Samuel A. Fricker · Christoph Thümmler
Anastasius Gavras *Editors*

Requirements Engineering for Digital Health

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Chapter 1
Digital Health

Christoph Thümmler

Abstract Healthcare is the biggest and fastest growing industry in the world and is one of the domains that are expected to grow significantly over decades to come. Underlying cause for this are the current demographic developments which are showing similar patterns almost worldwide with a strong growth of the population share of individuals over 65 years of age.

1.1 The Book

Healthcare is the biggest and fastest growing industry in the world and is one of the domains that are expected to grow significantly over decades to come. Underlying cause for this are the current demographic developments which are showing similar patterns almost worldwide with a strong growth of the population share of individuals over 65 years of age.

In the near future we will witness the emergence not only of groundbreaking new technologies in health and care but the emergence of completely new care systems with the need for large-scale integration of different types of technologies such as 4G and 5G, m-health applications, e-health clouds, and others. In this context requirements engineering will evolve from an expert domain initially left to a relatively small number of insiders to a critical skill set which in certain settings might well be applied by trained non-experts or informed users.

Although there can be no doubt that regional healthcare providers instantiating and implementing a new technology will in most cases seek expert advise to keep costs under control, small surgeries or pharmacies might rely on an informed decision by their owners who would probably be reluctant to invest a five-digit sum in a technology consultant. After all, following the 20–80 % rule (80 % effect out of 20 % effort) might be the only realistic and feasible approach for micro-, small-, and

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medium-sized enterprises (SME). But also smaller departments and managers working with in-house consultants might be interested in exploring the basics of requirements engineering in healthcare in order to map the terrain and enable them to clearly identify those areas that might be suitable for self-management and separate them from those tasks which would require professional input.

However, expert knowledge with regard to requirements engineering in the medical domain is limited and scattered across the literature and the identification and access of suitable and relevant content is time consuming and increasingly expensive.

This book intends to give an urgently needed and guided interdisciplinary overview over key aspects of requirements engineering in health and care to non-experts, students, and those requirements engineers unfamiliar with the healthcare, wellness, and ambient-assisted living domains. The book aims in particular at providing the readers with expert know-how from the shop floors rather than plane theoretical textbook knowledge. This book is not intended to replace a comprehensive textbook on requirements engineering but should complement academic literature wherever healthcare domain-specific knowledge is required or wherever the reader might be faced with real-world challenges in the healthcare, wellness, and ambient-assisted living domain.

This chapter maps the terrain and provides an overview of digital health, its roots and origins, the evolution, the socioeconomic context, and the future outlook (*Christoph Thümmler*). In the *requirements engineering chapter* (Chap. 2) we will provide view from experienced experts on the application of methods and tools and on best practice (*Samuel Fricker*). Due to the regulative implications healthcare is fundamentally different from many other industrial domains and careful considerations of legal and ethical aspects are mandatory for successful instantiation and implementation of new technology and subsequently of utmost importance for requirements engineering processes. We will discuss these in a chapter on *laws and regulations for digital health* (*Eleni Kosta*) (Chap. 3) and a chapter on *ethics for digital health* (*Ai Keow Lim Jumelle*, *Ioana Ispas*) (Chap. 4). Due to progressive globalization and in particular to secure interoperability and compatibility standardization is becoming more and more important in order to prevent fragmentation and island solutions. Details will be discussed in the *standards for digital health* (*Karima Bourquard*) chapter (Chap. 5). Most processes these days are expected to be user driven in order to optimize uptake and ensure sustainability. This is a principle close to the heart of requirements engineering and is reflected by the chapter on *user experience for medical personal and patients* (*Oli Mival*, *David Benyon*) (Chap. 6). Safety, security, and privacy are key requirements in the health and care domain and always have high priorities in any instantiation and implementation of new technology. Although the underlying security technology is an expert domain in its own right we will discuss the basics in the *patient safety and privacy, software security, and business resilience* chapter (*Mario Hoffmann*) (Chap. 7). Technological aspects take center stage in the practical settings and details of a pragmatic approach are outlined in a chapter describing how to elicit, analyze, and check requirements for a digital health solution (*Mojca Volk*) (Chap. 8). Finally, the book takes a more

abstract holistic approach on *how to plan and define a digital health product* (*Jakob Rasmussen*) to provide some guidance not only to medical professionals, patients, and clinical managers, but also to entrepreneurs and decision makers in the financial and administrative domains (Chap. 9).

1.2 Who Should Read This Book

The book provides a high-level overview about the current healthcare, wellness, and ambient-assisted living landscape and discusses the specific challenges and requirements of applying requirements engineering in this particular domain. While it is certainly an advantage if readers have a background in requirements engineering it is by no means a prerequisite. It has been the intention of the authors to create an access point for the highly diverse group of professionals typically involved in the implementation and instantiation of new technologies and the assessment of the associated requirements.

The book addresses medical practitioners, managers, engineers with little or no experience in requirements engineering, and requirements engineers with no experience in the healthcare domain.

This editorial also provides a high-level overview for decision makers in order to develop a better understanding of the processes involved in requirements engineering in the health and care domains in order to estimate implementation efforts and time lines. The book also addresses students and educators in requirements engineering, medicine, nursing, and digital health.

For researchers and academics the book will deliver background information to understand the background and the complexities of digital health and provides the required high-level knowledge for successful research funding applications. The book also provides an introduction for managers and professionals dealing with implementation and innovation processes in health and care as part of their general duties without necessarily holding an engineering degree.

The different chapters are based on the experience of practitioners in the relevant areas and provide clear practical guidance on real-world problem solving in the healthcare, wellness, and ambient-assisted living domain.

1.3 Historical Developments

Since the introduction of the Elizabethan Laws in England in the sixteenth century, which would only allow licensed recognized physicians to practice medicine in a radius of seven miles around London, the delivery of care has come a long way. Medicine has been subject to rapid progressive changes fuelled and driven by societal developments such as the industrial revolution and Bismarck's welfare

legislation and historic landmark events such as the Crimean Wars, which led to the birth of the Red Cross and World War II, which ultimately led to the industrial style production of pharmaceuticals, such as penicillin. World War II also triggered the upcoming of healthcare systems as national institutions due to the high demand for care following wartime injuries and the limited financial resources of citizens almost everywhere in Europe. The British National Health Service (NHS) was never meant to be a long-term solution but was put in place as a free state-funded interims solution in 1948 to meet the needs of thousands of injured ex service men and women. The ambitious vision of free healthcare provision at the point of care ended already 4 years later in 1952 with the introduction of a prescription fee of one Shilling and a fee of one Pound Sterling for dental treatment.

In modern times the development of healthcare has been mainly driven by the microbiological revolution, the progress in nanotechnology, and the emergence of information communication technology. The upcoming of new manufacturing technologies especially in the polymer industry enabled the production of lighter and thinner materials, which boosted the surgical revolution of the 1960s. The baby boomers created a demand for mass production of pharmaceuticals in the 1970s. New microbiological manufacturing technologies enabled the synthesis of insulin and a whole range of substances in the 1980s. Genetics laid the foundation for individualized medicine and groundbreaking changes in the pharmaceutical sectors are lying ahead of us.

However, not only technological progress has shaped the evolution of healthcare. One of the main drivers has clearly been the transition from industrial and agricultural societies to service societies. Due to the postwar changes in our lifestyles the case mix in accident and emergency departments has completely changed. Acute surgical interventions have been in dramatic decline over the last 50 years or so. Through instant access to care, the recognition of the value of hygiene and the ubiquitous availability of antibiotics acute infections are either prevented or immediately recognized and treated. The problems associated with the rash and lavish prescription of antibiotics cannot be highlighted enough but is not of central relevance to the subjects addressed in this chapter.

Starting off in the 1960s there has been a major change in the healthcare paradigm shifting the focus from treatment to prevention. These days there is a clear focus on diagnostics with an ever-growing demand for digital imaging procedures, minimal invasive procedures, histopathology, and laboratory medicine. There are indications that this trend will continue to a point where profiling of the human genome as a standard procedure may soon reveal illnesses before they manifest themselves and show in the patient. This may even lead to “treatment without illness” and prophylactic procedures. However, there can be no doubt that acute medical and surgical interventions will be the exception rather than the rule and that the focus with regard to healthcare will be on monitoring, prevention, and (self-) management.

Worldwide the omnipotence of the Internet and the rapid progressive deployment of digital infrastructure are driving a process of virtualization and aggregation. This allows for the availability and accessibility of rocketing numbers of new healthcare, wellness, and ambient-assisted living services. The latest trend hereby is

the emergence of applications, which may be used on smartphones and other mobile devices such as tablets and notebooks. The market volume for m-health applications has been predicted by the European Commission at 17.6 billion Euro by 2017. Currently there are around 100,000 applications available globally [1]. Although this trend is in principle not unwanted and in a way leveraged by policy makers and governments it is not without problems for all parties involved. The application of m-health technologies requires certainly a review of the relevant liability legislation as neither doctors, nurses, nor healthcare providers can be held liable for applications which are purchased by patients online. There are also concerns regarding privacy and security as applications might collect information without the knowledge of the users and make them accessible to third parties without permission. Finally, mobile health applications might not be safe or not suitable altogether and there are currently still major issues with regard to standardization and certification of these technologies.

From an economic perspective healthcare is clearly the largest and fastest growing industry worldwide fuelled by demographic changes in our societies and lately another wave of groundbreaking new information communication technologies. There can be no doubt that the uncoordinated implementation of these technologies would put a devastating burden on social security systems. Successful developers and manufacturers will have to work much closer with the users in the future to demonstrate value for money and alignment with local and national health policies.

On the other hand the margins of the industries have grown progressively tighter and return of investment needs to be seen within months or years rather than in decades. Due to the links of the healthcare domain to the public sector and governments there is a growing need for strategies to estimate and facilitate social technological alignment for the benefit of all parties involved and for the sake of future prosperity. Requirements engineering has become more and more popular in recent years and has proven its usefulness. There can be no doubt that requirements engineering will play a pivotal role in the introduction to new technologies into health and care.

1.4 Socioeconomic Aspects of Health and Care

Healthcare is the largest and fastest growing industry globally. In 2013 for European countries the average GDP share spent on health has been around 10 %, and for the USA around 17 % with a widening gap between the growth of GDP and the rise in national healthcare expenditure [2, 3]. The average GDP share spent on health by the People's Republic of China has been 5.4 % in 2013 [4].

Although the current growth of healthcare expenditure has calmed down a bit primarily caused by the lapse of many pharmaceutical patents and the subsequent replacement by generic drugs, the beneficial effect has been absorbed by weak GDP growth data. The relationship between the overall GDP growth rate and the growth