

The Role of Digital Health Care Startups

Florian Rinsche

Digital health has become a real buzz word in recent discussions about transforming the healthcare system. One driver for digitization of healthcare are startups. Startups are newly emerging companies with a new business model that identifies a certain problem and tries to fix it. This essay sheds light on the role of digital health startups with respect to the healthcare system. Digital health startups can be found in all areas and all degrees of digitization: from digital presentation of analogue content to deep learning with processing of and reaction to incoming information. When comparing the U.S. with Germany, the economic ecosystem of the U.S. is much more attractive for digitization as well as for startups. Nevertheless, the German startup-scene is catching up. As digitization in healthcare is a relatively new trend, it will change the art of providing health care. To foster innovation in healthcare through digital health startups some regulation must be changed.

Contents

1	Introduction	186
2	Digital Transformation in Health Care	187
3	Digital Health Startups in Germany and the US	189
4	Future Trends of Digital Health	190
5	Concluding Remarks	192
	References	194

1 Introduction

Digital health is a real buzz word recently and does not merely depend on the startup scene. Opportunities and, above all, risks of the technology are currently being discussed intensively. Almost every company in healthcare is developing its own strategy to digitize their services. Digital enterprises, on the other side, enter the healthcare marketplace to bring their services to the healthcare context. A third source of digitization are startups. Independent of healthcare or not, startups have a somewhat different philosophy than big established companies which involves identifying small problems in life and trying to find solutions.

For some, digital health startups are an inspiration; for others, they appear to be a threat. Most of the health care enterprises view digital health startups as a chance to foster their own digital transformation- either through partnership or through mergers and acquisition.

The founders of digital health startups are different in many respects, but what they do have in common is a clear vision. Together, they bring the conventional and fragmented healthcare to the 21st century. The patient of the future is digitally proficient, independent, and mobile- so he expects the same from his healthcare provider.

One example is the app mySugr. The founder of mySugr developed the idea after realizing he is regularly confronted with irregular daily routines and a lot of travel through his work as a consultant (Lindekamp and Lücker, 2014). This schedule presents a real challenge for good diabetes management: he struggles with continuously varying blood glucose, insulin, and carbohydrate levels (Westermann, 2017). To fix the problem, he developed a data driven app that helps him - and other users - to remember to use his insulin syringe and calculate the right doses for every situation. mySugr takes advantage of the current trend where patients are pivoting away from getting their health information from physicians toward relying on what Google or other online portals can deliver to the masses about health. As a medical device, mySugr went through the whole regulatory process to prove that it is founded on a real medical basis with supporting studies.

Besides the startups, even big players in health care want to invest in the area of digital health. One way is to digitize their own business model to boost efficiency and develop the business model further. Others choose to develop a value driven program around their original product. Yet another way is to build completely new business models that would not be feasible without big data and accompanying analytics to utilize the information to a greater extent than previously possible.

This essay tries to shed light on the role of digital health startups with respect to the health care system. The significance will be demonstrated in terms of monetary value as well as in terms of potential further development, where the latter will be more important

than current monetary values. Thereafter the future trends of the digital transformation and what should be done to enable growth will be analyzed with a summary and concluding remarks will be presented at the end of the essay.

2 Digital Transformation in Health Care

One of the most important sectors of almost every national economy is the healthcare system, with a share of the total economic performance of around 10 to 12 percent in Europe and up to 18 percent in the United States. As a result, any transformation of the healthcare system will be important for the entire economy of a country.

In many cases, the words “digitization” and “startups” are said in one breath. Nevertheless, both terms have their own meaning. According to Robehmed (2013), associate editor at Forbes, a startup company is defined as a newly emerging company with an innovative business model that solves a problem and has the aim to grow or achieve a high business value.

While the term “startup company” was relatively easy to define, the term “digitization” or “digital transformation” is not as easy. Digitization can be understood most simply as the conversion or convergence of analogue products, services, processes, and business models to a digital environment. A Study of the Bertelsmann Stiftung (2016) states digital health is a “cooperative or interactive application of information and communication technology to improve healthcare and the public health”.

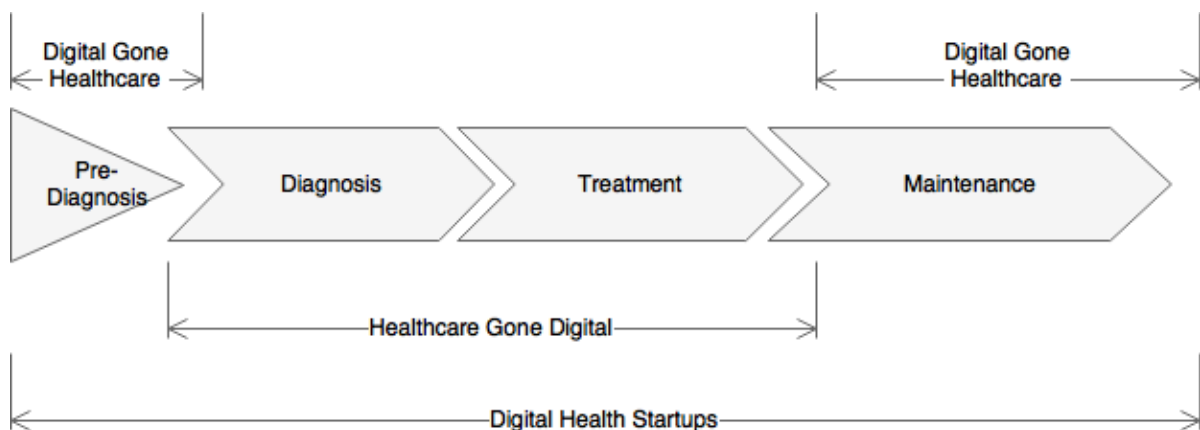
In terms of the digital transformation of healthcare, there are 5 definable degrees of digital transformation. First, digitization can be seen in the sense of an automatization. Analogue content is presented or reported in a digital way, e.g. information on a homepage, with information stored on data carriers instead of paper. Bilateral communication at this level does not exist between sender and receiver. In the second degree, there is communication between sender and receiver and a bilateral interaction. In this stage, two or more individuals communicate with each other via email or other messaging tools. The third degree is defined by the digital processing of data that are entered manually or digitally. Forth, objects of closed and open systems communicate with each other, e.g. the anesthesia machine takes patient information from the electronic health record (EHR), uses the data to calculate the right dose, and transfers the information back to the EHR. In the fifth degree, what is known as deep learning exists, i.e. learning algorithms that process incoming information react to the data and evaluate the results. If new patterns emerge, these will be considered in future processes. Technology of all of these degrees is currently used in healthcare.

The digital transformation of the healthcare system is driven by three different sources. As Elton and O’Riordan (2016, p. 137) quote, there are digital companies that step into the healthcare industry (“Digital Gone Healthcare”), there are healthcare enterprises that discover the digital space (“Healthcare Gone Digital”), and the third, final source of the

digital transformation is the startups that seek to solve problems with a new digital business model independent of huge companies.

Whereas most of the “Digital Gone Healthcare” Companies focus on business-to-consumer (B2C) business models, the “Healthcare Gone Digital” Companies have a stronger focus on the business-to-business (B2B) sector. The startups, however, are not limited to either model. Figure 11.1 shows the typical points of contact for each of the three sources of the digital transformation in healthcare.

Figure 1: Points of Contact of Digital Health Companies along the Healthcare Value Chain



In comparison to other industries, experts attest to a lower level of digitization in healthcare systems. Especially within the media, finance, and communication industries, the digital transformation has happened very quickly.

In the future, digital applications in healthcare will become more important. The growing demand for healthcare services will be a major driver of digital health all over the world, especially in ageing societies like Germany. It is expected that by 2060 more than one third of the entire population of Germany will be 65 years or older. The demand for healthcare services is expected to rise due to the increased proportion of elderly people (Statistisches Bundesamt, 2015). The number of care dependents is estimated to be around 3.25 to 4 million people till 2060.

The ageing population of Germany is expected to have a positive effect on the adoption of digitization within the healthcare system. While providers are slowly adopting digitization, most Germans are open to modern technologies. More and more elderly people are increasingly accustomed to using digital products in everyday life, so they want to use it for healthcare issues as well. The prevalent myth about digital healthcare was that only younger generations are receptive to it, and thus, digitized healthcare systems would not reach the core stakeholders of the health system. However, patients from all age groups are more than willing to use digital healthcare services and the number continues to grow.

3 Digital Health Startups in Germany and the US

The ecosystem of the US is much more attractive to founders in the digital community, which extends to a more attractive digital health community as well. Digitization is often discussed in a compelling, positive way in the US, whereas in Europe the concerns about digital technologies predominate conversation. Nevertheless, regarding Germany, the startup-scene is catching up. The Crunchbase database shows more than 530 digital startup companies in health care in Germany, and the numbers are rising with a gigantic growth potential.

It is estimated that the digital health market in the USA is about six times larger than in Germany. In the first quarter of 2016, over \$1.8 billion were raised in venture capital funds for digital health startups (Stoakes, 2016). This is just one expression of a cultural difference between the two countries. Whereas German physicians perceive risk for patients in digital applications, American doctors understand the need to adapt innovations to make further progress in medical development (Westermann, 2017).

When the potential of healthcare startups is high, their setbacks are as well. The main challenge for digital health startups remains in their business model: who will pay for the service. The people of Germany, or in whole Europe, are used to healthcare services being paid by their insurance, so their willingness to pay an additional amount of money is limited. While the structures of systems like the NHS are more beneficial to implement innovations on a large scale, the Germany Statutory Health Insurance (SHI)-system with currently approximately 110 different SHI-companies is a bit more difficult. The system of many smaller insurances in Germany can be beneficial since it creates an opportunity for different collaboration and competition, but the real challenge is for digital health to become part of the standard care of all SHIs. Up to this date there is no start up to tackle this issue in the first healthcare market.

Therefore, a lot of digital health startups enter the second healthcare market. In this part of the market, the startups operate in the consumer-oriented B2C area. So, for Germany, approximately half of all healthcare startups deal with monitoring or checking the current health status of a patient. More cost-savings are expected in therapy, diagnosis, and prevention than in the current application of the technology.

In healthcare, regulation is a large barrier for (new) enterprises entering the healthcare market. There is a dilemma between sophisticated regulation (FDA 510k approval¹³ in the U.S. and the CE-declaration of conformity in the EU¹⁴) designed to protect patients

¹³ In the U.S., the process of approval for medical devices is governed by Article 510k of the Food, Drug and Cosmetic Act (FD&C). The procedure is administered by the Food and Drug Administration (FDA).

¹⁴ With the CE-declaration of conformity, the manufacturer declares that ist product satisfies the special requirements for medical devices. The acronym „CE“ is an abbreviation for „Conformité Européenne“, the french term for „European Conformity“.

and the desire of the medical technology industries to have short innovation cycles to reduce the minimum time it takes to get to the market. Thus, if the goal of the startup is to enter the first healthcare market, it will be meaningful to consider the requirements of the respective regulatory framework from the very beginning. Relevant topics in this context are data protection, data security, and regulatory affairs. If the startup fits the strict regulatory requirements of Europe, it will be no additional challenge to meet the requirements in the US. For regulation of medical devices this dynamic is the other way around. Europe has a less strict regulatory framework than the US, leading some medical technology companies to prefer launching their product first in Europe before moving to the US market (Westermann, 2017).

The healthcare systems of the US and Germany are very different in many respects. Nevertheless, they struggle with the same problems with similar goals: financing the rising demand for care at reasonable or lower costs, enhancing the overall quality of the system, and increasing patient satisfaction. At this point, many digital startups come in to try solving existing problems that are not addressed incumbent companies within the industry. Startups may have disruptive solutions that begin in small niches, maybe at a lower quality in some dimensions, which press forward in more and more markets with increasing usability.

The main topics under this category are fitness and self-tracking applications. The successful startups in the German healthcare market are Clue, mySugr (Austria), Klara, Memorado, and Sonormed. Self-Tracking, which means the digital recording of body-related data, are also a trend in Germany. 57% of the population is using digital health applications, mainly mobile apps and 12% of the population is using wearables. People are looking for information regarding a healthy lifestyle as well as tracking their fitness and health data. Wearables and fitness/health trackers are overcoming initial skepticism about the technology and even reaching out of the fitness area. This expands to not only handling chronic conditions, but demand is also growing in all areas of individual lifestyles.

4 Future Trends of Digital Health

So far there is hardly any data on the actual use of digital technologies in healthcare, either in Germany or in the US. Also, it is unclear how they assess the risks of using these technologies. Currently, this period is characterized by a huge increase in the efficiency of information and communication technologies in general and in healthcare. Technology from other sectors and industries has already started to enter the healthcare market. As one example, the internet will integrate digital health into everyday life and act as a facilitator of change in the industry.

Digital health is expected to set the pace of development and deployment of new medical applications and will transform markets all over the world. This technology will facilitate increased access to healthcare services. As White & Case concluded from their survey, over 90% of companies say that digital health will have a tremendous influence within their overall business strategy. These companies are also willing to increase their investments in digital health.

According to Bauer (2017), there are 4 trends in the scene of healthcare startups. First, startups are engaging in artificial intelligence (AI), machine learning, telemedicine 2.0 (improved versions of existing telemedicine), and virtual reality (VR). Other trends -to complement the list- are the inclusion of data analytics, genomics/sequencing, digital medical devices, and population health management in modern technologies. This list is neither mutually exclusive nor collectively exhaustive. For example, artificial intelligence and genomics/sequencing are both based on data analytics.

Big data seems to be the most essential element of digital health and plays a crucial role in data-based decision making. In combination with data analytics, researchers and doctors can enhance their understanding of diseases on the one hand and patient behavior on the other hand. With this understanding, patients might get the right therapy faster than they would today. As more than half of American citizens struggle with a chronic disease (Centers of Disease Control and Prevention, 2016), a better understanding of patient behavior can improve population health management by taking more environmental factors and individual behaviors into account.

The massive amount of data collected will be used to improve the healthcare provided. Based on big data and data analytics, artificial intelligence and machine learning would be able to influence diagnosis and therapy of patients. One prominent example of this topic is the IBM Watson. In health care, this supercomputer is filled with countless medical studies and clinical data which act as the point of origin. To serve patients, the specific history of a patient is input into the IBM Watson so the supercomputer can specifically assist the doctor in diagnosis and therapy decisions. With the clinical studies in combination with patient histories, the IBM Watson learns and recommends diagnosis and therapy options based on the information provided. This information will be considered in similar cases in the future and will support the individual physician in everyday clinical life.

When focusing on hospitals, big data enables the application of value-driven health care. A progress complete with transparency, accountability, and economic efficiency is expected to foster the change of a system from volume to value-driven healthcare. Data analytics may give the doctor short-term or long-term feedback of his decisions and even allow for high and improving quality to be recognized and rewarded.

In the field of medical devices and virtual reality, robotic surgery is one of the key applications. This technology may enable surgeons to perform minimally invasive procedures that are now complicated in a more precise and controlled way than what can be achieved today with conventional surgery. In combination with continuous imaging technology and virtual reality, the surgeon will be able to better see what is going on inside the body. The main disadvantage is that surgical robots are currently very expensive so that they are mainly deployed in high-end state-of-the-art clinics within rich countries.

5 Concluding Remarks

To enable the digitization of the healthcare system, healthcare actors should demonstrate a basic openness to innovative solutions. Considering this, there is still a need to protect the fundamental rights of the humans which might be adversely affected through digitization. To address this, Germany and the European Union have worked out a Charter of Digital Fundamental Rights of the European Union that formulated essential rights in response to ongoing digitization (Digital Charter, 2016). The aim of this document is to guide digital change in a positive direction and to establish an essential framework of conditions.

Data protection and data security are important issues, especially within the healthcare system. Nevertheless, this should not lead to widespread refusal to use healthcare data for scientific purposes or hinder the improvement of the healthcare system in the context of data analytics. To ensure the aims of protecting and securing data are met, the regulators should define standards and terms of use. Also, a unified legislation for each country, at the least, should be created so that there is more transparency regarding these issues.

An interesting finding of the Bertelsmann Stiftung (2016) is that general population is more open to digital health applications than healthcare providers. This is observed through the rising demand within the second healthcare market. It is expected that this will lead to a boost within the first healthcare market. For providers, it is not enough to digitize existing products. Innovative solutions must be developed with innovative approaches to caring for the patient. Maybe the healthcare industry can learn from other industries, like the fintechs, as both healthcare and banking deal with credence goods.

To understand why a focus on digital healthcare startups is important, the automotive industry should be examined. Two recent topics in the automotive industry are electric mobility and autonomous driving. Both themes were innovated and made popular by startups, which did not originate from the existing automobile industry. The name Tesla is closely linked to the electromobility, and Google is one of the pioneers when it comes to autonomous driving. Both concepts have increased in demand so much that almost

all established manufacturers have now put these topics on their own research and production agendas.

This essay demonstrated that the regulatory framework for healthcare enterprises in general, and startups in particular, acts as one barrier to entry into the market. Becoming a standard part of care takes a long time in Germany and the US. The process is expensive, complex, and lacks transparency. It will be necessary to equalize the regulatory requirements for healthcare technologies between the countries, at least within Europe, to simply the processes in a transparent way with binding deadlines and clear responsibilities.

Digitization in healthcare is a relatively new trend. It will change the art of providing healthcare. Within this trend, digital health startups will asset the pace of development to surpass the technology available through incumbent companies. Startups may be one puzzle piece to achieving the triple aim of healthcare: better quality and better patient experience at lower costs (Berwick et al 2008). In addition to their meaning within the healthcare system, startups are important regarding economic and employment growth. In conclusion, to achieve digitization of healthcare and improve care in the US and Germany, regulations must be changed to promote innovation from digital healthcare startups and other companies taking steps to digitize the health system.

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