavras Chaves: saúde, sistemas de comunicação móvel, empreendedorismo, áreas subdesenvolvidas, empresas novas.

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Hamburg, November 2015 Rey Buckman

Table of Contents

1	Int	Introduction		
	1.1	Background	14	
	1.2	Problem Statement	16	
	1.3	Research Objective		
	1.4	Relevance and Originality of the Research		
	1.5	Thesis Structure		
2	2 Evolution of mHealth in Low- and Middle-Income Countries with reference to Brazil			
	2.1	Defining the Term mHealth (mobile technologies in healthcare)		
	2.2	Overview of the Brazilian Healthcare System		
	2.3	Trends of mHealth and their Implications for LMICs		
	2.3.1 The Promise of mHealth			
	2.	2.3.2 Critical Perspectives on mHealth		
3	Lit	terature Review		
	3.1	Introduction: Evaluation in Healthcare		
3.2 Literature Scan: Searching for a Managerial Model		Literature Scan: Searching for a Managerial Model		
	3.3 Context and Details of the Khoja–Durrani–Scott (KDS) Framework			
	3.	.3.1 KDS Evaluation Framework of e-Health solutions		
	3.	0.3.2 Questionnaire Tool		

4	Methodol	ogy	41
	4.1 Explan	ation and Justification for the Choice of an Exploratory Research Methodology	41
	4.1.1 W	orldviews: Moving from a Postpositive to an Interpretive Paradigm	
	4.1.2 M	ethodological Approach: Inspired by Stake's Interpretivism	45
	4.2 Resear	ch Design: Searching for Patterns in Semi-Structured Interviews	
	4.2.1 Sc	urces of Data Collection: Interviews	
	4.2.2 Da	ta Samples: Specialists and Entrepreneurs	
	4.2.2.1	Specialists Data Sample	
	4.2.2.2	Entrepreneurs Data Sample	
	4.2.3 Co	ellection of Data: Two Phases of Interviews	
	4.2.3.1	Interviews with Specialists	
	4.2.3.2	Interviews with Entrepreneurs	
	4.2.4 Da	ta Analysis: Search for Patterns	53
	4.2.4.1	Notes Taking and Partial Transcription	
	4.2.4.2	Identifying Patterns	53
	4.2.4.3	Personal Position and its Impact on the Findings	54
	4.3 Resear	ch Quality: Validation Throughout the Process	55
	4.4 The Re	search Methodology in a Nutshell (Summary)	57
5	Adapting	the KDS Framework to a Managerial Model for mHealth Start-ups	58
	5.1 Adapte	d Questionnaire Tool	
	5.1.1 Ge	eneral Adaptations to the Tool	59
	5.1.2 M	aintaining the Lifecycle Stages	
	5.1.3 Re	fining the Evaluation Themes	
	5.1.3.1	'Health Services and Health Status' Outcome	
	5.1.3.2	'Technology' Outcome	
	5.1.3.3	'Behavioral and Socio-technical' Outcome	
	5.1.3.4	'Economic' Outcome	
	5.1.3.5	'Readiness and Change' Outcome	71
	5.1.3.6	'Ethical' Outcome	72
	5.1.3.7	'Policy' Outcome	73
	5.1.3.8	'Entrepreneurial' Outcome	73
	5.1.4 Cl	arified Questionnaire Process and Scoring	75
	5.2 Adapte	d Evaluation Framework for mHealth Start-ups in LMICs	

6	Ev	alua	ting mHealth Start-ups in LMICs from the Entrepreneurs' Perspectives	82
	6.1	Init	ial Reactions to the Scores: Agreement with the Strengths and Weaknesses	82
	6.2	Тос	ol and Interviews Delivered Value but Need Improvements	83
	6	.2.1	Generally Added Value for Invested Time-Effort, but for Different Reasons	83
	6	.2.2	Main Critique: Ambiguous Questions	85
	6	.2.3	Lifecycle Stages versus Maturity Levels	87
	6	.2.4	Additional Questionnaire Functionalities	88
	6.3	Un	derstanding the Evaluation Scores and Strengths/ Weaknesses across all Start-ups	88
	6	.3.1	Evaluation Score for each Start-up	88
	6	.3.2	Relative Position of the Strengths and Weaknesses	90
	6	.3.3	Comparing the Relative Positions of the Themes across all Start-ups	91
	6.4	Out	come Themes are Complete, However	92
	6	.4.1	Impact, Technology, User-Behavior and Economic Model Were Naturally Considered.	92
	6	.4.2	Change Management and Policy Considerations Were 'Forgotten'	96
	6	.4.3	Ethics Led to Diverging Opinions	98
	6	.4.4	Entrepreneurial Outcomes Followed the Business Maturity	100
	6.5	Key	y Findings of Evaluating mHealth Start-ups in LMICs (Summary)	102
7	Co	onclu	isions	103
	7.1	Ma	nagerial Model Allows Quick, Profound Understanding of the Start-ups	103
	7.2	Coi	ntributions to the Research Field	105
	7.3	Pra	ctical Implications	107
	7.4	Lin	nitations and Future Research	108
D	ofor	onaa		111
	nnor	ndiv	3	125
A	ppei 1		nion of Informativa Interviewas, Visited Events and Continuous Evaluation	. 125
	1. 2	Cuid	view of informative interviewees, visited events and Continuous exchanges	125
	2. 2	Guic	il to Contact Entrement and	121
	з. 1	Ema	In to Contact Entrepreneurs.	122
	4. 5	Guic	enne for interviews with Entrepreneurs	124
	э. С	Mino	or Adaptations to Questions in Reference to Users	134
	6. 7	Com	piete Adapted Questionnaire 1 ool	137
	1.	Freq	uency of Outcome Themes per Relative Position for Two Groups	143

List of Abbreviations

4G	Fourth-generation mobile communication systems
ACS	Agentes Comunitário de Saúde (Community Health Agents)
CBA	Cost-benefit analysis
CEA	Cost-effectiveness analysis
CIO	Chief Information Officer
СМА	Cost-minimization analysis
CUA	Cost-utility analysis
D/K	Don't Know (one answer possibility in questionnaire)
ES	Empreender Saúde, now part of Live Healthcare Media
FGV-EAESP	Fundação Getulio Vargas – Escola de Administração de Empresas de São Paulo
HICs	High-income countries
ICT	Information and communication technology
IDRC	International Development Research Centre
KDS Framework	Khoja-Durrani-Scott Framework
LMICs	Low- and middle-income countries
mHealth	Mobile technologies in healthcare
MAST	Model for ASsessment of Telemedicine applications
РАНО	Organização Pan-Americana da Saúde (Pan American Health Organization)
PSF	Programa Saúde da Familia (Family Health Program)
QOL	Quality of life
SUS	Sistema Único de Saúde (Brazilian Unified Health System)
TDABC	Time-driven activity-based costing
UBS	Unidade Básica de Saúde (commonly known as 'posto de saúde', for people of a neighborhood or region to obtain basic medical attention)
UFPE	Universidade Federal de Pernambuco (Federal University of Pernambuco in the Northeast of Brazil)
UFPR	Universidade Federal de Paraná (Federal University of Paraná in the South of Brazil)
USA	United States of America
USD	US Dollar
VC	Venture capital
WHO	World Health Organization

List of Figures

Figure 1. Google Search Trends of the terms telemedicine, telehealth, eHealth and mHealth	20
Figure 2. mHealth taxonomy in three dimensions.	21
Figure 3. Venn diagram of multiple theory perspectives on mHealth start-ups in LMICs	33
Figure 4. Disability-adjusted life years (DALYs)	67
Figure 5. Relative position of strengths and weaknesses for each start-up.	90

List of Tables

Table 1. Khoja–Durrani–Scott (KDS) Evaluation Framework of e-Health Solutions	
Table 2. Overview of paradigms in three research traditions.	
Table 3. Study participants phase 1: specialists	
Table 4. Study participants phase 2: entrepreneurs and start-ups	50
Table 5. Validation throughout the research process.	
Table 6. Number of questions per lifecycle stage and outcome theme.	
Table 7. Maximum score per lifecycle stage and outcome theme	77
Table 8. Cumulative maximum score per lifecycle stage and outcome theme	
Table 9. Evaluation Framework for mHealth Start-ups in LMICs.	80
Table 10. Frequency of 'don't know' answers per start-up and outcome theme	85
Table 11. Evaluation scores for each start-up.	89
Table 12. Frequency of an outcome theme per relative position across all start-ups	
Table 13. Summary of key research contributions.	

Page 14 of 143

1 Introduction

1.1 Background

The Brazilian *Sistema Unico de Saúde* (SUS, Brazilian Unified Health System), which was implemented in 1988 to constitutionally guarantee healthcare to the entire population, widely improved the access to primary and emergency care. Health-related inequalities, which have mainly occurred due to differences in private health insurance, education, and income, have continuously declined (Almeida, Sarti, Ferreira, Diaz, & Campino, 2013). It is estimated that the SUS covers 80% of the current population (Kleinert & Horton, 2011). However, the lack of health centers, health professionals and drugs, due to the chronic underfunding of the public system, remain major barriers for patients and lead to long waiting lines (Garcia-Subirats, et al., 2014; Paim, Travassos, Almeida, Bahia, & Macinko, 2011). These characteristics, which were described for Brazil, are common for healthcare systems in low- and middle-income countries (LMICs) (AT Kearney, 2012a).

According to a report of the World Health Organization (WHO) Global Observatory, mobile health (mHealth) is a transformational force that improves health issues in developing and emerging countries (WHO, 2011). mHealth, defined as "mobile computing, medical sensor, and communications technologies for health-care" (Istepanian, Jovanov, & Zhang, 2004, p. 405), addresses all user groups in the healthcare system. The technology can help patient users not only during hospitalization or rehabilitation but also in everyday life. Moreover, healthcare professionals can use the solutions during emergency or routine visits and can attend patients over distance (Riley, Rivera, Atienza, Nilsen, Allison, & Mermelstein, 2011; Fogg & Adler, 2009). The greatest advantages of the application for health are that mobile technologies have the characteristics of being personal, intelligent, connected, and always with people (Fogg & Adler, 2009) what leads to the potential to support existing workflows inside the healthcare sector and between the healthcare sector and the general public (Mechael P. N., 2009). In Brazil alone, the potential cost reductions add up to USD 14 billion in the public and private sector, according to (PwC India, 2013). Globally, other consulting companies, multilateral organizations and researchers alike, identified mHealth as a potential solution to gain new revenues and reduce costs, while improving the quality and access to healthcare (AT Kearney, 2013; Qiang, Yamamichi, Hausman, Miller, & Altman, 2011; Freedman, 2014).

The potential of mHealth is emphasized through rapidly growing mobile phone markets. In January 2014, on average 1.34 mobile phones were registered per Brazilian, almost twice the world average of 0.85 (Teleco, 2014). Moreover, a rapid growth of 56% in mobile Internet is expected to increase the number of Brazilians that access the Internet via the mobile phone from 53.1 million to 120.8 million by 2017 (eMarketer, 2013). These developments, which are similar throughout many LMICs, provide the necessary infrastructure for mHealth to expand.

mHealth has the potential to improve healthcare for the many in LMICs and in Brazil, in particular. It is a new field for academia and practitioners alike. Research has not yet provided clear evidence on the clinical effectiveness of these solutions (Free, et al., 2013; Bastawrous & Armstrong, 2013; Hall, Fottrell, Wilkinson, & Byass, 2014; Scott & Mars, 2015). And only little evidence originates in Asia, Africa and South America, who produced only 10%, 6% and 2%, respectively, of the literature on impacts of mHealth in the years between 2008 and 2012 (Fiordelli, Diviani, Schulz, & Eysenbach, 2013). Furthermore, mHealth can still be considered as a niche solution. Even in the largest market, the United States of America (USA), total mHealth revenues reached only USD 6.2 billion in 2013, representing 1% of the overall healthcare spending in that year (Freedman, 2014). This issue is even more prevalent in LMICs, as most financing for the technology development originates from donor and non-profit organizations in Europe and the USA (WHO, 2011; Qiang, Yamamichi, Hausman, Miller, & Altman, 2011).

In order to increase the acceptance and understanding of this new field, various frameworks have been developed to evaluate mHealth solutions. Van Dyk (2014) recently presented a literature review of implementation frameworks. These span over a wide range of theoretical and practical concepts such as barriers of technology diffusion (Tanriverdi & Iacono, 1998), readiness assessment (Khoja S., Scott, Casebeer, Mohsin, Ishaq, & Gilani, 2007), layered implementation (Broens, Huis in't Veldw, Vollenbroek-Huttenw, Hermenswz, van Halteren, & Nieuwenhuis, 2007), technology acceptance theory (Alikarami, Moghadam, Javadi, & Vahdat, 2011), assessment of health system challenges (Leon, Schneider, & Daviaud, 2012), eHealth lifecycle theory (Khoja, Durrani, Scott, Sajwani, & Piryani, 2013) and van Dyk's own maturity model (van Dyk L. , 2013). Additionally, frameworks exist for the evaluation of the outcomes of the initiatives without providing implementation guidelines such as the evidence-based roadmap (van Gemert-Pijnen, et al., 2011) or the model for assessment initiated by the European Commission (Kidholm, et al., 2012).

1.2 Problem Statement

Although none of the above-mentioned, existing frameworks has been explicitly developed for the specific context of LMICs, some scholars have developed and tested the mHealth solutions in those countries. Especially the work of Khoja, Durrani, Scott, Sajwani, & Piryani (2013) seems relevant, as their Khoja-Durrani-Scott (KDS) Framework has not only been used in Asian developing countries, but has also been appropriated in the strategy and action plan for eHealth from the *Organização Pan-Americana da Saúde* (Pan American Health Organization, PAHO) (Santos, D'Agostino, Bouskela, Fernandéz, Messina, & Alves, 2014).

The KDS framework, which was originally developed for eHealth solutions, includes two dimensions. On a horizontal axis it relies on lifecycle stages to differentiate between four phases of an eHealth solution, namely 'development', 'implementation', 'integration' and 'sustained operation' stage. On a vertical axis, the framework incorporates several complex domains such as health outcome, technology innovation, behavior studies, policy-making and socio-economic development. For each of the intersections in the matrix, the KDS framework describes evaluation factors and evaluation questions. With the support of a questionnaire tool and a scoring model, the KDS framework provides a method to evaluate eHealth solutions.

Despite the merit the framework might offer, the approach disregards the importance of the actors that actually develop, implement and sustainably operate the mHealth solutions. Also the other above-mentioned frameworks do not incorporate the perspective of the individual or team driving the solution. Typical actors that initiate the development of mHealth solutions can be grouped in four categories: (1) physicians, nurses and managers in hospital institutions, (2) researchers in medical centers and other academic institutions, (3) employees in pharmaceutical, medical device, insurance, and information and communication technology (ICT) corporations and (4) entrepreneurs. Especially entrepreneurs are believed to drive the disruptive change in the traditionally conservative health sector (Freedman, 2014). Since Schumpeter's (1934) view on the creative destruction for the implementation of new ideas and Drucker's (1985) description of the existence, discovery and decision to exploit entrepreneurial opportunities, entrepreneurship has been established as a field of research (Shane & Venkataraman, 2000). And at the ninth annual 'Global Health and Innovation Conference' at Yale University in April 2012, one main outcome was the emerging awareness of mobile technologies and social entrepreneurship to

potentially transform global health (Kayingo, 2012). Yet, the research debate of mHealth and the KDS framework, in particular, have mainly evolved around technology and clinical literature (Ginige, Maeder, & Long, 2014), so that the entrepreneurs' perspective is under-represented. According to the author's best knowledge, no study has yet aimed to address this research gap at the intersection of mobile technologies, healthcare, entrepreneurship and LMICs.

1.3 Research Objective

The objective of this study is to analyze how the KDS framework applies as an effective managerial model to mHealth start-ups in LMICs and how the dimension of entrepreneurship integrates into this model. Therefore, this research aims at proposing a new approach for the analysis of mHealth solutions that takes into account the complexity that arises from the entrepreneurial perspective in the context of LMICs. Three intermediate objectives support the research:

- What criteria do specialists in the fields such as digital technologies in healthcare, local health systems and investment consider when evaluating mHealth start-ups in LMICs?
- Which process steps are necessary to practically evaluate mHealth start-ups in LMICs?
- How does the process generate an added value for the entrepreneurs?

1.4 Relevance and Originality of the Research

The originality of this research is to bring more theoretical knowledge with practical implications to the acceptance and understanding of the promising potential of mHealth, which can improve quality, access and costs in healthcare in LMICs. This study is also useful in the sense that, unlike most present frameworks that focus only on the effectiveness of the solution itself, this research acknowledges the entrepreneur as an important actor to achieve the needed change. Thus, the managerial model will add value to practitioners such as entrepreneurs and investors as well as researchers in the various disciplines.

1.5 Thesis Structure

The research will be presented in five chapters. After the introduction of the research background and objective in chapter 1, the research domain of mHealth and related fields will be explored in chapter 2. This chapter will also include a discussion about the Brazilian healthcare system as a practical reference case for the context of mHealth in LMICs.

Chapter 3 will introduce the evaluation in healthcare and provide an overview of different evaluation models for eHealth solutions. Additionally, this chapter will focus on the context and the detailed description of the KDS framework, which was the foundation for the development of the managerial model in this thesis.

Then, a thorough discussion of the applied methodology in chapter 4 will include the explanation and justification for the choice of the research methodology, the details for data samples and for data collection, the process of data analysis and the approach to ensure the research quality.

Following the description of the applied research methodology, the findings of the thesis will be presented in two steps. First, the inputs and results for the adaptation of the KDS framework will be presented in chapter 5. This process will include a critical review of the KDS framework, informed by interviews with specialists and by literature in broad areas such as entrepreneurship and investor theory, economic and business model theory as well as theories from the background of LMICs and social entrepreneurship.

In the second step, chapter 6 will demonstrate a practical application of the adapted framework with mHealth entrepreneurs that operate in LMICs. This section will be accompanied by the summary of the findings from interviews with the respective entrepreneurs.

To conclude, chapter 7 will present the conclusion on the findings regarding a managerial model for mHealth start-ups in LMICs, the implications of the exploratory research for practitioners and the risks and recommendations for future research.

2 Evolution of mHealth in Low- and Middle-Income Countries with reference to Brazil

2.1 Defining the Term mHealth (mobile technologies in healthcare)

The concept of mHealth was first described in an editorial titled 'UNWIRED E-MED: The next generation of wireless and Internet telemedicine systems' by Istepanian & Laxminaryan (2000) as a response to the quick expansion of mobile communication technologies in the area of healthcare. A few years later, Istepanian who coined the term provided with other authors the first widely used definition of mHealth as "mobile computing, medical sensor, and communications technologies for health-care" (Istepanian, Jovanov, & Zhang, 2004, p. 405). Istepanian, Jovanov, & Zhang (2004) presented mHealth as an evolutionary step of desktop telemedicine platforms within the overarching concept of eHealth.

Before discussing the drivers and implications of mHealth in more details, this section will briefly describe the terms telemedicine, telehealth and eHealth, which researchers and practitioners often use interchangeably (Fatehi & Wootton, 2012).

Bashshur, Shannon, Krupinski & Grigsby (2011) aimed at differentiating and classifying the concepts telemedicine, telehealth, eHealth and mHealth that they called domains of care. All domains share the attribute of substituting "ICT for physical co-presence during the exchange of information between the participants" (Bashshur R., Shannon, Krupinski, & Grigsby, 2011, p. 487). However, the authors argue that the terms are not interchangeable, but rather include unique components of activities, behaviors and content.

Telemedicine and telehealth are both characterized by the fact that they occur over distance. While telemedicine only includes a curative dimension, telehealth extends to preventative and promotive healthcare activities, including patient and provider education (van Dyk L. , 2014). The functions in telemedicine evolve from the medical care process to encompass consultation, diagnosis, monitoring and mentoring. In addition to those, telehealth also includes the components disease epidemiology, health behavior and education, health services management and policy, as well as environmental and industrial health (Bashshur R. , Shannon, Krupinski, & Grigsby, 2011).

The term eHealth has appeared later than the other two terms in the academic literature; but since its introduction in the late 1990s and early 2000s it has experienced a steep growth (Fatehi & Wootton, 2012). This expansion of the use of the term eHealth is highly linked to the success of the Internet and the subsequent cultural changes brought about by advances in ICT (Bashshur R. , Shannon, Krupinski, & Grigsby, 2011). One of the first definitions described eHealth as "an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve healthcare locally, regionally, and worldwide" (Eysenbach, 2001, p. 1). So, eHealth is not limited to healthcare over a distance, as telemedicine and telehealth are (van Dyk L. , 2014). Although several applications can be used to identify eHealth such as electronic health record, health information, clinical decision support system and physician order entry, an agreement on a clear definition is lacking (Bashshur R. , Shannon, Krupinski, & Grigsby, 2011).

As mentioned earlier, the term mHealth was introduced in response to the expansion of mobile technologies in the early 2000s and has gained popularity in more recent years, as a comparison of the four terms telemedicine, telehealth, eHealth and mHealth with Google Search Trends in Figure 1 confirms (Google, 2015). Also the literature review of Fiordelli et al. (2013) has highlighted that an increase in research of mHealth has especially occurred after 2008.



Figure 1. Google Search Trends of the terms telemedicine, telehealth, eHealth and mHealth. Reprinted from Google (2015).

In a recent study, Olla & Shimsky (2015) have proposed a taxonomy of existing and emerging mHealth applications in three dimensions: medical use cases, technical modalities and policy consideration, as shown in Figure 2.



Figure 2. mHealth taxonomy in three dimensions. Reprinted from Olla & Shimskey (2015).

However, Bashshur, Shannon, Krupinski & Grigsby (2011) have argued that the use of the term mHealth is rather based on a modality of the communication technology than a unique health domain and as such carries the risk to become redundant when the other three domains - telemedicine, telehealth and eHealth - will incorporate mobile communication technologies. Thus, mHealth should rather be described as cutting across all domains, according to van Dyk (2014). Likewise, in the Telemedicine Hype Cycle Report by the Gartner Group, which places applications and use cases along a market maturity cycle, Handler (2013) has removed the term mHealth in 2013, because he has considered the concept obsolete and nonspecific as it emphasizes the technology rather than the use in healthcare delivery.

This trend is indirectly confirmed by Istepanian & Zhang (2012), who have highlighted that the evolution of fourth-generation (4G) mobile communication systems will lead to the 4G health concept in the coming years, defined as "the evolution of mHealth towards targeted personalized medical systems with adaptable functionalities and compatibility with the future 4G networks" (Istepanaian & Zhang, 2012, p. 1). Derived from various literature reviews and classification of

mHealth services (Mechael & Sloninsky, 2008; Jadad, 2009; Vital Wave Consulting, 2009) in combination with the evolution of 4G technologies, Istepanian & Zhang (2012) have identified five major applications: (1) 4G wellness, prevention, and long-term chronic diseases management systems, (2) 4G mobile emergency care and response systems, (3) 4G medical multimedia services and diagnostic systems, (4) 4G personalization, and (5) social robotics and social medicine systems. These technological advancements have the potential to decrease healthcare disparities and inequality levels between high-income countries and LMICs (Istepanaian & Zhang, 2012).

Returning from this global, futuristic perspective, grave differences among various health systems remain and thus the capabilities and objectives for the implementation of mHealth differ. Many countries in Europe and Northern America as well as Japan and Australia have well-developed health systems. These countries aim at meeting citizens' expectations while controlling costs. Whereas LMICs tend to face the challenge of building a health infrastructure that delivers qualitative care to the masses. And even among and within these LMICs, there are differences between the very poor and the somewhat wealthier countries and groups of individuals (AT Kearney, 2012a). And thus the term mHealth will likely stay around for some time and clearly describes the type of start-ups this thesis aimed to research.

This paper focuses on mHealth in LMICs with reference to the case of Brazil. Brazil is an emerging economy that embraces several factors that can be regarded as representative for LMICs such as a large and growing population, a high urbanization while still serving a significant rural population, a split of private and public health sector, a steep income inequality, and a high penetration of mobile phones. For some LMICs, the Brazilian universal healthcare coverage, its focus on primary healthcare and its large group of community health workers may be a benchmark model (Macinko, de Souza, Guanais, & da Silva Simoes, 2007). Moreover, Brazil is the largest adopter of eHealth and mHealth in Latin America (Scott & Mars, 2015) and thus a regional benchmark for this new solution.

In the following sections, first the characteristics of the Brazilian health system will be described in more details and then this chapter will end with a broader discussion on the trends and implications as promise, critique and future outlook of mHealth in LMICs.

2.2 Overview of the Brazilian Healthcare System

The understanding of the socio-political context of a healthcare system is important for every entrepreneur in order to identify relevant actors and their underlying expectations. As a reference case, these actors and expectations for the Brazilian example will be summarized in this section.

Until the mid 1980s, the healthcare system was highly unequal, as 85% of all hospital expenditures went to private facilities in 1981. Moreover, care was mainly focused on treatment of diseases, rather than prevention. Subsequently, social movements, including groups of physicians and other health professionals, emerged and demanded reforms (Baer, Campino, & Cavalcanti, 2001). In this movement, health was seen not only as a biomedical problem, but also as a social and political issue. The demands for reforms, which civil society, rather than government, political parties or international organizations were pursuing, resulted in the approval of health as a citizen's right and a state's duty at the eight 'National Health Conference' in 1986. Two years later, the constitution, guaranteeing universal healthcare to all Brazilians, was proclaimed (Paim, Travassos, Almeida, Bahia, & Macinko, 2011).

Shortly after the reform, the hospital use increased by 53% between 1987 and 1991, while population rose by 2%, signifying that enlarged access was a major implication of the coverage for all (Baer, Campino, & Cavalcanti, 2001). Yet, the historic set-up and the reforms have rendered the Brazilian healthcare system rather complex with three levels of authority (federal, state, municipal) and a split between private and public subsectors for the three levels of care (primary, secondary, tertiary). These particularities will be explained in the following.

Brazil has three major levels of government that are relevant for the decision-making process for healthcare administration and the provision of services: one federal, 26 states, and 5,563 municipalities (Paim, Travassos, Almeida, Bahia, & Macinko, 2011). Although the federal government remained the principle source of public expenditure, it is not clear which level has ultimate authority over the system and the costs. This has led to different practices throughout the states and municipalities (Baer, Campino, & Cavalcanti, 2001). However, one major achievement of the objectives of the reforms to decentralize authority and reduce distance was the promotion of community participation and the focus on a community approach to healthcare (Kleinert & Horton, 2011). In order to institutionalize the participation, a structure was put in place with health councils and inter-managerial committees at the state and federal levels, where

decisions are reached by consensus (Paim, Travassos, Almeida, Bahia, & Macinko, 2011). For the community approach, more details will be discussed below in regards to the levels of care.

Another element of complexity of the Brazilian healthcare system is the network of providers and purchasers in a mix of private and public subsectors. Overall 53.58% of all health expenditure came from private funds in 2012, including 30.95% from out-of-pocket and 22.63% from other private sources such as private health insurance (World Bank, n.d.). The number of Brazilians with private health insurance grew from 24.5% in 1998 to 26% in 2008. Commercial firms provided most of these insurances. And people with insurance have reported to get better care (Baer, Campino, & Cavalcanti, 2001).

The main element of the public sector is the SUS, which was implemented in 1990, as result of the decentralization. The funding for the SUS is transferred on a per-person-quota basis from the Ministry of Health to the municipalities. The tasks of the SUS, which serves 80% of the population, include health promotion, surveillance, and education, as well as provision of care at different levels, which will be described below. Both subsectors, private and public, do not only operate in parallel, but also have several interfaces. For example, the SUS subcontracts certain services to the private sector. As a result, private providers dominate inpatient supply with 80% of hospital beds being private, while the public sector remains responsible for the majority of ambulatory care with 70% of all ambulatory cases. Another example of an interface is the out-of-pocket payment for public hospital stays and for ambulatory services and drugs (Paim, Travassos, Almeida, Bahia, & Macinko, 2011).

As mentioned before, there are three levels of care in Brazil, as in most other countries: primary, secondary and tertiary care. Primary care describes the first contact between patient and healthcare provider, while secondary and tertiary care include the further treatment by a specialist, which in the case of tertiary care usually occurs inside a hospital. The use of either level depends on ease of access and ability to pay in Brazil (Paim, Travassos, Almeida, Bahia, & Macinko, 2011).

Since the health reforms, the government has focused on primary care provision with the aim to provide access, to coordinate coverage to more complex levels, and to implement inter-sectorial health promotion and prevention. For this goal, special importance has been given to the *Programa Saúde da Familia* (PSF, Family Health Program), which started in the northern state

of Ceará in 1994 and became a nationwide strategy to restructure municipal health systems in 1998 (Paim, Travassos, Almeida, Bahia, & Macinko, 2011). The PSF is based on primary care teams that are made up of a general practitioner, a nurse, an auxiliary nurse and four to six *Agentes Comunitário de Saúde* (ACS, Community Health Agents). An important criterion to become an ACS in a community is to be from the same area. Prior medical knowledge is not necessary, as all ACS receive basic training. The teams are located at PSF clinics and assigned to a geographical area covering 600-1000 families. In 2010, the 33,000 PSF teams reached about 98 million people in 85% of all municipalities. By going directly to the people's homes, the ACS provide a first point of contact, coordinate care and work towards integration with other levels of care. As a result, not only hospital admissions have decreased and prevention has improved, but also the gathering of data has increased. The approach has ensured a permanent and systematic follow-up, whereas the main challenge is the integration with specialists' care and coordination with the state-level (Iwaya, et al., 2013).

Contrary to the primary care approach, which reaches a majority of the Brazilian population through the ACS, the access to the service of secondary and tertiary care is restricted, as the SUS depends on contracts with the private sector (Nascimento, 2013). For example, only 24.1% of scanners for a computer tomography (CT) and 13.4% of magnetic resonance imaging (MRI) scanners are public. Additionally, individuals with private health plans have preferential access to the specialists for inside and outside hospital care, as some physicians work in the private and public sector simultaneously. For tertiary care, it is also important to note that some high-cost procedures are subcontracted to private providers and public teaching hospitals, but paid by SUS (Paim, Travassos, Almeida, Bahia, & Macinko, 2011).

The above-mentioned facts that individuals with private health plans have better service in private institutions and preferential access to public institutions describe one aspect of inequality in the Brazilian healthcare system. These are rooted in education and income because middleand upper-income classes that buy health insurance or that receive health plans through employers on the formal labor market profit from inequality. Policies such as the PSF have supported the continuous decline of income-related health inequalities (Almeida, Sarti, Ferreira, Diaz, & Campino, 2013). Another form of inequality is regional. From all health insurance companies 61.5% are based in the southeast region and 65.5% of all insurance contracts are held there (Paim, Travassos, Almeida, Bahia, & Macinko, 2011). This inequality has lead to a chronic underfunding of the public system and has appeared as a major barrier for patients when entering the health service system. As a result, the lack of health centers, doctors and drugs have led to long waiting lines for treatment of any health issues (Nascimento, 2013; Garcia-Subirats, et al., 2014).

Another challenge is the supply and coordination of specialized care with primary care; for example, systematic, effective regulatory and referral mechanisms do not exist. So, it is difficult to change historical patterns (Paim, Travassos, Almeida, Bahia, & Macinko, 2011).

2.3 Trends of mHealth and their Implications for LMICs

2.3.1 The Promise of mHealth

Scholars and practitioners from various fields, covering technology experts, healthcare professionals, political decision-makers, managers of for-profit companies, researchers at multilateral organizations and social entrepreneurs evaluate mHealth as especially relevant to improve the health status in LMICs (Vital Wave Consulting, 2009; WHO, 2011; Istepanaian & Zhang, 2012; Källander, et al., 2013; Peiris, Praveen, Johnson, & Mogulluru, 2014; Scott & Mars, 2015). The factors that drive this change are manifold.

The first driver for mHealth is the penetration of mobile phones and the widening of network coverage with Internet capabilities in LMICs. While the market for new mobile subscribers is almost saturated in developed countries, emerging and developing markets are the main factor for fast growth (Bastawrous, Hennig, & Livingstone, 2013), as 70% of the over five billion subscribers worldwide live in LMICs (WHO, 2011) and 20% of the future connections will come from Latin America and Africa (AT Kearney, 2013). Moreover, approximately 90% of the world's population lives in areas with mobile coverage (Schweitzer & Synowiec, 2010) and especially Smartphones will dominate the expansion of mobile penetration in emerging markets (AT Kearney, 2013).

These facts about the penetration and network coverage of mobile phones highlight that the ubiquitous and widely used technology is the infrastructural foundation for the promise of mHealth and other mobile solutions in areas such as finance, education, or agriculture in LMICs (Akter & Ray, 2010; Motamarri, Akter, Ray, & Tseng, 2012).

The second driver for mHealth in LMICs is grounded in its promise to improve health. On a national level, Lee, Liu and Lio (2014) have recently demonstrated in a study of 61 countries that investments in ICT infrastructure and education improve health indicators such as life expectancy, under-five mortality or incidents of tuberculosis. The health challenges in LMICs are twofold. On the one hand, the countries suffer from a double disease burden, stemming from the increasing prevalence of non-communicable diseases while continuing to combat against communicable diseases (Kahn, Yang, & Kahn, 2010). And on the other hand, LMICs experience a global shortage of adequate healthcare workers, who are often costly or unavailable to reach (Qiang, Yamamichi, Hausman, Miller, & Altman, 2011), an overcrowded system and a lack of access to information (Bastawrous & Armstrong, 2013), while at the same time, populations and consequently demand for healthcare is growing, especially in Asia, Africa, and Latin America.

As mHealth requires less infrastructure (Curioso & Mechael, 2010), it has the potential to overcome the above-mentioned challenges and to improve the quality, access and costs of health services (Akter & Ray, 2010; Qiang, Yamamichi, Hausman, Miller, & Altman, 2011). In a wider perspective most applications of eHealth have been used to enlarge the geographic access to healthcare, improve data management or facilitate the communication between patients and providers (Lewis, Synowiec, Lagomarsino, & Schweitzer, 2012). Especially in primary health care, eHealth and mHealth made significant contributions (Panir, 2011). In LMICs, mobile phones have been the most common device (Motamarri, Akter, Ray, & Tseng, 2012; Lewis, Synowiec, Lagomarsino, & Schweitzer, 2012), as the technology offers the potential capacity to combine pictures and voice in order to overcome barriers from illiteracy and different languages (Mechael P. N., 2009). In addition, the extreme needs in LMICs for new ways to access affordable, qualitative healthcare services leads to greater demand and higher acceptance from both user groups, patients and healthcare professionals (PwC, 2012).

In brief, the second driver of mHealth offers new capacities to the health system as a whole such as improved access to information, two-way communication at the point of care, support of workflows (Mechael P. N., 2009) and patient-focused, personalized diagnosis and treatment (Ginige, Maeder, & Long, 2014).

Although LMICs are in need for mHealth, most of the technology to build-up the new capabilities is being developed in high-income countries (WHO, 2011). This third driver is

characterized as a new business field, which offers large opportunities by creating new revenues or reducing costs. Earlier studies estimated that the potential global market for mHealth would be between USD 50 billion and USD 60 billion by 2015 (McKinsey, 2010; AT Kearney, 2012b) and that mHealth might support the reduction of USD 400 billion in costs in OECD countries (AT Kearney, 2013). According to Allied Market Research, the global mHealth market will reach USD 58.8 billion only by 2020 (Franco & Jeevane, 2013). Again others have estimated the market size to be even as low as USD 1.5 billion in 2012, USD 2.4 billion in 2013 and USD 21.5 billion in 2018 (BCC Research, 2014) or USD 23 billion by 2017 (PwC, 2012). Despite the different forecasts due to diverging definitions and expectations, the expected short timeframe and large growth rates associated with mHealth are more important.

Also in Brazil, there are opportunities for 'big business' through revenues and savings to offer more access to care. According to PwC (2012), mobile health revenues will reach USD 700 million in Brazil by 2017, making the Latin American country the seventh largest mHealth market worldwide. Moreover, "mHealth could enable an additional 28.4 million people access to the healthcare system in Brazil, without having to add a doctor" (PwC India, 2013, p. 3) and enhanced productivity could allow the treatment of an additional 4.3 million patients due to potential cost reductions of USD 14 billion in the public and private sector (PwC India, 2013).

However, mHealth must still be considered a niche in the global health funding, as only a small fraction was spent on mHealth (Macharia, 2012; Freedman, 2014). So, it is rather the growth opportunities, the fact that the technologies will penetrate all eHealth markets, the opportunity for new players to enter the healthcare market such as ICT companies and the promise to improve the health of all groups in the society that make mHealth globally and particular in LMICs attractive.

2.3.2 Critical Perspectives on mHealth

Despite the promising drivers for mHealth, there are also many challenges for mHealth to realize its potential. Firstly, mHealth opportunities are fueled by push innovation, rather than pull mechanisms such as demand. Thus, expectations might drive a bubble and result in redundant and wasted funding decisions (Qiang, Yamamichi, Hausman, Miller, & Altman, 2011), as push innovations might lead to mHealth applications that do not take into account cultural contexts as well as local, national and regional health objectives (Mechael P. N., 2009; Panir, 2011).

Furthermore, non-profit and donor organizations as well as governments are the primary source for funding in LMICs. Although exact numbers vary, some studies estimate these sources to be 70-90% of the total primary funds (Lewis, Synowiec, Lagomarsino, & Schweitzer, 2012; Qiang, Yamamichi, Hausman, Miller, & Altman, 2011). So although government support and adequate funding are important factors for successful mHealth implementations (Ginige, Maeder, & Long, 2014), the combination of push innovations and unsustainable funding might lead to inadequate implementation, as the initiatives do not focus on true health needs (Scott & Mars, 2015).

Secondly, some people have concerns that mHealth negatively impacts health workers' job security (Chang, Njie-Carr, Kalenge, Kelly, Bollinger, & Alamo-Talisuna, 2013) and the human side of health interactions (Ginige, Maeder, & Long, 2014). The implementation of mHealth also requires readiness and change management (Scott & Mars, 2015) as well as real involvement of local teams from the initial planning to full operation, as sometimes socio-economic aspects were found to stronger influence success than technical aspects (Ginige, Maeder, & Long, 2014).

Similarly, the third challenge lies within the implicit expectation that once the technology becomes available, the health outcome would improve automatically. However, technologies are only a tool and require reliable and relevant content (Mechael P. N., 2009). Panir (2011) has argued that the role of ICT is marginal in low-resource settings and will not have any impact as long as the vulnerabilities in the livelihood of the poor will not be integrated. This includes "the understanding of the ability of the poor to access, to assess, and to apply information and to act upon it" (Panir, 2011, p. 197). For example, Scott & Mars (2015) have highlighted that official mobile penetration statistics are in some countries such as Brazil over 100%, but not all groups within the society have equal access and ability to use these technologies due to affordability of airtime, sharing of phones in one household, or access to electricity to recharge phones.

The final and most often highlighted challenge against the promise of mHealth evolves around evidence. Many studies and systematic reviews of the mHealth field arrived to the conclusion that there was either inconsistent or limited evidence for the clinical effectiveness, the impact on health service and process indicators, the costs of the solution, the patients' and health professionals' acceptability, or the final health outcomes (Källander, et al., 2013; Free, et al., 2013; Bastawrous & Armstrong, 2013; Hall, Fottrell, Wilkinson, & Byass, 2014; Peiris, Praveen, Johnson, & Mogulluru, 2014; Chib, van Velthoven, & Car, 2015; Scott & Mars, 2015).

One of the main reasons for this poor evidence-base stems from the nature of mHealth projects. Most mHealth initiatives were pilots from start-up projects to demonstrate proof of concept (Ginige, Maeder, & Long, 2014; Panir, 2011). Evidences described examples and case studies, what rendered the findings informal, not solid, not clinical and not economic (Kahn, Yang, & Kahn, 2010; Qiang, Yamamichi, Hausman, Miller, & Altman, 2011; Gurman, Rubin, & Roess, 2012). This led some researchers to coin the term 'pilotitis' in mHealth, the "overcrowding of pilot studies for the same or similar projects or tools in the same country or area" (Andach Group, 2012, para. 5). Consequently, there was great lack of large-scale mHealth applications in LMICs (Sanner, Roland, & Braa, 2012; Källander, et al., 2013; Scott & Mars, 2015).

However, this pilotitis might be an expected 'disease' at this time, as mHealth is an emerging technology. In a study of AT Kearney (2012a), commissioned by GSMA, the consultants forecasted that pilots would dominate the mHealth field for the next years. An explanation might be that the reasons for pilotitis in mHealth are two sides of the same medal. On the one hand, the conservative healthcare sector requires the demonstration of clinical effectiveness in feasibility studies before adoption on larger scale. This is traditionally done via smaller pilot projects to control the impact factors, costs and shorter duration. On the other hand, before projects will be launched on large scale, pilots must deliver meaningful results via validity tests in real clinical environments what is often a long-term, costly process. But governmental decision-makers and healthcare providers often require preliminary evidence to launch the validity tests, what would be a return to the first side of the medal (Ginige, Maeder, & Long, 2014). This paradox might be the reason why mHealth seems to be stuck in the start-up phase (Dalberg, 2013).

The next chapter will discuss different dimensions of mHealth evaluation models with a focus on the KDS framework and the entrepreneurial perspective.

3 Literature Review

3.1 Introduction: Evaluation in Healthcare

"Investors and innovators do not appear to be waiting for evaluators' reports to make their decisions, and increased mHealth intervention development appears inevitable. To make their best contribution to the field, evaluators will need a strategy to get out ahead of the design process" (Sherry & Ratzan, 2012, p. 1) and to propose effective paths for the development of sustainable business models around the mHealth solution.

Within the broader field of healthcare interventions, evaluation has been defined as "attributing value to an intervention by gathering reliable and valid information about it in a systematic way, and by making comparisons, for the purposes of making more informed decisions or understanding causal mechanisms or general principles" (Øvretveit, 1998, p. 9). Healthcare evaluation is seen as aiming to produce objective and credible evidence in regards to the advantages and issues of the field. So, contrary to basic research that tests a theory or a hypothesis, evaluation research aims at determining the success, failure or unintended effects of real world operations in achieving certain objectives. As technologies and solutions are constantly evolving, the field of mHealth evaluation should be creative and flexible to address the requirements of different stakeholders such as healthcare providers, program developers, patients and policymakers (Bashshur, Shannon, & Sapci, 2005).

Yet, the methodologies to achieve this purpose can differ greatly. Scientific papers in the mHealth field, which can be mainly attributed to a positivistic tradition, argue that formal, standardized and validated evaluation tools that are applied to real-world cases and that can lead to high-quality best practices of successful solutions must be developed, in order to establish an evidence base and an understanding of the different factors that influence the development, the implementation and the operation of mHealth solutions (van Heerden, Tomlinson, & Swartz, 2012; Tomlinson, Rotheram-Borus, Swartz, & Tsai, 2013; Scott R. E., 2010).

More nuanced, Ekeland, Bowes, & Flottorp's (2012) systematic review of reviews analyzed conclusions of different methodologies that were used to assess telemedicine interventions. According to the authors, the conclusions depended on the philosophical paradigms that were chosen for the methodology. Reviews, which included only positivist methodologies, claimed

that "more controlled studies of better quality including standardization of methodological aspects" (Ekeland, Bowes, & Flottorp, 2012, p. 8) were needed. Whereas reviews that combined the positivistic paradigm with naturalistic methodologies concluded that methodologies should also address "telemedicine innovations as complex and ongoing innovations in naturalistic settings" (Ekeland, Bowes, & Flottorp, 2012, p. 8).

As stated in section 1.3, the objective of this study is to analyze how the KDS framework applies as an effective managerial model to the mHealth sector in LMICs. Therefore, I will, first, briefly describe the literature scan, which I performed, in order to identify and select the KDS framework as the basis for this study. Secondly, I will present the KDS framework and its different aspects in details, including some critiques from other scholars. For my literature search, I have mainly relied on Google Scholar for initial keyword searches and then used the snowball principle to guide my subsequent search in identifying relevant literature.

3.2 Literature Scan: Searching for a Managerial Model

In the search for a managerial model, I was looking for an evaluation framework, which allows the entrepreneur to guide his or her decision-making process in the evolution of the start-up.

As shown in the Venn diagram in Figure 3, the evaluation of mHealth solutions in LMICs is a complex mix of multiple theory perspectives. According to my knowledge, no study has yet attempted to address this challenge from the entrepreneurial perspective. Thus, the research gap consists of the intersection of the fields of mobile technologies, healthcare, LMICs and entrepreneurship.



Figure 3. Venn diagram of multiple theory perspectives on mHealth start-ups in LMICs.

As mentioned above, several studies concluded that there has been a lack of research available within the general field of mHealth (Kahn, Yang, & Kahn, 2010; Gurman, Rubin, & Roess, 2012; Fiordelli, Diviani, Schulz, & Eysenbach, 2013) and the evaluation thereof (Walshe, 2007; Kidholm, et al., 2012; Khoja, Durrani, Scott, Sajwani, & Piryani, 2013). Not only the research fields are in their infancy themselves, but also the existing evaluation models only provide partial theories at the integrative section for the phenomena of evaluating mHealth solutions.

Furthermore, research and knowledge that originates in LMICs with a focus on entrepreneurship (Bruton, Ahlstrom, & Obloj, 2008) or mHealth (Fiordelli, Diviani, Schulz, & Eysenbach, 2013) is lacking, in general. Theories, which emerged in high-income countries, often do not apply to LMICs because they fail to incorporate differences in infrastructural contexts and worldviews (Hoskisson, Eden, Lau, & Wright, 2000; Mangaliso & Lewis, 2012). In the context of this study, quantitative rigor, which disregards these paradigmatic differences (Mangaliso & Lewis, 2012), might not allow to achieve the intended research objectives.

Although entrepreneurship research has existed for some time now (Bygrave W. D., 1989; Shane & Venkataraman, 2000), it is a fairly new debate within healthcare research. It is expected, however, that a surge in entrepreneurship, attracted by the potential to use mobile technologies for innovation in healthcare, will push to lower the barriers to enter this market (Krohn & Metcalf, 2014).

In the subsequent search for a model, I tried to find an evaluation model, which already covered a maximum of the dimensions, which were highlighted in Figure 3. In a recently published systematic review of evaluation frameworks in telehealth, including mHealth, van Dyk (2014) broadly separated frameworks that focused on providing guidelines for implementing and evaluating the outcomes and frameworks that emphasize primarily the evaluation of outcomes of solutions. The latter include, for example, the evidence-based roadmap for the development of eHealth technologies (van Gemert-Pijnen, et al., 2011) or the Model for ASsessment of Telemedicine applications (MAST) initiated by the European Commission (Kidholm, et al., 2012). Van Dyk (2014) excluded those from her review and so do I, as I aim at providing a managerial model rather than a pure evaluation of outcomes.

Van Dyk (2014) differentiated the other evaluation concepts, which combined outcome evaluation with implementation guidelines, based on the formats that were applied: (1) statements/ outcomes associated with Likert-like scales, (2) guidelines based on longitudinal studies, (3) lifecycle frameworks, and (4) comprehensive models.

Although none of the frameworks, which were included in the review, described the reasons for choosing a particular underlying theoretical framework, the lifecycle frameworks were especially relevant for the objectives of this thesis. These frameworks linked successful implementation and expected outcomes to certain lifecycle phases (van Dyk L. , 2014); and thus, they offered a potential basis for a managerial model for a start-up, which also evolves over time. The two frameworks included in this category were the layered telemedicine implementation model (Broens, Huis in't Veldw, Vollenbroek-Huttenw, Hermenswz, van Halteren, & Nieuwenhuis, 2007) and the Khoja-Durrani-Scott (KDS) framework for the development of a comprehensive eHealth evaluation tool (Khoja, Durrani, Scott, Sajwani, & Piryani, 2013).

Especially the KDS framework "acknowledged the need for different assessment strategies throughout this implementation lifecycle" (van Dyk L. , 2014, p. 1292). Moreover, from the presented frameworks in van Dyk (2014), only one framework explicitly focused on the evaluation of eHealth solutions in the context of LMICs: the KDS framework. It was not only published in the cooperation of researchers from high-income countries (HICs) and LMICs, but also developed through field research in Asian LMICs such as Afghanistan and Pakistan (Khoja S. , Scott, Casebeer, Mohsin, Ishaq, & Gilani, 2007; Khoja, Scott, & Gilani, 2008; Durrani & Khoja, 2012).

In a different but related context, Santos, D'Agostino, Bouskela, Fernandéz, Messina, & Alves (2014) have used the KDS framework to establish a monitoring instrument of telehealth in Latin America for the *Organização Pan-Americana da Saúde* (Pan American Health Organization, PAHO). This highlights the relevance of the KDS framework beyond its initial borders in Asia towards other regions with LMICs.

In conclusion, I chose the KDS framework as the basis for the managerial model in this study because of the assessment strategy per lifecycle stage as well as the background and the applicability of the framework to LMICs. In the next section, I will describe in more details the context and the aspects of the KDS framework.

3.3 Context and Details of the Khoja–Durrani–Scott (KDS) Framework

The KDS framework is a result of a larger study, which is partially performed within the PAN Asian Collaborative for Evidence-Based eHealth Adoption and Application (PANACeA). This network of health researchers and institutions from twelve developing countries in Asia was funded by the International Development Research Centre (IDRC) in Canada from August 2007 to July 2011 (Sajwani, Khoja, & Durrani, 2011).

Based on the eHealth readiness assessment tools for healthcare institutions from (Khoja S., Scott, Casebeer, Mohsin, Ishaq, & Gilani, 2007) and Scott's (2010) framework that supports users in the evaluation approach at different stages of the eHealth solution, the research team (Khoja, Durrani, Scott, Sajwani, & Piryani, 2013) aimed at providing a "systematic and comprehensive approach to evaluating e-health initiatives and make it easier to compare" (p. 48).

First, an in-depth review of peer-reviewed and gray literature helped to select 40 articles, which were forwarded to a three-member panel to identify theories and concepts related to the evaluation of eHealth. Then, the theories and concepts were discussed with a group of users in eHealth and experts in evaluation regarding their relevance to eHealth. Additionally, the theories were mapped against the eHealth related lifecycle from Scott (2010), in order to assess which part of the lifecycle they would mostly influence. As a result, a list of evaluation themes was identified. In a final consolidation, a matrix was developed aligning the evaluation themes and the lifecycle stages. This matrix, the KDS framework for eHealth evaluation, was then shared with the PANACeA network to gather comments and develop evaluation factors for each intersection of a theme and a lifecycle stage (Khoja, Durrani, Scott, Sajwani, & Piryani, 2013).
3.3.1 KDS Evaluation Framework of e-Health solutions

The full framework, including the evaluation factors, is shown below in Table 1. On the horizontal axis of the matrix are the lifecycle stages of an eHealth solution: (1) 'development' stage, (2) 'implementation' stage, (3) 'integration' stage and (4) 'sustained operation' stage. The objectives at the 'development' stage are to lay the foundations for an eHealth solution on identified and assessed needs, an environmental scan, a readiness assessment, existing capacities and within a broad social and equity-based perspective. During the 'implementation' stage, the process involves preparing, introducing and initially practicing the eHealth solution. Afterwards, the 'integration' stage aims at combining separately produced components, subsystems or health issues as well as resolving any problems in their interactions. Finally, the 'sustained operation' stage is ongoing when the eHealth solution performs without interruptions for longer term and becomes a routine health activity (Khoja, Durrani, Scott, Sajwani, & Piryani, 2013).

On a vertical axis, the matrix shows the evaluation themes, which cover a broad range of topics. The 'health services' outcomes describe the change in the health status of a patient or a community, which every clinical or health intervention should aim at. 'Technology' outcomes include the software, hardware and connectivity infrastructure necessary for the eHealth solution. Within the 'economic' outcomes several concepts regarding affordability and cost-effectiveness are incorporated. The 'behavioral and socio-technical' outcomes are based on the social and behavioral impact of the eHealth solution. This process aims at analyzing, monitoring and managing the intended and unintended social consequences of the eHealth solution. In addition, the 'ethical' outcomes address the moral and ethical issues originating from the practice, research and use of the user to implement and manage an eHealth solution and on the other hand the management of changes in existing processes. Finally, 'policy' outcomes are needed to assist the structured and consistent practice of eHealth solutions in general (Khoja, Durrani, Scott, Sajwani, & Piryani, 2013).

For each of the different themes of evaluation (vertical), the KDS framework has identified associated factors that influence the certain stages (horizontal) of the eHealth lifecycle. The results are shown in Table 1.

	Development	Implementation	Integration	Sustained Operation
Health	• Ongoing and periodic assessment of	 Improved diagnosis and treatment of 	 Health impact leading to 	 Health impact showing
Services	health status, existing services, needs,	disease conditions	change in disease status	change via indicators
Outcomes	and opportunities	• Improved decision support and clinical care	• Social impact due to improved	 Stability of services
		and health management	access and quality of services	• Wide reach
		 Improved access to care 	 Stability of services 	
		 Barriers and facilitators 	• Improvement in quality of life	
		 Acceptability of e-health 		
		Better clinical safety		
		 Improved quality of care 		
		 Functional independence among staff 		
		• Equity of care		
		Stability of services		
		• Effects on the delivery of medical care		
Technology	 Development cost, availability, 	Interoperability	 Appropriate in a variety of 	 Scalability
Outcomes	affordability	• User-friendliness/usability	conditions	 Cost benefit
	 Interoperability and standardization 	• Appropriate in a variety of conditions	 Relevant to existing and 	 Ability to be
	• Well-designed software	• Relevance to existing and growing needs	growing needs	incorporated into policy
	Reliable hardware	• Flexible (can be modified to suit	 Broader interoperability 	
	 Technical efficiency or fix 	local/cultural/social needs)		
	Timeliness	• Efficiency/error rates		
	• Cost	• Accuracy		
	 Robust and reliable networking 	• User acceptance		
	• Easily adaptable to different settings	_		
	(patenting)			
	• Cultural acceptability			
	 Environmental viability 			
Economic	• Affordability	• Cost-utility	• Cost-benefit	 Improved DALYs
Outcomes	• Cost minimization	-		 Improved QALYs

Table 1. Khoja–Durrani–Scott (KDS) Evaluation Framework of e-Health Solutions. Adapted from Khoja, Durrani, Scott, Sajwani, & Piryani (2013).

	Development	Implementation	Integration	Sustained Operation
Behavioral	• Human resource factors (management	 Strategy for e-health implementation 	 Penetration/diffusion of 	 Adoption/adaptation of
and Socio-	style, working relationship,	• User-friendliness	innovation (addressing the	technology on a wider
technical	communications flow, staff	 Human–computer interaction 	digital divide)	scale
Outcomes	motivation)	• Direct benefits to users in routine work	 Strategy for broader e-health 	
		Benefits in learning	adoption	
		 Penetration/diffusion of innovation 		
		(addressing the digital divide)		
		• Trust		
		• Beneficence/non-maleficence (client,		
		provider, organization)		
		Problem handling		
		• Gender issue/gender divide		
Ethical	• Prioritizing e-health over other issues	• Sensitive to socio-cultural issues	• All of the following in a	• Security
Outcomes	• Moral consideration	• Security	broader perspective:	
	• Autonomy (client based)	• Liability	• Sensitive to socio-cultural	
	• Justice and equity	• Licensure	issues	
	• Selection of study subjects/patients	• Reimbursement	• Security	
	and population		• Liability	
	• Securing identity and maintaining		Licensure	
	confidentiality of patient information		• Reimbursement	
Readiness	Plan for change management	• Effective change management (preparation	• Effective change management	• Modification
and	Individual, organizational, and	and action)	(maintenance)	• Improvement
Change	societal readiness to technology	• Training of all staff, including clinical and		Customization
Outcomes	change	management starr		
	requirements eligitation phase			
	selection of vendor, solution			
	evaluation features etc			
Policy	• Policies for change management	• Limited changes in organizational and	 Policy changes to facilitate 	Healthy public policy
Outcomes	Scope for innovations	national policies to facilitate e-health	broader adoption	and organizational
Outcomes	• Funding support for research	implementation	implementation and	practice
	i ununig support for research	implementation	innovation in e-health	• Knowledge sharing with
				other organizations and
				countries
	1	1	1	

DALY: disability-adjusted life-year; QALY: quality-adjusted life-year.

Table 1. (continued).

3.3.2 Questionnaire Tool

Based on the above-shown KDS framework, the research team in the PANACeA network has developed four separate evaluation tools for each of the lifecycle stages. Each tool has a separate question set to represent the different perspectives of users of the evaluation tool, namely manager, healthcare provider, and client (Khoja, Durrani, Scott, Sajwani, & Piryani, 2013). At the time of this thesis, the tools have not yet been validated. Nevertheless, the question sets were available on the website of the project: http://panacea-evaluation.yolasite.com.

For each question the respondent could choose among six options that are linked to a Likert-like scale: unsatisfactory (1), below expectations (2), meets expectations (3), above expectations (4), extraordinary (5), and don't know (1). The numbers represent the weight per question. The maximum score would occur, when all questions are answered with extraordinary, so five on the Likert-like scale. The score per theme is then calculated by dividing the sum of the points from the answers with the maximum possible score per theme. The total score would be an average across all themes.

According to the description on the website of PANACeA, the individual percentages per theme would allow the evaluator to identify strengths and weaknesses of the eHealth solution in addition to the total score. However, as mentioned before, neither the website nor the paper about the KDS framework provided any details about the validity and the interpretation of the questionnaire tools and the associated scoring. Also the details about the composition of the evaluation tool and the suggested evaluation process were not given at this point in time.

Despite these shortcomings, the KDS framework for eHealth evaluation seemed to be the first and most promising step on my exploratory research towards an effective managerial model for mHealth start-ups in LMICs. In the following chapters, I will describe the methodology I have applied and the findings I have revealed regarding my research objective to propose a new approach for the analysis of mHealth solutions that takes into account the complexity, which arises from the entrepreneurial perspective in the context of LMICs.

4 Methodology

The following chapter will first explain the reasons for adopting an exploratory research approach by outlining the philosophical assumptions and paradigms that were defining the research design for this approach. Then, the chapter will continue to describe the process of sample selection, data collection and data analysis. Finally, the criteria that were used to ensure the research quality will be highlighted.

4.1 Explanation and Justification for the Choice of an Exploratory Research Methodology

"Qualitative research begins with assumptions, a worldview, the possible use of a theoretical lens, and the study of research problems inquiring into the meaning individuals or groups ascribe to a social or human problem. To study this problem, qualitative researchers use an emerging qualitative approach to inquiry, the collection of data in a natural setting sensitive to the people and places under study, and data analysis that is inductive and establishes patterns or themes." (Creswell, 2007, p. 37).

Within qualitative research, the researcher adopts a stance towards the nature of reality that is based on the idea of multiple realities, which are relative to different and subjective perspectives from individuals and groups. Meaning is created through human interactions (Creswell, 2007). Thus, qualitative research is often applied to study phenomena in the environments, where they naturally occur and where social actors can contribute with their meanings to understand the phenomena. This approach allows answering questions about how and why social experiences are created (Denzin & Lincoln, 2005). In order to acquire firsthand knowledge for this form of study, the research has to get close to the participants in the study and collaborate with the people in the field. This allows to describe the people's own views of reality (Creswell, 2007).

As shown in section 3.2, research on mHealth entrepreneurship in LMICs lacks significant scientific research. Thus qualitative research is particularly appropriate to explore new phenomenon and develop theories, when partial theories do not capture the complexity of the

issue (Sofaer, 1999; Creswell, 2007). Details necessary to deeply understand the phenomena of evaluating mHealth start-ups in LMICs can only be captured in human interactions (Creswell, 2007) and by illuminating the experiences of individual specialists and entrepreneurs in the field (Sofaer, 1999).

In addition to the methodological arguments above, my personal objective for this research project was to immerge into the ecosystem of mHealth and generate scientifically based findings, which have a relevant impact for practitioners (Bruyat & Julien, 2000; Bygrave W. D., 2007). Prior to the start of the research and throughout the process, I participated in several events and met various stakeholders in the mHealth ecosystem to discover the field (see appendix 1 for complete list). To make this personal immersion explicit, I applied a personal and literary rhetorical style for writing the report that allowed me to convey the story behind the findings (Creswell, 2007).

4.1.1 Worldviews: Moving from a Postpositive to an Interpretive Paradigm

Within the qualitative research field exist different paradigms for making claims about knowledge. These three distinct paradigms, which are summarized in Table 2, are called: positivism and postpositivism, interpretivism and critical postmodernism (Gephart, 2004).

In positivism and postpositivism, the methodological approach is based on an emphasis on rigorous methods for the collection and analysis of empirical data. This process is guided by a cause-and-effect orientation that aims at revealing singular true realities. The process of a series of logically related steps often follows a deterministic based theory and encourages the use of validity approaches (Creswell, 2007). In this approach, the researcher establishes hypotheses or propositions, which are deducted from theory, and verified or falsified through the research (Gephart, 2004).

Researchers in the interpretive paradigm, on the contrary, start from the intent to make sense of the meanings of others (interpret), which are developed in interactions and through historical and cultural norms. The inquirers aim at understanding and describing the complexity of views that originate from the world, rather than from the formation of categories of views or the production of qualitative facts to verify/falsify hypotheses. Implications of divergent meanings are seen to

influence how people understand and respond to the world (Creswell, 2007). This process of interpretation is shaped through a researcher's own background and leads to a theory, describing "how different meanings held by different persons or groups produce and sustain a sense of truth, particularly in the face of competing definitions of reality" (Gephart, 2004, p. 457).

Both above-mentioned paradigms do not take into account how the historical emergence of social structures forms contradictions in the contemporary context of social action and human freedom. The approach of critical postmodernism aims at uncovering the relationships that underlie dominance and subjugation to ultimately transform social order. By making people aware of the constraints on their own actions, the approach allows emancipation (Gephart, 2004).

	Positivism and Postpositivism	Interpretivism	Critical Postmodernism
Assumptions about reality	Realism: Objective reality that can be understood by mirror of science: definitive/probabilistic	Relativism: Local inter- subjective realities composed from subjective and objective meanings: represented with concepts of actors	Historical realism: Material/symbolic reality shaped by values and crystallizes over time
Goal	Discover truth	Describe meanings, understanding	Uncover hidden interests and contradictions
Tasks	Undertake explanation and control of variables: discern verified hypotheses or non-falsified hypotheses	Produce descriptions of members' meanings and definitions of situation: understand reality construction	Develop structural or historical insights that reveal contradictions and allow emancipation, spaces for silenced voices
Unit of analysis	Variable	Verbal or nonverbal action	Contradictions, critical incidents, signs, symbols
Methods focus	Uncover facts, compare these to hypotheses or propositions	Recover and understand situated meanings, systematic divergences in meaning	Understand historical evolution of meanings, material practices, contradictions, inequalities

 Table 2. Overview of paradigms in three research traditions.
 Adapted from Gephart (2004); based on Lincoln & Guba (2000).

Most research in management studies builds on positivism and postpositivism, as those mirror quantitative research techniques, in which many scholars were trained and which seemed to have a preference in highly ranked journals (Gephart, 2004; Piekkari, Welch, & Paavilainen, 2009).

I started my research with a postpositivist intention. At the beginning, my objective was to answer the research question by reviewing literature and interviewing people to identify those variables or categories that would predict success in the form of strengths and weaknesses of mHealth startups in LMICs. I believed that there would be a form of underlying truth, which could be applied to all startups, and which I could use to build the theory for a management model, including an evaluation framework and a questionnaire tool, based on the work of (Khoja, Durrani, Scott, Sajwani, & Piryani, 2013). I wanted to adapt the KDS framework and tool to the mHealth context of LMICS and use multiple cases of entrepreneurs, who tried out the evaluation, in order to make generalizable claims about the applicability of the adapted model.

Throughout the research process, however, I realized that though wording and description of the variables or evaluation themes might be the same for all start-ups, the meanings that people attach to them differ. Especially the entrepreneurs described different meanings in the results and dimensions of the evaluation depending on their context and lived experience. This change of perspective might have happened because I gradually moved from a researcher role into the point of view of an evaluator. But only when I moved back into the perspective of the researcher of the phenomenon, after the in-field interviews, I realized the change.

So, I came to the conclusion that it is important for an evaluator to make sense of the meanings people attach to their experience in order to allow an adequate interpretation of the complexity surrounding and influencing the individual or team of entrepreneurs, the mHealth start-up itself and the larger ecosystem (Creswell, 2007; Bygrave W. D., 2007). I had to open up the boundaries again, to redirect my research question and to refocus the evaluation interviews with the entrepreneurs (Piekkari, Welch, & Paavilainen, 2009). Subsequently, as a researcher aiming at answering 'how the KDS framework applies as an effective managerial model to the mHealth sector in LMICs and how the dimension of entrepreneurship can be integrated into this model', an approach that was inspired by a rather interpretive than a postpositivist paradigm allowed me to capture the nuances, which were visible in the multiple views of reality of this young phenomenon.

I have struggled to adapt the interpretive research paradigm, as my tendency has been to believe that there existed identifiable, generalizable and measurable variables that caused certain individuals and start-ups to have success. Moreover, there seemed to be a convention, a shared set of norms, in the fields of international business (Piekkari, Welch, & Paavilainen, 2009) and entrepreneurship (Bygrave W. D., 2007) to attach higher generalizability, validity, and value to

positivistic research traditions. But these only allow a narrowed perspective for both, interpretation and observation of meanings (Piekkari, Welch, & Paavilainen, 2009). In the context of this study, where the researcher also became the evaluator of a phenomenon, an approach inspired by an interpretive paradigm seemed most suitable.

4.1.2 Methodological Approach: Inspired by Stake's Interpretivism

In the process of designing the research, my methodological approach was mainly inspired by Robert Stake, a case study researcher, who not only identified himself as an interpretivist (Stake R. E., 1995) but also the main reviewers assigned to an interpretive paradigm (Creswell, 2007; Baxter & Jack, 2008; Piekkari, Welch, & Paavilainen, 2009; Crowe, Cresswell, Robertson, Huby, Avery, & Sheikh, 2011; Hyett, Kenny, & Dickson-Swift, 2014).

According to Stake (2005), researchers should seek to understand what is common and what is particular about a case, involving the nature of the case, the historical background, the physical setting as well as the economical, political and institutional contextual factors. In order to achieve this goal, Stake (1995) advised the researcher to have a personal interaction with the case, in order to develop the case in relation with the informants, and to engage the reader in joining the interaction and discovery.

Although this thesis is not a case study, the methodological approach was inspired by the philosophical assumptions, the paradigms and the research methods from (Stake R. E., 1995; Stake R. E., 2005). Thus, the following description of the research design will draw on aspects of him and other interpretivist approaches. Moreover, in the limitations and future research in chapter 7.4, I will explore reflections of alternative research approaches.

4.2 Research Design: Searching for Patterns in Semi-Structured Interviews

The research design includes the topics sources of data, sample and collection of data as well as data analysis.

4.2.1 Sources of Data Collection: Interviews

The exploratory research approach allows the integration of several sources of data, given the information has relevance and fits into the study (Creswell, 2007). The application of different sources is seen to provide higher quality to the findings and uncover diverse meanings (Stake R. E., 1995). For this research, two main sources of data were chosen.

Interviews in two Phases:

- In the first phase, semi-structured interviews with five specialists were conducted to enrich the theoretical perspective in addition to the literature scan. The specialists were from various fields, including mHealth, Brazilian healthcare system and investment. The specialist interviews were held in April and May 2014. Three of the five interviews lasted around 51 minutes. One interview was 31 minutes and another took 79 minutes.
- The second interview phase was performed with five mHealth entrepreneurs in the sense of an evaluation process. The adapted KDS tool had two functions during the interview. On the one hand, the answers were used to evaluate the potential strengths and weaknesses of the start-ups. On the other hand, the tool guided the interview schedule, which was enriched by open-ended questions. Four of the interviews with the entrepreneurs were held in June and July 2014. And one interview was held in June 2015. The entrepreneurs needed between seven and 15 minutes to answer the questionnaire. And the length of the interviews varied between 34 and 76 minutes, depending on the availability.

Informal Knowledge:

In order to emerge into the research field, I had informal exchanges with various stakeholders in the mHealth ecosystem, browsed through websites and participated to multiple events (see appendix 1 for a detailed overview). Some of the knowledge I was able to get during those exchanges helped me to gain additional perspectives, which supported the evaluation.

4.2.2 Data Samples: Specialists and Entrepreneurs

The main source of data used in this research was interviews with important stakeholders in the mHealth ecosystem, namely specialists and entrepreneurs. Thomas (2011) argued that participants, in this research specialists and entrepreneurs, could not be selected to be representative because they will always be framed in certain dimensions. Thus, the interview partners were not selected randomly, but rather through familiarity, which Thomas (2011) called local knowledge.

4.2.2.1 Specialists Data Sample

At the beginning of this study, I engaged in collaboration with Empreender Saúde (ES), Brazil's largest network and platform for digital health start-ups, which was integrated in Live Healthcare Media in early 2015. Three of the specialists were pre-selected and contacted through ES. One of them, Magdala Novaes (2014), had won shortly before the interview the 'Health XL Award' for the most influential person in healthcare innovation in Latin America (Health XL, 2014). The other two, Cláudio Giulliano Costa (2014) and Michele Nogueira Lima (2014), were pre-selected due to previous cooperation with ES and their specialist status in the community. The final two specialists were selected through my network at the university. Ana Malik (2014) has been a professor for public health administration at FGV-EAESP. Gilberto Ribeiro (2014), a guest speaker at FGV-EAESP, has worked for Brazil's largest social impact investor and has been involved with the evaluation of mHealth start-ups for the company's investment portfolio. Table 3 provides a short overview of the profiles of the specialists as well as the date and length of the interview.

Interviewee	Date (length)	Description	Specialty		
Michele Nogueira	14 th April	Professor for Computer	mHealth researcher, focus		
Lima (Lima, 2014)	2014 (52 min)	Science at UFPR	on security		
Cláudio Giulliano	17 th April	Diretor Presidente at	eHealth consultant; former		
Alves da Costa	2014 (31 min)	FOLKS e-Saúde	CIO of Municipal Secretary		
(Costa, 2014)			of Health in Sao Paulo		
Ana Maria Malik	24 th April	Professor for Public	Research focus Brazilian		
(Malik, 2014)	2014 (51 min)	Health Administration	healthcare system		
		at FGV-EAESP			
Magdala de Araújo	24 th April	Professor for Health	Coordinator for telehealth		
Novaes (Novaes,	2014 (79 min)	Informatics at UFPE	and mHealth projects;		
2014)			research focus on telehealth		
			networks		
Gilberto Ribeiro	8 th May 2014	Partner at VOX Capital	Social Impact Investor,		
(Ribeiro, 2014)	(51 min)		portfolio includes mHealth		
			companies		

UFPR: Universidade Federal de Paraná (Federal University of Paraná in the South of Brazil) CIO: Chief Information Officer UFPE: Universidade Federal de Pernambuco (Federal University of Pernambuco in the Northeast of Brazil)

Table 3. Study participants phase 1: specialists.

Moreover, the five specialists were geographically dispersed with one person in the Northeast and one person in the South of Brazil and three people in São Paulo. Two of the specialist interviews were face to face and three via Skype. Three of the interviews were held in Portuguese and two in English. Prior to the interview, all specialists agreed that I could refer to their statements personally.

4.2.2.2 Entrepreneurs Data Sample

The entrepreneurs were also selected based on a combination of the network of ES and of myself. In order to achieve the study purpose to get in-depth feedback, the evaluation process of the start-ups was relatively time intensive and required a certain transparency. So, I relied on the entrepreneurs' willingness to perform the evaluation questionnaire and to meet for the interview. Consequently, I cannot claim that the selected start-ups represented a particular key exemplar or outlier status prior to the selection (Thomas, 2011). In total, I contacted eleven start-ups, out of which three did not find time; two met with me for an informal exchange but did not perform the questionnaire; one performed the questionnaire but did not meet with me; and five answered to the questionnaire and met with me for the interview. All findings were based on the latter group.

Initially, I focused on start-ups, which had operations in Brazil, in order to capture the perspectives around applying the KDS framework in a geographically bounded context (Creswell, 2007). Also, this gave me the opportunity to perform all interviews face to face. Later, I added one evaluation with a start-up, which was based in the Netherlands and operated in Tanzania, in order to analyze, if the findings from the Brazilian context could be transferred to other LMICs. In the Netherlands, I was also able to perform the interview face to face.

Three of the interviews were conducted in English, one in German and one in Portuguese. Table 4 shows a short summary of the start-ups and entrepreneurs, which were interviewed. The names were codified to guarantee anonymity.

All material from the interviews with the specialists and entrepreneurs were recorded and partially transcribed, as further explained in the next section.

Start-	Founded	Lifecycle Stage	Country	People	Features	Area	Condition	Users	Private/
up									Public
Α	9 th November	Implementation	Brazil	4	SMS	Pre-/ post-operative	Chronic	Institutional	Private
	2013					care, Treatment	conditions	providers	
						adherence			
В	7 th January	Development	Brazil	9	Smartphone,	Self-management,	Prevention,	Wider	Public,
	2012				Tablet	Data gathering	Well-being	population	Private
С	1 st January	Development	Brazil	3	Smartphone,	Information,	Chronic	Patients, Wider	Public
	2014	_			Tablet	Training/ education	conditions,	population	
							Prevention,		
							Well-being		
D	1 st January	Sustained	US/ Brazil	75	Smartphone,	Health promotion,	Prevention,	Wider	Public,
	2005	Operation		(1 in	Tablet	Self-management	Well-being	population	Private
		_		Brazil)			_		
Е	12 th January	Sustained	Netherlands	5	SMS,	Treatment	Prevention,	Wider	Public
	2013	Operation	/ Tanzania		Voicemail	adherence,	Well-being	population	
		-				Training/ education			

Table 4. Study participants phase 2: entrepreneurs and start-ups.

Start-up	Evaluated by	Interview	Length of	Interview
		Date	Questionnaire/	Language
			Interview (in min)	
Α	Founder	1 st June 2014	12/34	English
В	Founder	4 th June 2014	11/66	German
С	Co-Founder	9 th June 2014	7/ 76	Portuguese
D	Country Manager	18 th July 2014	15/62	English
E	Business Developer	23 rd June 2015	49/46	English

Table 4. (continued).

4.2.3 Collection of Data: Two Phases of Interviews

4.2.3.1 Interviews with Specialists

The specialist interviews were the main element, in which the topics for the necessary adaptations of the KDS framework emerged. The basic interview guideline is presented in appendix 0. The questionnaire tried to identify the main elements to evaluate mHealth start-ups in LMICs and particularly in Brazil.

The first set of questions sought to describe the experience of the interviewees in regards to their specialty such as mHealth, Brazilian health system or investment as well as to establish a common understanding of the term mHealth. Additionally, the questions worked to build a relationship and break the ice.

In the next section of the questionnaire, I followed two objectives. On the one hand, I wanted to familiarize the interviewee with the topic of evaluation of mHealth start-ups. And on the other hand, I used the answers to estimate the existing knowledge and natural tendency towards certain evaluation structures, as all specialists had prior experience with evaluation of some form.

The third set of questions focused on key points for mHealth evaluation in LMICs and in Brazil, in particular. I asked open-ended questions with an indirect reference to the key elements of the KDS framework: (1) lifecycle stages, (2) outcome themes and (3) scoring. This allowed me to critically review the KDS framework, while at the same time explore new perspectives. Especially regarding the outcome themes, I gained wider knowledge.

In some interviews, I moved forward into the fourth set of questions, which were directly related to the KDS framework. In these interviews I briefly showed and described the KDS framework. Then, I asked explicit questions regarding the added value and potential applications of the KDS questionnaire tool. This phase was used to assess the structure, clarity and content of the tool.

Throughout question sets three and four, I used the flexibility of this research method to follow the leads of the interviewees and picked-up side comments to explore related topics. In this way, I discovered additional concepts of evaluation.

Finally, at the end of the interview, I asked about their perception of the importance of evaluation tools for the advancement of the mHealth field to allow a strategic angle on the debate.

4.2.3.2 Interviews with Entrepreneurs

Once the individual entrepreneurs agreed to participate in the research, I sent them a short description of the research and evaluation process in an email, as shown in appendix 3. The email also included a definition of each lifecycle stage and a link to the questionnaires on 'Google Forms'. The entrepreneurs were asked to choose a questionnaire according to their assessment of the lifecycle stage of their start-ups and to complete one of the questionnaires.

After the self-evaluation was completed, I transformed the answers into a MS Excel spreadsheet and calculated the scores with a semi-automated process. All together the transformation took me around 30 minutes. Then, I spent another 30-60 minutes on reviewing the results. During this process, I searched on the Internet for information that could provide additional perspectives on the start-up and its ecosystem.

I did not provide any results to the entrepreneurs prior to the meeting of the interview. For all interviews I followed a basic guideline, which is presented in appendix 4.

At the beginning of the interview, I briefly repeated the context of the interview, provided an overview of the main phases for the interview, and explained how I transferred the answers into the scoring model and how I calculated the score. Only then, I presented the printed scorecard on a one-pager. I waited shortly for the entrepreneur to get an overview of the numbers. Afterwards, I made a quick summary how I would interpret the strengths and weaknesses of the start-up, based on the results from the questionnaire. Then, I started the interview by asking, if the entrepreneur would agree with my interpretation.

Throughout the next 20-40 minutes of the interview, I did not follow a pre-defined path. I rather used the entrepreneurs' reactions to go through the various outcome themes. This allowed me to get an impression of the themes that the interviewees perceived as most relevant. However, I based some of my follow-up questions on my previous analysis. Due to time constraints, not all aspects were discussed in all interviews. My objective in this part of the interview was to move into the role of an evaluator that tried to get a holistic understanding of the strengths and weakness of the start-up and that could gain insights on the potential for success of the start-up in the future. Once all relevant aspects of the evaluation were covered, I officially ended the evaluation part.

In the final phase, I asked questions regarding the perceived added value of the evaluation. In this part, I was especially interested, (1) if the invested time was worth the benefit, (2) if the entrepreneurs learnt something new about the company and (3) if they would consider repeating the process.

4.2.4 Data Analysis: Search for Patterns

4.2.4.1 Notes Taking and Partial Transcription

During the interview processes, I took notes, which were mainly used to capture key comments and to formulate follow-up questions. Additionally, I digitally recorded all ten interviews to ease the reconstruction of the meaning that the entrepreneurs conveyed in the interviews. I did not transcribe the exact words of the respondents, as my research interest rather lied in the meaning and context that the interviewees provided (Stake R. E., 1995).

Yet, I partially transcribed the main statements and quotes to be used in the writing of the report. Also, I transcribed the exact wording of the questions that I asked, in order to crosscheck the path of the actual interview with the pre-defined interview guidelines.

4.2.4.2 Identifying Patterns

Throughout the search for meaning, the inquirer "searches for patterns, for consistency, for consistency within certain conditions" (Stake R. E., 1995, p. 78).

According to Stake (1995), there are two strategic ways to generate new meaning from data about cases: (1) direct interpretation from an individual instance and (2) categorical aggregation of several instances into a class or category. The tendency to use categorical aggregation is expected to be greater in studies that aim at gaining an understanding on an issue or refining a theory.

I used two techniques to identify the patterns in the interview transcripts and to ultimately provide useful indications for actions to entrepreneurs, investors and researchers (Hlady-Rispal & Jouison-Laffitte, 2014). In the first step, I analyzed the data vertically, meaning within one interview. I used direct interpretation to understand the complexity of the knowledge that the

specialist provided or the experiences that the entrepreneurs shared with me. Secondly, I followed a vertical analyze across interviews, trying to establish categorically aggregated meaning with confirming or contrasting statements regarding the same topics, or additional insights within new perspectives.

During the specialist interviews, I focused on contextualizing the patterns in the scope of the KDS framework, whereas the entrepreneurial interviews relied on the answered questionnaires from the adapted framework, as reference for interpretation (Creswell, 2007).

For the interviews, I used a guideline with open-ended questions, as described in the previous section. When asking the questions, my objective was to move beyond simple 'yes' and 'no' answers towards explanations that would allow me to link the knowledge and experience to theory (Stake R. E., 1995).

4.2.4.3 Personal Position and its Impact on the Findings

As neutrality is impossible for an interviewer, I also had to take a stance (Fontana & Frey, 2005). This differed for the roles I had. For the specialist interviews, I was only in the role of the researcher. For the interviews with the entrepreneurs, I used two roles. At the beginning, I explained the context of the study and the purpose of the interview, as the researcher. Then, I performed the interview as the evaluator. And finally, I returned to the role of researcher and inquired about the added value of the evaluation process. With all entrepreneurs I had preceding discussions about their companies at different occasions and I participated to various events in the start-up ecosystem (see appendix 1). In some cases, I had also participated to company presentations and seen other forms of documents.

My prior involvement with the entrepreneurs and the ecosystem influenced my interactions with the participants (Stake R. E., 1995). For example, it allowed me a certain familiarity with the context and encouraged the entrepreneurs to be transparent and open to share insights. But it also shaped the focus of my evaluation questions, as I had pre-conceived ideas about strengths and weaknesses of the start-ups. The collaboration with ES and my personal network supported me to gain access to the specialists and entrepreneurs, but this might have also led to a convenience sample (Hyett, Kenny, & Dickson-Swift, 2014). After the interviews, I did not perform an

iterative approach by sharing the adapted framework with the specialists or my notes with the entrepreneurs. So, I did not provide the opportunity to the participants "to discuss and clarify the interpretation, and contribute new or additional perspectives" (Baxter & Jack, 2008, p. 556).

Moreover, I did conduct the study in foreign languages. My mother tongue is German and one of the entrepreneurs was also German. All other interviews and documents were either in English, which was only the mother tongue of one entrepreneur, or in Portuguese, which is not my mother tongue. The different languages might have led to diverging interpretations.

In order to address these impacts on the study and make my personal position comprehensible to the readers, I applied certain processes, which are described in the next section.

4.3 Research Quality: Validation Throughout the Process

"All research, positivist and interpretivist, must be robust and characterized by integrity and trustworthiness" (Leitch, Hill, & Harrison, 2010, p. 68). But how this quality is achieved differs among the research methodologies.

As mentioned in chapter 4.1.1, management studies tend towards positivistic traditions (Gephart, 2004; Piekkari, Welch, & Paavilainen, 2009) and thus qualitative research of all forms is often assessed with the objective to discover "the truth underlying the relations among variables, by means of research that is characterized by the traditional criteria of internal and external validity, reliability, objectivity, and generalizability" (Leitch, Hill, & Harrison, 2010, p. 72).

In interpretive research, the purpose is neither to verify nor to refute a prior theory, but rather to further develop theories, which are related to the lived experiences of people. So, quality measurements cannot only be applied to the outcome, but quality should be internalized in the complete research process, according to (Leitch, Hill, & Harrison, 2010). Based on Angen's (2000) term of validation instead of validity regarding research quality, Leitch, Hill & Harrison (2010) summarized three elements to ensure quality in an interpretive research paradigm: (1) ethical validation, (2) substantive validation and (3) valid interpretation of the researcher. These are summarized in Table 5.

In ethical validation, the objective of the researcher is to develop the self-awareness of the participants by asking about the helpfulness of the research for the target population, the presentation of alternative explanations and the improved awareness of social interactions. Substantive validation is based on careful consideration of the researcher's biases and the change of those from early on in the study until completion of the research. Finally, the researcher's interpretation of the topic must be valid and convincing for the audience (Angen, 2000). Moreover, "being sensitive to and capitalizing on redirections is a sign of quality" (p. 572), according to (Piekkari, Welch, & Paavilainen, 2009).

	Research Design and	Analysis	Interpretation
	Data Collection		
Ethical	Moral stance	• Give voice to	Generative potential
Validation	 Practical value 	participants	• Addresses 'so what'?
	• Understand meanings	Choice of method	question
	Research process	 Transforms actions 	
Substantive	 Intersubjectivity 	Record own	• Self-reflexivity
Validation	• Self-reflexivity	transformation	Record own
	• Popular & personal	• Present disconfirming	transformation
	understandings	cases	• Evidence of conceptual
	• Researcher's paradigm	Theoretical candor	• development
	& pre-understandings	• Transparency	• Dynamic research process
	• Access		• Transparency
Researcher	Characteristics &	 Personal involvement 	Craft work
Quality	attributes		
Quality	• Indicators of credibility	 Visibility of 	• Rhetoric & persuasion
	Moral stance	researcher's work	
	Purpose of research		

 Table 5. Validation throughout the research process.

 Adapted from Leitch, Hill, & Harrison (2010)

4.4 The Research Methodology in a Nutshell (Summary)

In summary, this exploratory research for a new approach to analyze mHealth start-ups in LMICs relies on a research paradigm, which was inspired by Robert Stake's (1995, 2005) interpretivism, assuming that there were multiple realities, existing in lived experiences of entrepreneurs.

First, semi-structured interviews with five specialists in mHealth, Brazilian healthcare system and investment were used to identify necessary adaptations for the KDS framework and tool, which Khoja, Durrani, Scott, Sajwani, & Piryani (2013) proposed. Then, the adaptations to the framework and questionnaire tool were made.

In the second phase, the associated questionnaire tool was tested with five start-ups, operating in Brazil and Tanzania, and semi-structured interviews were conducted with the entrepreneurs to gain insights about the start-ups and to understand the complexity of evaluation and decision-making in this context.

The findings will be described in two chapters. First, a detailed discussion of the managerial model, so the adapted KDS evaluation framework and questionnaire tool, will be shown in chapter 5. Second, the results of the trials and interviews with the entrepreneurs in the field will be presented in chapter 6.

5 Adapting the KDS Framework to a Managerial Model for mHealth Start-ups

The process for the adaptation of the model to evaluate mHealth start-ups in LMICs was bottomup. First, I entered into the micro details of the questionnaire tool and critically analyzed possible adaptations, based on the interviews with the specialists and additional literature. As described in the methodology, this was an iterative process, switching between interviews and literature. The result will be presented in the following section 5.1. Second, I established a new synthesized evaluation framework in section 5.2, describing the key concepts, which were used for each evaluation theme, based on the original KDS framework from Khoja, Durrani, Scott, Sajwani, & Piryani (2013). Both together, the questionnaire tool and the adapted evaluation framework, form the basis for the managerial model for mHealth start-ups in LMICs.

5.1 Adapted Questionnaire Tool

Based on the KDS framework, the research team in the network of the PAN Asian Collaborative for Evidence-Based eHealth Adoption and Application (PANACeA) developed four separate evaluation tools to evaluate each lifecycle stage of an e-health program. Each tool has a separate question set to represent the different perspectives of the users of the evaluation tool (i.e. manager, healthcare provider, and client) (Khoja, Durrani, Scott, Sajwani, & Piryani, 2013). Although the tools have not yet been validated and made available for general use, I was able to retrieve the question sets from the project's website: http://panacea-evaluation.yolasite.com. I copied all questions into a MS Excel spreadsheet and made the changes based on literature and the interviews with the specialists.

The following section will present an overview of the changes in five parts: (1) general adaptations of the tool, (2) lifecycle stages, (3) evaluation themes, (4) questionnaire process and scoring, and (5) technical solution for the questionnaire tool.

5.1.1 General Adaptations to the Tool

Focus on one set of questions from the entrepreneurial view

All interviewees mentioned that different perspectives must be reflected in the evaluation process. In particular, the users' or customers' view seem to play an essential role, according to the interviewees. Novaes (2014) even proposed to include the patient actively in the conceptual development phase. Yet, there was no agreement among all specialists on how to practically integrate the various stakeholders directly in the metrics of the evaluation.

In the KDS tool, three different questionnaires ensure the representation of the manager's, health provider's and client's perspective. In the details, however, it seems as if the KDS tool focuses on the perspective of hospital managers and political decision makers. This might be due to the background of Khoja, Durrani and Scott, the main researchers of the framework.

Although different perspectives are highly important for the evaluation process, I chose the management view as basic tool. This study focuses on the framework as a managerial model for the entrepreneur and is thus concerned with the perspective of the company that offers the mHealth solution. Still, the discussion below will highlight how different views will be integrated.

Despite the focus on the management view, I crosschecked the other two questionnaires (i.e. health provider and client) regarding their overlap and analyzed the unique questions concerning their usefulness for the entrepreneurial view. In the health provider questionnaire was one question in the 'health services' theme and four questions in the 'ethical' theme at the 'development' stage that were not already part of the management view. In the client questionnaire was no question that was not already part of the management or health provider questionnaires. After the analysis, all of the following five questions were included unchanged in the questionnaire:

- 2.1.7. Clear indicators for measuring outcomes in health services and health status have been determined (from health provider questionnaire)
- 7.1.1. Ethical guidelines have been followed in selection of study participants for the testing or pilot phase (from health provider questionnaire)
- 7.1.4. mHealth initiative has the potential to improve Equity in health among gender and social groups for client (from health provider questionnaire)
- 7.1.5. mHealth program has the potential to improve Autonomy of clients (from health provider questionnaire)
- 7.1.6. mHealth initiative has the potential to improve Equity in health among gender and social groups for staff (from health provider questionnaire)

At this point, the tool consisted of only one question set.

Language, Wording and Numbering

The original questionnaire was in English. In order to facilitate the discussion with respondents in Brazil and to broaden the scope of possible entrepreneurs to participate in the study, I translated the tool into Brazilian Portuguese. No professional language check was performed.

Further, the KDS framework differentiated between staff and clients, which might be necessary for eHealth applications in hospitals. However, for the wide adoption of mHealth in various contexts and for simplicity, I changed all ambiguous wording into 'user', representing the person that uses the mHealth application (see appendix 5 for a detailed overview).

Each question had a three-digit code, identifying theme (1^{st} digit) , lifecycle stage (2^{nd} digit) and number of question in the theme and at the stage (3^{rd} digit) . The order of the themes was adjusted to allow a better flow of the questionnaire (see chapter 5.1.3 for details). The new order for the outcome themes was: (1) introduction, (2) health services and health status, (3) technology, (4) behavioral and socio-technical, (5) economic, (6) readiness and change, (7) ethical, (8) policy, and (9) entrepreneurial. For the second digit, the numbering remained unchanged: (1) development, (2) implementation, (3) integration and (4) sustained operation.

For all questions that remained unchanged until this point, the word 'eHealth' was changed to 'mHealth'.

Introduction of the Questionnaire

At the beginning of the questionnaire, the questions for the introduction were changed, in order to fit the context.

Original Tool	Adapted Tool
Country	Deleted
Gender	
Name of the Project	1.1.2. What is the name of the mHealth
Name of Institution	company/ initiative?
Experience with mHealth Project	1.1.3. When was the start of the mHealth
(Months and years)	initiative (mm/yyyy)?

In addition, six questions were added to improve the classification of the start-ups regarding (1) size, (2) technical features, (3) area, (4) medical conditions, (5) users, and (6) public or private sector focus. For some of those questions a dropdown list provided pre-conceived ideas, based on available classifications from the literature.

- 1.1.4. How many people currently work for the mHealth initiative?
- 1.1.5. Which features are used by the mHealth initiative? Dropdown: Text-messaging (SMS), Add-on/ Device, Voice, Video, Multimedia messaging service (MMS), Smartphone/ Tablet App (based on Fiordelli, Diviani, Schulz, & Eysenbach (2013)).
- 1.1.6. Which area does the mHealth initiative impact? Dropdown: Health promotion, Selfmanagement, Communication/ Information, Remote monitoring, Data gathering, Diagnosis, Treatment adherence, Training/ education (based on Klasnja & Pratt (2012); Free, et al. (2013a); Fiordelli, Diviani, Schulz, & Eysenbach (2013)).
- 1.1.7. On which group of medical conditions does the mHealth initiative focus? Dropdown: Chronic conditions, Prevention/ Well-being, Acute conditions (based on Fiordelli, Diviani, Schulz, & Eysenbach (2013); Porter, Pabo, & Lee (2013)).
- 1.1.8. Who are the main users of the mHealth initiative? Dropdown: Individual healthcare providers (e.g. doctors, nurses), Institutional healthcare providers (e.g. hospitals, pharmacies), Patients, Wider population (based on Orwat, Graefe, & Faulwasser (2008); Mosa, Yoo, & Sheets (2012); Free, et al. (2013a)).
- 1.1.9. Are the users of the mHealth initiative mainly in the scope of the public (SUS) or private sector? Dropdown: Public (SUS), Private (based on Paim, Travassos, Almeida, Bahia, & Macinko (2011)).

5.1.2 Maintaining the Lifecycle Stages

All interviewees highlighted that the metrics and questions to evaluate mHealth startups should be differentiated depending on the status of development. However, no clear trend on the number of stages, the clear differentiation between stages or the specific names for each stage could be identified. For example, some compared the process to product lifecycles (Lima, 2014) and others used maturity levels to describe the different phases of a start-up (Ribeiro, 2014).

Thus, I decided to keep wording and definition of the KDS framework: (1) development, (2) implementation, (3) integration and (4) sustained operation stage (see chapter 3.3 for details).

5.1.3 Refining the Evaluation Themes

The interviews with the specialists and the review of various literature revealed that all themes were relevant. However, some themes were mentioned more frequently than others (i.e. the socio-technical features and the economic business model), indicating that those are of higher importance for the evaluation. Moreover, one theme was added, as the interviews revealed that a focus on the entrepreneurial perspective was missing. In the following, I will describe how the questions in each theme across the four lifecycle stages were adapted.

5.1.3.1 'Health Services and Health Status' Outcome

As the questions in the health theme of the KDS framework included not only service related issues, but also health status relevant questions, I changed the title to 'health services and health status'. In the following, I will refer to this theme in the short form 'health'.

Moreover, two questions at the 'implementation' stage were focused on eHealth. Thus, I merged them into one general question.

Original Tool	Adapted Tool
In comparison to baseline, mHealth	2.2.6. In comparison to baseline,
improves time and quality of decision	mHealth improves time and quality of
making of healthcare providers	decision making
In comparison to baseline, mHealth	
improves/increases decision making in	
management of health services and	
unit/institution	

5.1.3.2 'Technology' Outcome

Although the formulation of the questions was eHealth driven, the technology points were seen to fully apply to mHealth. Of the three interviewees, who reviewed the complete KDS question set, none mentioned any concerns (Lima, 2014; Novaes, 2014; Ribeiro, 2014). In addition, I checked the questions in detail and finally concluded to leave them unchanged.

5.1.3.3 'Behavioral and Socio-technical' Outcome

The KDS framework developed the 'behavior and socio-technical' theme based on sociotechnical theories and social impact assessment. I agree that both, socio-technical analysis and social impact assessment, are important. Yet, they are unique theories. Socio-technical theories try to understand the social aspects of technology implementation; in other words, the interactions between humans and technology (Khoja, Durrani, Scott, Sajwani, & Piryani, 2013; Coiera, 2007). Whereas social impact assessment tries to focus on social consequences or social changes that might be results of the technology-based health intervention (Vanclay, 2003).

As the 'ethical' theme also included some questions related to social impact assessment, I clearly separated the two unique fields and integrated all issues regarding social impact in the 'ethical' theme (see 'ethical' outcome in section 5.1.3.6).

Although the theme 'behavior and socio-technical' in itself was not explicitly mentioned by the interviewees, the content of those topics was highlighted. Especially user-acceptance of technology and the human aspects of technological change were seen as highly important in this field (Lima, 2014; Novaes, 2014). Therefore, this theme was replaced directly after the 'technology' theme.

In the identification of social groups, the KDS framework relied on the work of Braveman & Gruskin (2003). Although several groups were identified in the research (i.e. socioeconomic, racial/ ethnic or religious groups, or groups defined by gender, geography, age, disability, or sexual orientation), only one group was explicitly considered in the design of the eHealth solution, namely gender. All other groups were indirectly included in the questionnaire under the term 'social groups'.

In the Brazilian mHealth context, as shown in chapter 2.2, three of those social groups play a significant role: (1) socioeconomic groups address the high income inequality, (2) gender groups address especially in the public sector the over-representation of female patients, and (3) age groups address issues around the novelty of the technology. Therefore, two questions were merged and re-formulated to address these groups explicitly.

Original Tool	Adapted Tool
Gender sensitivity and equity of staff	4.1.4. Different social groups of users
have been considered in	(e.g. socio-economic, gender, age) have
designing/acquiring technology for	been considered in designing/acquiring
mHealth initiatives	technology for mHealth initiatives
Sensitivity and equity among different	
social groups of staff have been	
considered in designing/acquiring	
technology for mHealth initiatives	

5.1.3.4 'Economic' Outcome

The questions in the economic theme can be grouped in three sub-themes: (1) outcome, (2) costs and reimbursement, and (3) affordability and incentives.

Outcome

Outcome evaluations were explicitly and implicitly included in the themes and questions across all stages of the 'economic' theme and at the 'sustained operation' stage of the 'health' theme. As shown in Table 1 in section 3.3.1, the influencing factors in the economic theme of the KDS framework were described for each of the lifecycle stages as: (1) affordability and costminimization, (2) cost utility, (3) cost-benefit, and (4) improved quality-adjusted life-years (QALYs) and improved disability-adjusted life-years (DALYs). Note that QALYs and DALYs are a form of cost-utility evaluation (Beresniak, et al., 2013). All health evaluation models will be described in the following.

In addition to the influencing factors of the 'economic' theme in Table 1, the description in the analysis part of the paper mentioned that "cost-effectiveness will determine the least costly system that is capable of delivering a specified set of outcomes" (Khoja, Durrani, Scott, Sajwani, & Piryani, 2013, p. 50).

Also, the 'health' theme highlighted at the 'sustained operation' stage measures of "health impact showing change via indicators" (Khoja, Durrani, Scott, Sajwani, & Piryani, 2013, p. 51) "on the basis of [...] impact on quality of life" (Khoja, Durrani, Scott, Sajwani, & Piryani, 2013, p. 50).

It seemed to me as if the KDS framework and tool did not differentiate enough among general terms for the various methods of health outcome evaluation. This renders the framework not fully comprehensible on the methods of outcome evaluation, as highlighted in one interview (Ribeiro, 2014). The investment specialist mentioned that it was important to differentiate the terms that were used for the outcome evaluation, as they implied different meanings. In order to clarify the terms, I drilled deeper into the theory of health outcome evaluation models.

There are four methods for outcome evaluation in healthcare: (1) cost-minimization analysis (CMA), (2) cost-effectiveness analysis (CEA), (3) cost-utility analysis (CUA), and (4) costbenefit analysis (CBA). In CMA, two interventions with the same outcome are compared on the sole basis of costs (Slothuus, 2000). CEA uses the same concept of costs, but measures the outcome of different alternatives in natural units. The objective is to find a solution with the lowest costs per unit. If the intervention is worth its costs, however, is not determined (Slothuus, 2000). CUA also tries to achieve a given goal for the lowest costs. In contrast to CEA, CUA allows to integrate more than one dimension to measure the goal of a health intervention. One such example is the measurement of QALYs, in which the outcome is shown in a single index as the gain in quality and life years (Slothuus, 2000). More specifically, "QALY is the product of life expectancy (estimated in years) and its quality over that time (estimated in utilities or OOL [quality of life] units)" (McGregor & Caro, 2006, p. 947). This concept can be applied to determine decisions for project implementations by aggregating total improvements for groups of individuals (Slothuus, 2000) and compare those across medical specialties (Räsänen, Roine, Sintonen, Semberg-Konttinen, Ryynänen, & Roine, 2006). Finally, CBA transfers benefits of a health intervention into monetary units, as a mirror to the costs. On the sum of benefits and costs a discount rate can be applied in order to calculate the net present value of the mHealth initiative. This allows comparison across sectors, for example in the policy decision-making process. The CBA provides a statement about the worth of pursuing a certain health goal (Slothuus, 2000; Beresniak, et al., 2013).

As mentioned above, Ribeiro (2014) stated in the interviews that the questions and descriptions for the 'health' and 'economic' outcomes in the KDS framework were not fully clear. Further, he revealed that it would be important to focus on one economic evaluation model, which would elaborate over time.

For the implementation phase, the KDS tool used two questions to express the objective of reducing costs of service, summarized as CMA. However, Slothuus (2000) argued that "CMA is used when two interventions that are being compared have the same outcome" (p. 31). Consequently, CMA might only apply to mHealth start-ups that aim at comparing their product with similar or identical products of competitors. Moreover, mHealth does not always reduce costs; sometimes it changes the value proposition of a product or service and consequently adds new or larger revenue streams. CMA seems too one-dimensional to evaluate the economic impact of mHealth start-ups. So, I decided to delete the two questions regarding CMA.

	Origina	al Tool			
mHealth reduces cost of service					
(cost-minin	nization)	for the	insti	tution	
mHealth reduces cost of service					
(cost-minimization) for the clients					

Concerning CEA in the KDS framework, it should be highlighted that the 'health' theme included various questions regarding the outcome measures in natural units. While CEA tries to reach a given goal for as little costs as possible (Slothuus, 2000), mHealth is characterized as being a very new field, in which it is often unknown what the specific goal might be and which offers a very of still undiscovered services (Costa, 2014). Consequently, the term CEA was excluded for the adapted tool.

Similar to the QALY term, which was introduced above, also the DALY concept is a form of CUA. Although the KDS framework in Table 1 mentioned CUA at the 'implementation' stage of the framework, it only raised QALY and DALY specific questions at the 'sustained operation' phase of the 'health' and 'economic' theme in the questionnaire tool.

After an original study by Harvard University and World Bank, the WHO embraced the DALY measurement to study the global disease burden (Horton, 2012). DALY is a "sum of years of life lost (YLLs) and years lived with disability (YLDs)" (Murray, et al., 2013, p. 2197), shown in Figure 4.



Figure 4. Disability-adjusted life years (DALYs). Adapted from Planemad (n.d.).

After the initial publishing of results for the disease burden in 1990 with 107 diseases and injuries and ten risk factors (Murray C. J., 1994), the most recent assessment of data on disease, injuries and risk was done for 2010 based on 235 causes of death and 67 risk factors (Murray, et al., 2013). In addition to supporting the set-up of national health priorities, the DALY can "provide a comparable measure of output for intervention, program and sector evaluation and planning" (Murray C. J., 1994, p. 429).

Although QALY has been the most important indicator for the assessment of health interventions in particular in the US and the UK (Räsänen, Roine, Sintonen, Semberg-Konttinen, Ryynänen, & Roine, 2006), it has been much criticized and highly controversial (Slothuus, 2000; Räsänen, Roine, Sintonen, Semberg-Konttinen, Ryynänen, & Roine, 2006; McGregor & Caro, 2006; Beresniak, et al., 2013). The QALY measurement relies on the assumption of the existence of perfect health and an equivalent value of QOL units in the eyes of society (McGregor & Caro, 2006). However, due to different theoretical definitions, results of the measurements can be divergent. Thus, a recent study from the European Consortium in Healthcare Outcomes and Cost-Benefit Research (ECHOUTCOME), funded by the European Commission, suggested to abandon QALY (Beresniak, et al., 2013).

For the reasons of, firstly, aiming at only one evaluation model, which elaborates in complexity over time, and secondly, avoiding the controversies around the QALY, the wording of CUA and of QALY were not included in the questionnaire and model. DALY remained, however, because the WHO has used the concept as reference, especially towards the policy formulation to reduce the global disease burden and the measurement of health interventions in LMICs. The questions in the 'health' and 'economic' themes at the 'sustained operation' stage were adapted.

Original Tool	Adapted Tool
mHealth improves longer term health	2.4.1. mHealth improves in longer term
indicators, such as Quality adjusted life	the health indicator disability-adjusted
years (QALYs) or Disability adjusted	life years (DALYs), meaning it
Life years (DALYs)	decreases early deaths and/or decreases
	the number of years lived with disability
Impact of investments in mHealth on the	5.4.1. Impact of investments in mHealth
health indicators, Quality adjusted life	on the health indicator disability-
years (QALYs) or Disability adjusted	adjusted life years (DALYs) has been
Life years (DALYs) has been calculated	calculated

Consequently, the outcome sub-theme of the economic dimension of the evaluation tool focuses on CBA as a single evaluation model, which develops in complexity with the progress of the mHealth solution. CBA is particularly important in situations with limited resources, where informed decision about the efficient allocation of resources have to be made (Slothuus, 2000). mHealth solutions in LMICs have to constantly proof their worth to allocate investments in a chronically underfunded environment, as shown in chapter 2.2.

Moreover, the CBA allows a company to make cross-disease comparisons (Slothuus, 2000). Benefits must be based on an outcome measures. At the 'development' stage of the 'health' theme, indicators to assess the impact of the mHealth initiative on health services and/or status should already be identified. In a further step, the improvements due to the mHealth solution should be compared to either the former way of working or in the case of creating a new service to a reasonable alternative. The level of improvement can be obtained from the continuous measurement of the change of the previously defined indicators. Following the measurement of the 'health' indicators, the benefits and costs should be transformed into monetary values (Slothuus, 2000; Beresniak, et al., 2013). During this process all impacts on resources should be considered, even those that did not occur directly for the mHealth company or that arose later in the process (Chib, van Velthoven, & Car, 2015). For example, a mHealth initiative, which sends reminders to patients to take certain medicines, does not only improve the health status of the patient, but also increases the costs for the supply chain of pharmacies and the reimbursement fees for insurance companies, while at the same time the revenues of pharmaceutical companies increase. After all impacts have been estimated, the CBA can be completed. In order to reflect the need to consider all resources, two explicit questions were added to the 'implementation' and the 'integration' stage of the 'economic' theme.

- 5.2.3. Impact of mHealth initiative on resources in wider societal perspective such as relatives, hospitals and municipals have been considered
- 5.3.2. All costs and resources in a wider societal perspective have been quantified in monetary values

Costs and Reimbursement

The costs can be viewed from two perspectives: (1) societal perspective and (2) company perspective. The former is difficult to assess, but it is of importance for the CBA analysis, as discussed in above. The latter is subject of discussion at this point.

All four outcome evaluation concepts, CMA, CUA, CEA, and CBA, agree on the criterion of costs to be measured in monetary units. Yet, there is extensive debate about how the monetary value of costs should be calculated in healthcare. One approach, developed by Kaplan & Porter (2011), is called time-driven activity-based costing (TDABC), which aims at assigning costs to each process step of an individual patient along a typical path for a medical condition.

Complex cost models such as the TDABC are often not appropriate for entrepreneurs and startups, as mentioned by Ribeiro (2014) in the interview. As smaller companies dominate the mHealth field, it can be more relevant to focus on simple cost models such as Osterwalder, Pigneur, Smith, Clark, & Pijl's (2010) theory on the business model canvas, which suggested splitting the recurring costs into fixed and variable costs only.

More specific to healthcare but also simple, Scott, et al. (2007) identified three cost factors in their literature review of outcome indicators in telehealth: (1) time and distance for transportation, (2) operational human resources, and (3) capital for equipment.

In addition to the question of which costs occur and how they should be calculated, the general debate in healthcare expands around how costs should be reimbursed. Reimbursement is a very unique feature of healthcare, increasing its complexity. For many medical conditions, providers provide the health service to patients and are later reimbursed by the patient directly or through insurance companies indirectly. In the case of many mHealth initiatives such as Smartphone apps, the mHealth companies are not reimbursed but receive direct revenues, for example for each download of the app. Consequently, reimbursement could be seen as additional revenue

stream in addition to usage fees, renting and leasing fees, and advertisement, among others in the business model (Osterwalder, Pigneur, Smith, Clark, & Pijl, 2010).

Ribeiro (2014) mentioned in the interview that it was important for a start-up to plan expected revenues and costs from the very beginning of the development process, in order to develop a sustainable business model. According to him, many companies face barriers on this issue.

In the tool of the KDS framework, the only question in regards to costs arose at the 'integration' phase. Especially from the perspective of investors this is too late (Ribeiro, 2014). Therefore, one question was added at the 'development' stage. In order to enlarge the perspective on revenue streams, the two questions of reimbursement models were modified.

Original Tool	Adapted Tool
	5.1.2. Model for cost structure for the
	mHealth initiative has been prepared
Cost for integration of mHealth initiative	5.2.2. Model for cost structure for the
has been calculated	mHealth initiative has been calculated
Reimbursement model for	5.1.1. Model for revenue streams such as
institution/provider has been prepared	sales, fees and reimbursement has been
	prepared
Reimbursement model for	5.2.1. Model for revenue streams such as
institution/provider is in place	sales, fees and reimbursement has been calculated

The four questions regarding the revenue streams and the cost structure of the start-up build the corner stones for the evaluation of the self-sustainable business case of the mHealth initiatives.

Affordability and Incentives

The KDS framework integrated the concept of affordability in the tool to reflect the financial acceptance of the technology. In other words, affordability expressed the willingness of users to pay for the eHealth solution (Khoja, Durrani, Scott, Sajwani, & Piryani, 2013). The measure for willingness-to-pay was also implicitly expressed in the questions around the concept of CBA. So, it can be assumed that if the business case is positive and the societal benefits are high, the solution will be affordable and accepted.

Yet, the KDS framework highlighted the need to consider incentives for health providers. On the one hand, it can be argued that based on a positive results of an adequate CBA, all stakeholders

should adopt the mHealth solution. But this is often not the reality, according to Costa (2014), who has consulted various industry players in the adoption of eHealth solutions. The barriers for the adoption and use of new technologies in Brazil are high, as Malik (2014), whose research focus is the Brazilian health system, mentioned in the interview. The system is fairly rigid towards change. Incentives must be not only monetary in nature but also about convincing main stakeholders about the benefits. As conclusion, three questions related to affordability at the 'development' stage were deleted and the questions regarding incentives were left unchanged.

Original Tool	Adapted Tool
Affordability of desired technology has	Deleted
been considered for its selection for the	
mHealth initiative	
Affordability of mHealth initiative has	
been considered for users	
mHealth initiative is affordable in the	
given environment	

5.1.3.5 'Readiness and Change' Outcome

At the 'development' stage of the theme 'readiness and change', two questions seemed to focus more on organizations such as hospitals. Companies that develop end user initiatives such as Smartphone apps might not be able to answer these questions. Thus, those two questions were merged into one question to allow a broader applicability.

Original Tool	Adapted Tool
Preparation of human resource in terms of changes in practices, working relationships, and flow of communication has been planned	6.1.4. Preparation of human resource in terms of changes in practices, working relationships, management process and flow of communication has been planned
Changes in management processes for mHealth implementation have been planned	

5.1.3.6 'Ethical' Outcome

The 'ethical' theme consisted of two major concepts: (1) practical ethical questions stemming from the use of mHealth, e.g. data security and (2) questions regarding social equity, e.g. the improvement of inclusion (Khoja, Durrani, Scott, Sajwani, & Piryani, 2013). The former has been adequately addressed by the existing questions (Lima, 2014).

Regarding the latter, social impact assessment tries to focus on social consequences or social changes that might be results of the technology-based health intervention (Vanclay, 2003), as mentioned above in the 'behavioral and socio-technical' theme. According to Scott & Mars (2015), mHealth has the potential to increase health equity, what is especially important in LMICs. Thus, two questions based on Wolk & Kreitz's (2008) social innovation theory were added at the 'integration' and 'sustained operation' stage, in order to reflect social impact strategies and to explicitly foster inclusion.

- 7.3.1. Plan in place to further improve equity in health through improvement of points of inclusion for social groups in mHealth initiative
- 7.4.1. Plan implemented to further improve equity in health through improvement of points of inclusion for social groups in mHealth initiative

Finally, three questions regarding the social groups were adapted in line with the discussion in the theme 'behavioral and socio-technical'.

Original Tool	Adapted Tool
mHealth initiative has the potential to	7.1.4. mHealth initiative has the
improve Equity in health among gender	potential to improve equity in health
and social groups for client	among social groups (e.g. socio-
mHealth initiative has the potential to	economic, gender, age)
improve Equity in health among gender	
and social groups for staff	
mHealth initiative improves Equity in	7.2.4. mHealth initiative improves
health among gender and social groups	equity in health among different social
for client	groups of users
mHealth initiative improves Equity in	
health among gender and social groups	
for staff	
5.1.3.7 'Policy' Outcome

In the interview, Malik (2014) highlighted that on a general level decision makers must be accompanied by practical evidence to adopt the change. In order to emphasize early in the process the importance of disseminating outcome and research, one question was added at the implementation phase.

8.3.6. Plan is in place to dissemination research/program outcomes to concerned decision and policy-makers

5.1.3.8 'Entrepreneurial' Outcome

In addition to the seven themes, especially the interview with Ribeiro (2014), the social impact investor, revealed one major shortcoming of the KDS framework. Although the tool allowed evaluating what an initiative was doing, it did not describe how and more importantly who was the main driving force inside the initiative. Freedman (2014), for example, suggested that start-ups would be an important actor in driving the disruptive change in the health sector.

According to my knowledge, no mHealth evaluation model or related framework has yet tried to incorporate the entrepreneurial perspective in the context of LMICs. Thus, I looked at existing frameworks and decision-making criteria used by entrepreneurs and investors to assess start-ups.

Usually investors assess companies in two steps called due diligence: (1) screening and (2) evaluation (Zacharakis, 2010). In this assessment process the investors look among other things at the abilities and capabilities of the entrepreneur and the team (Harvey & Lusch, 1995; Smart, 1999; Kaplan & Strömberg, 2004; Mason & Stark, 2004; Zacharakis, 2010; Bernstein, Korteweg, & Laws, 2014). Although Hall & Hofer (1993) argued that entrepreneurial and team capabilities are not of importance in the initial screening phase, a study of Mason & Stark (2004) highlighted the high importance of human capital criteria in the overall due diligence process. Studies of Mason & Stark (2004) and Kaplan & Strömberg (2004) associated the assessment of the entrepreneur and team with the internal risk that rested within the investment from the venture capital (VC) perspective. This risk assessment of the VC of the invested company (Kaplan & Strömberg, 2004; Mason & Stark, 2004; Zacharakis, 2010).

Theories about other investor types showed that for example business angels, who typically invest in early-stage start-ups, also looked at human capital before and during the investment process. However, there was no clear trend regarding the importance of human capital for the different investor types, business angel and VC (Mason & Stark, 2004; Maxwell, Jeffrey, & Lévesque, 2011).

A study of Colombo & Grilli (2010) of new technology companies confirmed the theory on the importance of human capital for start-ups and continued to explore the concept by assessing the impact of human capital criteria on the growth of a company. The findings suggested that human capital had a direct and indirect impact on the growth of a company. The direct effect was mainly driven through the managerial and economic university education of the entrepreneur as well as the working experience in the field of technology of the start-up. The indirect effect of human capital on the growth resulted from the fact that VC providers were attracted by certain human capital characteristics, namely managerial and economic university education as well as managerial working experience. In other words, if a company had high human capital, it attracted VC more easily, which in return led to higher growth (Colombo & Grilli, 2010).

These findings of growth are also in line with a study of The Small Business Development Center of the Bradley University that analyzed failure, so the contrary of growth. The study named incompetence, lack of managerial experience and lack of experience in the line of service as major causes for start-up failure (Statistic Brain, 2014).

Additionally, business model theories, especially in the field of social entrepreneurship highlighted the significance of human capital aspects in regards to building a team (Wolk & Kreitz, 2008).

As mentioned previously, the KDS framework did not include 'entrepreneurial' outcome measures and thus lacked an important dimension to be used as a managerial model. The entrepreneur's self-assessment of the company's human capital might help to identify an important perspective on the strengths and weaknesses for future growth of the start-ups. Therefore, I included questions regarding the entrepreneurial and team aspects in an eight theme of the adapted framework.

At the 'development' stage:

- 9.1.1. Plan to adopt requirements for management team of mHealth initiative concerning education in management/ economic studies as well as work experience in managerial and mHealth related fields has been prepared
- 9.1.2. Requirements for team positions and skills have been prepared

At the 'implementation' stage:

- 9.2.1. Education in management/ economic studies as well as work experience in managerial and mHealth related fields for management team of mHealth initiative are in place
- 9.2.2. Organization structure and processes have been prepared
- 9.2.3. Requirements for team positions and skills have been decided

At the 'integration' stage

- 9.3.1. Organization structure and processes are in place
- 9.3.2. Team positions and skills are in place

Moreover, the interview with Lima (2014) revealed the importance to look at the rapid change of technology as special feature for mHealth. In the early 90s, Senge (1990) developed the theory of continuous organizational learning in a system as main driver for success. So, one question at the 'sustained operation' stage was added to reflect the need to stay ahead of the technological changes:

9.4.1. Plan is in place for continuously learning in the organization in order to adapt technological and other changes concerning the mHealth initiative

5.1.4 Clarified Questionnaire Process and Scoring

Process

After all changes to the evaluation tool were implemented, the complete questionnaire was completed, as shown in appendix 6. Table 6 shows an overview of the number of questions per lifecycle stage and outcome theme. In total, the questionnaire has 122 questions, excluding the introductory questions. The original KDS question set with the integration of all views in one questionnaire had 128 questions.

	Development	Implementation	Integration	Sustained Operation	
Introduction	9				
Health Services	7	12	5	4	28
and Health Status					
Technology	13	7	1	2	23
Behavioral and	4	2	1	1	8
Socio-technical					
Economic	3	4	3	1	11
Readiness and	5	6	2	3	16
Change					
Ethical	5	5	1	1	12
Policy	5	6	3	2	16
Entrepreneurial	2	3	2	1	8
	44	45	18	15	122

Table 6. Number of questions per lifecycle stage and outcome theme.

The design of the KDS framework suggested that at each lifecycle stage the questions for the current and all previous stages should be answered. I adopted this process, as the lifecycle stages build-up on each other, and so the combination of the previous and the current stages allow a comprehensive overview of the mHealth solution. In practice this means that an entrepreneur at the 'development' stage would answer all 44 questions for that phase. An entrepreneur at the 'implementation' stage would answer all 44 questions from the 'development' stage plus all 45 questions from the 'implementation' stage, so in total 89 questions. The same logic continues for the next stages. The nine introductory questions are only asked once and do not count into the totals or scoring.

Several questions directly test, if something has been planned at one stage and then implemented or monitored in the subsequent stages. A risk of asking both questions is that it might create the feeling of redundancy. One solution would have been to merge the two questions. Yet, I thought it might be interesting to keep both questions to test for inconsistencies. This will be subject to further discussion after the application with the entrepreneurs.

Score

The KDS framework proposed that for each question the respondent could choose among six options that are linked to a Likert-like scale: unsatisfactory (1), below expectations (2), meets expectations (3), above expectations (4), extraordinary (5), and don't know (1). The respondent would not see the numbers, when answering, and would not know how the answers would be scored. Further, in the KDS framework there was no weight for single themes or questions, meaning that all questions had the same importance for the score. Table 7 shows the maximum score per lifecycle stage and outcome theme, if all questions would be answered with 'extraordinary', so 5 on the Likert-like scale. The score per stage and theme would then be calculated by dividing the sum of the points from the answers per lifecycle stage and theme with the maximum possible score.

	Development	Implementation	Integration	Sustained Operation	
Haalth Commisse	25	(0	25		140
Health Services	55	00	25	20	140
and Health Status					
Technology	65	35	5	10	115
Behavioral and	20	10	5	5	40
Socio-technical					
Economic	15	20	15	5	55
Readiness and	25	30	10	15	80
Change					
Ethical	25	25	5	5	60
Policy	25	30	15	10	80
Entrepreneurial	10	15	10	5	40
	220	225	90	75	610

Table 7. Maximum score per lifecycle stage and outcome theme.

As mentioned above, an entrepreneur at the 'implementation' stage, for example, would also answer the questions of the previous 'development' stage, so the final maximum score would be cumulative. Table 8 shows the cumulative maximum scores. The final score would then be calculated by dividing the sum of the cumulative points from the answers with the cumulative maximum possible score.

	Development	Implementation	Integration	Sustained Operation
Health Services	35	95	120	140
and Health Status				
Technology	65	100	105	115
Behavioral and	20	30	35	40
Socio-technical				
Economic	15	35	50	55
Readiness and	25	55	65	80
Change				
Ethical	25	50	55	60
Policy	25	55	70	80
Entrepreneurial	10	25	35	40
	220	445	535	610

Table 8. Cumulative maximum score per lifecycle stage and outcome theme.

5.2 Adapted Evaluation Framework for mHealth Start-ups in LMICs

As a result of the above-described analysis of the questionnaire tool through the interviews with the specialists and through the literature, I established a new synthesized evaluation framework, based on the original KDS framework from Khoja, Durrani, Scott, Sajwani, & Piryani (2013). In a matrix, Table 9 shows factors that influence the development of the mHealth solutions over time. This adapted matrix is called 'Evaluation Framework for mHealth Start-ups in LMICs'.

Reproduced from the KDS framework, the horizontal axis shows the lifecycle stages of a mHealth solution: (1) 'development' stage, (2) 'implementation' stage, (3) 'integration' stage and (4) 'sustained operation' stage (see section 5.1.2 for detailed analysis).

On a vertical axis, the matrix shows the eight evaluation themes (see section 5.1.3 for detailed analysis). The themes 'technology', 'readiness and change' and 'policy' were not significantly modified. The 'health' theme was extended to explicitly include outcomes related to services and status of health. For the 'behavioral and socio-technical' outcomes, the relevant social groups in LMICs were clarified and the factors around equity of care were moved to the 'ethical' theme. Within 'economic' outcome, the theoretical concepts were clarified and synthesized into one model, namely cost-benefit-analysis (CBA), which elaborates over time. This development moves from the identification of revenue streams and cost structures, via the description of a business model and the analysis of benefits and costs in a larger societal perspective to eventually the improvement of disability-adjusted life-years (DALYs). Finally, an eight theme was added to reflect the entrepreneurial perspective, in order to emphasize the importance of the main driver of the mHealth solution. I marked the differences between the adapted 'Evaluation Framework for mHealth Start-ups in LMICs' (Table 9) and the original 'KDS Framework for eHealth solutions' (Table 1) in bold.

The adapted framework and the adapted questionnaire tool are the two main elements for the managerial model for mHealth start-ups in LMICs. They include evaluation criteria from specialists in the fields of mHealth, local health systems and investment to take into account the complexity from the entrepreneurial perspective in the context of LMICs. In the next chapter, I will present the findings from the application of the model to practical examples.

	Development	Implementation	Integration	Sustained Operation
Health Services and Health Status	Development • Ongoing and periodic assessment of health status, existing services, needs, and opportunities	Implementation Improved diagnosis and treatment of disease conditions Improved decision support and health management Improved access to care Barriers and facilitators Acceptability of mHealth Better safety Improved quality of care Stability of services Effects on the deliverer of care	Integration • Health impact leading to change in disease status • Social impact due to improved access and quality of services • Stability of services	Sustained Operation Health impact showing change via indicators Improved DALYs Stability of services Wide reach
Technology	 Development cost, availability, affordability Interoperability and standardization Well-designed software Reliable hardware (if applicable) Technical efficiency Timeliness Cost of technology Robust and reliable networking Easily adaptable to different settings Cultural acceptability Environmental viability 	 Interoperability User-friendliness/usability Appropriate in a variety of conditions Relevance to existing and growing needs Flexible (can be modified to suit local/cultural/social needs) Efficiency/error rates Accuracy User acceptance 	 Appropriate in a variety of conditions Relevant to existing and growing needs Broader interoperability 	 Scalability Ability to be incorporated into policy
Behavioral and Socio-technical	• Human resource factors of the users (management style, working relationship, communications flow, motivation)	 Strategy for mHealth implementation User-friendliness Human-computer interaction Direct benefits to users in routine work Benefits in learning Penetration/diffusion of innovation (addressing the digital divide) Trust Beneficence/non-maleficence Problem handling Social group issues (e.g. socioeconomic, gender, age) 	 Penetration/diffusion of innovation (addressing the digital divide) Strategy for broader mHealth adoption 	• Adoption/adaptation of technology on a wider scale

 Table 9. Evaluation Framework for mHealth Start-ups in LMICs.

	Development	Implementation	Integration	Sustained Operation
Economic	 Revenue streams (e.g. license, reimbursement) Cost structure Incentives 	• Business model	 Cost-benefit-analysis in societal perspective 	Improved DALYs
Readiness and Change	 Plan for change management Individual, organizational, and societal readiness to technology change 'Involvement' of end user in requirements elicitation phase 	 Effective change management (preparation and action) Training of all users 	• Effective change management (maintenance)	 Modification Improvement Customization
Ethical	 Prioritizing mHealth over other issues Moral consideration Autonomy (client based) Justice and equity Selection of study subjects/patients and population Securing identity and maintaining confidentiality of patient information 	 Sensitive to socio-cultural issues Security Liability Equity of care 	 All of the following in a broader perspective: Sensitive to socio-cultural issues Security Liability Equity of care 	• Security
Policy	 Policies for change management Scope for innovations Funding support for research 	• Limited changes in organizational and national policies to facilitate mHealth implementation	• Policy changes to facilitate broader adoption, implementation, and innovation in mHealth	 Healthy public policy and organizational practice Knowledge sharing with other organizations and countries
Entrepreneurial	• Team positions • Required skills	Organization structure Management team	• Established company	• Continuous organizational learning
DALY, disability-	-adjusted life-year			

Table 10. (continued).

6 Evaluating mHealth Start-ups in LMICs from the Entrepreneurs' Perspectives

In the following section, I will describe the findings from the self-evaluation of five start-ups and the related interviews with the respective entrepreneurs. The presentation of the findings will be in three parts, aligned with the three parts of the interview schedule (see appendix 4).

In the first part of the interviews, I presented to the entrepreneurs the results of the scoring (see section 6.3.1) and made a brief interpretation how I would see the strengths and weaknesses of the start-ups, based on the results. Then, I asked them if they would agree with my interpretation. Secondly, I will present the results of the last part of the interviews, in which I inquired about the added value and possible repetition of the process. This step also provided some recommendations from the interviewees for concrete improvements of the questionnaire tool and evaluation process. In the third part of this section, I will return to the scores of the evaluation and provide the details of the results. Finally, I will describe the findings regarding each outcome theme in details. I will not focus on the answers themselves, but rather consider valuable insights for the evaluation and for the phenomena of mHealth in LMICs in general.

In most instances of the use of additional sources, I have not given the references, in order to guarantee the anonymity of the start-ups.

6.1 Initial Reactions to the Scores: Agreement with the Strengths and Weaknesses

Three of the five entrepreneurs (A, C, E) agreed with the interpretation. Start-up B and D did not directly answer the questions, as some themes contained many don't know (d/k) responses. The reactions of the confirming start-ups were differentiated, but unanimous in the agreement with the interpretation of the strengths and weaknesses.

"Results are not really surprising at all." (Entrepreneur A).

"Yes, it makes sense." (Entrepreneur C).

"I think that [the interpretation] is very much correct. It is exactly what happened actually. [...] I do think it is a great observation." (Entrepreneur E).

Moreover, Entrepreneur E positively mentioned that the strengths in the 'technology' and 'behavioral and socio-technical' theme seemed to represent the profile of the company, which aims at building mobile technology solutions for social change through empowered behavior.

Regarding the weaknesses, Entrepreneur A added that he expected those themes to be low for two main reasons. He argued, on the one hand, that the company still needs flexibility to adapt to markets and customers and to pivot the solutions. And on the other hand, he said in regards to the low scores in the 'ethical' and 'policy' theme, that some themes are not relevant for the successful deployment to some customer groups. These and more findings will be discussed in the following.

6.2 Tool and Interviews Delivered Value but Need Improvements

6.2.1 Generally Added Value for Invested Time-Effort, but for Different Reasons

The respondents needed between seven and fifteen minutes to answer the questionnaire. One respondent spent even 46 minutes, but it might have been that he paused during the process. For the others, there was no correlation with the length of the questionnaire and the time needed. The length of the interviews varied between 34 and 76 minutes, depending on the availability of the entrepreneurs (A: 34 min, B: 66 min, C: 76 min, D: 62 min, E: 46 min).

Entrepreneur D initially understood the questionnaire as a survey and not an evaluation tool. As she has previously worked in marketing and issued many surveys herself, she perceived the questionnaire as too long and some questions as redundant. Start-up D was probably the most developed company among the respondents. The company had recently received a very large investment and employed at the time of the interview 75 people worldwide. Consequently, the entrepreneur suggested that "for a mature start-up other proven more business-like tools might be more relevant than this framework" (Start-up D).

Start-ups A, C and E, however, highlighted that the questionnaire encouraged them to take a step back and to reflect on the non-obvious dimensions of their business. "Technology is obvious for a start-up, so this framework opens to other aspects," said Entrepreneur C.

Furthermore, Start-up E highlighted the speed, with which the analysis was performed, and the depth and precision of insights the evaluation was able to achieve.

"I think [the analysis] proofs us a really interesting thought on what we should focus on [...] and where we can improve. And I think that in that sense you did the processing [...] of the data very quickly and very precisely. And you analyzed it very in-depth. So that's really something helpful for us to understand. [...] This kind of analysis on here [pointing to the scorecard with hand-written notes], where you analyze the different things and the outliers, which are and which are not in bandwidth. Those are interesting to see. [...] And then see that translate into the specific questions, where you say: 'This is weird because everywhere you say it does not meet expectations and then out of the sudden here you say extraordinary, how does that come?' That combination is most powerful. And apparently you can do that within 30 to 45 minutes. So perfect approach." (Entrepreneur E).

The quote shows that Entrepreneur E perceived this process with a brief one-pager of scores and in-depth questions about certain outliers of the results offered an alternative to other processes of, for example, large consultancy firms that would sometimes provide their results of elaborated impact analyses four-weeks later, when the answers had already become obsolete and irrelevant, due to the rapidly changing environment.

Entrepreneurs A and E were also the only ones to explicitly ask for the overviews of the scores for further use and asked to receive links and recommendations that I was able to provide.

Additionally, the two entrepreneurs at the earliest stage, Entrepreneurs B and C, mentioned "a similar exercise must be done in regular periods, in order to map different phases of the process, to see changes over time, to identify areas for focus and to communicate on the status" (Start-up B). On the one hand, Entrepreneur B remarked that some major improvements to the tool would have to be implemented before reusing it. And on the other hand, Entrepreneur C directly asked to use the following questionnaires in the next phases of the project.

6.2.2 Main Critique: Ambiguous Questions

One of the main axes of improvement was related to the ambiguity of the questions. Table 10 shows the number of questions that were answered with 'don't know' (d/k). As the answer d/k counted towards the score with 1 point - the same as the lowest score 'unsatisfactory', this choice had a significant impact on the final scores.

	Start-up A	Start-up B	Start-up C	Start-up D	Start-up E
Overall	17 of 89	7 of 44	5 of 44	60 of 122	13 of 122
	(19.1%)	(15.9%)	(11.4%)	(49.2%)	(10.7%)
Health Services and	7 of 19			16 of 28	3 of 28
Health Status					
Technology	1 of 20	6 of 13		9 of 23	2 of 23
Behavioral and	2 of 8			1 of 8	
Socio-technical					
Economic				10 of 11	1 of 11
Readiness and	2 of 11		2 of 5	8 of 16	2 of 16
Change					
Ethical			1 of 5	2 of 12	1 of 12
Policy	5 of 11	1 of 5	1 of 5	14 of 16	4 of 16
Entrepreneurial			1 of 2		

Table 10. Frequency of 'don't know' answers per start-up and outcome theme.

There were several reasons why questions were answered with d/k. Firstly, Entrepreneurs A, B and D did not understand for several questions, if the questions referred to the company, the solution, the end-user, the country, the ecosystem or any other player or level. Especially Entrepreneurs B and D struggled with some questions, as their product development did not have a direct hardware component and they focused on the app development, which was hosted on the Smartphone architecture. So, Entrepreneur B suggested splitting the questionnaire by country and/or by type of company to allow more specific questions to company and national contexts.

"I would split the questionnaire. I would say to orientate it towards a country. And I would orientate it to the company to ask more explicit questions. Maybe one can create groups such as hardware and software. And at the beginning, when you ask for area and medical condition, you can have specific questions to this issue, in order to make it more individual. This will benefit the company more." (Entrepreneur B).

Additionally, Entrepreneur A emphasized the need for more mHealth-focused questions.

"I would recommend to see if there could be anything relevant specifically to mobile health. [...] I felt that a lot of these questions could be asked for other types of health things like eHealth. There is much on technology infrastructure and backbone on the technology side, maybe there are things you can ask about." (Entrepreneur A).

Secondly, Entrepreneurs B, C and D proposed to improve the organization of the questionnaire, linking the themes to each other and building in headlines that state the objective of groups of questions to help the respondent to understand the context of the questions. Moreover, Entrepreneur D continued, the groups of questions could be divided upon more pages, so that a progress bar on the bottom would visualize more accurate how much is left.

Thirdly, Start-ups C and E, which characterized themselves as social enterprises, misunderstood some questions regarding the 'ethical' theme, which was partially related to improving equity in the population.

Fourthly, all entrepreneurs mentioned that some questions were not understood because of the wording. Entrepreneurs C and D, who answered to the questionnaire in Portuguese, which I translated without a professional spelling check, especially remarked this. One proposal from Entrepreneur D was to add the option 'not applicable' to avoid too many d/k answers.

Finally, the most d/k answers were registered for Start-up D. The company was more mature than the other companies, as mentioned before. In addition, the interviewee recently joined the company as first employee in Brazil in the function of business developer for Latin America. So although she was an entrepreneur for a new market, she did not found the company. Although this circumstance was also true for Entrepreneur E, he, on the contrary, worked since the early beginnings in a smaller team and in a single office with direct contact to the company founders.

6.2.3 Lifecycle Stages versus Maturity Levels

From the point of view of Start-up B, the development process had two stages: (1) development of prototype with main functions and (2) first product release, which also included detailed description of strategy, finance and team set-up. Consequently, some questions were perceived as not applicable at the 'development' stage. At this early stage, the strategy was still considered flexible, as major strategic choices such as partnering with major companies, for example, might influence the business model and functionalities (Start-up B). Also Entrepreneur A underlined the need for the company to remain flexible, although he answered the questions at the 'implementation' stage. Even Entrepreneurs D and E, who were at the 'sustainability' stage, mentioned that their business model might still be subject to change.

However, start-ups at later maturity stages were clearer which elements of the business would evolve. Start-up D focused on developing the market expansion and adapting its product.

"We had a round of investment last year. [...] We keep growing. We keep growing [...] I don't even want to give you examples, because I might be going the wrong way anyway. There will be like 5, 10, 20 different ways. [...] I don't want to point one, as we might go to the other one." (Entrepreneur D).

For Start-up E, the next step was to transform into a financially sustainable business model.

"The model is still quite lacking. Did we do a sufficient way of calculating, if this is something that adds benefits to person life? Yes, we made that balance. Did we monetize it? No. So, we don't have an idea that this dollar earns two dollars back. [...] There is no model where we can say that for the next five years we can sustain this innovation, based on what we develop now." (Entrepreneur E).

Start-up C reflected about the need to test and pivot their service in the market, but emphasized less the unclarity of the prototype and product release. This might be linked to the fact that the mHealth solution of Start-up C was a spin-off from the company's existing, more mature desktop application. Start-up B, on the other hand, developed their first product in partnership with a large technology partner and shortly after the interview was the deadline to present the technical functionalities to the partner. This might be a reason why the interviewee focused on distinguishing between prototype and product release.

Entrepreneur B also made a comment regarding the wording of the scoring. He perceived that scoring based on satisfactory levels seemed to be more related to the ecosystem in the country. Regarding a company, Entrepreneur B believed that formulating maturity levels might be better. Although the reflection about the separation and naming of different phases and scorings of a start-up was an interesting follow-up of the debate, which I also had with the specialists (see chapter 5.1.2), no clear agreement among the different views could be found.

6.2.4 Additional Questionnaire Functionalities

In addition to the improvement ideas above, some entrepreneurs had suggestions for additional functionalities of the questionnaire. Entrepreneur A suggested to add an option to bookmark interesting questions to review later. This underlined the reflective usage of the questionnaire.

Moreover, Start-ups A and D, were interested in a visual of the score and a benchmark to other companies directly after completing the questionnaire. Further, their recommendations for improving the business highlighted that the visual feedback could be enriched with the support of videos, links and articles. And the methodology for asking questions could be improved through additional question types such as closed questions and questions that require written answers.

6.3 Understanding the Evaluation Scores and Strengths/ Weaknesses across all Start-ups

Before diving deeper into the findings regarding the individual outcome themes, I will briefly present the results of the scores for each start-up, the relative position of the strengths and weaknesses per start-up and an analysis of the themes across all start-ups.

6.3.1 Evaluation Score for each Start-up

Table 11 shows the scores for each start-up. In the middle, scores are shown per theme and lifecycle stage. The right column shows the cumulative score (see section 5.1.4 for description of the scoring mechanism). The score is highlighted in green and aligned on the right side, if the result is greater than or equal to 75%, or in red on the left side, if it is less than or equal to 30%.

	Score	Cumulative Score			
Start-up A	Development	Implementation	Integration	Sustainability	Implementation
Health	46%	45%			45%
Technology	52%	77%			61%
Beh/Soc-Tech	85%	20%			63%
Economic	87%	75%			80%
Ready/Change	56%	47%			51%
Ethical	48%	44%			46%
Policy	52%	23%			36%
Entrepreneur	30%	53%			44%
	55%	49%			52%
Start-up B	Development	Implementation	Integration	Sustainability	Development
Health	83%				83%
Technology	55%				55%
Beh/Soc-Tech	100%				100%
Economic	73%				73%
Ready/Change	56%				56%
Ethical	68%				68%
Policy	60%				60%
Entrepreneur	40%				40%
	66%				66%
Start-up C	Development	Implementation	Integration	Sustainability	Development
Health	49%				49%
Technology	63%				63%
Beh/Soc-Tech	65%				65%
Economic	60%				60%
Ready/Change	44%				44%
Ethical	52%				52%
Policy	44%				44%
Entrepreneur	40%				40%
	54%				54%
Start-up D	Development	Implementation	Integration	Sustainability	Sustainability
Health	57%	23%	44%	95%	46%
Technology	51%	71%	80%	20%	56%
Beh/Soc-Tech	90%	60%	100%	100%	85%
Economic	20%	20%	40%	20%	25%
Ready/Change	52%	53%	20%	60%	50%
Ethical	76%	92%	80%	20%	78%
Policy	32%	20%	20%	60%	29%
Entrepreneur	100%	67%	60%	60%	73%
	56%	46%	46%	61%	52%
Start-up E	Development	Implementation	Integration	Sustainability	Sustainability
Health	54%	75%	80%	100%	74%
Technology	82%	100%	100%	100%	90%
Beh/Soc-Tech	100%	100%	100%	100%	100%
Economic	27%	35%	47%	20%	35%
Ready/Change	92%	67%	50%	87%	76%
Ethical	80%	84%	80%	100%	83%
Policy	84%	47%	60%	80%	65%
Entrepreneur	90%	93%	100%	80%	93%
	77%	74%	72%	88%	76%

Green/ right side: greater than or equal to 75%; Red/ left side: less than or equal to 30%

Table 11. Evaluation scores for each start-up.

6.3.2 Relative Position of the Strengths and Weaknesses

The objective of this thesis was not to provide a threshold for start-ups to forecast the strengths and weaknesses or the start-up's potential for success. Additionally, there was no reference point or benchmark for the scoring, as even the original KDS framework has been recently developed and not yet tested (see section 3.3). Therefore, I could only assume the strengths and weaknesses of the individual outcome themes in the relative position of the scores against each other.

In Figure 5, I listed the relative position of the outcome themes for each start-up according to the results of the scores. The relative position is based on the ranking of the final scores of the themes from highest to lowest. For example, the 'economic' theme for Start-up A was with 80% the highest result among all themes, while the same theme was with 25% the lowest result among all themes for Start-up D. Thus, I suggested that the 'economic' outcome was a strength for Start-up A and a weakness for Start-up D. With the relative position for each start-up, I could now compare the results of the themes across the start-ups.

Start-up A (Implementation Stage)
Economic Outcomes
Behavioral and Socio-technical Outcomes
Technology Outcomes
Readiness and Change Outcomes
Ethical Outcomes
Health Services and Health Status Outcomes
Entrepreneurial
Policy Outcomes

Start-up C (Development Stage) Behavioral and Socio-technical Outcomes Technology Outcomes Economic Outcomes Ethical Outcomes Health Services and Health Status Outcomes Readiness and Change Outcomes Policy Outcomes Entrepreneurial

Start-up E (Sustainability Stage) Behavioral and Socio-technical Outcomes Entrepreneurial Technology Outcomes Ethical Outcomes Readiness and Change Outcomes Health Services and Health Status Outcomes Policy Outcomes Economic Outcomes Start-up B (Development Stage) Behavioral and Socio-technical Outcomes Health Services and Health Status Outcomes Economic Outcomes Ethical Outcomes Policy Outcomes Readiness and Change Outcomes Technology Outcomes Entrepreneurial

Start-up D (Sustainability Stage)
Behavioral and Socio-technical Outcomes
Ethical Outcomes
Entrepreneurial
Technology Outcomes
Readiness and Change Outcomes
Health Services and Health Status Outcomes
Policy Outcomes
Economic Outcomes

Figure 5. Relative position of strengths and weaknesses for each start-up.

6.3.3 Comparing the Relative Positions of the Themes across all Start-ups

Once I had the relative position for each of the eight outcome themes per start-up, I analyzed the frequency for a theme to be on a specific rank. Table 12 shows the ranks horizontally and the themes vertically. The content of the table represents the frequencies of how often a theme was placed on a specific rank. For example, the 'health' theme was once on rank two (Start-up B), once on rank five (Start-up C) and three times on rank six (Start-ups A, D, E). In a second step, I multiplied the frequency with the rank and formed the sum in the column on the far right side of the table. The calculation for the 'health' theme, for example, was [(1x2)+(1x5)+(3x6)]=25. Finally, I ranked the themes according to the sums from lowest to highest.

On a first view, these results suggest that across all mHealth start-ups in this study, the 'behavioral and socio-technical' outcomes were the strongest (lowest sum) and the 'policy' outcomes were the weakest (highest sum). The next section will dive deeper into the findings of the individual outcome themes.

	1st	2nd	3rd	4th	5th	6th	7th	8th	Sum
Behavioral and Socio-technical	4	1							6
Technology		1	2	1			1		19
Ethical		1		3	1				19
Economic	1		2					2	23
Health Services and Health Status		1			1	3			25
Readiness and Change				1	2	2			26
Entrepreneurial		1	1				1	2	28
Policy					1		3	1	34

Table 12. Frequency of an outcome theme per relative position across all start-ups.

Table 12 shows the frequencies across all start-ups, which participated in this study. In Appendix 7, I provided a further analysis of the frequency in two groups of start-ups: (1) early stage (Start-ups A, B, and C), and (2) late stage (Start-ups D and E).

6.4 Outcome Themes are Complete, However____

In the following section, I will describe the findings regarding the outcome themes in details. I will not focus on the answers themselves, but rather consider valuable insights for the evaluation and for the phenomena of mHealth in LMICs in general. The considerations of the entrepreneurs of the outcome themes in the interviews in combination with the relative positions of the themes, in other words the strengths and weaknesses, formed four groups: (1) 'health', 'technology', 'behavior and socio-technical' and 'economic' outcomes were naturally considered, (2) 'readiness and change' and 'policy' outcomes were forgotten, (3) 'ethical' outcomes led to diverging opinions and (4) 'entrepreneurial' outcomes followed the business maturity.

6.4.1 Impact, Technology, User-Behavior and Economic Model Were Naturally Considered

Start-ups A, B and C were in the earlier lifecycles stages. Start-up B, at the 'development' stage, clearly stated that the team was currently more focusing on the technological feasibility and user-friendliness of the product, as they planned to move only after the prototype demonstration further into the economic model. Thus, the evaluation of the 'economic' theme was with 73% relatively high.

"For us, as we currently have a deadline due to our partnership with SAP, it is important to finalize the prototype. And thus, strategy is secondary. Strategy is a part, but not the main topic. We have colleagues that will deal with the first product release in the future. But now we need his resource for the development team. [...] Once we have the prototype, we can work on the strategy because we will then also look for financing [...] or specific acceleration programs. And then you have to refocus your product anyways." (Entrepreneur B).

Start-up C focused on improving the access to information for health services for low-income customers. The mobile application was an extension of the existing desktop version and consequently technically feasible. The company had already proven its impact on people, but struggled to generate paying customers and thus the lack of clarity on a self-sustainable business model led to a lower score of 60% of the 'economic' outcomes. Start-up A, which was at the

'implementation' stage, perceived to have a well developed revenue and cost structure and accordingly scored 80% in the 'economic' outcomes. Moreover, their technology development was also strong due to continuous testing and high emphasis of this dimension.

"I think we have a really good idea of economic outcomes. We are very clear on pricing, what the incentives are, what we need to improve in order for us to get paid. Our cost structure is very clear. So that's not an issue. [...] We obviously spent a lot of time thinking through developing technology and behavioral and socio-technical outcomes because that's so necessary in having a success, right. We always test and tweek. So, we are quite aware of that." (Entrepreneur A).

All three start-ups were very much concerned with finding the right solution to fit the market needs, which they have identified. An issue for Start-up C was that they believed to only have an indirect impact on the health status of the population, as they improved the orientation of patients towards the services of the public sector. But they had no influence on the service itself.

"The tool helps to organize the waiting line. Everybody goes straight to the emergency and waits for twelve hours to be attended. In some cases, the person could go to a UBS [commonly known as 'posto de saúde' to obtain basic medical attention], which might be much closer and be attended quicker and solve the issue in the same way. But the problem that people have in their mind is that 'I will go to the emergency because there I know I will be attended at some point'. And in reality, these are things that might happen. I receive these messages every day. The person went to the UBS and there was no physician. And now? [...] You see, it sometimes does not only depend on us to solve the problem. If the government allows physicians to be missing, they are missing. But the idea is to improve the perception, which might already help." (Entrepreneur C).

The focus of start-up A with their application for pharmaceutical companies, on the contrary, was not the health of the patients directly, but rather the outcome for the business client in the pharmaceutical industry. Parameters for patient satisfaction such as engagement with the mHealth solution and the change of behavior, e.g. purchasing more medicines, were seen as means to achieving these objectives.

"Part of those [weaknesses] might not be as fully relevant to what we are doing. For instance regarding 'health services and health status' outcomes, as you will find in mobile health, the healthcare of the actual patient is not always the priority. In this case the pharmaceutical industry, it is just about patients staying on the medication longer, having a more positive brand image of the actual drug, so that they would repurchase it and obviously adhere to the medication. The services and status are secondary to the marketing outcomes." (Entrepreneur A).

For Start-ups D and E the results of the scoring for the 'economic' theme were equally low at 25% and 35%, respectively. The reasons, however, differed. As seen in Table 10 above, Entrepreneur D answered all except for one question with d/k. In the interview, I asked the entrepreneur that it seemed strange that the company did not have a business model after 9.5 years. She replied by asking: "Why did Facebook buy Whatsapp?" "Data," I replied. Entrepreneur D smiled and said: "Next question". Later in the interview, I learnt that the company had just raised USD 18 million in its first round of investment. And in February 2015, the start-up was sold to an American sports apparel company for USD 475 million. In the interview, Entrepreneur D highlighted that the company evolved from 1,000 users worldwide in 2005 to 65 million users in 2014, through which the company had crowd-sourced four million unique foods and beverages, including nutrition details. The USD 18 million funding was mainly used for the international expansion and development of new functionalities that allow customization, which resulted in 85 million users by May 2015. The interests of the American apparel company in the start-up was linked to its long-term objective to integrate the platform with the embedded sensors in its fitness apparel, according to industry reports.

Differently, the low score for Start-up E, a social enterprise like Start-up C, resulted from the fact that with the current model "the company will not sustain the innovation for the next five years" (Start-up E). In the first phase of the company a business model was not even present, as the then initiative just started with an idea to solve a social issue. And so the "business model was done in a rush" (Start-up E). Over time the company was able to demonstrate that the solution added value to person's welfare and improved the national health services in Tanzania. The start-up, however, was struggling for this initiative to establish a self-sustainable business model, as the end-users, pregnant mothers in rural Tanzania, were and will not be able to pay for the service. According to Entrepreneur E, "except for the government there are little to none actors that are

willing to pay for the solution". He estimated that only 25% of the current users would be interested to continue the service in a paid model. Nevertheless, in the larger portfolio of the start-up, the Tanzanian initiative was often used as a signature project and supported Start-up E to raise one of the largest investments in social enterprises in The Netherlands in January 2015.

Regarding the question of measuring disability-adjusted life-years (DALYs), both Start-up D and E, recognized the importance to understand the solution's impact in the broader healthcare system, but did not confirm if this could or should be done with the measurement of DALYs. Start-up D had shown that millions of people share the company's objective to live a healthy lifestyle and the statistics showed that people already lost weight. However, the analysis of the data did not clearly confirm, if obesity and other patterns for health issues in the society were impacted. Similarly, Start-up E knew about the number of mothers that were better informed before, during and after their pregnancy, but according to Entrepreneur E, it was too early to demonstrate the impact on infant mortality and other health indicators on a macro-level.

"We have an information service that provides people with maternal health and antenatal care information. [...] Everything that relates to that is something, where the initiative improves the live of the participant. If they know when to go to the clinic because they are reminded that they need to go in five days, they don't go 5, 6 or 8 times too many. That means for them it's additional value. For the clinic, it's a clear benefit because they don't get people that wait for maybe 8 hours. [...] If I look at the improved health outcome, that's even more clear. People actually know what to eat, how to take care of the hygiene, how to take care of the personal and the baby's well being. And that means that eventually there is an improved benefit for the life of the participant and the life of the baby. [...] There is a really difficult calculation that maybe if the baby is healthy, it will add some economic potential to the country in general. We can say that if the baby comes to life in good health it will add some value to the economy over time. Does this one dollar change that thing or that one SMS text? Quite difficult to put into a perspective." (Entrepreneur E).

6.4.2 Change Management and Policy Considerations Were 'Forgotten'

During all interviews the themes 'change' and 'policy' received the least attention. Some of the entrepreneurs did not directly address those dimensions, as it seemed unclear to them if the questions referred to the company level, national system level or global industry level (Start-ups A, B, D). Although there seemed to be an expectation that the technological changes would impact the way the health systems work and the players such as insurance companies and physicians interact (Start-up B), most change management and policy-making reflections were on a company level. For example, Start-up A used an agile product development process to flexibly adapt to customer needs. Or Start-up B was involved in discussions of formulating industry-wide standards, in order to anticipate the influence of larger players on the start-up. However, none of the start-ups elaborately planned how to manage the change they were expecting due to impact of mobile technologies on the healthcare systems at large, e.g. the remote delivery of care and the new skills of physicians (Scott & Mars, 2015). Start-ups C and D mentioned that they actively adapted to the market reactions of their users, but also did not follow a wider change strategy.

Nevertheless, the questions for the 'readiness and change' theme were perceived as supporting the reflective process. Entrepreneur A, for example, said that those kinds of topics were sometimes lost in the daily business of an entrepreneur (Start-up A).

"I think the other interesting thing was the 'entrepreneurial' and 'readiness and change' outcomes, which are more structural, more related to the capacity of the company. Those were quite reflective because I think in implementation you are still so focused on getting it out there, implementing, making the sale. You don't really think about change. You sort of go with the flow. I think implementation in itself requires you to change, and to pivot and to move, as we have been doing. [...] My prediction is that a lot of companies in implementation will be low in those because they are implementing, so they simply don't have the bandwidth." (Entrepreneur A).

Regarding the 'policy' theme, Start-ups C and E seemed more involved and understood the questions rightly in reference to the political ecosystem. In the Brazilian context of the public sector, Entrepreneur C mentioned that the success of mHealth depended very much on the awareness and interest of the political decision-makers that were in office for four-year terms and

had to balance many priorities. According to the entrepreneur, the government started to acknowledge the improvements that private mHealth companies could bring to the public health sector but it was still only the beginning.

"I think in the minds of the government, they start to understand that it is very difficult for them to do everything. The government opens up tool to the population that are from private companies or open source, supporting the development of solutions. But it is still very isolated. There is no general willingness of politics. I think there is a tendency without return, but how long it will take to, for example, provide fiscal incentives for companies to create an impact, it is difficult to say. It depends very much on the character of the politician." (Entrepreneur C).

Similarly, national policy makers in Tanzania, where Start-up E operated, only focused on wider digitalization of the healthcare system, but did not have a specific focus to actively increase the development of mHealth solutions. They were only interested in the solution once it gained traction in the population growing to 500,000 users and had support of major mobile operators.

"The Tanzanian government was not interested at all to make this work. They said: 'Really great initiative, good luck, and we don't really think this is going to have an impact.' When, we had 500.000 users, they said 'Now that you build your track record, we see the added benefit, we see there is an impact and we see how that's going to impact the healthy behavior and the healthcare of the patients.' So, the Tanzanian government joined the initiative. Now, out of the sudden, there is policy involvement because you have to adhere to regulations they make because also they put funding forward." (Entrepreneur E).

The awareness for the 'political' theme from Start-ups C and E might result from the companies' focus on low-income populations, which are mainly served through the public sector.

6.4.3 Ethics Led to Diverging Opinions

All start-ups directly addressed the 'ethical' theme, which was broadly divided into ensuring data security and achieving health equity among different social groups. Start-ups B and D explicitly mentioned that data security was considered during the development of the solution. More specifically, Start-up B expected that in addition to their efforts, larger industry players and national regulations would drive the set-up of standards and norms. Start-up D stored all data anonymously and only used key indicators such as age, height, weight, level of activity and food and beverages intake, in order to align with the data security policies.

Although all start-ups were aware of issues in health equity across different social groups, the set-up of the solutions defined how they addressed those problems. Start-up A developed various use cases for their mHealth solution. As Entrepreneur A answered the questionnaire from the use case in the pharmaceutical industry, he said:

"The 'ethical' and 'policy' outcomes are not really relevant in this case because actually it's unethical, kind of, some of the stuff that's being done. Honestly, it's not necessarily unethical, but through avoidance of pharmaceutical vigilance, you don't necessarily have the best of the patient in mind. [...] I think it is just a feature of health in general. I think there are many disincentives in health, probably more in pharmaceuticals than in hospitals and clinics, and particularly in the Brazilian setting, where a lot is paid in the private sector. Maybe mobile health accentuates this. [...] In the Brazilian setting, you always worry about avoiding, avoiding policy changes and requirements, avoiding being blamed by Ministry of Health, shutting your whole company down." (Entrepreneur A).

Thus, the low score in the 'ethical' theme for Start-up A reflected that ethics were not perceived as fully relevant to the adoption of the solution in the pharmaceutical industry, which focused on increased medication adherence and brand image, rather than improved 'health status and health services' outcomes.

Slightly different, Start-up D believed that its solution, though only accessible via Smartphone app and most effective in combination with a nutritionist, could decrease inequality, as it gives access and support to live a healthy lifestyle to everyone, indifferent of socio-economic status.

For the co-founders of Start-up B, improving healthcare of people throughout society was a personal motivation to start the company and they actively searched for these essential criteria when hiring people. However, the development of the solution itself did not focus on explicit parameters that address equity, as the start-up focused on the technical solution.

On the contrary, the primary focus for Start-ups C and E, two explicitly communicated social enterprises, was on the impact of their solutions on the health equity among different social groups in society.

"We want to reduce the asymmetry of information among social classes. We want to empower the lower classes to have the same information as the higher classes, so to have access to the health system. Although the lower classes do not have the same power to buy the things that the higher classes have, at least they have the same level of information and they know what is available to them. The person should not miss treatment just because she doesn't know where to go. This is the first point, to try, to inform where to go. Our proposition is to facilitate this search." (Entrepreneur C).

Further, Entrepreneur E said that

"As social enterprise, it makes a difference to work on mHealth; there is a difference regarding where money is earned and what the monetary value is. [...] The mission and vision we stand for: 'mobile technological solutions for social change'. There is a mobile solution, which is the technical component. And there is social change for behavioral change or social influence." (Entrepreneur E).

In order to achieve its objective to support business clients in reaching large groups of people with messages that have social impact, Start-up E involved the ecosystem and built partnerships with the communities. Although the company was designed to solve a social issue by "empowering people to take better decisions to improve their lives" (Start-up E), an accidental effect was addressing other equity issues such as gender and income gaps.

6.4.4 Entrepreneurial Outcomes Followed the Business Maturity

For the three Start-ups in earlier stages (Start-ups A, B, C), the 'entrepreneurial' outcomes had the relatively lowest scores (see Figure 5 above). Start-up B, which had not been incorporated at the point of the interview, was not yet ready to define a company structure. One of the co-founders started the idea in the USA and then moved to Australia, where he worked with the development team. Entrepreneur B lived in Brazil at the time of the interview and worked part-time on the start-up. The team had not decided how to set-up their global company and expected that the financing might have major impacts on the decisions for the structure. For example, some funds require start-ups to be based in the country of the fund. Other factors such as customer base and business model might also have an impact on the number of employees and required skills.

Similarly, Start-up C also mentioned that the feedback of the users would be key to define the details of the set-up of the solution. At the time of the interview, Entrepreneur C was unsure which skills and personalities would be needed for the mHealth solution and foresaw different possible strategies. He said: "We don't know yet, how the users will react once the tool is available. For example, if we give the user the possibility to exchange, to complain, or to say what works and what doesn't, we might generate a demand to manage this information in the tool. But if the users just use it as a guide to search an UBS, then there won't be feedback and not much need to intervene." However, some major organizational choices were pre-defined as the mobile solution was based on an existing desktop solution and the application was designed around the Brazilian healthcare system. At this point, all positions were filled but the high uncertainty for the next steps rendered the score low.

For Entrepreneur A, the low score in the 'entrepreneurial' theme was expected for any start-up, as most of the entrepreneurial learning would come over time and would take time to grow strong in the team.

"In terms of the 'entrepreneurial' outcomes, I think that's something that comes in time because you need to develop the proper workflows. We are learning. [...] Just any implementation phase might be lacking this." (Entrepreneur A). Moreover, he also perceived that an overall characteristic of the mHealth solution itself should be to be flexible. In the interview, we did not elaborate further on how the need of the product to be flexible would translate into an organization.

"I think what we have done is a pretty agile technology development process. What we do is the trunk of the tree and then we branch of to whatever is needed. [...] You spend a lot of time understanding how your technology should be tweeked to [the client's] demands. [...] Any mHealth initiative should be incredibly flexible and adaptive, whether it's an app or a text-messaging thing. The system is too complex to come up with this one solution that works for all." (Entrepreneur A).

In the case of Start-ups D and E, which were both at the 'sustainability' stage, the scores for the 'entrepreneurial' outcomes were among the strengths (see Figure 5 above). Although Start-up D employed 75 people globally, out of which one was based in Brazil and two in Europe, the company was still considered a start-up and had some organizational issues to clarify. According to Entrepreneur D, the open structure gave opportunities for flexibility and to advance projects, depending on the needs of the customers.

Start-up E grew organically since the beginning to have a global reach, with two main organizational hubs, one in the Netherlands and one in Uganda. The company had planned the next product and service evolutions, but did not concretely define the company set-up for the future. Entrepreneur E believed, however, that the organic growth would be an evolution of the current organization.

The way that we set-up is on organic growth from the start. We started our first project in Uganda, so we have an office in Uganda. That's just the way that it grew over time. [...] Now, we don't have a specific idea on where it's going to head in the future. But development tells us that we need to go to a different country. Also, when Tanzania is the biggest market, we need more people in Tanzania. We have project managers that are quite mobile." (Entrepreneur E).

For both, Start-up D and E, the entrepreneurial development can be rather seen as an evolution than a defining element for the future. This might be linked to the maturity of the business and its sustainable position in the market.

6.5 Key Findings of Evaluating mHealth Start-ups in LMICs (Summary)

The findings from applying the questionnaire and interviewing with five entrepreneurs, operating in Brazil and Tanzania, highlighted that the managerial model had some merit. Firstly, the relative position of strengths and weaknesses for each start-up, based on the scoring, correlated with the entrepreneurs' expectations of their implicit and in-depth knowledge of their own startups. Secondly, most entrepreneurs perceived the evaluation process, including the answering of the questionnaire and the semi-structured interview, as added value to support the reflection on their start-ups. Thirdly, the simplicity and precision of the results from the managerial model and the evaluation process offered a viable alternative to other evaluation tools, according to some entrepreneurs.

Despite these merits, the findings also revealed some shortcomings of the managerial model and evaluation process. Most notably, some ambiguous questions led to a significant amount of 'don't know' answers, which in return impacted the scoring. Based on the advantages and disadvantages of the questionnaire, recommendations of improvements were captured from the entrepreneurs.

In addition to the general findings, the results of the scores and outcome themes were analyzed. First, an analysis of the relative position of the themes against each other was proposed as alternative to absolute thresholds, in order to forecast the strengths and weaknesses of the startups. This analysis suggested that across all mHealth start-ups in this study, the 'behavioral and socio-technical' outcomes were the strongest and the 'policy' outcomes were the weakest themes. 'Technology' and 'ethical' outcomes seemed rather strong, while 'readiness and change' and 'entrepreneurial' outcomes appeared rather weak. The outcomes 'health' and 'economic' were in the middle and had neither a tendency towards strong nor weak.

Secondly, in the details of the considerations of the entrepreneurs, four groups of themes were identified: (1) 'health', 'technology', 'behavior and socio-technical' and 'economic' outcomes were naturally considered, (2) 'readiness and change' and 'policy' outcomes were forgotten, (3) 'ethical' outcomes led to diverging opinions and (4) 'entrepreneurial' outcomes followed the business maturity.

Finally, none of the entrepreneurs mentioned that an overall outcome theme was missing.

7 Conclusions

7.1 Managerial Model Allows Quick, Profound Understanding of the Start-ups

When I started to emerge into the field of mHealth, I was fascinated by the technology's potential to change the lives of the large, underserved populations in LMICs. Yet, I quickly noticed that this new field was still a niche phenomenon within healthcare globally and lacked a reliable body of evidence in LMICs, in particular (see section 1.2). In my search for evidence, I perceived that the majority of studies focused at most on the solution and its impact, but disregarded the main driver for the adoption of innovations: the entrepreneurs. I believed that improving the effectiveness of these entrepreneurs would in return increase the adoption of mHealth solutions and finally contribute to my long-term objective to ameliorate the health status in LMICs. The first step on this path was the development of a managerial model, which integrated the evaluation of mHealth solutions and the entrepreneur's perspective.

In addition to the theoretical development of the model, I wanted to perform preliminary analyses in the field with entrepreneurs to get a first understanding how this approach was of use to them. My objective was not to achieve academic rigorousness, claiming to validate the model by testing, but rather to provide additional input to the theoretical development.

Nevertheless, I was surprised how well and profoundly I understood the start-ups strengths and weaknesses with a relatively low investment of time. On average the entrepreneurs needed 18.8 minutes to answer the questionnaire, I needed approximately 45 minutes to analyze the results and each of the interviews lasted for 56.8 minutes, on average. After only two hours in total, the entrepreneur and I, as an evaluator, had a well-structured understanding of the strengths and weaknesses of all relevant aspects of the mHealth start-up. What were perceptions and intuitions before became measurable and articulable insights of the start-up. For example, prior to the evaluation I knew some details about Start-up A from a public presentation, research on the website and several conversations with the entrepreneur. I perceived that the company had a strong business value proposition and a value-delivering technology, but lacked a measurable focus on its impact on health. The score and interview confirmed my perception and in addition identified possible weaknesses in policy and ethical outcomes, which might endanger the sustainable adoption of the solution.

Based on the feedback of the added value (see section 6.2.1), it is unlikely that entrepreneurs would use the tool as it is. On the one hand, the tool and process require some improvements. And more importantly, on the other hand, the entrepreneurs would need some form of feedback, which is either automatically generated or personally provided. The interviews proved to be important to the reflective interaction of the entrepreneur in the evaluation process and thus increased the quality of the managerial model.

The analysis of the scores across all start-ups (see section 6.3) indicated a first attempt to get an analytical and comparative overview of the ecosystem from the perspective of start-ups. Although the results were by no means exhaustive, they suggested that mHealth start-ups tended to focus on 'behavioral and socio-technical' outcomes and disregarded 'policy' outcomes. Through this alternative perspective a preliminary macro-level indicator allowed to view the opportunities and challenges for wider mHealth adoption in LMICs through the eyes of the start-ups and its entrepreneurs. If the results would hold true across a larger sample in Brazil or several LMICs, it would suggest, for example, that the user perspective was of highest priority for mHealth start-ups, but they neglected to develop a change management approach in an unfavorable institutional environment.

7.2 Contributions to the Research Field

The objective of this study was to propose an effective managerial model, which offered a new approach for the analysis of mHealth solutions by taking into account the complexity that arose from the entrepreneurial perspective in the context of LMICs. The basis of the theoretical model was the KDS framework, including the questionnaire tool and scoring model, from the work of Khoja, Durrani, Scott, Sajwani, & Piryani (2013). In order to achieve the research goal, three intermediate objectives guided the study. Table 13 shows the objectives and the findings that were identified as patterns in the interviews. Additionally, the table provides for each finding the reference section in this thesis.

One of the main axes of improvement for the questionnaire that was identified from the analysis of the interviews with the entrepreneurs was related to the ambiguity of the questions. For some start-ups, several questions were answered with 'don't know' (d/k). As the answer d/k counted towards the score with 1 point - the same as the lowest score 'unsatisfactory', this choice had a significant impact on the final scores. The next evolution of the managerial model may propose a solution to this issue by improving the questions themselves or by integrating the option 'not applicable' to answer the questions (see section 6.2.2 for detailed discussion).

Furthermore, research from and about LMICs, although increasing, is still lacking, as shown in sections 1.2 and 4.1. The evidence base may benefit, if future research continues to be conducted from and with the people from LMICs.

Research Objectives	Findings	Section				
Criteria that specialists in the fields such as mHealth, local health systems and investment						
consider eval	uating mHealth start-ups in LMICs					
	Agreement that start-ups go through different development phases, but no agreement on naming and definition of the stages; original KDS lifecycle stages maintained	5.1.2				
	All original themes from the KDS framework seen as relevant, but some need clarification in the details	5.1.3				
	User-acceptance of technology and human aspects of technological change seen as highly important (Lima, 2014; Novaes, 2014)	5.1.3.3				
	Models for health outcome evaluation not fully comprehensible. Need to focus on one model, which develops in complexity over time (Ribeiro, 2014)	5.1.3.4				
	Identify and plan expected revenue streams (including sector specific streams such as reimbursement) and cost structures from the very beginning of the development process (Ribeiro, 2014)	5.1.3.4				
	High barriers for adoption and use of new technologies in Brazil;	5.1.3.4 /				
	system rigid towards change; need not only for monetary incentives to convince main stakeholders (Costa, 2014; Malik, 2014)	5.1.3.5				
	mHealth can potentially improve health equity (Scott & Mars, 2015)	5.1.3.6				
	Missing entrepreneurial theme to understand the impact of personality and experience of the entrepreneurs on the success (Ribeiro, 2014)	5.1.3.8				
Process steps	to evaluate mHealth start-ups in LMICs					
	Semi-automated questionnaire tool and scoring system	5.1.4				
	Answers to questions subjective to entrepreneurs' interpretation	6.4				
	Scoring seen as entry point for discussion					
	Partially inaccurate scoring due to ambiguous questions	6.2.2				
	Themes with few questions significantly impacted by outliers	6.3				
	Average scores hide information from outliers	6.3				
	Interview schedule to enrich the quantitative score with additional	Intro to 6 /				
	qualitative insights	Appendix 4				
Added value	for the entrepreneurs					
	Three of five entrepreneurs agreed with the interpretation of	6.1				
	strengths and weaknesses from the scoring					
	Evaluation encourages an entrepreneur to step back and reflect on	6.2.1				
	non-obvious dimensions of a start-up's performance	() 1				
	Evaluation allows to quickly gain in-depth insights	6.2.1				
	and might not be transferable or repeatable; others might reveal	4.2.4.3				
	anterent results for the entrepreneurs					

Table 13. Summary of key research contributions.

Page 107 of 143

7.3 Practical Implications

The results of this thesis are not based on pure theoretical development of a concept; rather its merits are supported by first attempts to analyze its application with potential users. Similar to a start-up, I went into the field and gathered feedback to identify the value proposition of the managerial model.

I focused on the entrepreneur as the main user of the managerial model. To stay in the language of start-ups, the entrepreneurs were the only customer segment I chose. For them, the managerial model delivers value as support to understand the implicit strengths and weaknesses of the young companies. Many things can go wrong in the evolution, but the 'Adapted Framework for mHealth Start-ups in LMICs' provides a comprehensive overview of all elements to guide mHealth start-ups to successfully pass through their lifecycle stages. And the questionnaire tool asks the right questions to go into depth in the self-assessment. Yet, an interview-based use of the scoring adds an important value to the reflective process. The model can be seen as complementary tool, as it allows integrating several perspectives in one simple questionnaire.

Furthermore, the content of the managerial model could also be interesting to additional customer segments, i.e. investors and other users that need a tool to quickly identify strengths and weaknesses of potential investment targets, business partners or maturity levels across regional mHealth sectors. Ribeiro (2014), for example, mentioned that he might be interested to use certain elements of the tool, which could enrich his current evaluation metrics of start-ups, especially if those companies develop mHealth solutions. The questionnaire tool helps the evaluator to ask the right questions to get an overview of the start-up. Based on the overview of strengths and weaknesses, the evaluator knows which follow-up questions to ask, in order to gain in-depth insights. The interview schedule in appendix 4 can further support this inquiry. In a lateral study, a different application of the managerial model may create a discussion between what investors forecasted and what entrepreneurs said about a given start-up.

In addition to the scores related to the evaluation of single start-ups, this thesis provided in section 6.3 a possible approach to analyze multiple start-ups and to compare the results across various solutions. For each start-up, I used the scores to transfer the list of outcome themes into relative positions towards each other. With the relative position of the themes, I could now compare the results across the start-ups. On a first view, these results suggested that across

mHealth start-ups, the 'behavioral and socio-technical' outcomes were the strongest and the 'policy' outcomes were the weakest. This analysis allowed a glimpse at opportunities to apply the management model to understand maturity levels across regional mHealth sectors.

To sum up, this thesis delivered an evaluation process that entrepreneurs can apply themselves, including a questionnaire tool, a semi-automated analysis and an interview schedule. This managerial model may probably work most effectively in the interaction between the entrepreneur and an automatic or manual evaluator. For my personal reference, it was a first step to scientifically underpin my practical objectives, which focus on improving health in LMICs.

7.4 Limitations and Future Research

While greatest care was taken while collecting, analyzing, and interpreting the findings of this study, there were three potential limitations in regards to the inputs of the questionnaire, the sample selection and the notion of success.

The answers to the questionnaire fully relied on the entrepreneur's interpretation. There was no reference given what would be expected for a maximum score. Additionally, the entrepreneurs were not asked to support their answers with comprehensible information. For example, they could claim that "clear outcomes for mHealth and indicators for measuring outcomes have been defined" extraordinarily. But they did not have to support the claim by naming and describing these outcomes. The quality of the outcomes and indicators would only be revealed during the interview, for which comparable expectations were again missing. Ribeiro (2014) mentioned in the interview that for the assessments he had conducted for investment decisions, he tried to support each measurement with traceable evidence. Research focusing on the evolution of the questionnaire tool may want to propose an approach, in which appropriate data sources and reference examples for the answers are taken into account.

Another limitation was linked to the data samples, especially the entrepreneurs. For each startup, one person answered to the questionnaire and was interviewed. The single view might have impacted the findings, as, for example in one case, many questions were not fully answered. Moreover, four of the entrepreneurs operated in Brazil, a middle-income country, and one entrepreneur operated in Tanzania, a low-income country. Although theory from other LMICs
was integrated, the learning from practical applications was from few countries. Also, the selected participants were mainly from mHealth areas, supporting and surrounding the diagnosis and treatment of chronic conditions or providing preventive and well-being applications. Future research may benefit from integrating several perspectives per start-up from more start-ups, operating in several countries and using mHealth solutions for diagnosis and treatment to validate comparable findings.

The third limitation of this study is about the notion of success. None of the entrepreneurs directly addressed the scoring mechanism or the issue of future success. It should be repeated that this thesis did not aim at providing a set of variables that forecast success, what might be the objective of positivistic research traditions. Rather this work tried to complement the theory with a different angle on the evaluation process, which was necessary to evaluate mHealth start-ups in LMICs. Nevertheless, different views exist on what success is for mHealth start-ups. In general, the success of start-ups is often defined by the team's potential or actual achievement to raise venture capital. This capital is for most traditional investors linked to the market evaluation, so to the amount of the revenues and the size of the market (Mason & Stark, 2004; Zacharakis, 2010). In healthcare, however, quality and access extend the dimensions of success in addition to financial aims. Thus, success could also mean the impact on people - more people have access or the impact on quality of care - people are healthier. My personal preference is to define success as the solution's ability to support the provision of qualitative health access for underserved populations. In this approach, the self-sustainable business transforms from being the ultimate goal of the organization to providing the means to achieve the impact on quality and access. Future research may want to elaborate on this discussion. Social entrepreneurship offers a possibility for that.

In addition to the limitations, another possibility for future research relates to the form of the study. I chose to apply an exploratory research, which relied on a research paradigm that was inspired by Robert Stake's (1995, 2005) interpretivism, assuming that there were multiple realities, existing in lived experiences of entrepreneurs. In order to further understand the managerial model, the strengths and weaknesses may be analyzed in single or multiple case studies that link the development of a start-up with the evolution of the scores. Stake (1995, 2005) described three types of case studies: (1) intrinsic cases to uncover the particulars of a single case, (2) instrumental cases to gain understanding on an issue or to define a theory, and (3)

collective cases that refer to multiple, instrumental cases, which are studied in unison, parallel or sequential order. For entrepreneurship in general, Bygrave (2007) proposed to focus the research on longitudinal studies of extreme outliers in the sense of Schumpeterian entrepreneurship. Another future research may choose to apply a more positivistic research paradigm, in order to validate the managerial model and test the framework as a measurement tool across a significant amount of start-ups.

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Appendix

1. Overview of Informative Interviewees, Visited Events and Continuous Exchanges

	Date or	Date or		
Informants / Events	periods of	Description		
	exchange			
Health 2.0 Latin America	$6^{\text{th}} / 7^{\text{th}} \text{Dec}$	Conference promotes, showcases and		
Conference	2013	catalyzes new technologies in healthcare		
Hugo Fuchon	10 th Feb 2014	PhD student, healthcare governance in low-		
		income communities in Sao Paulo, Brazil		
Mahiti Godoy, Maxwell	13 th Feb 2014	Informar Saúde (Grupo BEM)		
Moreno dos Santos				
Fernanda Viana	Feb-Jul 2014	Master student at FGV, telehealth in Brazil		
Dr. Marlei Pozzebon	Feb-Apr 2014	Lecturer of 'New Technologies and Social		
	_	Innovation' at FGV		
Alexander Schmitz-Kohlitz	21 st May 2014	Founder and Director AkitPartners,		
	-	Healthcare investor		
Camila Crispiniano	28 th May 2014	Manager 'eHealth Selfcare' at Telefonica		
Marcos Pereira de Almeida	5 th June 2014	Director NH Investimentos, eHealth investor		
Carlos Pessoa	9 th June 2014	Director Wayra Brazil, Investor and incubator		
Lasse Koivisto	9 th June 2014	CEO ProntMed, eHealth entrepreneur		
Gilberto Ribeiro	10 th June 2014	Partner VOX Capital, Social impact investor		
Dr. Silvia Masiero	Sept-Dec 2014	LSE Fellow, research: technology for		
	-	development		
Dr. Tony Cornford	Sept-Dec 2014	Associate Professor at LSE, research: digital		
	_	technologies in healthcare		
Dr. Christian Busch	Sept-Dec 2014	LSE Fellow and Associate Director at		
		Innovation and Co-Creation Lab		
Health 2.0 Europe	$10^{\text{th}} / 11^{\text{th}} \text{ Nov}$	Conference promotes, showcases and		
Conference	2014	catalyzes new technologies in healthcare		
Oxford Africa Conference	$22^{nd} / 23^{rd}$ May	General conference on Africa, included		
	2015	specific healthcare panels		
eHealth Venture Summit	17 th Nov 2015	at Health IT Forum of Medica, world's largest		
		trade fair on medical technologies		
Empreender Saúde Team	Network for digital health start-ups; Dr. Vitor Asseituno,			
	Dr. Raphael Gordilho, Nathália Nunes, Tymo Nakao			
SYTE Institute	Intelligence reports, consulting and M&A in eHealth;			
	Dr. Andreas Keck, Justus Wolff			
Kate Michi Ettinger	Independent researcher and health entrepreneur, focusing on			
	medical technolo	medical technologies in LMICs		
Aline Menden	Managing Direc	Managing Director at Endeva, focusing on research, facilitation		
	and consulting of inclusive business			

2. Guideline for Interviews with Specialists

Interview Guideline – Specialist		1		
Interview Guideline - Specialist				
Name:	Date:			
Organization:	Time: from to			
Position/ Responsibility:	Location:			
My name is <u>Rey Buckman</u> . Currently, I am in the first year	r of the Professional Master Program	m		
in International Management (MPGI) at the university F	undação Getulio Vargas - Escola d	le		
Administração de Empresas de São Paulo (FGV-EAESE	2). This semi-structured interview	is		
conducted in the frame of my master thesis, which I write u	nder the supervision of Edgard Bark	<u>i</u> .		
(Working) Title and Research Question of	of the Master Thesis			
mHealth Evaluation: An Exploratory Research of a Framew	vork in Brazil			
- Can the Khoja–Durrani–Scott (KDS) comprehensiv	e e-Health evaluation framework an	d		
tool be applied to mHealth in Brazil?				
Interview Introduction	2			
My research objective is to analyze the KDS evaluation fr	amework regarding its usefulness for	or		
the evaluation of mHealth companies and products in Braz	il. This will be achieved in two step	s.		
First, I interview several specialists in the mHealth field	d in Brazil with the support of th	is		
interview guideline in order to identify key points for mHe	alth evaluation. These will be used	to		
understand possible adaptations of the KDS framework	and tool. In addition, I perform a	in		
unsystematic literature scan in order to substantiate those ad	daptations. Second, I support mHeal	th		
organizations in Brazil to apply the adapted KDS tool to the	eir companies and products in order	to		
subsequently discuss the results in an interview.				
This interview will last approximately <u>60 minutes</u> . I wou	lld be very grateful, if you answere	d		
every question openly based on your personal and profess	tional experience. If you allow, I with	11		
make notes and record our conversation in order to finally	capture the overall situation and dra	w		
consolidated conclusions.				
Do you have any further questions? Then. I suggest we s	start.			
Master Thesis: mHealth Evaluation Framework	Rey Buckma	ın		

2

Interview				
Objective of Question	f Question Questions			
	In this study, we use the WHO definition of mHealth as the "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices". ¹ Additionally, we apply van Dyk's model to differentiate mHealth to telemedicine, telecare, telehealth and eHealth. ²			
Build relationship;	eHealth (not only over a distance) (preventative, promotive and curative healthcare delivered over a distance) (curative metalisticare delivered over a distance) (curative (curative) telemedicine (curative) telemedicine (curative) telemedicine			
Create common understanding of mHealth;	1. Since when have you been involved in the overall eHealth (use of ICT for health) field?			
Estimate experience in mHealth field;	2. How are you engaged in the mHealth sector?			
	If possible explore more on the experience of the interviewee in order to understand the background and focus of the professional experience. For example, ask about the development of mHealth over the past years, discuss challenges and opportunities, or enquire about successful projects.			

¹ WHO. (2011). *mHealth: New horizons for health through mobile technologies*. Retrieved 2014 from Global Observatory for eHealth: http://www.who.int/goe/publications/goe_mhealth_web.pdf ² van Dyk, L. (2014). A Review of Telehealth Service Implementation Frameworks. *International Journal of Environmental Research and Public Health*, 11, 1279-1298.

Master Thesis: mHealth Evaluation Framework

Rey Buckman

3

	Evaluation has been defined as: "Attributing value to an intervention by gathering reliable and valid information about it in a systematic way, and by making comparisons, for the purposes of making more informed decisions or understanding causal mechanisms or general principles." ³	
	3. Have you ever performed an evaluation of a mHealth company or product?	
	If no,	
Familiarize with the topic of evaluation;	a. Do you plan to perform a mHealth evaluation?	
Estimate knowledge and/or bias for certain evaluation structures;	4. Please describe briefly the evaluation you have performed or plan to do.	
Describe general position towards mHealth evaluation	5. Do you think mHealth evaluation is important for the development and growth of the field? Why?	
	6. How can mHealth evaluation contribute to the development of the field? Especially for companies.	
	7. What are challenges in doing a mHealth evaluation?	
	8. How do you describe the phases of a mHealth project? KDS life-cycle stages (Development, Implementation, Integration, Sustainable Operation)	
Identify key points for mHealth evaluation; Compare (indirectly) to the KDS evaluation tool	 9. Whose view should be included in the evaluation of mHealth? Three viewpoints in the KDS tool (Manager, Healthcare provider, Client) 	
	10. Which areas are important in mHealth evaluation? Why? Seven evaluation themes in KDS framework (Health services, technology, economic, readiness and change, behavioral and socio-technical, ethical, policy)	

³ Øvretveit, J. (1998). Evaluating Health Interventions: an introduction to evaluation of health treatments, services, policies and organizational interventions. Berkshire: Open University Press.

Master Thesis: mHealth Evaluation Framework

4

	11. How should the mHealth companies be evaluated? Likert scale for statements in the KDS tool [unsatisfactory (1), below expectations (2), meets expectations (3), above expectations (4), extraordinary (5) and don't know (1)]?
	Briefly describe the Khoja–Durrani–Scott (KDS) e-Health evaluation framework and tool including life-cycle stages, evaluation themes, viewpoints and scoring model
	The mHealth field is a new phenomenon and most solutions are in the small-scale pilot stage. Only few companies and products have successfully survived the implementation phase. Thus, my research and the following questions <u>focus</u> on understanding the difference between <u>implementation</u> and <u>integration</u> , especially from the viewpoint of the <u>management</u> .
	12. What do you think about the four life-cycle stages in the KDS framework?
(The questions in this section are not systematically addressed, rather only if the previous questions lead to a detailed review of the tool.) Review the structure of the KDS tool;	13. What is your opinion on the three viewpoints in the KDS tool?
	14. What is your view on the evaluation of statements linked to a Likert scale in the KDS tool?
Assess clarity and understanding of the KDS tool;	15. From the seven evaluation themes, which are more relevant? Are any themes missing? Why?
Review the content of the questionnaire for the KDS tool	16. Which questions are more relevant for the theme <i>health services</i> ? Are any points missing? Why
	17. Which questions are more relevant for the theme <i>technology</i> ? Are any points missing? Why
	18. Which questions are more relevant for the theme <i>economic</i> ? Are any points missing? Why
	19. Which questions are more relevant for the theme <i>readiness and change</i> ? Are any points missing? Why

Master Thesis: mHealth Evaluation Framework

Rey Buckman

5

	20. Which questions are more relevant for the theme <i>behavioral and socio-technical</i> ? Are any points missing? Why?
	21. Which questions are more relevant for the theme <i>ethical</i> ? Are any points missing? Why?
	22. Which questions are more relevant for the theme <i>policy</i> ? Are any points missing? Why?
	23. Do you think that the KDS evaluation tool would increase productivity, make it easier to work and be useful for mHealth companies and products in Brazil? Why?
Review the application of the KDS tool:	
Third-party estimation of the user acceptance of mHealth companies for the KDS tool (017: usefulness	24. Do you think that the KDS evaluation tool would improve performance and enhance effectiveness of mHealth companies and products in Brazil? Why?
Q 18: effectiveness, Q 19: ease of use); ⁴	25. Do you think that learning to use, becoming skillful at using and using the KDS evaluation tool would be easy?
Identify added value and potential situations of application of the KDS tool ⁵	Why?
	26. Name three situations, in which the KDS evaluation tool would add value to mHealth companies and products in Brazil. Describe briefly your choice.

Thank you very much for taking the time for this interview.

Master Thesis: mHealth Evaluation Framework

⁴ Segars, A. H., & Grover, V. (1993). Re-examining perceived ease of use and usefulness. MIS Quarterly, 17 (4),

⁵ Silius, K., & Tervakari, A. M. (2003). An evaluation of the usefulness of web-based learning environments: The ⁵ Silius, K., & Tervakari, A. M. (2003). An evaluation of the usefulness of web-based learning environments: The Networks and E-learning. 8-9 May. Valencia: Springer.

3. Email to Contact Entrepreneurs

Dear ____,

Thank you very much for your interest to participate to this study of mHealth Entrepreneurship.

For my master thesis, I have developed a model to evaluate mHealth start-ups from the perspective of the entrepreneurs.

In order to perform the evaluation, I need to collect your answers to some questions. Afterwards, I will prepare the evaluation, as basis to discuss the results. The questionnaire takes about 30 minutes.

There are four different questionnaires, depending on the lifecycle stage of the development of your start-up. Please select ONLY the questionnaire that is most appropriate to your company.

Development Stage: The process of establishing mHealth solutions informed by an environmental scan, needs assessment, existing capacity, and implemented within a broad social and equity based perspective http://goo.gl/forms/0wFVrxCfC8

Implementation Stage: Implementation is the process involving preparation for, introduction of, and initial practice of an mHealth solution (pilot) http://goo.gl/forms/KksUjxy9a7

Integration Stage: For mHealth, integration is a process in which separately produced components, subsystems or health issues are combined and problems in their interactions are addressed to improve the quality and effectiveness of health services and care <u>http://goo.gl/forms/TWnQQwhzAG</u>

Sustainability Stage: Sustained operation is a state where a mHealth application has performed satisfactorily without interruption for an extended period of time. This refers to the stage where routine health activities are carried out using mHealth as an integral component http://goo.gl/forms/9hL7oIH3pN

I am looking forward to a fruitful exchange with you.

Kind regards,

Rey

4. Guideline for Interviews with Entrepreneurs

Interview G	uideline - Entrepreneur
Name:	Date:
Organization:	Time: from to
Position/ Responsibility:	Location:
My name is <u>Rey Buckman</u> . Currently, I ar	n in the first year of the Professional Master Program
in International Management (MPGI) at	the university Fundação Getulio Vargas - Escola de
Administração de Empresas de São Paul	o (FGV-EAESP). This semi-structured interview is
	which I write under the supervision of Edgard Barki

(Working) Title and Research Question of the Master Thesis

mHealth Evaluation: An Exploratory Research of a Framework in Brazil

- Can the Khoja–Durrani–Scott (KDS) comprehensive e-Health evaluation framework and tool be applied as a management tool for mHealth in Brazil?

Interview Introduction

My research objective is to analyze the <u>KDS evaluation framework regarding its usefulness for</u> the evaluation of mHealth companies and products in Brazil. This will be achieved in two steps. First, I interviewed several specialists and investors in the mHealth field in Brazil in order to identify key points for mHealth evaluation. These were used to understand possible adaptations of the KDS framework and tool. In addition, I performed an unsystematic literature scan in order to substantiate those adaptations. Second, I support mHealth entrepreneurs in Brazil to apply the adapted KDS tool to their companies and products in order to subsequently discuss the results in an interview based on this interview guideline.

This interview will last approximately <u>60 minutes</u>. I would be very grateful, if you answered every question <u>openly</u> based on your <u>personal and professional experience</u>. If you allow, I will make notes and record our conversation in order to finally capture the overall situation and draw consolidated conclusions. All information will be treated confidential.

Do you have any further questions? --- Then, I suggest we start.

Master Thesis: mHealth Evaluation Framework

Rey Buckman

2

Interview			
Objective of Question	Questions		
Introduction; Explain scoring process	Researcher explains how the answers from the questionnaires transferred into the scoring model and how the results were calculated.		
	Researcher presents the scorecard for the start-up.		
Presentation of scorecard; initial reaction; confirmation of strengths	Allow interviewee time to review the numbers.		
	Researcher makes a quick summary how the results could be interpret regarding the strengths and weaknesses of the start-up.		
and weaknesses	 What is your first reaction to the score? Does the interpretation of the strengths and weaknesses represent your current challenges? Why or Why not? 		
	Researcher to follow the interviewee's path, based on the reactions and focus for discussion.		
Review details of evaluation; Inquire about entrepreneurs understanding and sense-making process; Perform in-depth evaluation; Review strengths and weaknesses	 3. Some examples for questions to enter into details and follow-up: Health: Which indicators were used? What outcome is measured? How is customer satisfaction measured? Technology: How are the development processes structured? Behavioral and Socio-technical: How is the user integrated in the process? How is the technology tested with users? Economic: What is the value proposition of the company? Readiness and Change: How have you developed the change management plan? Ethical: How does the company create social value? Policy: How do you engage with the larger ecosystem to establish sustainable policies? Managerial and Organizational: How was your team formed? 		
Review added value of evaluation; Inquire about learning; Assess possibilities to repeat and replicate; Identify modifications	 4. How useful was this evaluation exercise for you? What especially? 5. What have you learnt about your company that you were not aware of before? 6. Would you repeat the evaluation? a. If no, what has to change? 		

Thank you very much for taking the time for this interview.

Master Thesis: mHealth Evaluation Framework

Rey Buckman

5. Minor Adaptations to Questions in Reference to Users

As mentioned in chapter 5.1.1, KDS differentiated among the terms staff, clients, providers, and institutions, what might be necessary for eHealth applications in hospitals. However, for the wide adoption of mHealth in various contexts and for simplicity, I changed all ambiguous wording into 'user' or 'stakeholder', representing the person that uses or assesses the mHealth application.

Original Tool	Adapted Tool		
Health Services and Health Status			
2.2.5. In comparison to baseline, mHealth	2.2.6. In comparison to baseline, mHealth brings		
brings improvement in the communication	improvement in the communication		
between healthcare providers at different			
centres			
2.2.11. In comparison to baseline, mHealth	2.2.10. In comparison to baseline, mHealth brings		
brings Improvement in safety of clinical	Improvement in safety		
practices			
2.2.12. In comparison to baseline, mHealth	2.2.11. In comparison to baseline, mHealth brings		
brings efficiency of healthcare staff	efficiency		
2.2.13. Clients satisfaction has increased	2.2.12. User satisfaction has increased with the		
with the service provided through mHealth	service provided through mHealth		
Technology			
No minor changes			
Behavioral	and Socio-technical		
Direct benefits of mHealth program on	4.2.1. Direct benefits of mHealth program on		
working environment and social working environment and social interaction ar			
interaction among staff are ensured	users are ensured		
Adoption of mHealth among all genders of	4.2.2. Adoption of mHealth to social groups of		
staff has been ensured	users (e.g. socio-economic, gender, age) has been		
Adoption of mHealth to all social groups	ensured		
of staff has been ensured			
Adoption of mHealth among all genders of			
clients has been ensured			
Adoption of mHealth to all social groups			
of clients has been ensured			
Diffusion of mHealth among all genders	Diffusion of mHealth to social groups of users (e.g.		
of staff has been ensured	socio-economic, gender, age) has been ensured		
Diffusion of mHealth to all social groups			
of staff has been ensured			
Diffusion of mHealth among all genders			
of clients has been ensured			
Diffusion of mHealth to all social groups			
of clients has been ensured			

Original Tool	Adapted Tool
Continous assessment of gender adoption	Continuous assessment of social adoption among
among staff is conducted	users is conducted
Continous assessment of social adoption	
among staff is conducted	
Continous assessment of gender adoption	
among clients is conducted	
Continous assessment of social adoption	
among clients is conducted	
	Economic
Benefits for clients and institution have	5.3.1. Benefits for users have been quantified in
been quantified	monetary values
Cost-benefit analysis of mHealth initiative	5.3.3. Cost-benefit analysis of mHealth initiative
has been done from the institution's	has been done from the user's perspective
perspective	
Cost-benefit analysis of mHealth initiative	
has been done from the client's	
perspective	
Incentives for healthcare provider have	5.1.3. Incentives for stakeholders have been
been decided	decided
Incentives for healthcare providers are in place	5.2.4. Incentives for stakeholders are in place
Readin	ess and Change
Plan for motivation of staff to accept	6.1.5. Plan for motivation of users to accept
mHealth initiative has been developed	mHealth initiative has been developed
Plan in place to ensure effective	6.2.1. Plan in place to ensure effective preparation
Preparation of staff for implementing	of user for implementing mHealth initiative
mHealth initiative	
Appropriate time and effort done for	6.2.2. Appropriate time and effort done for training
training of all staff, including clinical and	of all users
management staff	
Benefits to staff in improving their	6.2.3. Benefits to user in improving their capacity
capacity through mHealth has been	through mHealth has been ensured
ensured	
Sufficient efforts are made to enhance	6.2.4. Sufficient efforts are made to enhance trust
trust of staff and clients on mHealth	of users on mHealth initiative
initiative	
Time management issue of staff has been	6.2.6. Time management issue of user has been
addressed	addressed
Strategy is in place for broader mHealth	6.3.2. Strategy is in place for broader mHealth
adoption in the institution	adoption
Plan is in place for wider adoption and	6.4.2. Plan is in place for wider adoption and
adaptation of mHealth throughout the	adaptation of mHealth
Institution	
Appropriate time and effort done for	6.4.3. Appropriate time and effort done for
refresher trainings of all staff, including	refresher trainings of all users
clinical and management staff	

Original Tool	Adapted Tool		
Ethical			
Plan is in place to ensure Security of	7.1.2. Plan is in place to ensure security of users		
patient's identity and maintaining	identities and to maintain confidentiality of users		
confidentiality of patient information	information		
Informed consent of clients has been	7.1.3. Informed consent of users has been obtained		
obtained			
mHealth program has the potential to	7.1.5. mHealth initiative has the potential to		
improve Autonomy of clients	improve autonomy of users		
Beneficence and non maleficence of	7.2.1. Beneficence and non maleficence of mHealth		
mHealth initiative for client, provider, and	initiative for users, provider, and institution have		
institution has been ensured	been ensured		
Plan implemented to ensure Security of	7.2.3. Plan implemented to ensure security of user		
patient's identity and maintaining	identities and to maintain confidentiality of user		
confidentiality of patient information	information		
mHealth program improves Autonomy of	7.2.5. mHealth program improves autonomy of		
clients	users		
	Policy		
No minor changes			

6. Complete Adapted Questionnaire Tool

See chapter 5 for full discussion of the adaptation of the questionnaire tool.

Development Stage (1)	Implementation Stage (2)	Integration Stage (3)	Sustainability Stage (4)
Introduction (1)			
1.1.1. What time is it now? The aim of this question			
is to estimate the time for taking the survey (there is			
no evaluation of your speed; so, take as much time			
as needed)			
1.1.2. What is the name of the mHealth company/			
initiative?			
1.1.3. When was the start of mHealth initiative			
(mm/yyyy)?			
1.1.4. How many people currently work for the			
mHealth initiative?			
1.1.5. Which features are used by the mHealth			
initiative? Dropdown: Text-messaging (SMS), Add-			
on/ Device, Voice, Video, Multimedia messaging			
service (MMS) Smartphone/ Tablet App			
1.1.6. Which area does the mHealth initiative			
impact? Dropdown: Health promotion, Self-			
management, Communication/ Information, Remote			
monitoring, Data gathering, Diagnosis, Treatment			
adherence Training/ education			
1.1.7. On which group of medical conditions does			
the mHealth initiative focus? Dropdown: Chronic			
conditions, Prevention/ Well-being, Acute conditions			
1.1.8. Who are the main users of the mHealth			
initiative? Dropdown: Individual healthcare			
providers (e.g. doctors, nurses), Institutional			
healthcare providers (e.g. hospitals, pharmacies).			
Patients Wider nonulation			
1.1.9. Are the users of the mHealth initiative mainly			
in the scope of the public (SUS) or private sector?			
Dropdown: Public (SUS), Private			

Page 138 of 143

Development Stage (1) Implementation Stage (2)		Integration Stage (3)	Sustainability Stage (4)
	Health Services and Healt	h Status Outcomes (2)	
2.1.1. Enough data/information is available on the general health status of the population	2.2.1. Indicators to assess changes in health services and status have been monitored	2.3.1. Impact showing changes in disease incidence and prevalence, and health status have been adequately measured	2.4.1. mHealth improves in longer term the health indicator disability-adjusted life years (DALYs), meaning it decreases early deaths and/or decreases the number of years lived with
2.1.2. Data on health status is monitored and updated regularly	2.2.2. Outcomes showing changes in health services and status have been adequately measured	2.3.2. In comparison to baseline, mHealth improves control of disease and change in health status of the population	disability 2.4.2. mHealth brings improvement in quality of life of the users
2.1.3. Data on health status is monitored <u>reliably</u>	2.2.3. In comparison to baseline, mHealth brings improvement in access to health services	2.3.3. Impact showing social change in the community due to improvement in health services and health status access, quality and cost of care have been adequately measured	2.4.3. mHealth has improved key health indicators in the population
2.1.4. Need for mHealth is determined on the basis of identified gaps in health status/services (access, quality, safety, delivery or cost of health care) through baseline study or existing evidence	2.2.4. In comparison to baseline, mHealth brings improvement in quality of health services	2.3.4. mHealth brings social change in the community due to improved access, quality and cost of care	2.4.4. mHealth program is available for use to a large number of services
2.1.5. Clear outcomes of mHealth in terms of improvement in health <u>services</u> have been determined	2.2.5. In comparison to baseline, mHealth brings significant reduction in cost of health services	2.3.5. Users are generally satisfied with the mHealth application as stable and it could be integrated with routine services	
2.1.6. Clear outcomes of mHealth in terms of changes in health status have been determined	2.2.6. In comparison to baseline, mHealth brings improvement in the communication		
2.1.7. Clear indicators for measuring outcomes in health services and health status have been determined	2.2.7. In comparison to baseline, mHealth improves time and quality of decision making		
	2.2.8. In comparison to baseline, mHealth significantly improves diagnosis of health problems		
	2.2.9. In comparison to baseline, mHealth significantly improves treatment of health problems		
	2.2.10. In comparison to baseline, mHealth brings Improvement in safety		
	efficiency		
	2.2.12. User satisfaction has increased with the service provided through mHealth		

Development Stage (1)	Implementation Stage (2)	Integration Stage (3)	Sustainability Stage (4)
	Technology Ou	itcomes (3)	
3.1.1. Appropriate technology options (Software,	3.2.1. Selected technology has been found	3.3.1. Interoperability of the mHealth technology	3.4.1. Scalability of the technology has been
Hardware and connectivity) for the desired mHealth	acceptable by the users.	with other equipment and programs has been	considered for replication to a larger scale
initiative have been identified		tested	
3.1.2. Assessment of technology options (Software,	3.2.2. Selected technology has been found		3.4.2. Ability of technology to be incorporated
Hardware and connectivity) for the desired mHealth	appropriate for a variety of uses other than mHealth		into large scale health strategy has been
initiative have been conducted			considered
3.1.3. Availability of desired technology in the	3.2.3 Selected technology is relevant to the current		
market has been considered for its selection for the	and future needs of the user		
mHealth initiative			
3.1.4. Comparison of cost for developing or	3.2.4 Selected technology is flexible, i.e. can be		
acquiring technology (including free and open	modified to suit gender/cultural/social needs		
source) has been conducted			
3.1.5. Interoperability, integration with existing	3.2.5 Efficiency of technology in terms of reduction		
technology, and standardization have been	in error rates has been established		
considered for its selection for the mHealth initiative			
3.1.6. Architecture of the software for future	3.2.6 Efficiency of the technology has been		
expansion has been assessed	measured against a gold standard or best available		
· ·	technology		
3.1.7 Reliability, stability and user safety have been	3.2.7 Automization (Automation) of technology has		
confirmed for hardware	been considered for future		
3.1.8 Reliability and stability of the network			
required for the particular mHealth initiative have			
been considered			
3.1.9 Efficiency of technology in given conditions			
(weather, geography, infrastructure) has been			
considered			
3.1.10 Ownership of technology and its copyrights			
have been explored			
3.1.11 Environmental impact of the technology has			
been considered			
3.1.12 Recycle and reuse of technology have been			
planned			
3.1.13 Downtime planning (Backup planning) of			
technology has been done			

	Imprementation Stage (2)	Integration Stage (5)	Sustainability Stage (4)				
Behavioral and Socio-technical Outcomes (4)							
4.1.1. User-friendliness of the mHealth technology has been ensured	4.2.1. Direct benefits of mHealth program on working environment and social interaction among users are ensured	4.3.1. Diffusion of mHealth to social groups of users (e.g. socio-economic, gender, age) has been ensured	4.4.1.Continuous assessment of social adoption among users is conducted				
4.1.2. User capacity and skills have been considered in designing/acquiring technology for mHealth initiatives	4.2.2. Adoption of mHealth to social groups of users (e.g. socio-economic, gender, age) has been ensured						
4.1.3. User understanding and comprehension have been considered in designing/acquiring technology for mHealth initiatives							
4.1.4. Different social groups of users (e.g. socio- economic, gender, age) have been considered in designing/acquiring technology for mHealth initiatives							
	Economic Out	tcomes (5)					
5.1.1. Model for revenue streams such as sales, fees and reimbursement has been prepared	5.2.1. Model for revenue streams such as sales, fees and reimbursement has been calculated	5.3.1. Benefits for users have been quantified in monetary values	5.4.1. Impact of investments in mHealth on the health indicator disability-adjusted life years (DALYs) has been calculated				
5.1.2. Model for cost structure for the mHealth initiative has been prepared	5.2.2. Model for cost structure for the mHealth initiative has been calculated	5.3.2. All costs and resources in a wider societal perspective have been quantified in monetary values					
5.1.3. Incentives for stakeholders have been decided	5.2.3. Impact of mHealth initiative on resources in wider societal perspective such as relatives, hospitals and municipals have been considered	5.3.3. Cost-benefit analysis of mHealth initiative has been done from the user's perspective					

Development Stage (1) Implementation Stage (2)		Integration Stage (3)	Sustainability Stage (4)
	Readiness and Chan	ge Outcomes (6)	
6.1.1. Standard tools have been used to measure	6.2.1. Plan in place to ensure effective preparation of	6.3.1. Plan is implemented to ensure continuation	6.4.1. Plan is in place to facilitate customization,
individual and organizational readiness for mHealth	user for implementing mHealth initiative	of change management for maintaining the	modification and improvement of mHealth
initiative	1 0	mHealth program	initiative as and when needed
6.1.2. Plan in place to ensure 'involvement' of end	6.2.2. Appropriate time and effort done for training	6.3.2. Strategy is in place for broader mHealth	6.4.2. Plan is in place for wider adoption and
users in all phases such as needs assessment,	of all users	adoption	adaptation of mHealth
vendor/solution evaluation, selecting features of			
mHealth solution etc			
6.1.3. Change management plan has been developed	6.2.3. Benefits to user in improving their capacity		6.4.3. Appropriate time and effort done for
for mHealth implementation	through mHealth has been ensured		refresher trainings of all users
6.1.4. Preparation of human resource in terms of	6.2.4. Sufficient efforts are made to enhance trust of		
changes in practices, working relationships,	users on mHealth initiative		
management process and flow of communication			
has been planned			
6.1.5. Plan for motivation of users to accept	6.2.5. Support is available for all users in case of any		
mHealth initiative has been developed	problems in using the technology		
	6.2.6. Time management issue of user has been		
	addressed		
	Ethical Outc	omes (7)	
7.1.1. Ethical guidelines have been followed in	7.2.1. Beneficence and non maleficence of mHealth	7.3.1. Plan in place to further improve equity in	7.4.1. Plan implemented to further improve
selection of study participants for the testing or pilot	initiative for users, provider, and institution have	health through improvement of points of inclusion	equity in health through improvement of points
phase	been ensured	for social groups in mHealth initiative	of inclusion for social groups in mHealth
			initiative
7.1.2. Plan is in place to ensure security of users	7.2.2.Negative outcomes have been documented		
identities and to maintain confidentiality of users			
information			
7.1.3. Informed consent of users has been obtained	7.2.3. Plan implemented to ensure security of user		
	identities and to maintain confidentiality of user		
7 1 4 milledid initiation has the material to immediate	information		
7.1.4. mileath initiative has the potential to improve	7.2.4. mHealth initiative improves equity in health		
equity in health among social groups (e.g. socio-	among different social groups of users		
economic, gender, age)	7.2.5 mHealth program improves autonomy of users		
2.1.5. Infreduit initiative has the potential to improve	7.2.5. Infleatin program improves autonomy of users		
7.1.4. mHealth initiative has the potential to improve equity in health among social groups (e.g. socio- economic, gender, age) 7.1.5. mHealth initiative has the potential to improve autonomy of users	7.2.4. mHealth initiative improves equity in health among different social groups of users7.2.5. mHealth program improves autonomy of users		

Page 142 of 143

Development Stage (1)	Implementation Stage (2)	Integration Stage (3)	Sustainability Stage (4)						
	Policy Outcomes (8)								
8.1.1. Institutional policies are in place to enhance	8.2.1. Changes are made in policies (organizational	8.3.1. Dissemination of research/program	8.4.1. Policies are in place to make mHealth part						
trainings and support change management	or government) to facilitate mHealth implementation	outcomes to concerned decision and policy-	of the overall strategy and organizational						
		makers has been conducted	practice						
8.1.2. Institutional policies are in place to determine	8.2.2. Policies to determine licensure of healthcare	8.3.2. Policy changes are made to facilitate	8.4.2. Policies are in place to facilitate						
scope for innovations, such as mHealth	providers for mHealth practice are in place	adoption of mHealth by other users who were not using it before	knowledge sharing with other organizations and countries						
8.1.3. Institution provides funding for innovations or	8.2.3. Policies regarding reimbursement of	8.3.3. Policy changes are made to facilitate							
customizations in mHealth	healthcare providers for mHealth practice are in	networking with other users through mHealth							
	place								
8.1.4. Government provides or facilitates funding	8.2.4. Policies to determine liability for mHealth								
for innovations or customization in mHealth	practice are in place								
8.1.5. Piloting of mHealth has not taken priority	8.2.5. Changes in policies are ensured to be aligned,								
over other more pressing health priorities that have a	and not conflicting, with other government or								
proven benefit on health of the population	organization programs.								
	8.2.6. Plan is in place to disseminate								
	research/initiative outcomes to concerned decision								
	and policy-makers								
	Entrepreneurial	Outcomes (9)							
9.1.1. Plan for management team of mHealth	9.2.1. Education in management/ economic studies	9.3.1. Organization structure and processes are in	9.4.1. Plan is in place for continuously learning						
initiative has been prepared to provide the necessary	as well as work experience in managerial and	place	in the organization in order to adapt						
education in management/ economic studies as well	mHealth related fields for management team of		technological and other changes concerning the						
as work experience in managerial and mHealth	mHealth initiative are in place		mHealth initiative						
related field									
9.1.2. Requirements for team positions and skills	9.2.2. Organization structure and processes have	9.3.2. Team positions and skills are in place							
have been prepared	been prepared								
	9.2.3. Requirements for team positions and skills								
	have been decided								

7. Frequency of Outcome Themes per Relative Position for Two Groups

See chapter 6.3 for description of relative positioning.

Frequency of an outcome theme	per relative rank across earl	ly stages (Start-u	p A, B, C)
1 7	1		

	1st	2nd	3rd	4th	5th	6th	7th	8th	Sum
Behavioral and Socio-technical	2	1							4
Economic	1		2						7
Technology		1	1				1		12
Health Services and Health Status		1			1	1			13
Ethical				2	1				13
Readiness and Change				1		2			16
Policy					1		1	1	20
Entrepreneurial							1	2	23

All double frequencies are from the two start-ups at the 'development' stage

	Frequency	y of an outcome	theme per relativ	e rank across the	sustainability stag	ge (Start-uj	p D, E)	
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	1st	2nd	3rd	4th	5th	6th	7th	8th	Sum
Behavioral and Socio-technical	2								2
Entrepreneurial		1	1						5
Ethical		1		1					6
Technology			1	1					7
Readiness and Change					2				10
Health Services and Health Status						2			12
Policy							2		14
Economic								2	16