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Digitalization in Healthcare

Implementing Innovation and Artificial Intelligence

Springer

Future of Business and Finance

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Digitalization in Healthcare

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Foreword

With regard to the last few decades, computing sciences have brought many innovations to nearly all economic and scientific branches worldwide in an astonishing way. Examples are automation in aviation, production lines in the car industry, the engineering as well as the telecommunication sector, etc. Although one may describe these contents groundbreaking and—the pace of changes—breathtaking, the most exciting change has yet to come: digitalization in health care.

We are still at the very beginning of a transformation process. We now start to implement big data, artificial intelligence, robotics, and telemedicine in health sciences as well as in the clinical setting. Digital technologies will surely accelerate the pace of gain in knowledge and lead to an extended range of possibilities and services in health care.

The vivacious and rapid digital development of both scientific findings and clinical structures will lead to a shift in our view on and understanding of the role of healthcare workers and patients themselves; it will change the way doctors practice their occupation, but also the interaction with their patients may be completely different from today . . .

Digitalization—in these terms—surely bears the potential to fundamentally redefine our understanding of health care. It also may be associated with questions, uncertainties, and even "adverse effects":

- How will technology affect the relationship between physicians and their patients?
- Will digitalization lead to a gap between tech-savvy and "conservative" patients or even end up in a two-class medicine?
- Can we expect transparency in this process both for healthcare workers and for patients?
- How can empowerment of patients be implemented and professionals educated?
- What will be the economic implications of digitalization?
- What will be the ecological implications of digitalization?
- How extensive will be the influence of tech and business companies on the healthcare system?
- What about legal responsibility and liability in times of technically assisted decision making?
- Which other ethical and which medicolegal aspects must be taken into account?

These are only a handful of questions arising in this context, showing the necessity of an open and transparent culture of education and discussion in this process. It is inevitable that healthcare professionals need to be more and more informed and educated; this may enable them to play a leading role in designing a road map to digitalization in order to bring balance to a trend which is currently primarily driven by technical or economic interests. The only reasonable way of implementing this innovation is by ensuring broad social acceptance, participation, and sustainability—both in economic and ecological ways.

It is undeniable that the change will come, so we better be prepared . . .

Hamburg, Germany Pedram Emami

Preface

Our current times are often characterized as volatile, uncertain, complex, and ambiguous (VUCA). New business models based on digitalization and artificial intelligence have started to affect nearly every industry, requiring every stakeholder to entirely rethink how they work. This development has also found its way into the health sector. Already today, the healthcare system is characterized by the opportunities arising from increasing digitalization. Patient data are exchanged across the classic boundaries of institutions, medical monitoring of patients is now possible from anywhere, and we are seeing autonomous systems on the intensive care units in hospitals.

But how does digitalization in health care continue its way? How will patients be treated in the future? What role do nurses and doctors play in a digitalized healthcare environment?

If these questions have sparked your interest, then you should read this book. This innovative book reflects the recent developments stated above while providing comprehensive outlooks on what healthcare stakeholders need to do in order to remain competitive in the future. It provides an unparalleled mix of expertise of respected international authors from health care, academia, and the industrial world. The authors present their work on and expertise in how to innovate in health care, spanning from the fields of artificial intelligence and applications of computer vision, through dentistry and radiology, to ethical implications. This book aims at healthcare decision makers, investors, entrepreneurs, researchers, and students. It offers readers novel impulses and productive takeaways for their current and future work.

Each chapter is self-contained and provides the necessary respective prerequisites. Some chapters are more business-oriented while others are more technical in order to address a diverse audience. In their chapters, the authors also make concrete recommendations on how to apply innovation to health care and demonstrate the potential of their approaches to create economic value in real-world applications.

This book would not have been possible without Ms. Rocio Torregrosa, our commissioning editor. We would like to thank her and all the other Springer staff, in particular Mr. Anand Ventakachalam and Ms. Sayani Dey, involved for their professionalism, tireless ability to read multiple drafts, and help improving the book.

Our deepest thanks also go to our families, friends, and partners for their patience and support in writing this book.

Deggendorf, Germany	Patrick Glauner
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October 2020	

About the Book

Digital technologies are currently dramatically changing health care. This book introduces the reader to the latest digital innovations in health care in fields such as artificial intelligence, points out new ways in patient care, and describes the limits of its application. It also offers essential guidance in the form of structured and authoritative contributions by domain experts spanning from artificial intelligence to hospital management to radiology to dentistry to preventive medicine. Furthermore, it shares ideas and experiences of industry veterans, in particular on how AI-driven solutions could solve long-standing issues in the fields of health care and hospitalization. It also gives advice on what new digital technologies to consider for becoming a healthcare market leader in the future. Taken together, these contributions provide a “road map” to guide decision makers, physicians, academics, industry representatives, and other interested readers to understand the large impact of digital technology on health care today and its enormous potential for future development.

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About the Editors

Patrick Glauner is the Founder and CEO of skyrocket.ai GmbH, an artificial intelligence consulting firm based in Bavaria, Germany. In parallel, he is a Full Professor of Artificial Intelligence at Deggendorf Institute of Technology, a position he is honored to hold since the age of 30. He has previously published two books with Springer on *Innovative Technologies for Market Leadership* and *Creating Innovation Spaces*, respectively. His works on AI were featured by New Scientist, McKinsey, Imperial College London, Udacity, the Luxembourg National Research Fund, Towards Data Science, and others. He is also Area Editor of the *International Journal of Computational Intelligence Systems* (IJCIS). He was previously Head of Data Academy at Alexander Thamm GmbH, Innovation Manager for Artificial Intelligence at Krones Group, a Fellow at the European Organization for Nuclear Research (CERN), and a visiting researcher at the University of Quebec in Montreal (UQAM). He studied at Imperial College London and also holds an MBA. He is an alumnus of the German National Academic Foundation (Studienstiftung des deutschen Volkes).

Philipp Plugmann has been doing multidisciplinary work for the last 20 years in parallel to practicing as a dentist in his own clinic in Leverkusen, Germany. He is also Full Professor for Interdisciplinary Periodontology and Prevention at SRH University of Applied Health Sciences. His first book on innovation in medical technology published in 2011 was reviewed by Cisco. His second book on innovation published with Springer in 2018 got more than 50,000 chapter downloads in its first 15 months. Previously, he held multiple adjunct faculty appointments for more than twelve years and has won multiple teaching awards. He also holds an MBA, an MSc in Business Innovation, and an MSc in Periodontology and Implant Therapy (DGParo) and is currently pursuing his third doctorate. Plugmann has given research talks in the field of innovation at conferences at Harvard Business School, Berkeley Haas School of Business, Max Planck Institute for Innovation and Competition, and Nanyang Tech University, Singapore. Plugmann is a serial entrepreneur and advisor to several companies, including a global technology consultancy—DataArt.

Guido Lerzynski has 10 years of experience in the management of acute hospitals. Currently, he is chief executive director of the St. Marien-Hospital Cologne, the St. Marien Ambulatory Care Centre, the Neurological Therapy Centre (NTC), and the private Kunibert Hospital. He is also an authorized representative of St. Marien Hospital Association. His special interest focuses on the evaluation of outcome measures in acute hospitals. He studied medicine and public health at Edinburgh and Düsseldorf University and holds an MBA in General Management. He is an alumnus of the German National Academic Foundation (Studienstiftung des deutschen Volkes).

Artificial Intelligence in Healthcare: Foundations, Opportunities and Challenges

Patrick Glauner

1 Introduction

In recent years, artificial intelligence (AI) has started to change our lives in a way that humanity has never seen before. We now take speech recognition, personalized pricing and autonomously driving cars (just to name a few AI applications) for granted. All of these functionalities are now available for free—or for very little cost—at any time and anywhere in the world. Given the increased level of automation of human or manual tasks through AI, productivity and customer experience have started to skyrocket. AI has also started to disrupt healthcare. This chapter provides an introduction to the field of AI. It also discusses recent applications in healthcare, opportunities and challenges and examines possible solutions. Other chapters of this book present further AI applications in healthcare. This chapter therefore also enables readers with the necessary foundations in order to get the most out of those chapters.

2 Artificial Intelligence

Most people have encountered the term "artificial intelligence" for the first time only a couple of years ago. However, AI has been an academic discipline since the mid-1950s (McCarthy et al. 1955), while some of its roots date to the late 1930s or even before. This chapter provides a brief introduction to the field of AI, presents recent developments and discusses challenges and how this field may evolve in the coming years and decades.

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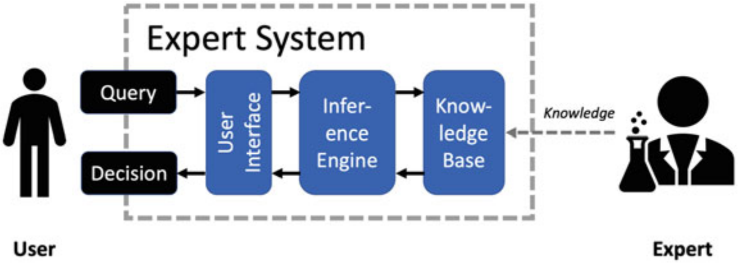

Fig. 1 Expert system. Source: author

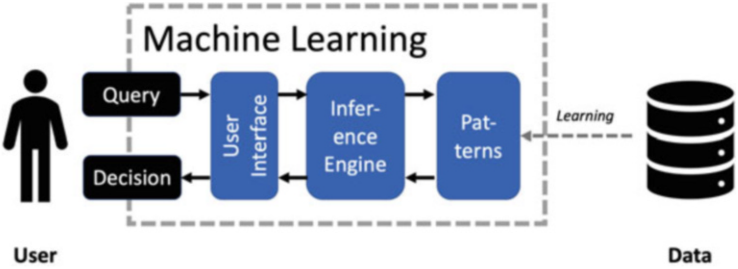

Fig. 2 Machine learning. Source: author

2.1 Foundations

Ever since the 1950s, AI methods have typically been distinguished into two fundamentally different disciplines: expert systems and machine learning. On the one hand, expert systems incorporate rules that were manually derived by gathering and generalizing the knowledge of domain experts. These rules are then applied to inputs in order to make predictions or decisions. The concept of expert systems is depicted in Fig. 1.

On the other hand, models based on machine learning[1] do not directly incorporate expert knowledge. Instead, these models examine examples and then find (also referred to "learning" or "training" as) underlying patterns in and among these examples. These patterns are typically being found through statistical methods. In order to make predictions or decisions, these patterns are then applied to inputs. The concept of machine learning is depicted in Fig. 2.

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[1] Historically, the term "data mining" was often used. However, that term usually describes a somewhat larger discipline. During the last decade, that term has lost relevance and tends to be used less frequently nowadays. Instead, the term "data science" has become more popular in recent years. That field aims to apply machine learning models to solving real-world problems.

Generally, neither expert systems nor machine learning is generally better. The choice of methodology depends on use case-specific constraints such as availability and quality of data, computational resources, tolerated prediction errors and others. Both, expert systems and machine learning, have their respective advantages and disadvantages: Expert systems, on the one hand, have the advantage that they are understandable and interpretable and that their decisions are therefore comprehensible. On the other hand, it often takes a great deal of effort, or sometimes it even turns out to be impossible to understand and describe complex problems in detail.

Example 1 Spam filtering To illustrate this difficulty, an example of spam filtering is very helpful: First, the variance of the vast amount of spam emails is enormous. Second, spam emails do not necessarily use languages and grammar correctly, which can cause inaccuracies and ambiguities. Third, the type of spam that is being sent out by spammers is dynamic and changes over type. Creating an expert system for spam filtering is thus a challenge.

The three factors of complexity, uncertainty and dynamics occur in a variety of fields and often prove to be a common limiting factor when building expert systems. Machine learning has the advantage that often less knowledge about a problem is needed as the algorithms learn patterns from data. However, that data is sometimes not available or data quality may be a limiting factor. In contrast to expert systems, however, machine learning often leads to a black box whose decisions are often neither explainable nor interpretable. Nonetheless, over the decades, machine learning has gained popularity and largely replaced expert systems.

2.2 The Three Pillars of Machine Learning

The field of machine learning can broadly be separated into three so-called pillars: supervised learning, unsupervised learning and reinforcement learning. An interconnection can be made between each pillar and human learning: Imagine when you were a kid, you walked through the park with your parents. Your parents then pointed at various animals, say a cat, a dog and a bird. You perceived the visual and audio signals from your eyes and ears, respectively. In addition, you got an explanation of what type of animal you were seeing. That pillar is called **supervised learning**, in which you get an explicit explanation or “label”. Mathematically speaking, supervised learning uses pairs $\{(\mathbf{x}^{(1)}, y^{(1)}), (\mathbf{x}^{(2)}, y^{(2)}), \ldots, (\mathbf{x}^{(m)}, y^{(m)})\}$, where $\mathbf{x}^{(i)}$ is the input vector and $y^{(i)}$ the label. The goal is to learn a function $f\colon y^{(i)} = f(\mathbf{x}^{(i)})$ that infers the label from the input. This is also called function induction, because rules from examples are derived. In any case, the labels y give an unambiguous “right answer” for the inputs $\mathbf{x}$.

When you continued your walk through the park, you perceived more cats, dogs and birds of different colours and sizes. However, that time you did not get any supervision from you parents. Instead, you intuitively learned how to distinguish cats, dogs and birds regardless of their individual attributes. That is an example of **unsupervised learning**, which aims to find hidden structures in unlabelled data $\{\mathbf{x}^{(1)}, \mathbf{x}^{(2)}, \ldots, \mathbf{x}^{(m)}\}$.

In many problems, it is essentially impossible to provide an explicit supervision to a learning problem. In **reinforcement learning**, we mainly think in terms of states, actions, transition between states and rewards or penalties you get subject to your performance. That is how humans actually learn most of the time. One great example of how humans learn in a reinforced way is riding a bicycle. It is awfully difficult to explain someone else how to ride a bicycle. Instead, as kids, we tried out how to ride it. If we did the wrong moves, we got hurt. Concretely, we were in different states and tried to find the right transitions between states in order to remain on the bicycle.

2.3 Recent Developments

Since 2006, the field of neural networks has seen a number of advances. A neural network is depicted in Fig. 3.

Multi-layer neural networks are now often referred to as deep learning (LeCun et al. 2015; Goodfellow et al. 2016). This term describes that (deep) neural networks have many hidden layers. This type of architecture has proven to be particularly helpful in detecting hidden relationships in inputs. Although this was already the case in the 1980s, there was a lack of practical and applicable algorithms for training these networks from data first and, second, the lack of adequate computing resources. However, today there is much more powerful computing infrastructure available. In addition, significantly better algorithms for training this type of neural network have been available since 2006 (Hinton et al. 2006).

As a result, many advances in AI research have been made (Iansiti and Lakhani 2020). Examples are autonomously driving cars or the computer program AlphaGo. Go is a board game that is especially popular in Southeast Asia, where players have a much greater number of possible moves than in chess. Traditional methods, with which, for example, the IBM program Deep Blue had beaten the then world chess champion Garry Kasparov in 1997, do not scale to the game of Go, since the mere increase of computing capacity is not sufficient due to the high complexity of this problem. It was only until a few years ago the prevailing opinion within the AI

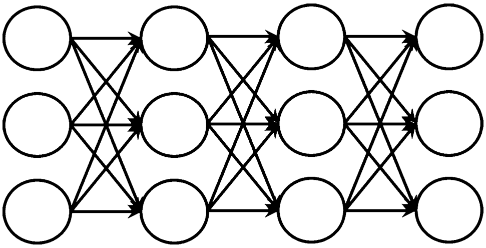

Fig. 3 Neural network connecting input nodes (left column) to output nodes (right column). Source: author

community that an AI, which plays Go on world level, was still decades away. The UK company Google DeepMind unexpectedly revealed their AI AlphaGo to the public in 2015. AlphaGo beat South Korean professional Go play Lee Sedol under tournament conditions (Silver et al. 2016). This success was partly based on deep learning and led to an increased awareness of AI worldwide. Of course, in addition to the current breakthroughs of AI mentioned in this section, there have been a lot of further success stories and we are sure that more will follow soon.

Aside from technological advances, the access to AI knowledge has fundamentally changed. This process started in around 2011, when Stanford professors Andrew Ng, Sebastian Thrun and others made their courses available to everyone through online platforms (Ng and Widom 2014). This type of platform is often referred to as massive open online courses (MOOCs). Popular MOOC platforms include Coursera,[2] Udacity[3] and edX.[4] Until 2011, one could usually only learn AI through a few selected university courses and books. That knowledge was also mainly available in developed countries, and potential learners in emerging markets struggled to access corresponding sources. The so-called democratization of AI knowledge has started to fundamentally change how we learn, a trend that is currently also being further accelerated due to COVID-19. The democratization of AI knowledge has also been identified as a massive accelerator of the Chinese AI leadership (Lee 2018).

3 Applications in Healthcare

AI has started to disrupt healthcare by providing better patient care while cutting waiting times and costs. Early works on applying AI in healthcare started in the 1970s. For example, MYCIN (Shortliffe and Buchanan 1975) is an expert system that identifies bacteria causing severe infections, such as bacteraemia and meningitis. It recommends antibiotics treatment and adjusts the dosage for patient's body weight. MYCIN is based on Dendral (Lederberg 1963), which is considered the first expert system. It was mainly applied to problems in organic chemistry. Further early uses of artificial intelligence in medicine have been surveyed in the literature (Clancey and Shortliffe 1984; Miller 1994).

In the following decades, we have witnessed improvements of computing power (Koomey et al. 2010), the abundance of data thanks to the Internet (Rajaraman and Ullman 2011) and noticeable advances in the fields of computer vision (Dougherty 2009) and natural language processing (Banko and Brill 2001; Mikolov et al. 2013; Brown et al. 2020). These have led to a large number of applications of AI in healthcare, including, but not limited to, in radiology (Li et al. 2020; Chockley and Emanuel 2016), screening (Patcas et al. 2019; McKinney et al. 2020), psychiatry

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[2] http://www.coursera.org.

[3] http://www.udacity.com.

[4] http://www.edx.org.

(Graham et al. 2019; Fulmer et al. 2018), primary care (Blease et al. 2019; Liyanage et al. 2019), disease diagnosis (Alić et al. 2017), telehealth (Pacis et al. 2018), analysis of electronic health records (Bennett et al. 2012), prediction of drug interactions and creation of new drugs (Bokharaeian et al. 2016; Christopoulou et al. 2020; Zhou et al. 2018), prediction of injuries of football players (Borchert and Schnackenburg 2020) and others.

In addition, other chapters of this book discuss further applications. There are also a number of surveys on AI in healthcare (Jiang et al. 2017; Tomar and Agarwal 2013; Yu et al. 2018; Reddy et al. 2019; Davenport and Kalakota 2019).

We now also present one of our on works in greater detail. Surgeries are one of the main cost factors of healthcare systems. To reduce the costs related to diagnoses and surgeries, we have previously proposed a system for automated segmentation of medical images in order to segment body parts like liver or lesions (Trestioreanu et al. 2020). The model is based on convolutional neural networks, for which we showed promising results on real computed tomography scans. The deep learning algorithm is part of a larger system that aims to support physicians by visualizing the segments in a Microsoft HoloLens, an augmented reality device as depicted in Fig. 4.

Our approach depicted in Fig. 5 allows physicians to intuitively look at and interact with the holographic data rather than using 2D screens, enabling them to provide

Fig. 4 3D visualization of liver segmentation in a Microsoft HoloLens (left): the segmented liver volume (right) was separated from the input volume—a scanned torso (centre) (Trestioreanu et al. 2020). Source: author

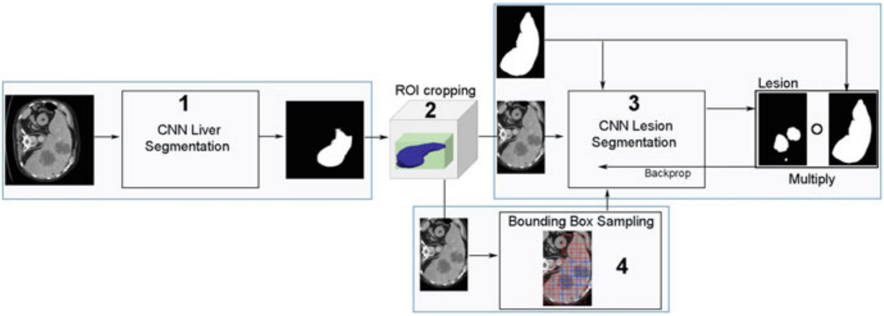

Fig. 5 System architecture (Trestioreanu et al. 2020). Source: author

better healthcare. Both, the machine learning algorithm and the visualization, utilize high-performance graphical processing units (GPUs) in order to enable physicians to interact efficiently with our system.

4 Opportunities

AI has the potential to skyrocket healthcare by providing more personalized patient care while cutting waiting times and costs. This section discusses some opportunities, and other chapters of this book discuss further opportunities.

Various studies have started to make predictions of what the hospital of the future may look like (Gebreyes et al. 2020; Savino and Latifi 2019). Due to shrinkage of technology and its reduction of costs, a transformation of inpatient treatment to outpatient treatment looks likely for patients because the technology needed to care is becoming more mobile. Physicians and nurses will then be supported by AI-driven technology 24/7 and come to the patients' homes when needed. Rooms will also likely become more flexible and can be adopted to patient-specific needs.

Nurses spend a lot of their time in moving patients on hospital beds from one room to another, for example from the patients' rooms to examination rooms or treatment rooms. However, they are trained specialists and could allocate their time better to actually providing care to patients. Given the advances of autonomously driving cars (Yurtsever et al. 2020), it seems likely that hospital beds will become autonomous in the near future. They could then autonomously move patients from one room to another. There is no need to create detailed and costly maps of hospitals, as simultaneous localization and mapping (SLAM) algorithms (Bresson et al. 2017) can learn those while exploring the hospital and become increasingly better over time.

AI also looks promising to advancing personalized medicine, i.e. selecting appropriate or generating optimal therapies from the context of a patient's disease, their genetic content and other molecular or cellular analysis (Hamburg and Collins 2010). Doing so would particularly help to reduce cancer mortality (Chin et al. 2011). Initial steps of employing AI and big data-driven approaches towards personalized medicine have been made (Cirillo and Valencia 2019). AI is expected to make further progress in that direction in the coming years. Quantum computers could play a crucial role in these kinds of high-dimensional optimization problems. An excellent introduction to quantum computing for the general audience is provided in Akenine (2020).

Overall, it seems unlikely that a large number of physicians or nurses would be made redundant by AI in the foreseeable future. Instead, AI will support them by providing better assistance in decision making and automating other tasks. Doing so will allow them to better allocate their time to interaction with patients and examining or treating challenging cases.

5 Challenges

AI has recently started to disrupt healthcare. It has, furthermore, the potential to skyrocket healthcare in the foreseeable future. In this section, we address a number of challenges, technical and non-technical, that need to be solved in order to make this possible. We also discuss how these challenges could be solved.

5.1 Methodological Advances in Artificial Intelligence Research

While AI has recently made a lot of progress in terms of applications, its underlying methodology has not made that much progress (Milne 2020). Currently, there are a number of methodological and technical challenges that need to be addressed in order to make considerable progress in AI and its applications in healthcare. This section discusses some of the most critical ones.

The recent focus on deep learning has created the impression that deep learning models may *generally* be more powerful than others. However, the "no free lunch theorem" (Wolpert 1996), which is to our surprise largely unknown both in industry and academia, shows that this is impossible. Rather, deep learning models usually excel in some disciplines like big data-driven computer vision or natural language processing, while they do not excel in others (Marcus 2018). Deep learning models also come with an enormous need for resources, such as the number of training examples, training time (Brown et al. 2020) or electricity. As a consequence, it may cost millions of dollars to train a model from scratch (García-Martín et al. 2019). Instead, humans learn efficiently from just a few examples while using substantially less energy (Spicer and Sanborn 2019).

Most machine learning models only learn correlations between inputs and outputs. However, such correlations may actually be *spurious* (Calude and Longo 2017) and thus be of limited usefulness. The literature presents a vast number of spurious correlations, such as between the people who drowned after falling out of a fishing boat and the marriage rate in Kentucky (Vigen 2015). As a consequence, interpretability, i.e. understanding *why* a (black box) machine learning model makes a certain prediction, is challenging. Nonetheless, progress in interpreting models has been made in recent years (Ribeiro et al. 2016). Instead, we are actually interested in identifying causal relationships (Schölkopf 2019). It has long been known that correlations do *not* imply causations. Learning causations would substantially improve interpretability and reduce the impact of biases (Glauner et al. 2018), i.e. learning from unrepresentative data sets, of models. An example of a bias is depicted in Fig. 6. By learning causations instead, models would become more reliable. Subsequently, stakeholders, such as physicians, patients and healthcare providers, would then be willing to place more trust in them.

Further challenges that IBM's AI division, known as IBM Watson, encountered in healthcare are discussed in Strickland (2019).

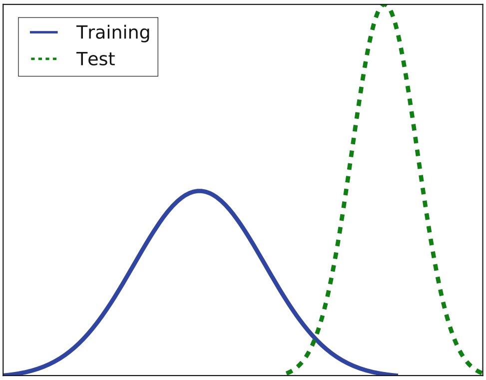

Fig. 6 Bias: training and test/production data sets are drawn from different distributions. Source: author

5.2 Impact of Artificial Intelligence on Our Society

When looking at the rapid progress of AI, the question arises as to how the field of AI will evolve in the long term, whether one day an AI will exceed the intelligence of a human being and thus potentially could make mankind redundant. The point of time when computers become more intelligent than humans is referred to in the literature as the *technological singularity* (Shanahan 2015). There are various predictions as to when—or even if at all—the singularity will occur. They span a wide range, from a period in the next 20 years, to predictions that are realistic about achieving the singularity around the end of the twenty-first century, to the prediction that the technological singularity may never materialize. Since each of these predictions makes various assumptions, a reliable assessment is difficult to make. Overall, today it is impossible to predict how far away the singularity is. The interested reader is referred to a first-class and extensive analysis on this topic and a discussion of the consequences of the technological singularity in Shanahan (2015).

In recent years, various stakeholders have warned about the so-called killer robots as a possible unfortunate outcome of AI advances. What about that danger? Andrew Ng has set a much-noticed comparison (Williams 2015): Ng's view is that science is still very far away from the potential killer robot threat scenario. In his opinion, the state of the art of AI can be compared to a planned manned trip to Mars, which is currently being prepared by researchers. Ng further states that some researchers are also already thinking about how to colonize Mars in the long term, but no researcher has yet tried to explore how to prevent overpopulation on Mars. Ng equates the scenario of overpopulation with the scenario of a killer robot threat. That danger would also be so far into the future that he was simply not able to work productively to prevent it at the moment, as he first had to do much more fundamental work in AI research. Ng also points to potential job losses as a much more tangible threat to people by AI in the near future.

These fears need to be addressed by researchers, product developers and educators. Otherwise, a lot of stakeholders, such as patients and physicians, may not adopt AI-driven healthcare products or services.

Furthermore, data protection regulation frameworks such as the General Data Protection Regulation (GDPR) (European Commission 2012) could severely limit AI applications in healthcare (Przyrowski 2018). GDPR was also intended to limit the power of major international tech companies. It has been argued that, however, exactly the opposite has happened as small companies do not have adequate resources for becoming GDPR compliant (Yueh 2020). Policy makers and regulators should therefore rethink GDPR and other data protection frameworks in order to find a better trade-off between data protection and innovation (Larrucea et al. 2020).

5.3 Education and the Need for Data Literacy

A few years ago, one of our managers made a very interesting statement:

> When solving a problem, we first need to use our human intelligence. Only then AI is able to add value later on.

We therefore need to properly understand problems as well be able to think in terms of data and the underlying statistics before looking at AI. However, it has been reported in the literature that a lot of physicians do not seem to learn statistics, i.e. one of the building blocks of AI, during their studies or tend to forget it later on Gigerenzer (2015). The following problem is meant to test your expertise in statistics.

Problem: What Does a Positive Test Result Mean?

0.8% of people have disease D. A D test returns a correct positive 98% of the time and a correct negative 97% of the time. The test returns positive for John. Does he have disease D?

Have you found the solution? Let us walk through the solution step by step:

Solution

We need to think in terms of probabilities and conditional probabilities. From the problem description, we can infer the following:

1. $P(D) = 0.008$, i.e. 0.8% of people have disease D.
2. We also know that the conditional probability $P(+|D) = 0.98$ ("The probability of a positive test *given* the person examined has disease D"), which is the correct positive of 98%.
3. Furthermore, we know that $P(-|\neg D) = 0.97$ ("The probability of a negative test *given* the person examined does not have disease D"), which is the false negative of 0.97%.

We are interested in the following probability $P(D|+)$, i.e. having the disease given a positive test. We cannot directly compute this probability. Instead, we need to apply **Bayes' rule** (alternatively Bayes's law, Bayes's rule or Bayes's theorem):

$$P(A|B) = \frac{P(B|A)P(A)}{P(B)} = \frac{P(B|A)P(A)}{P(B|a)P(a) + P(B|\neg a)P(\neg a)},$$

where $\neg$ denotes the logical negation. We assume binary attributes.[5] For a derivation and intuitive explanation, the interested reader is referred to the literature (Gigerenzer 2015).

We can now use Bayes' rule for our problem:

$$\begin{aligned} P(D|+) &= \frac{P(+|D)P(D)}{P(+)} = \frac{P(+|D)P(D)}{P(+|D)P(D) + P(+|\neg D)P(\neg D)} \\ &= \frac{0.98 \times 0.008}{0.98 \times 0.008 + 0.03 \times 0.992} \approx 0.2085 = 20.85\%. \end{aligned}$$

Given the result of 20.85%, John most likely does not have D despite the positive test result.

If you struggled to solve this problem, do not feel ashamed. Plenty of physicians in fact incorrectly assume that John definitely had disease D, given the positive test[6] (Gigerenzer 2015). See this as an opportunity to become more literate in data analytics, which is a good step towards understanding the foundations of AI. You will then be able to provide better healthcare to your patients while remaining competitive. You will find plenty of great statistics courses on the MOOC platforms listed in Sect. 2.3.

In recent years, plenty of companies have started to invest in AI in order to remain competitive. However, the sad truth is that some 80% of AI projects fail or do not add any business value (Nimdzi Insights 2019; Thomas 2019). One of the underlying causes is how AI is taught at universities, which usually only discuss purely methodological aspects of AI (Glauner 2020b). That is a serious limitation. There is clearly an acute need in industry for experts who get the big picture of what needs to be done so that AI adds value to companies. Educators need to address that issue by also enabling students to think in terms of **AI innovation management**. We have started in September 2020 at the Deggendorf Institute of Technology to teach a novel and internationally unique course on this topic (Glauner 2020a) that addresses that need. Students learn a number of challenges, both technical and

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[5] A more general definition for multi-valued attributes is $P(A|B) = \frac{P(B|A)P(A)}{P(B)} = \frac{P(B|A)P(A)}{\sum_{a \in A} P(B|a)P(a)}$.

[6] Note that in real-world medical cases, there is usually more evidence, such as pain or pre-existing diseases, that contributes to a physician's decision making.

managerial, that companies typically face when becoming AI-driven companies. They also learn respective best practices along the entire data journey and how these lead to deployed applications that add real business value.

6 Conclusions

In this chapter, we first provided an introduction to artificial intelligence for the general audience. We looked at its foundations, the three pillars of machine learning, recent developments in and around deep learning as well as the democratization of AI education through massive open online courses (MOOCs). We then presented a number of AI applications in healthcare. Next, we showed opportunities of how AI could skyrocket healthcare in the coming years. However, there are a number of challenges, technical and non-technical, that are currently limiting AI and its applications in healthcare. We discussed these challenges, including hypes around deep learning, the need for learning causal relationships instead of correlations, fears and the lack of statistics training in many medical schools. We also examined how these challenges could be solved in the future.

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Opening the Door for Digital Transformation in Hospitals: Management's Point of View

Guido Lerzynski

1 Introduction

In 2018, there were around 1900 hospitals in Germany under private, municipal or non-profit ownership, which treated a total of more than 19 million patients (Destatis 2020). Most of these facilities have joined to form hospital associations. Except for university hospitals, there are hardly any single hospital locations left. All hospitals pursue the goal of providing their patients with the best possible care, but the framework conditions for the individual facilities vary. Even though the refinancing of treatment costs in Germany is regulated on a nationwide basis via the German Diagnosis-Related-Group System (G-DRG), subsidies for investments in buildings and facilities are the responsibility of the federal states. There is great heterogeneity here in the provision of investment funds. In essence, two aspects are of importance here. Firstly, the amount of funds made available for the existing infrastructure of hospitals is not sufficient to adequately reflect progress in healthcare. The German Hospital Federation (Deutsche Krankenhausgesellschaft) speaks of an annual investment gap of 3.7 billion Euros for German hospitals (DKG 2017). Secondly, the amount of investment made available by the federal states has fallen significantly in the last two decades. At 3.3%, the investment ratio of hospitals is well below the economic investment ratio of 19.9% (Fig. 1).

To implement investments in the digital infrastructure of a hospital, it is necessary to tap additional sources of financing. Depending on the corporate structure, different financial framework conditions arise for the individual hospital. For example, access to the capital market is only available for a few, usually private, hospital companies. This heterogeneity also reflects the current state of the digital infrastructure in German hospitals.

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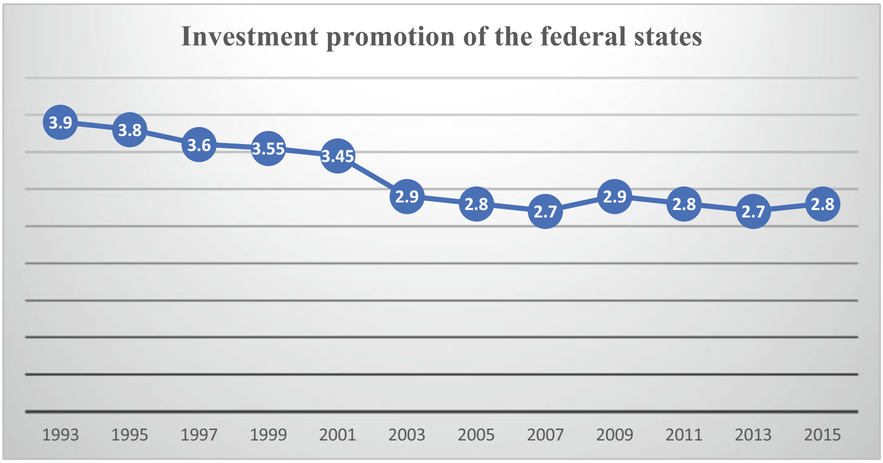


Fig. 1 Investment promotion of federal states (billion Euros per year). Data from (DKG 2017). Source: author

Another aspect is the regulatory component of self-administration in the German healthcare system. In this structure, the representatives of statutory health insurances, the National Association of Statutory Health Insurance Physicians and the German Hospital Federation are called upon to find answers to the requirements of the healthcare of the citizens. Each of the three parties primarily represents its own interests, which often leads to difficult compromises and a high complexity of decisions. There is insufficient openness to innovation within self-government (Stiftung Münch 2016). Innovations in the German healthcare system can only ever be successful if they are also reimbursed. This requires that applications are included in the health insurers' catalogue of services. However, there are sometimes major hurdles to this inclusion. The Innovation Fund of the self-administration is an aid to improving the process. Test phases of new methods and processes are financed directly via the fund; if the evaluation is positive, they are to be transferred to standard care.

It is therefore not surprising that Germany is only in penultimate place in the Digital Health Index ranking (Thiel et al. 2018). Although none of the countries examined has a perfect level of digitalisation, most of them are far ahead of Germany in their efforts—and that applies to all three dimensions examined: the political-strategic approach, the technical prerequisites and the actual use of data.

The potential for digitalisation of healthcare is huge. For example, McKinsey (2018) estimated in a widely acclaimed study that if the digital tools already available today were fully exploited, up to 34 billion euros could be saved annually in the German healthcare system, simply by increasing efficiency. Around 18 billion euros of this could be achieved by using paperless data and the conversion of communication to online interactions alone, and a further six billion through the automation of work processes. Such projections are currently based on several assumptions. It is therefore questionable whether the sum mentioned represents an underestimation of the potential that can be achieved. This refers in particular to the short-term perspective. In addition to the financial aspects, the benefits of the digital transformation also include improvement of the quality of care, which benefits every patient.

2 Digitalisation Strategies

Many hospital managers are very aware of the need for a digitalisation offensive, but implementation is often terribly slow. This is not just a matter of a lack of financial resources, but also of sticking with tried-and-tested processes and structures by employees, a lack of know-how, as well as concerns about inadequate data security (Kaltenbach et al. 2018). This is the only way to explain why the fax continues to be used as a means of communication between outpatient and inpatient care. The paperless hospital has not yet been achieved to any significant extent in many institutions. Compared to other industries, hospitals are in many cases still far behind in the application of digital infrastructures.

In many hospitals, data is stored in different systems that cannot yet be brought together centrally. Digital interfaces and uniform data communication would be required to bundle the information.

Digitalisation in hospitals is not an end but a beginning. All processes must be oriented towards the benefits they can offer. For example, digital processes should always be geared to the primary goals of patient care, or to the goals of the health system—such as improving the quality of care services or reducing the burden on care structures (Fig. 2). As a rule, digital applications are always cross-cutting issues that help to meet the increasing challenges at various levels and to improve the quality of care (Dahlweid and Roccaro-Waldmeyer 2019).

Not to be forgotten is the improvement of cost-effectiveness for the institution, which can save resources and thus costs through better process chains and

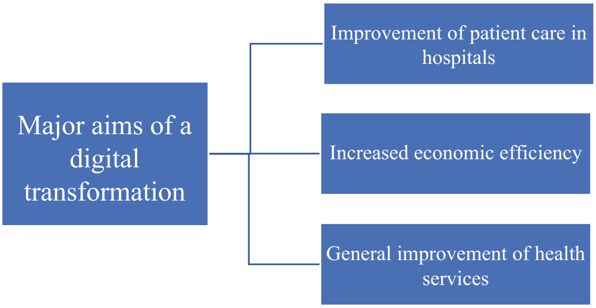


Fig. 2 Major aims of a digital transformation in hospitals (Topol 2019). Source: author

automated procedures. Ultimately, this is the “return on investment” from the management perspective.

Digital solutions are mostly accepted because of the benefits they bring to patients, doctors, nurses and other healthcare professionals. Digital processes and the solutions themselves should therefore be tailored to the users’ needs. In the institution, digitalisation should not be a burden, but rather the goal of process improvement or simplification.

3 The Development of a Digitalisation Strategy

There is no universal solution for the transformation strategy of an institution. Every hospital must find a way to approach digital transformation on its own. Basically, it is a matter of describing a vision of how the hospital wants to operate in the short, medium and long term, in order to position itself successfully in the healthcare market. Without the implementation of a digital agenda, the successful economic positioning of a hospital will become more difficult in the future, as competitors will be able to operate more efficiently and will be more attractive for employees. Employee surveys conducted in our company in recent years have shown that the introduction of digital infrastructures and software solutions is highly appreciated by employees and represents a competitive advantage in the battle for employees. Moreover, digital applications such as the electronic patient file are merely the foundation for the use and analysis of other key technologies (e.g. artificial intelligence and big data) (Topol 2019).

Even if there is no single approach to the development of digital transformation, certain key points in the approach have proven to be successful. It is self-evident that process changes in hospitals must not only be tolerated, but actively shaped. Therefore, when developing a digital agenda, it is not only the managers who should exchange ideas. Rather, those directly affected must be involved in the development of the agenda. Ideally, this also applies to the patient, who is best placed to judge the sense and nonsense of process changes. Depending on the orientation of the hospital, there will be different emphases on how digital processes must be developed over time and how they interact with each other. Therefore, every hospital needs a specially aligned project chain with a timescale, to make the transformation process a success.

The first step is the establishment of a working committee, which must be composed of interdisciplinary members. This necessarily includes representatives of the works council. There must be no “top-down” specifications in this committee that would prevent any discussion process. At our facilities, we have set up a hospital-related IT commission that defines the digital agenda from the perspective of each facility. At a higher level, there is an IT steering committee in the parent company, whose task is to steer the respective local transformation processes at a superordinate level (Fig. 3). Ground-breaking decisions on hospital information systems and software providers are made there, to establish a common framework

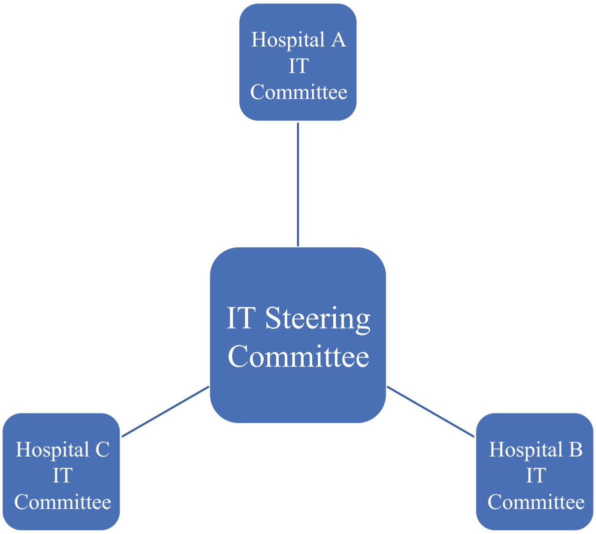


Fig. 3 Organisational structure for the implementation of a digital agenda in our hospital group. Source: author

for all facilities in the company network. Only in this way can processes be designed in a uniform and cost-effective manner within our hospital group.

The respective implementation and accentuation then take place in the individual hospital. In the same way, the timeframe for the implementation of process solutions is thus left to the respective institution. Representatives from the respective IT commissions of the individual hospitals are also members of the higher level IT steering committee.

Considerations on how to build a digital strategy should start with considerations on the definition of digital fields of action. As an example of a digital field of action, the electronic medical record is mentioned here (Fig. 4).

Each hospital defines its own digital fields of action. Depending on the orientation of the hospital, digital fields of action can be prioritised differently, but there are cornerstones that every hospital should work on, e.g. digital workflows and processes.

In a second step, measures must be developed for the fields of action. Each measure must be checked against the following four criteria: benefits, feasibility, costs and timeframe. Conflicts often arise at this point, as the costs and benefits of the application can contradict each other. A management veto is often unavoidable here.

Nevertheless, these criteria should be used to prioritise. A differentiation according to the Eisenhower matrix (Fig. 5) can be helpful in this task. When prioritisation has taken place, the action plan for the digital agenda can be decided upon in the institution. Once the decision-making bodies have also approved the proposed strategy, the agenda should be presented to all employees. This is an important step

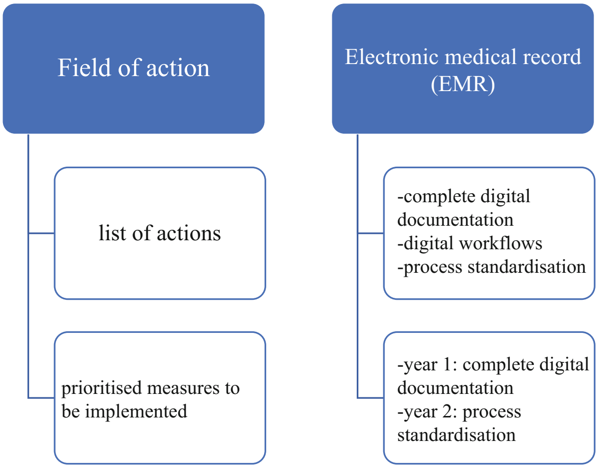


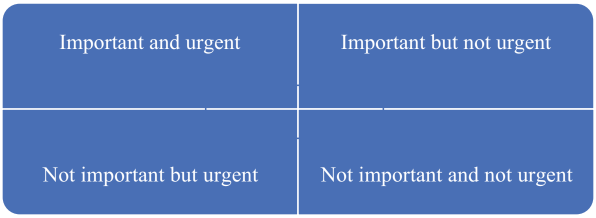
Fig. 4 Definition of fields of action and prioritisation of measures in the development of a digital agenda. Source: author

in creating transparency for the employees. It is not unusual for critics to be won over by a transparent presentation of the plans. For this reason, early involvement of members of the works council is crucial.

However, it must not be concealed that theory and practice can differ here. It is not uncommon for a decision that has been made to be adjusted because legal requirements or billing processes have been modified. In such cases the category "urgent" often wins over "important". Especially in the long-term strategies one or the other important point can fall victim to unimportant but urgent matters.

Ideally, implementation and monitoring of the measures should be carried out by the same working body. Depending on the level of development and the available financial and human resources of the institution, the implementation period of the digitalisation strategy varies, and may often take 3–5 years.

At regular intervals, the committee must examine the extent to which the digital agenda plan can be adhered to, or whether deviations are necessary, e.g. due to technical innovations. Even if the plan is delayed by financial aspects, it is important not to lose sight of the overall strategy.



Important and urgent	Important but not urgent
Not important but urgent	Not important and not urgent

Fig. 5 Prioritisation of measures using the Eisenhower matrix. Source: author

This transformation will never be complete, the road for the hospital of the future will not end. There will be new technologies that build on each other. The hospital of the future will continue to change. The digital transformation will comprehensively link the hospital organisation with other care structures in the healthcare system. A problem arises only if one does not start the transformation.

4 How Can Measures Be Successfully Implemented?

In the past couple of years, I have been involved in several digitalisation projects—sometimes successfully, sometimes less successfully. Most projects followed a certain pattern. To be able to realistically assess a project at the beginning, the following passages might be helpful for IT working groups and hospital management.

4.1 Planning

After an often lengthy planning phase, in which the requirements were agreed upon in a working group and a degree of target achievement was determined, the exact timing of the implementation of the new application must be planned in a second step. To ensure future success, the time planning for the implementation requires the views of the institution to be aligned with the respective external companies, but also with the representatives of the IT department. Misunderstandings can only be resolved later with a great deal of effort. Often the expectations of the end users and the providers of the technology lie far apart, so that an intensive exchange in advance can avoid later conflicts. This includes visiting hospitals where the technology has been successfully applied. The honest answers of staff in other hospitals who are already using the technology are important for your own decision-making process and may already revise some decisions. An “in vitro” presentation of the technology alone is not sufficient. Everything that must be adapted afterwards and deviates from the current project plan entails costs that may delay a project and endanger it.

4.2 Implementation and Setbacks

Users often hope for full functionality at the start of implementation, which can be very deceptive. In practice, the functionality of the application is achieved gradually. Incorrectly adjusted configurations can even lead to a reduction in functionality in the first days and weeks of the application. Only after further support does the functionality of the application develop over time. A second setback in functionality is also not uncommon and again requires the attention of those responsible for the process. The path to complete functionality can be long and time-consuming. Nevertheless, it is worth the effort, because in the course of time processes lead to new functionalities that are of great importance for the transformation strategy (Fig. 6).

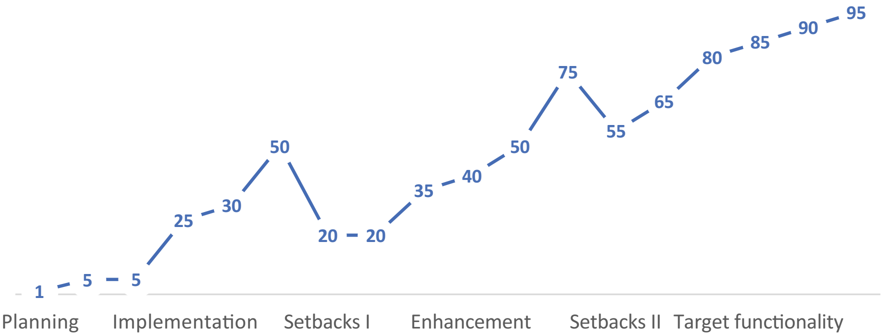


Fig. 6 The implementation of digital applications in hospitals over time (degree of functionality between 0 and 100). Source: author

5 Defining a Digital Strategy Is Only the First Step

With the implementation of the digital agenda, a first transformation step for the hospital is underway. The hospital of the past is developing into a networked hospital of the future. It should be transformed into a digitally supported, intelligently functioning control platform that is oriented to the patient's medical needs. It starts even before the inpatient stay and ends long after it. The hospital then becomes a cog in the network of healthcare facilities that are geared to the patient's problem. The previously closed system of an inpatient facility is abandoned. The hospital is part of a supply chain for the sick person.

Although the concept of the hospital of the future is initially linked to the availability of basic technologies, it requires at least as great a change in thinking and action from the people involved (Werner and Struchholz 2019). The way in which hierarchies and communication behaviour are lived in hospitals will change radically. In the future, medical services will be embedded in integrated processes and much more work will be done at interfaces. Expert knowledge will be disseminated, as it will be available transparently to everyone. This requires a new open corporate and communication culture.

6 Interaction Between Supply Structures in the Healthcare Sector

The hospital of the future will have to network with other healthcare providers. Ideally, a uniform supply chain will be focused on the patient. In concrete terms, this means barrier-free communication of patient data. Regardless of which care level the patient receives, data can be exchanged in a uniform and comprehensible manner. Whereas purely technical specifications, standards or unstructured documents (e.g. in PDF format) are of marginal help, so-called semantic standards enable largely automated processing and correct interpretation from one IT system to another. All without the respective specialist personnel, who formerly had to rework the data manually. One can compare these new terminologies with a dictionary of diseases and symptoms agreed upon by international experts and used in different countries. This ensures that electronic patient records not only consist of a free text with notes, but also contain the medically required data according to a certain pattern in a machine-readable form.

The term "interoperability" describes the ability of different systems to work together as seamlessly as possible. As soon as healthcare professionals—be they general practitioners or hospitals—work with IT systems that are semantically interoperable, they can exchange their patients' health-related data with clear and precise meaning (Fig. 7). This interoperability not only enables physicians to share electronic patient records with other physicians and hospitals, but also to structure them according to a specific medical terminology: artefacts (objects, processes, properties) provide a standardised meaning of human language. These are expressions used within a specific disease area. Only uniform, agreed semantics make it possible to interpret data in terms of content and thus process it at all—a central prerequisite for creating real added value for healthcare.

If the cross-sectoral digitalisation of the healthcare system is to be promoted, a machine-readable exchange of patient data between all participants in the healthcare system is essential. Medical knowledge in healthcare is traditionally exchanged using clinical coding, represented by specialist terminology, to transport information and translate it in a meaningful way.

Once this step of cross-sectoral digitalisation has been achieved, a further milestone in patient care can be reached through targeted data analysis. A strong analytical basis ensures that health data improves the decision-making process. It

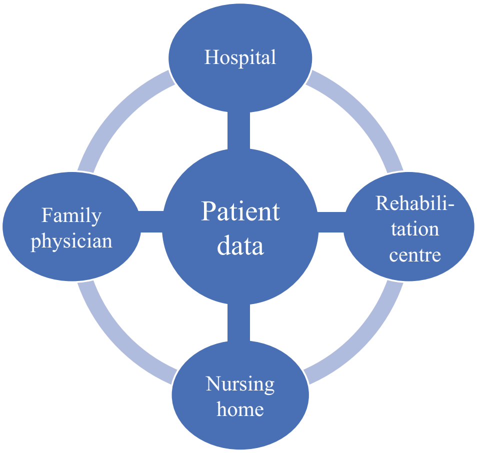


Fig. 7 Patient data in a digitally networked supply chain. Source: author

Table 1 Adoption model for analytics maturity (AMAM classification)

Stage	
0	Fragmented stand-alone solutions
1	Foundation building: Data aggregation and data governance
2	Core data warehouse workout: Centralised database with an analytics competency Centre
3	Efficient, consistent internal and external report production and agility
4	Measuring and managing evidence-based care, care variability and waste reduction
5	Enhancing quality of care, population health and understanding the economics of care
6	Clinical risk intervention and predictive analytics
7	Personalised medicine and prescriptive analytics

Source: HIMSS (2019)

is a clinical decision-support tool that can bring many economic advantages for the hospital, but also for any other participant in the healthcare system.

The Healthcare Information and Management Systems Society HIMSS has summarised the maturity of the available analysis data in the AMAM classification (Table 1). From a single fragmented solution in stage 0 to the availability of personalised medicine in stage 7, the scale provides the perspective for the coming years (HIMSS 2019). A successfully implemented digital transformation thus leads to the next step of a deeper use of patient data. The analysis of big data and the availability of personalised medicine will move the transformation of the healthcare system to the next level.

7 IT and Data Security

Despite all the opportunities that digitisation brings with it, we must not lose sight of the risks in terms of data and IT security. Health care facilities were and remain a popular target for hackers and criminals. Attacks on the IT network structure in hospitals were used to generate patient data which is then illegally resold. But also extortion of funds by directly influencing the control of hospital processes (radiology, intensive care unit, etc.) with the consequence of endangering patients has occupied hospitals in the past. The attack on the IT infrastructure of the Lukas Hospital in Neuss in February 2016 should be mentioned here as an example of how a hospital can be threatened in its core processes from one moment to the next.

The European data protection regulation has strengthened the rights in handling patient data in the past couple of years. From the hospital's point of view this has advantages and disadvantages. On the one hand, individual data are better protected against access by third parties, on the other hand, regulations are often an obstacle to an institution's digitisation strategy.

If we set out to drive forward digitisation in hospitals, it is by no means enough to limit the strategy to the development of hospital processes. It is equally necessary to provide adequate financial resources for IT and data security. A restrictive allocation of financial resources may have serious consequences in the event of an attack on the IT infrastructure or the loss of patient data. This has also been recognised by the Federal German Government. In a new law proposal the allocation of funds for the digitisation of hospitals will be linked to the investment in IT security (KMA 2020).

I would not deny that IT security is equally important in other economic sectors, but the lives of patients depend on the functionality of IT processes in hospitals as digitisation progresses. This is what makes this sector so vulnerable and important. Hospital management must always be aware of this responsibility and act vigorously.

8 Conclusions

The digital transformation of hospitals will lead to far-reaching changes in process chains, all of which will benefit treatment quality and patient safety. As treatment costs continue to rise, greater process efficiency will make it possible to achieve cost efficiency at the same time. Classical ideas of a hospital in which doctors, nurses and administration work side by side will be replaced in the future by a new healthcare infrastructure. The future hospital will become an important part in an entire process chain for the patients' benefit.

It will incorporate a review of the entire current "hospital business system" and of determining where opportunities and risks arise through new technologies in diagnostics, therapy and communication. The relevance of this broader approach becomes clear when considering the use and integration of artificial intelligence, sensor technology, augmented reality, big data, health clouds or robotics. These topics will cause massive changes in hospital processes—with serious consequences for today's structures. This will also radically change hospital management.

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Opening the Door for Digital Transformation in Hospitals: IT Expert's Point of View

Pascal Grüttner

1 Introduction

Looking back a quarter of a century the author was in the middle of his medical education and the first one having an email-address at the institute of anatomy at the University of Cologne. X-rays had been developed on films and manually transported through the clinics in big brown paper bags. Medical records were analog and hospital information systems—if in use—had the main purpose to support administration.

I swapped my doctor's coat to a computer keyboard and saw a great development of information technology (IT) in hospitals since then. But in vain you would look for flying taxis or Atlas robot performing a back flip. You will not even find a regular use of mobile devices for doctors, nurses, or patients. Although the patients begin to become technical leaders in mobile medicine, having multiple apps to support medication, report vaccination status, or even register electrocardiograms (only by wearing a smartwatch).

The days of monolithic systems are over. Of course, homogeneity remains a value, but the future is to open health IT to interaction. Service oriented architecture and standardized interfaces are enablers for the exchange of data between different health IT systems (Sunyaev et al. 2010).

Beyond all technical equipment there also has to be a focus on the processes. Digital transformation has to support processes, especially in patients care. It is not sufficient to take a paper form and reproduce it on screen. Think of everything that happens before, while and after filling the data to the form. The form fields are nothing more than a simple storage. The impact resulting from a precise analysis of

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the process and a perspicacious implementation is much higher and represents the real value of digitalization.

Last year I met a friend at a congress who works as a doctor in anesthesia. During a break, he told me that he had to check a patient record. He took his smartphone, established a virtual private network (VPN) to the hospital, started the hospital information system (HIS) and checked the last blood values and other medical data. My friend, at this time, was employee in a well-known hospital in Great Britain, a country that ranges way above Germany in the digital health index inquired by Thiel et al. (2018).

It is a truism that hospitals have to open their doors for digital transformation, and this is what IT experts think, they should let in.

2 Recommended Areas of Digital Activities

Whether you are at the beginning of applying digital infrastructure and processes to your hospital or if you are on a good way or even fine tuning your digital health IT, it is recommended to set up two kind of retaining structures.

These are (1) areas of (digital) activities and (2) guard rails to channel IT decisions (3.1). Let me introduce the areas of activities on which we focus in our company. We divided them into groups with different prioritization.

Group 1: absolutely necessary/essential
- Basic IT infrastructure.
- Electronic medical record (EMR).
- Improvements by digital processes.
- Corporate digital spirit.

Basic IT infrastructure No mobile medicine can be established without stable and safe network—including wireless network at least in all areas where patients are treated—and modern hardware for the workstations.

Electronic medical record (EMR) The benefits of using EMR, i.e. augmented transparency, efficiency, reliability, or the reduction of repeated examinations (Bertram et al. 2019) are generally accepted and will therefore not be discussed in this chapter. EMR is often not clearly differentiated from the electronic health record (EHR). The definition used here refers to the description provided by Healthcare Information and Management Systems Society HIMSS (Garets and Davis 2006) where EMR contains all the data of the patients stay within the healthcare organization. In Germany the corresponding terms would be “Elektronische interne Patientenakte (iEPA)” for EMR or rather “Einrichtungsübergreifende Elektronische Patientenakte (eEPA)” for EHR (Bertram et al. 2019).

EMR requires not only the appropriate IT infrastructure but also software that provides the relevant features and interfaces as well as an IT organization that is able to ensure 24/7 support.

Improvements by digital processes Digitalization is not an end in itself. It has to ease the daily work or reduce bottlenecks. Doctors or nursing staff wish for tangible support by digitalization. And they do have concrete expectations of how technology can help to improve their work (Taylor et al. 2017). There, EHR was mentioned most. Based on the authors own experience simple things, like digital dictation or speech recognition, are frequently requested. Furthermore, healthcare professionals would profit from tools, that enable mobile work, starting as simple as using a messenger or having mobile access to information on the healing state and progress.

Corporate digital spirit Especially the younger people in organizations are motivated and encouraged by digital culture (Microsoft Corp. 2018). The healthcare sector in Germany is taillight regarding the digitalization level according to different industries (Weber et al. 2018).

Thus, it could be considered a fortune that during the corona pandemic hospitals had been forced to not only think about but actually establish new ways of communication and collaboration. Especially for well-known video conferencing software an increase of usage could be found (Bölling 2020). This boost did not only appear within organizations. It was also noticed in patients who started using telemedicine for consultations (Klös 2020).

Group 2: highly desirable

- Cross-sectoral networking.
- Rationalization of administrative areas.
- Decision support systems.
- Information platforms and learning management systems.

Cross-sectoral networking The huge amount (82.7%) of paper-based communication from doctors in clinics towards their colleagues established in medical practice (Obermann et al. 2017) reveals the necessity of transforming intersectoral communication. The value of Electronic Data Interchange (EDI) as a common way of transferring data between organizations has already been shown in the 1960s (Niggl 1994).

The "Telematikinfrastruktur (TI)" that is currently rolled out in Germany aims to close the tremendous gap between ambitions and reality. The interested reader may decide on his own about the ranking of a communication standard like "Kommunikation im Medizinwesen (KIM)" on an innovation scale. KIM enables participants of the TI to transfer documents like doctor's letters in a secure and encrypted manner (Gematik 2020).

Rationalization of administrative areas This aspect is strongly associated with the management of the hospital. IT at this point will treat administrative areas similar to the other areas of the hospital. The areas of activities as mentioned in group 1 do also apply here.

Information platforms and learning management systems Medical knowledge is rapidly increasing. There are authors like (Densen 2011) who even predict an exponential growth. Irrespective of whether this is really the case it is clear that the current and future amount of knowledge require effective tools to access information and to foster the individual process of learning. This is what (Apt et al. 2016) declare as the end of knowledge-saving education.

Group 3: further stage of development

- Telehealth.
- Use of data.

Telehealth Although the benefit was already known, the coronavirus pandemic clearly pointed out how useful telehealth can be. While examinations are an integral part of medical practice, there are enough cases where physical contact between patient and physician is not necessary. For example, the bariatric surgery is one of the fields where patients can benefit from telemedicine services. Online appointments do also relieve the consultation hours in clinics. Further useful applications are multidisciplinary or interdisciplinary team meetings.

And from a technical point of view, it is often easy to implement basic services of telehealth and thus recommended to do so. But even intraoperative video consultations are possible. The author recommends that any IT department should help the hospital to realize the value of telehealth. But only by paying attention to data privacy and relevant aspects of IT security. The interested reader is invited to keep the last sentence in mind for all implementations mentioned in this chapter.

Use of data The healthcare sector is one of the greatest producers of data (Fig. 1) and will have the largest increase up to 2025 (Informationsdienst des Instituts der deutschen Wirtschaft 2019). Before thinking of the extended use of data it

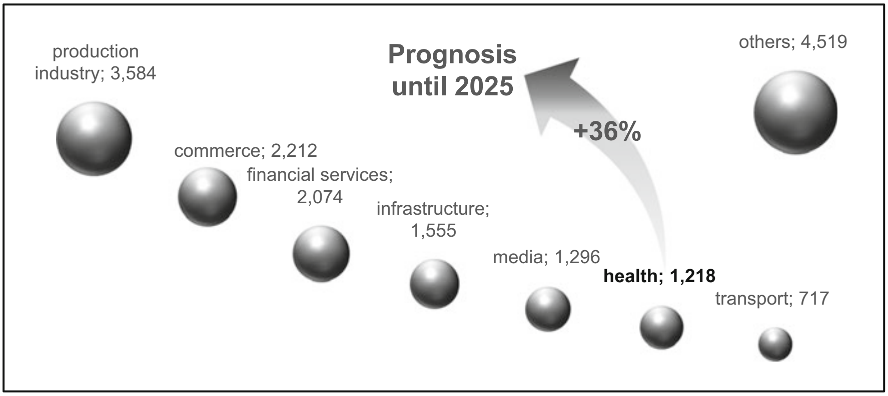

Fig. 1 Data producers 2018 in exabytes (Informationsdienst des Instituts der deutschen Wirtschaft 2019). Source: author

is important to handle the current situation. Hospitals have many data sources and data storages. Data comes from simple input devices (i.e. keyboard, storage media, scanners), network (i.e. cloud services or smart devices), healthcare (i.e. photographical wound documentation, measuring of vital data, digitalized intensive care units, laboratory, diagnosis), medical devices and technology (i.e. radiology, central sterile supply department, refrigerators), and future devices like the internet of things (IoT) or even humanoid robots like Pepper.

Often all these data sources have different storage locations. Interfaces to the HIS are highly recommended but not always possible to be established. The central filesystem could be a save (backed) alternative, but we often do have decentralized data storage, for example, hard disks in the medical devices, network attached storages (NAS), sometimes even flash drives. In addition, there are many software products storing data within their own proprietary database structure.

All the facts mentioned before are hard to handle for any IT department. It is recommended to have a detailed documentation of data flows within hospital and to inform the users and the management, in case of any insecure storage or transportation of data and to cover these points by a risk management strategy.

In our company we established a data warehouse to be able to have a common base for reporting and data analysis. This is indeed a useful concept particularly to enable controlling to handle the huge amount of data. According to (Crasselt et al. 2019/20) most of the data within the data warehouse is for financial accounting, cost, revenue, or performance analysis, in conclusion to support administration.

For the future we also need to concentrate on the value of medical data to support the healing process, to analyze incidents (i.e. spreading of germs), to recommend appropriate measures or to improve research. In the authors opinion even predictions should be part of everyday life and not only subject of research demonstrated by (Lu et al. 2019).

In our company we are currently developing a professional part-time education and training concept for data analysts with a special focus on healthcare data.

Finally, the importance of consistent and unified semantics has already been mentioned in the chapter "Opening the Door for Digital Transformation in Hospitals – Management's Point of View."

Group 4: forgotten things?

It was interesting when discussing the areas of activities in an interdisciplinary project-group in our company that one aspect had not been addressed, even if it seems to be of great relevance. Everything concerning digital diagnosis or therapy appeared to be a kind of science fiction. Radiologist agreed that AI systems will be some sort of digital colleagues in near future, assisting to cope with the increasing amount of image data.

But in other disciplines reservation against IT helping doctors in their very own responsibilities to decide about diagnosis or therapy is perceptible. Regarding the levels of automation in man-computer decision making as introduced by (Sheridan and Verplank 1978) and adopted by (Hauß and Timpe 2002) it is clear that already at level five (of ten) the doctor would only remain the executor of a computerized decision and action proposal.

Maybe this results in a conflict between the responsibility of the doctor, reservation against new technologies, often hiding the way they calculated their results and the concern towards the regulatory or even more the legal implications. The levels of responsibility concerning ethical aspects of algorithms in the healthcare system are described by (Jannes et al. 2018).

3 Further Success Factors in Digital Transformation

As mentioned above, we are still facing many steps before we will reach the goal of hospitals being able to use the full potential of IT. The following subchapters substantiate further success factors we found in our company.

3.1 Organizational Structure Is More Than Theory

The organizational structure of the IT department is a crucial factor for effective and recognized work. These are main needs of the hospitals that should be matched by different IT teams:

(a) immediate support,
(b) stable and reliable IT systems (hard- and software, infrastructure),
(c) understanding of the complex processes in hospitals,
(d) quick and flexible development of individual solutions.

Whereas (a) and (b) are well-known aspects since IT had been introduced to hospitals, the need of giving advices to the management of the clinics and to provide customized solutions to the specialist's departments nowadays distinguishes the helpfulness of IT departments. Translating that into an organization chart, results in teams are depicted in the following Fig. 2.

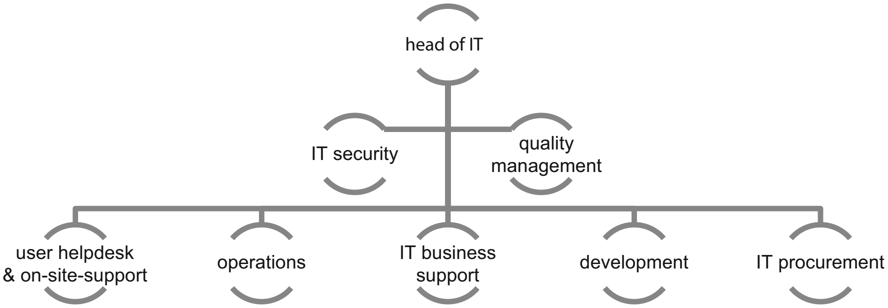

Fig. 2 Proposal of an organization chart for IT teams in hospitals. Source: author

Team user helpdesk (UHD) and on-site-support (OSS) represents the single point of contact (SPOC) for any user questions or problems. The operations-team is responsible for running the technical platforms, data centers, and further infrastructure including HIS.

Besides the traditional fields IT departments should realize the importance of optimizing the consistency of the treatment process (Lenz and Kuhn 2004) and giving processual support to the users. The team IT business support can be compared to the technical sales teams in other industries. They are counselors and project managers and contact persons for the operations management of the hospitals. It is recommended to entrust people with that role, who are familiar with medical or nursing processes in hospitals. Former nurses, for example, who studied health management, have an excellent background to join those teams.

Although IT needs standardization, we have to identify smooth-running, efficient, or effective individual processes, which are valuable too. The IT department together with the users has to determine in which cases standardization is more important than individualization and vice versa. For many individual processes, it is useful to have an own team of developers that are experienced with HIS, communications servers, (health care) interfaces, etc. to be able to quickly build flexible in-house solutions.

The specific requirements of purchasing IT components or services result in the advice of maintaining a small procurement team. It is recommended to negotiate an own purchasing guideline for IT, based on the hospitals principles but mentioning the fact that the market of IT components follows other rules, like buying replacement parts at auction platforms or having cost-intensive licenses with complex dependencies on user-, client-, or core-counts. Not to forget manufacturers changing their licensing models every few years.

Concerning the organization of IT security three roles are expedient: an independent information security officer complemented by an IT security officer in the IT department and by an IT security coordinator in the hospital.

Finally, to support the continual service improvement the author recommends a responsible person for quality management.

IT Is a Management Issue

Do you have a chief information officer (CIO) in your organization? And what about a chief digitalization officer (CDO)? The position had been introduced for the first time at a university hospital in Germany in 2017 (Hoffmann 2017). And that is still underrepresented (3.7%) in comparison to other industries but records an enormous increase (+1900%) within the last few years (Merx and Merx 2020). Mentioning the CDO here does not mean that the author recommends the CDO as a new and separate position in the organization. The personal union with the CIO is conceivable as proposed by Michael Fuchs (Baumgartner 2016). Important is to be aware that digitalization needs a strategic and process-oriented approach as well as systemic perspective.

Where does IT ranges in your hospital? If it is not a management issue, the author invites you, to get close with the following lines.

If the self-perception of the IT department does not aim beyond user support and running the platforms, potential gets neglected. Healthcare providers are in need of an IT strategy that is thoroughly thought through and regularly updated. This strategy must be considered by the top-level executives. In a way that they not only authorize but at the same time appropriate the strategic objectives of IT in their organization. In our company we chose a period of 5 years where the IT goals are determined. But as already mentioned: the general development of IT is fast and thus within the timespan be aware of implementing changes, if necessary.

Another crucial factor is to give the employees guiding principles of whom I will present a list after mentioning the most important aspect in my opinion. IT in hospitals—as anywhere else—will be successful, if it fits the needs of the users. Which means, it has to be user centric. This is digital leadership, where IT gets an understanding of how the users will benefit from technical solutions. After having heeded that key factor you should additionally take a look at your IT landscape, which should fit to these principles: offer interoperability, follow technical standardization, harmonizing departments and clinics, providing secure and performant infrastructure, making a broad range of information available, extending medical documentation, homogeneity as long as functionality is at least acceptable, being open-minded for new ideas, allowing to learn from mistakes.

In Fig. 3 these principles are shown as matrix extending between being more technical or focusing the users and along the axis from information to process.

We call it guard rails to channel IT decisions. Clear and comprehensible decisions contribute to acceptance and the principles mentioned above are used to achieve this objective and to challenge the digital transformation.

Hospitals are forced to attain economic advantages. Specialization and scaling effects increased their efficiency (Laloux 2017). This focus makes it hard to give

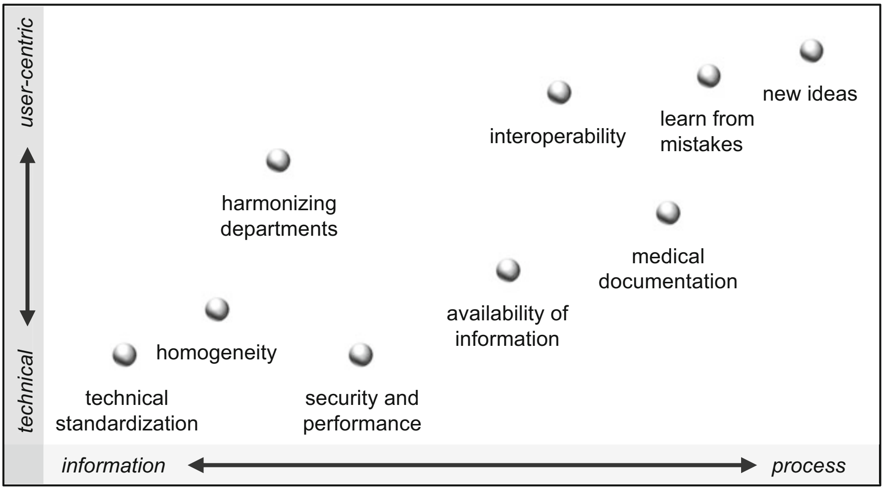

Fig. 3 Challenging the digital transformation. Source: author

room for new ideas and much less to allow to learn from mistakes. Modern IT strategies and digital leadership build a huge contrast to these prerequisites. Development is iterative and mistakes are unavoidable. It is important to have good concepts to deal with them and to avoid them wherever possible. But mistakes are part of the business and thus are treated in the best way by accepting their occurrence.

In former times it was often difficult to realize interfaces between several IT systems. In consequence homogeneity has had positive effects on the work with IT. The HIS suppliers followed holistic approaches providing all-in-one solutions. Today this kind of software is outdated (Günther and Heitmann 2020) and reservations against the HIS occur mainly by the clinical staff.

For the IT department it is more complex to handle a lot of different IT services and interfaces. But it is also a truth that nowadays the interoperability grows, and the management of IT services has become easier (Mauerer et al. 2020). As a conclusion the author recommends a well-balanced mixture of homogeneity and best of breed.

3.2 Who Drives the Change?

I always remember some funny cartons, when I do experience the clash of cultures between IT experts and other human beings; aliens versus stone age men? And let me extend the thought by drawing the image of a surgeon talking to an internist. In fact these jokes already explain the most central need when we want do establish IT-driven changes in hospitals. The people are making the difference. The users have to be convinced.

The best way to do this is to involve them from the beginning of each IT project. The most complicated step is often to clearly find out the requirements on the users' side. We do always start with a precise documentation of these needs. During the project partial deliveries of the current results should be reviewed by IT experts as well as by the users. Be aware that the procedure model of suppliers often does not follow such agile concepts and may lead to unwished surprises after rollout.

Another question is relevant for IT changes: who supports the change? It is important for the IT department to cooperate with all teams when establishing a new IT service. Consequently, the service transition must not be forgotten to assure seamless operation.

3.3 You Are Not Alone

Financial resources as well as humans working on digital transformation are rare as reported by the (Bundesverband der Krankenhaus-IT Leiterinnen und Leiter 2018). In particular when talking about well-educated experts in IT there is a considerable backlog.

Outsourcing is a possibility to deal with the lack of human resources. Intense and standardized parts of the business, primarily with a low need of sector knowledge, are preferred units for outsourcing. In our company we do have external partners for some main areas, which are UHD, network management, managed services, and device-as-a service.

UHD Only the first level support is executed by the external partner. Our own UHD team is responsible for second level tasks. We determined the 40 most frequent incidents and described standardized procedures to solve them. Every problem that cannot be solved be the external UHD is redirected to our second level support by using a ticket system. In addition, we defined a list of keywords (i.e. intensive care unit or medication) that directly involve our colleagues to avoid possible threats for patients.

Network management In an environment with about 400 switches and two main locations we engage another external company to setup and monitor (including troubleshooting) the active network components.

Managed services The two central and redundant data centers in our company are administrated by a managed services provider who is also responsible for regular update service and patch management.

Device-as-a-service The amount of nearly 2500 workstations in our company ties up notable capacities. To relieve the OSS we are partnering with a supplier who covers the whole process which reaches from selling (on the base of a 5 years contract and the concept of leasing), first setup, delivery up to service.

We defined only five standardized workstations: A tiny desktop client, two types of notebooks, one FAT-client for rare applications that do require high local performance, and finally a device to work in environments with special hygiene requirements.

Further outsourcing is recommended and should be taken into consideration if it saves human resources or money. But always be aware of keeping the specialized competences that are required in healthcare IT within the IT department.

3.4 Never Underestimate the Power of Start-ups

Some hidden champions driving the digitalization in healthcare are start-ups. When looking for new ideas of useful apps it is recommended to take established suppliers and start-ups into account. There are several solutions provided by healthcare start-ups, based on modern technical concepts. They are often highly interoperable.

3.5 Connect Yourself

Do not wait for any software to solve the requirement of interoperability. The IT department should establish a communication service on its own and have experts in their own ranks to implement interfaces (i.e. HL7). Do also plan a budget for external support at this point to be sure to have enough yearly resources for the optimization of data flows.

3.6 Step by Step or: Be Pragmatic

Define your measures and then implement your digital assets step by step. Depending on the impact it may be wise to start with a proof-of-concept or pilot projects. We have been successful by beginning with a centralized datacenter, a performant, and secured network infrastructure including wireless network, a homogeneous rollout of HIS, specialized systems, i.e. in cardiology, a data warehouse, picture archiving and communication system (PACS), and patient data management system (PDMS) for intensive care units.

Followed by electronic patient chart and medication process (which should finally end up in closed loop medication) and drug safety aiming for complete EMR.

4 Conclusion

The doors are open for digital transformation in hospitals. Management is willing to make resources available, IT departments are capable to evaluate and establish new IT services and the employees are to a large extent open-minded for digital support of their daily work.

Hospitals should collect and prioritize the areas of digital activities in interdisciplinary teams. The single steps have to be planned and executed. It is important to start working on digital transformation. In Germany the mean digitalization ranking according to EMRAM is not as high (2.3) as the mean in Europe (3.6) which is shown in Stephani et al. (2019). And if there are gaps on a basal level (i.e. incomplete wireless network), that is the point of departure. If once started, stick to it.

The digital transformation will not stop. It is a continuous change process. Starting with IT services itself, that should be governed by continual service improvement. Best practices, standardization, quality and risk management provide well-defined support. In addition, own guard rails to channel IT decisions can be defined to make decisions transparent and the digital transformation reliable.

Adequate investments in IT security are investments in the future. Even though they were not explained in detail within this chapter, the author appeals to take IT security seriously.

Modern organizational structures improve the work of the IT department which should be in close interaction with the management. IT should be strategic as well as operative and never forget to focus on the users and the patients. Their benefit of technical solutions is the real sense of meaning and purpose.

By reason of the permanent lack of human resources in the healthcare sector cooperation with external partners in basic IT areas helps the IT department to focus on the specific characteristics of hospitals.

The IT scenery is changing. Start-ups and established companies are offering new solutions and flexible technologies. Healthcare functionality even reaches the consumer sector, for example, by implementing fast healthcare interoperability resources (FHIR) in smartphones (Becker 2018). This results in an empowerment of the patients and the author is convinced that in future patients will be one of the most relevant drivers of the digital transformation in healthcare.

Finally, it is important to remember that we are humans. Digital transformation does not mean that we should transfer into machines or be better than computers (Peterka and Michael 2019). Computers and humans will be co-workers. In the end we do need a wise and responsible mixture between technology and humanity to successfully walk along the way of digital transformation.

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Digitalization from the Patients' Perspective

Julia Plugmann and Philipp Plugmann

1 Introduction

Digitalization in health care is often discussed from the professionals' point of view (e.g. physicians, dentists, nurses), but what about the patients' perspective? Patients face new challenges: They are a cost factor, which has to be monitored. This requires access to all their health care data plus additional information. Patients' behavior may well be measured in the future—mandatory genetic testing could be on the horizon, and in times of coronavirus the question of compulsory vaccinations arises once again. There is more: Should every German citizen automatically become an organ donor by law? Should opting out mean having to make a written declaration? And should the system punish people who opt out, e.g. by putting them last on the waiting list if they need an organ transplant? Is this environment really conducive to creating high acceptance of digitalization from the patients' point of view? We conducted the following three studies, which will help to understand patients' needs and perspectives in the age of digitalization in health care, especially in the hospital environment. Ultimately, patients' acceptance of innovation and digitalization is crucial to the success of implementing new technologies in health care. To achieve higher acceptance, policymakers should promote public campaigns to communicate the advantages of these technologies for all patients in the health care system.

2 Three of Our Studies from Recent Years

During the period from 2014 to 2020, we worked on several studies researching different aspects of patients' perspectives in the field of digitalization and innova-

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tion. The research focused on patients' willingness to share and hand over their health care and non-medical data, as well as the acceptance of digital products and services in the hospital environment and in general.

2.1 Results from Study No. 1

We turn first to some of the results from a study we presented in July 2014 at the "12th Open and User Innovation Conference" at the Harvard Business School (Boston, USA). This was organized by Prof. Eric von Hippel (Massachusetts Institute of Technology, MIT) and Prof. Karim R. Lakhani (Harvard Business School, HBS). The title was "Users (Patients) willingness to open personal health data for an innovative APP to receive a more efficient health care service." In our abstract, we expounded our research work:

As there is a relationship between periodontal disease and widespread diseases like diabetes or cardiovascular disease, this is an interdisciplinary situation for the user (patient). Personalized health care data management is needed to prevent further threats to the patient's health. The DMD (Doctor of Dental Medicine) can measure relevant parameters in the oral region to define the status of the periodontium on a timeline. The MD (Medical Doctor) has access to all information about the general disease profile of the user (patient).

It would be more efficient for the patient, MD, and DMD to exchange data, combined with information that the patient adds to the app, which is then visible for all three parties (DMD, MD, and patient). This interdisciplinary approach could help users (patients) and reduce costs in health care systems through prevention and by providing early warning indicators. The technology exists, but are patients willing to provide data and information in an app of this kind?

For this paper, from January to December 2013, in a multicenter study (4 dental clinics), we interviewed 528 patients with a periodontal disease history in two groups. In the first group ($n = 244$), no user had a prior general disease. In the second group ($n = 284$) they had a minimum of one general disease or more. We found that 93% of the second group would open their individual health care data to such an innovative app, allow the MD and DMD to enter certain medical parameters, and would also input information daily/weekly such as how they feel, what they eat and if they still smoke. In the first group, 32% would open their individual health care data to such an innovative app.

Our empirical results showed significantly that there is a high user (patient) willingness to share personal health data with an innovative app in order to receive a more efficient health care service, among the group of users who have a periodontal disease history *and* one general widespread disease or more. This user willingness should be used to develop appropriate IT solutions, implement them in the health care market, and reduce costs for the health care system. The benefit to users is the prevention of further medical threats to their health.

This study, which we presented in 2014 in the USA, marked the start of the "Dr. Dr. Plugmann APP," which we developed and presented in different international health care digitalization contests. We used the feedback from participants and organizers to improve our app, and it was used in local private practices to help patients. In 2017 the app was sold.

2.2 Results from Study No. 2

The first study, presented in 2014, only considered the flow of health data between the patient, MD, and DMD in interaction with software (an app) and using mobile devices. Having identified in the first study the very high user (patient) willingness (93%) to share personal health data with an innovative app in order to receive a more efficient health care service, the next question was: What if data collection would be expanded to create a holistic approach? The holistic approach to deliver a better health care service to the user (patient) would need medical and non-medical data about the user. The influence of such a future user community and the potential results from research data based on the future IT service could also help to develop open innovation processes and future research in the open innovation field (Chesbrough and Bogers 2014). These thoughts led us to conduct the following study, which was presented in November 2015 in Santa Clara/Silicon Valley (USA) at the "2nd World Open Innovation Conference (WOIC)." The conference was organized by Prof. Henry Chesbrough, Faculty Director of the Garwood Center for Corporate Innovation, University of California, Berkeley Haas School of Business. The structure of this research study presented in 2015 is described on the following pages.

Research Question

We prototyped a future IT health care service that would be offered by an open innovation driven health care IT company. That IT product (service) would collect all the personal medical and non-medical data it can get—with the individual's permission—depending on the electronics and sensor system technologies. The research question was whether users would be willing to transfer all their medical and non-medical data to a future IT service provided by an open innovation driven health care IT company. Does such a future IT service prototype meet users' needs? And does it lead to a high level of willingness to transfer all data to an open innovation driven health care company that offers this service? Usually today (in the year 2021) this would be something more like an AI-supported cloud solution with integrated devices.

Secondary Data

From February 2014 to February 2015, in a multicenter study in Cologne and Bonn (4 dental clinics and 6 medical practices) in Germany, we interviewed 821 patients and asked them about the importance of several factors. Out of more than 2439 patients, just 821 met the inclusion criteria. The inclusion criteria for patients were: a past history of dental and medical illness; age 20–75 years; at least one chronic medical disease (e.g. diabetes or coronary heart disease); experienced in using IT;

and a positive attitude to IT services. The definition of data in this study means all data which can be collected in a way that makes sense for a holistic health care IT service approach. For example: food, preparation of food, weight, sports, health data and history, stress profile, genetic risks if testing available, environment, sleep time and quality, regeneration profile, hygiene profile, sun exposure, and protection. The integration of various electronic sensors and devices is required. We emailed 67 directors of small and midsized technology companies in the health care industry in Germany and Belgium to ask for interviews. Just 17 replied and 8 accepted an interview.

Primary Data

For this follow-up study, we chose a multicenter study with two steps. First, we used a qualitative research method, where we interviewed eight directors of small and midsize German and Belgian technology companies in the health care sector. We asked about their views on future scenarios of technological products and services for patients based on present or future technologies and concepts. In parallel we interviewed 16 patients, who had a combination of dental and medical illness history, about their expectations of such products in the future, and their willingness to transfer their personal data to an open innovation driven health care company. We then clustered the interviews in three main sectors on the industry and patient side. Next we designed a prototype IT model, and in step two of the study we presented it to patients who met our inclusion criteria. Using a quantitative research method, we asked them questions from a standardized questionnaire, designed based on the experiences of the interviews.

Data Analysis

After the interviews (step 1), the main subjects discussed were identified and written down. Later the main subjects of the interviews were coded. The coding helps to identify patterns, and to develop a list of standards from the point of view of the industry and of the user.

The questionnaire that was used to ask questions to users (step 2) was designed based on the results of the interviews. It reflected the most important subjects that came out of the interviews. Finally, the users' answers to the standardized questionnaire were analyzed using statistical analysis software (IBM SPSS 22.0).

Future Health Care IT Service Prototype Model

This prototype model of a future health care IT service included currently available IT applications in combination with currently available sensor systems technology and electronics, but the combination concept itself is not currently available and represents a future technology approach. This future concept allows users (patients), as the legal owner of their data, to transfer all dental, medical, and other data that they and the company define as relevant, to the health care company (subject to the user's consent), in order to receive an efficient health care service. The open innovation process allows every single user to see anonymous data from other customers, to benefit from research results based on outcomes from the common data pool of this specific user community, and to interact directly with the company to communicate user wishes. These can then serve to develop an individual evolution model in a very short time to meet user needs.

2.2.1 Findings

On the user side, the results showed that the factor of being able to influence the future IT service in health care through an open innovation process was important to 91.1% ($n = 748$) of the patients. The security of IT data came in second place with 89.4% ($n = 734$). In third place was the ability to benefit from scientific research results based on the data pool of the future IT service community, with 86.6% ($n = 711$). If these three important standards of an open innovation process, IT security, and scientific results from the community data pool would be guaranteed, overall 87.8% ($n = 721$) of the patients would be willing to transfer their whole medical and non-medical data as mentioned above, in order to receive an efficient health care service.

2.2.2 Conclusions

The results of the paper showed that patients who satisfied the inclusion criteria identified three important factors as being a required standard before they would be willing to transfer their medical and non-medical data: an open innovation process which integrates users and their ideas, IT security, and the ability to benefit from the data pool (research results) of the users of this service. Provided these three standards are met, the empirical study showed significantly that there is high user (patient) willingness to transfer personal medical and non-medical data to a future IT service provided by open innovation driven health care companies, in order to receive an efficient health care service.

This paper made a contribution to understanding users' relevance in and their willingness to participate in the open innovation process (Von Hippel et al. 1999), what standards are expected from the users' perspective in the open innovation process (Chesbrough and Bogers 2014) and how far companies have to open themselves up in the open innovation process (West 2003) to succeed in the future health care services market.

2.3 Results from Study No. 3

After processing the results of studies no. 1 and no. 2, which were presented in 2014 and 2015, we started to discuss the next research study. Electronic health records (Atasoy et al. 2019), boundary risks, emotion, and consumer willingness to disclose personal health information (Anderson and Agarwal 2011), and the new challenges and opportunities resulting from digitalization in health care (Menvielle et al. 2017) will influence the acceptance of future health care on the patients' side. So the question was: What level of acceptance does digitalization in health care have from the patients' perspective, especially in the hospital environment?

Study Design

We conducted a multicenter study in three dental clinics and one clinic of general medicine. The clinics were in the cities of Bonn, Leverkusen, Cologne, and Düsseldorf (Northern Westphalia, Germany). The age of the patients ($n = 142$) was between 20 and 85. Between January 2019 and June 2020, a questionnaire was put to patients, who were chosen at random. 36 patients were asked in each practice. The patients could answer “YES” or “NO.” The inclusion and exclusion criteria for the persons surveyed in this research study were as follows:

Inclusion criteria:

- Individuals who had been treated in hospital at least once.
- Age: 20–85 years.

Exclusion criteria:

- Individuals who had never been treated in hospital before.
- Age: younger than 20, older than 85 years.

We also asked the patients about why certain processes should be provided in person. The responses from this qualitative part of the study will be published at a conference in 2022. We took 14 processes that occurred frequently for us in the hospital environment, and asked patients about their acceptance if this process would be led by artificial intelligence (AI), robotics, or an automated voice. We also asked if communication with the hospital staff and physicians could be delivered through an iPad, augmented reality (AR)/virtual reality (VR), or an avatar.

Pre-results

We are still in the process of analyzing the demographic parameters with SPSS and performing the qualitative part of the evaluation, but as pre-results we can give readers the following information. Here are the current initial statistical findings on patients’ acceptance (as percentages):

1. Check-in: (AI driven, automatic voice) 92%
2. Waiting room and call to go to the treatment room: (AI driven, automated voice) 84%
3. Providing data about personal medical, dental and mental history: (AI driven, automated voice) 56%
4. Going to the X-ray room and getting an X-ray: (AI driven, robotics, automated voice) 31%
5. Taking blood: (AI driven, robotics, automated voice) 6%
6. Receiving diagnosis information from the staff or physicians: (via iPad, AR/VR, avatar) 14%
7. Educational information about the treatment: (via iPad, AR/VR, avatar) 23%
8. Educational information about drugs: (via iPad, AR/VR, avatar) 21%
9. Receiving information about a bad prognosis: (via iPad, AR/VR, avatar) 1%

10. Receiving information that a family member has died: (via iPad, AR/VR, avatar) 2%
11. Receiving information about, e.g. a non-operable cancer diagnosis: (via iPad, AR/VR, Avatar) 0%
12. Being transported in self-driving hospital beds: (AI driven, robotics) 64%
13. Condition monitoring by apps: (AI driven, automated voice) 81%
14. Post-treatment feedback services, customer satisfaction questions: (AI driven, automated voice) 76%

The pre-results show that standardized processes like check-in, being called from the waiting room, entering an X-ray room, condition monitoring by apps, and self-driving hospital beds have a certain high acceptance, but if it is a serious talk about non-operable cancer or a terminal diagnosis, the patients want to have a personal talk. This face-to-face interaction has still an extremely high value for the patient. Unfortunately, from the global perspective of all international health care systems, it is often the case that nothing like enough time or resources are available for this kind of personal interaction. This scarcity will only increase in the future.

3 Conclusions

Today, with regard to digitalization in health care, it may seem that from the patients' perspective "face-to-face interaction" is the dominant requirement for the acceptance of communication in health care systems, especially in the hospital environment. But the future will change everything. Health care systems do not have much time for feelings. This time for personal contact will be a luxury in the future, for those who can afford "face-to-face interaction." If an AI system can analyze an X-ray, the AI can also transfer the patient and their data to the next doctor or department. Robots can take blood, information can be transmitted digitally and communicated by automated voices, avatars, or fantasy characters, and no face-to-face interaction is needed. If the pre-surgical or pre-treatment discussion is standardized, a virtual talk (telemedicine) or a video is acceptable. Notifying the death of a family member by tablets, avatars or AI is out of step with today's ethical standards, but in times of social distancing (coronavirus), with time constraints caused by economic pressure in the health care system and fewer people willing to work in health care, these kinds of automatization, digitalization, and cost-optimization strategies will open the doors to the increasing dominance of AI, telemedicine, and AR/VR in health care with less and less face-to-face interaction. This process is unstoppable. And by the way, as unethical as this "no face-to-face communication" or long-distance telemedicine combined with AI and robotics seems to be, for space travel and the colonization of new planets, this kind of health care system will be the standard of the far future.

Summarizing these three research studies, it seems that the issue is not so much digitalization and automatization as such—even the transfer of health care and non-medical data seems acceptable to patients—but rather the strong desire for face-to-face interaction in one room. Further research over the years ahead will deliver more results in this field and give a better understanding of digitalization in health care from the patients' perspective. AR/VR technologies, new AI applications, and new haptic innovations could one day perhaps give patients the feeling of "face-to-face interaction" even if the physician or staff is not present. This could emotionally help individuals and families to deal with very sad news. We need innovative products and services for the new mode of "face-to-face interaction" to solve the problems of the future in health care from the patients' perspective.

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Digitalization in Rehabilitation

Pantea Pape

1 Introduction

How essential continuous and sustainable digitalized patient care is, we were recently able to experience first hand in the "Corona era" with social distancing. Meetings take place virtually. Patients communicate with their doctor from their living room via video. Digitalisation is an unstoppable phenomenon in all areas of life and also in health care. Genome sequencing data, health apps, or the electronic patient file are prominent keywords.

Big Data aims to elegantly revolutionise medical care by tracking down correlations in huge amounts of data. Doubts are countered with even more data. The basic methodological principles of evidence-based medicine are often ignored. However, the detection of causalities or the identification of benefits and harms in clinical studies are indispensable quality pillars in modern healthcare.

The introduction of the telematics infrastructure and the online applications of the electronic health card are the prerequisites for a nationwide digital networked health care system in Germany. With the E-Health Act coming into force at the beginning of 2016 and the start of the nationwide rollout of the telematics infrastructure in June 2017, the digitalization of the health care system in Germany has come to life. But what are the real benefits of digitalization for medicine and thus for the patient?

In its eight-point program, the National Association of Statutory Health Insurance Physicians supports the digitalization of health care in Germany on the basis of the concept "KBV 2020—Designing Care Together". However, the applications must be secure, cost-neutral and beneficial, and must ensure interoperability (Kassenärztliche Bundesvereinigung 2017).

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Two decisive trends that health policy will have to face in the coming years are demographic change and digitalization. The ageing of society requires new technologies in medicine and offers new opportunities for better and more efficient care. The aim is to maintain the independence of older people. At the same time, employees should work longer and longer and even the conditions for employment beyond the standard age limit should be made more attractive. Keyword: “Flexi Pension”. The so-called flexi pension in Germany was adopted at the end of 2016 in the “Act to make the transition from working life to retirement more flexible and to strengthen prevention and rehabilitation in working life” (‘Flexirentengesetz’). The Flexi-Rente should enable insured persons to improve their pension earlier and more flexibly.

However, many people are already not reaching the regular retirement age because their health is too poor. For this reason, the law on flexible pensions is intended to strengthen prevention and rehabilitation, for example, by means of instruments such as job-related check-ups, so that rehabilitation needs can be identified at an early stage. All this is, however, leading to ever increasing cost pressure in the health system too. It is therefore necessary to increase the efficiency of the system by adapting structures and regulatory requirements in such a way that more efficient service provision is possible. This means above all outpatient care, integrated care, improved patient control, case management and digitalization. This requires a stronger network formation up to network medicine and rehabilitation. Medicine and IT are growing ever closer together. Central keywords are e-health, telemedicine and telemonitoring.

The German Association for Rehabilitation (DVfR) was founded in Berlin on 14 April 1909 as the “German Association for the Care of Cripples”. The development from cripple care to modern rehabilitation was accompanied by a successive paradigm shift, no longer regarding the person affected as a recipient of benefits in need of help, but as a self-determined actor with the right to participate in society. The “law about harmonisation of rehabilitation benefits” (“Reha-Angleichungsgesetz”) that came into force on 1 October 1974 formally integrated the statutory health insurance funds into the group of rehabilitation service providers.

With the entry into force of the Ninth Social Code (SGB IX)—Rehabilitation and Participation of Disabled Persons—on 1 July 2001, the lengthy process of further developing and redesigning rehabilitation and disability law, which had lasted almost three decades and which the German Association for Rehabilitation had helped to shape from the outset, came to a provisional conclusion. More details are provided in Table 1.

Within a century, the German Association for Rehabilitation has transformed itself from an association focussing on physically disabled children and young people to an organisation encompassing all groups and aspects of the rehabilitation system.

§ 1 SGB IX Self-determination and Participation in Life in Society states that persons with disabilities or persons threatened by disabilities receive benefits according to this book and the benefit laws applicable to rehabilitation providers

Table 1 German social codes (SGB)

German social code Listing of German social code I–XII			
German Social Code I	*General part*	since 1. January 1973	Contains the basic programme of the SGB as well as definition and procedural regulations
German Social Code II	*Basic provision for job seekers*	since 1. January 2005	Includes the promotion of employable persons over the age of 15 up to the standard age limit of 65 or 67 as well as their relatives, if they do not have a sufficient income
German Social Code III	*Employment promotion*	since 1. January 1998	Concerns the services of the Federal Employment Agency (job placement and unemployment benefits)
German Social Code IV	*Common rules for social security*	since 1. January 1977	Regulates not only the law on total social security contributions and the definitions of basic social security concepts, but also the constitution of the social security institutions (organisation, social security elections, budget and accounting)
German Social Code V	*Social health insurance*	since 1. January 1989	Concerns the organisation, compulsory insurance and services of statutory health insurance funds and their legal relations with other service providers (doctors, dentists, pharmacists, etc.)
German Social Code VI	*State pension insurance*	since 1. January 1992	Concerns the organisation and benefits of the institutions of the German pension insurance (pensions due to old age, pensions due to reduction in earning capacity and survivors' pensions; benefits for medical, occupational and other rehabilitation)
German Social Code VII	*Statutory accident insurance*	since 1. January 1997	Betrifft organisation, Versicherungspflicht und Leistungen der gewerblichen und der landwirtschaftlichen Berufsgenossenschaften sowie der Unfallkassen der öffentlichen hand für die Versicherungsfälle Arbeitsunfall, Wegeunfall und Berufskrankheit
German Social Code VIII	*Child and youth welfare*	since 1. January 1991	Concerns offers and services of the public youth welfare institutions (especially youth welfare offices) to children and young people entitled to or in need of help as well as their parents and young adults
German Social Code IX	*Rehabilitation and participation of disabled people*	1. January 2001	Has the purpose of promoting self-determination and equal participation in life in society for disabled persons and persons at risk of disability and to avoid or counteract disadvantages
German Social Code X	*Social administration procedures and social data protection*	1. January 1981	Regulates the administrative procedure under social law, the protection of social data as well as the cooperation of social service providers among themselves and their legal relations with third parties
German Social Code XI	*Social care insurance*	since 1. January 1995	
German Social Code XII	*Social welfare*	since 1. January 2005	

in order to promote their self-determination and their full, effective and equal participation in life in society, to avoid or counteract disadvantages. Account shall be taken of the special needs of women and children with disabilities and of women and children at risk of disability and of persons with mental disabilities or at risk of such disabilities.

Rehabilitation is thus the silent star and at the same time a beacon of the health care system. Medical rehabilitation serves to restore participation in all areas of life.

Digital aids already increase the participation of those affected. It is estimated that rehabilitation measures keep well over 100,000 people a year fit for work who might otherwise have left the workforce early. It is therefore also a question of cost reasons for the welfare state. After all, a rehabilitation measure to maintain the ability of a person affected to work is of course cheaper than having to pay a permanent reduced earning capacity pension or even for lifelong care. This is another reason why the motto is "rehabilitation before nursing care".

Central aspects in rehabilitation are education and self-management. It is precisely here that digital applications can provide lasting support for desired changes in behaviour through clear objectives, interactive learning content, feedback functions and social reinforcement. Also in the field of rehabilitation aftercare, digital solutions can help to stay in contact with the person concerned and to transfer learned health-promoting behaviour into everyday life.

Digital technologies have permeated almost every aspect of our world today. Over the past decade, national and transnational organisations have developed strategies and action plans to help citizens and businesses make successful use of digital technologies. Digital technologies play a key role in promoting inclusion and preventing inequality (Fuchs and Bock 2018), making them central to ensuring fair and prosperous societies.

Rehabilitation facilities have to reckon with a fixed daily rate for each rehabilitant, and individual rehabilitation facilities are increasingly finding it difficult to keep to their budget. The individual therapies are personnel-intensive. Each rehabilitation facility has various specialists, physiotherapists, occupational therapists, speech therapists, etc. on its payroll. Whereas in the past, perhaps several physiotherapists had to laboriously help stroke victims, for example, to relearn how to walk, today an assistance system is often used. Thus, a therapist who supervises the exercises while the patient is moved by a robot or can move in a targeted and gentle manner with its help is all that is needed for his recovery.

However, the efficiency and success of the individualised rehabilitation measure stems from a healthy mix of classic and digital-robotics-supported therapy (Mehrholz et al. 2017). People who receive electromechanical-assisted gait training in combination with physiotherapy after stroke are more likely to achieve independent walking than people who receive gait training without these devices. We concluded that seven patients need to be treated to prevent one dependency in walking. Specifically, people in the first 3 months after stroke and those who are not able to walk seem to benefit most from this type of intervention. The role of the type of device is still not clear. Further research should consist of large definitive pragmatic phase III trials undertaken to address specific questions about the most effective frequency and duration of electromechanical-assisted gait training as well as how long any benefit may last.

It is also very important to have regular self-training, which the rehabilitee should carry out at home every day outside of therapy, for example, at the weekend or after rehabilitation. Those affected with high self-motivation and regular self-training achieve significantly better treatment results than those who only follow the prescribed therapies. For this very reason, the market for technical devices that are controlled via smartphone apps or check the execution of exercises is also becoming increasingly larger.

Neurological rehabilitation has been growing rapidly in importance in recent years. It aims to improve and stabilise brain functions and builds on the plasticity of the brain. On this basis, further therapeutic advances are emerging. It has been recognised that neuroplasticity is of great importance for the implementation of therapeutic concepts. Rehabilitation is a process in which the aim is to offer the most appropriate individual treatment. Because the therapies are sometimes time-consuming and energy-sapping, but also involve many repetitive forms of movement, new therapy methods, particularly technical-digital methods or robot-assisted procedures, have been developed further and are being introduced at rehabilitation clinics to an increasing extent. For people with cognitive impairment, there are promising opportunities for the use of innovative technologies in diagnostics and therapy (Müller and Schiering 2019). In addition to the use of notebooks and tablets, smart devices such as smartphones, smart watches, smart glasses and digital games for health (DG4H) can be used to support therapy or as a means of compensation (Culley and Evans 2010; Fish et al. 2008; Jamieson et al. 2017; Wiemeyer 2017).

The research project in September 2018 started the interdisciplinary third-party funded project "SmartInclusion" (Schiering, I., Müller, S. V.) at Ostfalia University in Wolfenbüttel, which is funded by the BMBF. The German Red Cross in Wolfenbüttel, the Academy for Advanced Training of the German Economy (FAW) and the medical technology company Hasomed from Magdeburg are involved in the 3-year joint project as joint partners.

The aim of the "SmartInclusion" research project is to provide digital support for people with intellectual disabilities in their professional (re-)qualification using mobile devices (smartphones, smart watches and smart glasses). While in medical and social rehabilitation the rehabilitation process is largely standardised with regard to functional deficits (memory, perception, etc.), vocational rehabilitation is characterised by the special requirements of the respective workplace. This results in a great heterogeneity and differentiation, which has so far been encountered in personnel-intensive, individual care relationships in vocational rehabilitation. Digitalisation is opening up new support possibilities here. Digital support via mobile devices is being implemented by implementing the "SmartInclusion" platform, which consists of a web application in combination with mobile applications, using a modular system. For users, the platform presents itself as an app that guides them through professional processes. With the RehaGoal App, work processes can be implemented individually and in a data protection-friendly manner.

The aim of this app is to break down barriers and build up independence. The project “SmartInclusion” is the continuation of the sub-project “The use of mobile devices in rehabilitation” in the current research focus “SecuRIn—Security Reference Model Industry 4.0”. Here, a widely used and well-evaluated intervention procedure, the “Goal Management Training” (GMT), was implemented as an app. In the SmartInclusion project, the existing app is being expanded to include the modules Orientation (OR) and Motivation Promotion (MF) and a clear focus is being placed on professional participation. With the RehaGoal App, work processes can be implemented individually and in a data protection-friendly manner.

Individual workflows can be realised very easily and individually with the help of workflows. This makes it possible to guide the rehabilitant through different tasks at different locations and to provide technical support in navigating between locations. The following scenario should illustrate the use of the app in a professional context: A user works in a cafe in the context of supported employment and should make a cappuccino. For this purpose, it is necessary on the one hand to divide a complex activity into sub-steps such as (1) Providing a cup, (2) Choosing the type of coffee, (3) Preparing coffee, (4) Serving coffee. The RehaGoal app, which runs on a smartphone (https://www.smarte-inklusion.de/) or a Smartwatch (https://www.ostfalia.de/cms/de/pws/muellers/.content/documents/Per-App-zur-Inklusion_NOT.pdf), for example, guides the user(s) through the various tasks and to the various locations in a simple, unobtrusive, error-free manner and without losing the thread. It thus serves the professional inclusion of people with intellectual disabilities in the primary labour market, who would have a much harder time without (digital) aids (Schiering and Müller 2019).

Depending on the severity of the impairment, this app can be used as a compensatory tool or as a method of behaviour management. If the user can only carry out the action steps correctly with the RehaGoal app, even in the long term, then the app is used as a means of compensation. However, if the mobile application is used in the sense of an intervention for behaviour management, then the workflows are adapted to the changing competence of the user (Levine et al. 2000a, b). Digital Games for Health (DG4H) used in rehabilitation include serious games such as EduGames, games for educational purposes and ExerGames for movement purposes and have now become a recognised form of intervention (Wiemeyer 2016). More generally, Serious Games can be assigned to certain areas of competence, especially prevention and rehabilitation. Accordingly, game genres and their game mechanics can be assigned to each area of competence (Wiemeyer 2017). In the neurocognitive competence area, thought and perception processes are promoted. If one refers these to game genres, then above all strategy, adventure, action, thinking and construction games are indispensable, since the game mechanics projected there are identical to the cerebral thought process of humans. Situations must be captured and evaluated, decisions made and problems solved on the basis of existing knowledge. By means of the graphic representation of the consequences of an action, the events caused can be questioned: Was the choice the right one to accomplish the task? The mental processes of players when choosing a strategy are complex. They have to analyse situations, understand the problem at hand, recognise the different choices in a given situation, grasp the difficulties, think of a solution, anticipate possible consequences of their decisions, decide which option they prefer and implement the chosen action. In addition, in order to make a decision at all, certain conditions often have to be met (e.g. understanding what actions are possible in the game, how the character can move, what possibilities for interaction exist, etc.). The perceptive area of competence comprises the sensomotoric abilities of the human being, such as eye-hand coordination or reaction ability. By sensomotoric—perceptive is thus meant the interaction of the perceptive nerve impressions (afferences = sensory) and the executing nerve impulses (efferences = motoric) in the very individual, unconscious perception context of the recipient (perceptive) (Krull Praxis 2018). Typical for the genre are action or shooter games in this area of competence. The game element usually follows the principle of localisation of objects and events and therefore claims the ability to orientate in space. The motor skills area includes physical characteristics such as strength, endurance and flexibility. Vestibular perception and reaction time also belong to this area. In digital games they often appear as movement games—exergames—and sports games (Kroll and Neubrand 2012). And finally, one of the most important areas of competence is the social. The basic urge to compare oneself is in the nature of man. In the social environment, cooperation, conflict, competitive thinking is encouraged and value systems are formed. As De Kort et al. describe in the study on online games, social networks can be maintained through local multiplayer games or through online games (De Kort et al. 2007). In terms of the game genre, role-playing games are particularly effective.

The far more efficient strategy is based on the patient-oriented development of neurogames. This is where the gamification process depicted in Fig. 1 comes into play, i.e. the gambling away of already known therapeutic and preventive measures. In doing so, the game developers largely use the interfaces already on the market—so to speak, the interfaces that enable communication between the game and the player, such as gamepads, balance boards or gesture control using Kinect cameras.

First and foremost, the mechanics of the game are at the forefront of the rehabilitation or prevention process (Ascolese et al. 2018). Since this process often proves to be lengthy and repetitive, developers also work closely with the patients to be treated in terms of game design. In the end, the patients must like the game, as they actively participate in the action. This close cooperation can already help to eliminate alleged differences during the development phase, which in retrospect would require an increased expenditure of time and money for the correction. In this way, an iterative process is used from the outset to make the game effective and efficient, satisfactory and user-friendly (Norman 2004). Apps or technical devices can also be used as preventive measures to effectively prevent some expensive rehabilitation measures in advance. These digital possibilities are discussed below. The ARYS system from yband therapy records the arm movements of hemiparesis or stroke patients. With the corresponding smartphone app, the progress in rehabilitation is visualised (Jakob et al. 2018, http://www.kbv.de/media/sp/2017_05_22_KBV__Acht_Punkte_Programm_Strukturwandel).

Robot-assisted therapy complements the previous classical therapy methods and often improves the motivation of the rehabilitee during a longer rehabilitation

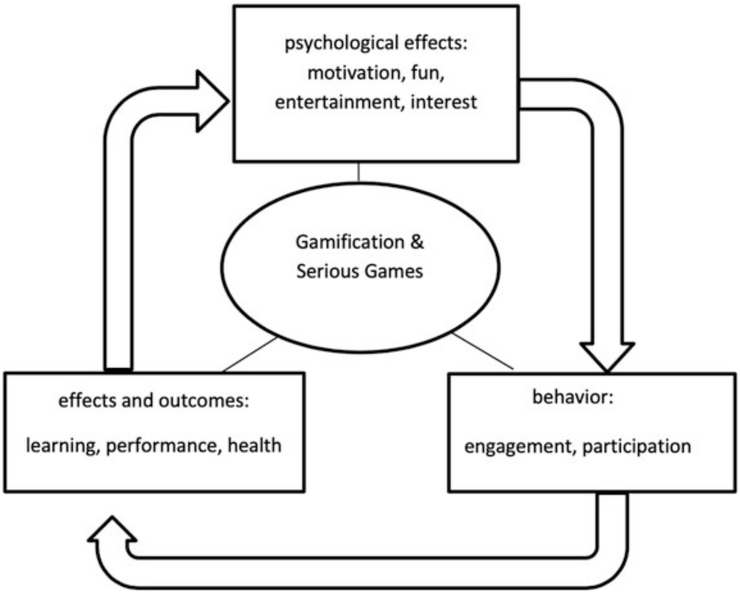

Fig. 1 Effect of serious games on behaviour change according to Wiemeyer (2016). Source: author

process. The robot-supported therapy methods do not replace classical therapy methods in physiotherapy and occupational therapy (such as Bobath, PNF, Vojta etc.). A big disadvantage of these robot-supported procedures is unfortunately that these devices are very expensive and therefore many rehabilitation clinics cannot afford them. For occupational therapy or physiotherapy practices these devices are usually not affordable at all.

The Armeo Therapy Concept from the Hocoma company is aimed at rehabilitation patients who suffer injuries as a result of a stroke, craniocerebral trauma or other neurological diseases which, among other things, lead to impairment of hand and arm functions. Studies show that intensive, repetitive and task-oriented therapy exercises on the affected arms in combination with a technical aid/therapy device have a very positive effect on the improvement of capability and functional disorders of the affected arm (Colomer et al. 2013; Daunoravicienea et al. 2018). There are three Armeo treatment devices.

The Armeo Therapy Concept from the company Hocoma is aimed at rehabilitants who have suffered the consequences of a stroke, a craniocerebral trauma. The ArmeoPower is a robotic arm exoskeleton that allows complete relief of the affected arm and actively supports the affected arm electromechanically, even if it shows no activity. The ArmeoSpring System, which is used at the Neurological Therapy Center Cologne, is an ergonomically adapted arm orthosis (“metal arm”) with a spring mechanism. The rehabilitant must already be able to move the arm easily in an active position, as he must guide the “metal arm” himself.

ArmeoBoom treatment concept consists of a sling system for arm weight relief. The patient can freely move the affected arm in a sling to perform exercises (for an illustration follow this link: https://www.az-heinke.de/wp-content/uploads/Armeo-Spring-3-1030x687.jpg).

All three Armeo devices are connected to a computer and the movements are displayed (visualised) on the screen. Interesting computer games are offered by the manufacturer of the device in the software program and greatly enhance the motivation of the rehabilitee. Furthermore, the computer software provides feedback to the rehabilitant and the therapist about the success of the exercises performed. The reporting possibility, i.e. the recording of the therapies by such technologies is important. Data becomes more transparent, measurable and can be entered into other systems/software and packed into the digital patient file. With regard to the effectiveness of improving the movement restrictions of a paralysed arm, the Armeo treatment method can be considered equivalent to the classic physiotherapeutic or occupational therapy concepts. This has already been demonstrated in many studies. However, the intensity of training is somewhat more intense with the Armeo method than with traditional methods, due to the motivational factors described above.

In order to train walking, high-frequency intensive gait exercises are required, similar to the Armeo, to promote neuroplasticity. For this purpose we use Lokomat in the Neurological Therapy Center Cologne.

During rehabilitation, patients must be challenged according to their individual abilities and beyond. Speed, load and robot support can be adjusted to the optimal therapy intensity (Exoskeleton Report 2020, https://exoskeletonreport.com/wp-content/uploads/2016/09/L6-LN-group_Hocoma.jpg).

The Lokomat is a robotic device to train walking ability. The Lokomat enables functional locomotion therapy that can be tailored to the individual needs of the rehabilitee. Assessments and feedback functions can also be used. The Lokomat training enables intensive patient therapy even in the early stages of rehabilitation, provides sensory feedback and leads to a physiological gait pattern through an individually adjustable exoskeleton and gait pattern (Van Kammen et al. 2019). The executive and weight support options can be individually adjusted and support the rehabilitee exactly when he or she needs assistance. This enables training above the rehabilitant's current abilities. The limitations of manual treadmill training are the physical strain on the therapist, at times even several therapists are required, limited training duration and intensity, limited feedback for the rehabilitant and lack of physiological or reproducible gait pattern. In contrast, the Lokomat uses Augmented Performance Feedback to increase the rehabilitation patient's own activity. Through precise assessments of the therapy sessions, even the smallest improvements are made visible to the rehabilitant, which increases motivation enormously. The integrated therapy games also maintain the rehabilitant's motivation and encourage a higher number of repetitions. The focus of the rehabilitant is directed away from the therapy and towards the therapy games, whereby pain and limitations are pushed into the background and therapy can be made more motivating and challenging. In addition to robot-supported and motor-assisted therapy, rehabilitation measures are increasingly taking place in virtual reality. Computer-based methods appear to be effective and efficient. Virtual Reality is used for three-dimensional and individualised movement and gait analysis. Research teams point out that these methods certainly promote patient motivation, not least when gamification aspects are still being incorporated into the therapy units. The visuo-spatial navigation in simulated reality that is possible here promotes training and rehabilitation through a high degree of immersiveness (Piefke and Ehlers 2019). Especially in rehabilitation, digitalization could help to save costs and improve care. In health care, it helps patients with a wide range of complaints to improve their quality of life through targeted forms of therapy. As part of the innovation project for the medical care of patients with stroke, heart attack or similar serious acute illnesses, health insurance companies are breaking new ground. Numerous studies have shown that digital self-training in aphasia leads to effective linguistic improvements (Lavoie et al. 2017; Zheng et al. 2016). For patients living with aphasia, the loss of speech ability due to a disease of the speech centre in the brain, health insurance companies will cover the costs of a new digital support "Aphasia-App Neolexon" (An exemplary exercise for patients' understanding of reading senses is given under the following link: http://www.kbv.de/media/sp/2017_05_22_KBV__Acht_Punkte_Programm_Strukturwandel).

With the app for speech therapy developed by the two speech therapists Dr. Mona Späth and Hanna Jakob, patients can practice independently and thus reactivate their language skills in the speech centre. The app is individually adapted to the insured person and, thanks to its digital approach, is a supplement to speech therapy treatment. The app allows you to set the theme and difficulty of the exercises individually for everyone. It is based on speech-therapeutic research into what a therapy should look like in order to help people with aphasia to learn to read, speak, understand and write again (Jakob et al. 2018). In this article, we can use the example of Sturz to illustrate the role of digitalization close to everyday clinical practice. Falls are a major risk for maintaining quality of life. Frequently, falls in old age are associated with increased morbidity and mortality and often lead to social isolation and loss of independence. Effective fall prevention is also possible for frail people, i.e. fragile very elderly people, so to speak. To this end, individual fall risk factors must be systematically recorded and multi-factorial measures for fall prevention must be implemented. In the case of fall prevention, the technology and IT work together with smartphones, artificial intelligence (AI) and a 3D model and show great added value. E.g. the start-up company Lindera does a mobility test consisting of a 30-second video of a 3D gait movement of a walking person with a simple smartphone camera, a psychosocial test, analysis and suggestions for prevention measures. This enables precise and objective movement analyses on the spot with the mobile phone—in the living room at home as well as in the doctor's practice.

This is just one example of modern medical, nursing and therapeutic care. Not only senior citizens and their families benefit from this technology, but also their attending doctors. It helps doctors, especially in rural areas, but also, as in the current situation with the Corona crisis, to determine the fall risk of their patients in a time-saving and objective manner and to provide patients with immediate individualised and evidence-based prevention measures.

In the field of digital fall prevention, there are several solutions that analyse the mobility of senior citizens in terms of their fall risk. For an analysis, sensors on the body must be adjusted. In the future, however, solutions that can be easily and quickly integrated into everyday care and that optimise existing fall prevention processes will become increasingly popular (Hua et al. 2018; Ganz and Latham 2020). In the field of neurorehabilitation, it is thus possible with certain algorithms to record parameters of the individual gait pattern, the ability to balance and the extent of movement and thus to evaluate, for example, the effectiveness of physiotherapy or occupational therapy and drug interventions.

Through objective feedback on the execution of therapeutic exercises, patients can be enabled to carry out medical training interventions independently and under guidance.

Already in advance, such apps can effectively prevent some expensive rehabilitation measures as preventive measures. The E-Health Act, which has been in force since 2016, stipulates that every insured person in Germany will be entitled to an electronic patient file (ePA) from 2021. This will allow important documents such as doctor's letters, medication plan, emergency data record or vaccination card to be stored.

In May 2018, the German Medical Association also agreed to a relaxation of the ban on remote treatment. Since then, telemedical care of patients is basically possible. Electronic patient files prevent dangerous drug interactions, telemedicine connects doctor and patient no matter where they are, and health apps strengthen chronically ill patients. All of this would be possible in Germany, but digital progress is not reaching patients sufficiently, a recent Bertelsmann study shows. "While Germany is still exchanging information on paper and working on the basics of digital networking, other countries are already taking the next steps", says Brigitte Mohn, member of the Bertelsmann Stiftung Executive Board. However, the new technological possibilities in Germany are not available nationwide and cannot be used for all patients. So far, little has been achieved in everyday care.

Regarding to the Digital Health Index, Estonia is at the top with a value of 81.9, followed by Poland with the lowest index value of 28.5 and Germany with 30.0 (a graphic display of the ranking is provided under the following link: https://www.bertelsmann-stiftung.de/index.php?id=11340#c1203567).

The better and more comprehensive the information content during the transition period from hospital to rehabilitation, the more individually the treatment plan can be adapted to the rehabilitee. The electronic file and the electronic discharge letter serve this purpose. Paper is no longer used. Medication and other orders are arranged digitally and can be accessed from anywhere. The tool Medication helps in placing orders/medication digitally which is being made visible for nursing staff through the digital signature and can be implemented immediately on the PC, thus deciphering of illegible handwriting and the eternal search for patient charts is no longer necessary. In an inpatient setting, we can no longer imagine the daily routine on the ward without an electronic patient chart. Processes on the wards are noticeably optimised. On the one hand, nursing staff can work out the doctor's orders at any location and computer even during the ward round. On the other hand, Medication increases transparency as to which medications were administered at which times or why administration was not possible. The interdisciplinary team can therapeutically extract all information about vital parameters, diagnoses, therapy goals and findings from the digital file and document them simultaneously.

2 Strengths and Weaknesses of the Current Offer

In addition to the lack of flexibility of our healthcare system, which cannot keep up with the pace of digitalization, the issue of data protection is a factor that cannot be ignored. IT security and support are necessary.

The instruments of technology assessment have existed for years, especially in medicine known as Health Technology Assessment (HTA). The basic model is the evaluation of benefits, risks and costs. Every effective intervention in medicine should undergo such an assessment, as is the case with pharmaceuticals. Health apps are reimbursed by health insurance companies without requiring proof of effectiveness. Currently, an app against tinnitus shows an exemplary erroneous development with regard to reimbursement (Stein 2016). Furthermore, it should not be forgotten that the data are sensitive patient data, which are particularly threatened by cybercrime. In addition, it should be remembered that a system failure can mean fatal data loss and, in the worst case, can cost lives. Data backup processes must therefore be adapted, especially if they are only carried out electronically. Appropriate equipment for telemedicine with especially powerful PCs is essential.

3 Conclusion

The advance of the digital revolution is bringing more and more possibilities to light, the variance of which is at the beginning of research. Digital games are no exception. Like every new medium, they contribute to the shaping of society and, vice versa, are depicted by it. The demand for new media that can be used for research purposes is constantly growing and can only be satisfied by a reflected conception and production of such media. This is why the phenomenon of digitalisation is in itself an evolutionarily so complex, proactive system that has far more potential than simply being a pastime. German rehabilitation facilities are nowhere near the way they are shown in the picture. The right infrastructure is still needed before doctors can view their patients in 3D on a virtual screen. The general nationwide implementation of the infrastructure is faltering—especially the electronic patient file. Future-oriented rehabilitation is not only based on the most modern therapy equipment, but also requires an interaction between "man and machine" (as visually displayed by the figure under the following link: https://www.rehacare.de/cache/pica/6/1/6/1/2/6/1/306911551363279/vollebreite_Digitalisierung-Krankenhaus_c-panthermedia-net.jpg).

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Digitalization in Dentistry

Philipp Plugmann

1 Introduction

The age of digitalization and innovation has hit the health care sector like a lightning bolt. Especially the process of dealing with the corona crisis has shown the need for digital communication, digital networking, telemedicine, and more. The influence of digitalization in health care is stronger than ever. Dentistry is already undergoing a digitalization process. The digital workflow starts with paperless clinics, meaning the whole documentation and patient management system is digitally driven. Dental imprints can be taken with an oral surface scanner, then the captured data can be optimized on-screen and sent to a CAD-CAM center, or milled in the clinic's own laboratory (using systems such as Cerec from Sirona or Tizian from Schütz Dental Group). Orthodontic treatment is also digitalized, and information for dental lab technicians can be transferred digitally too. Radiology and imaging services in a dental practice are usually digital, so there is no need to search for X-rays in filing cabinets, and the pictures are available quickly and easily on the servers.

This article gives you an overview of several innovative technologies whose history and development are leading the digitalization of dentistry into a new age. Risk factors like cyber crime and data privacy violations also need to be taken into account as dental patients get digital.

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2 3D Printing Technology

By itself and in combination with other technologies, 3D printing has enormous potential. Possible scenarios include building houses on the moon, manufacturing parts for cars or airplanes, and even producing biological structures like segments of skin for patients with accidental skin burns. The additive production process of 3D printing features in several future digital business model innovations (Feldmann et al. 2019).

The fact that 3D printing technology can be used in different industries makes it a good example of successful innovation management. So it was just a question of time until 3D printing arrived in dental medicine. The technology was developed in 1983 by the American Charles Hull (Ponsford and Glass 2014). It works by melting a material—e.g. plastic, metal, or resin—to gradually build up a structure which is defined by a software program that is influenced by the user. The history of 3D printing is over 40 years old (Fastermann 2012; Ponsford and Glass 2014; Feldmann et al. 2019).

The classification of 3D printing (Gebhardt 2017) is divided into three categories: solid, liquid, and gaseous. The material is applied in layers, which contrasts—and competes—with ablating technologies like CAD-CAM milling machines. With 3D printing, new dental crowns and bridges can be manufactured out of plastics. Currently it is not possible to manufacture these dental laboratory products out of ceramics at a high quality level, but several companies are working to improve 3D technology to include ceramics. As soon as it becomes possible to print ceramics in durable high quality, the CAD-CAM systems in the marketplace will experience a lot of pressure. But as a minimum we will need scientific studies to evaluate the long-term quality of those 3D printed products for the future.

The use of 3D printing technology in dentistry also demands education and training, because specialist knowledge of software packages and the digital design process is required to execute a really high-end dental medicine product. So there are additional services that 3D printing companies could offer around the 3D printer itself, to help people gain the expertise to use this technology. Users of such complex systems need support and training to improve their skills, and this leads to deeper interaction between the dentist and the dental laboratory technician to succeed as a team.

The field of application for 3D printing in dentistry is huge. In some cases the potentials of “rapid manufacturing,” “rapid prototyping,” and “rapid tooling” are the only way to produce individual parts in dentistry (like in implantology for individual supraconstructions and abutments) and other industries (Caviezel et al. 2017). For dental surgery in the field of implantology and periodontology, the production of drilling templates is useful. Also the 3D printing of bone structures of the maxilla or mandibula can support dentists to plan a surgical protocol in the pre-surgical stage preceding an oral surgery treatment, and achieve a better quality outcome. The 3D printing of bone defect regeneration parts out of synthetic bone regeneration material is also used in dentistry and in oromaxillary and facial surgery.

To obtain a desirable position of the teeth in orthodontic treatment, dental aligners can be 3D printed. A mouthguard used to treat bruxism, where people are continuously putting pressure on their teeth, or teeth whitening trays are use cases of 3D printing products in dentistry.

At an experimental stage, there are companies which are trying "bioprinting" to produce biological structures, so it is possible that bioprinted materials could be implemented in treatments for recessions of the gum or procedures for socket preservation after tooth extraction. But currently surgical techniques exist in oral surgery in which the patient's own tissues are used, so bioprinted products would make sense only in very special cases with a unique indication.

3 Digital Imaging in Dentistry

Digital radiology in dentistry and digital imaging are moving forward rapidly, delivering new and better opportunities to the dentist and patient. The speed of innovation in this sector is remarkable, and is helping clinics achieve higher quality and excellent outcomes (Yuzbasioglu et al. 2014). X-rays have been digitalized and low-dose computer tomography (CT) scans provide three-dimensional information—so just think about digital volume tomography (DVT)! Even the technology of real-time computer tomography shows the potential of digital imaging in dentistry (Joda and Brägger 2015).

The expression "digital workflow" has become a reality in dentistry. Work in the clinic is becoming more efficient. The costs seem to be lower but should be calculated exactly, because investments in different digital imaging products, plus servicing costs and interest, are in some cases not as cost-efficient as they initially appear. In the long term, the new innovative digital imaging technologies will lead to a better cost structure because you get more work done per time unit compared to working without digital imaging technologies.

The implementation of imaging science in dentistry is an unstoppable process which delivers advantages (Vandenberghe 2018):

"Gradually, and almost consecutively, digitalization has been adopted in the three major steps of the conventional patient work flow, resulting in three distinct processes:"

"(1) Digital patient: the acquisition of patient data is digitized (clinical information, X-ray based information or casts) and can now be stored or archived in the patient's digital records."

"(2) Virtual patient: mental planning of the patient's rehabilitation can now be assisted with a digital treatment planning and on-screen simulation (computer-aided design or CAD)."

"(3) Real patient: treatment procedures may be assisted with computer-aided manufactured (CAM) devices using milling or 3D printing technology."

The description of the digital, virtual, and real patient (Vandenberghe 2018) shows that we are not so far away from seeing the implementation of further digital technologies like augmented reality (AR) and virtual reality (VR) in consultation and treatment processes in dentistry. All subdisciplines of dentistry such as implantology, endodontics, orthodontics, esthetic and restorative dentistry, prosthodontics, and periodontology are touched by digital technologies and treatment procedures.

Especially the use of an intraoral camera helps the patient to understand the consultation better, while impressions taken with a digital surface scanner (Lanis and Álvarez Del Canto 2015) without all the impression material in the mouth mean a new level of comfort and less anxiety for the patient. For dentists, digital imaging combined with e.g. navigated implantology and digital computer-assisted planning in implantology (Verstreken et al. 1996) bring more safety and accuracy (Bover-Ramos et al. 2017), shorter times for planning, and a relaxed atmosphere to the team.

4 Cyber Security

Digitalization in health care bring risks to the organizations involved. In the new age of digitalization in dentistry, the threat of cyber attacks is a potential problem. Once a computer virus hits the IT infrastructure, various things can happen such as a shutdown of the whole system, encryption of patients' health care data or the time schedule, general medical information relating to the patients can be manipulated, changed, or partially deleted, and data can be stolen. All this has happened worldwide before and will happen again in the future. The first problem is that the practice owner is liable for all problems with the patients' health care data. In Germany, the law states that in the case of such an "IT emergency," the owner of the dental clinic has to inform every single person, even those who may no longer be patients of the clinic. And in this case, every one of those individuals is able to sue the dentist. The second problem is the "IT recovery," to secure and reactivate digital imaging data like X-rays or scanning procedures, time schedules, health care information, and the documentation of quality and hygiene management protocols. In this case it is only possible to recover the IT system if the IT architecture includes a second server, updates of anti-virus software, and other IT security components. Without an investment in state-of-the-art IT infrastructure, the digitalization of dentistry can turn into a nightmare. The third problem comes from the Internet of Things (IoT): in some clinics, the level of digitalization is nearly 100% and the clinic's very expensive high-tech products such as treatment chairs, intraoral scanners, and 3D printers are all interconnected as one big infrastructure with the clinic's main server and digital net—which could be affected by a cyber attack. The costs could be tremendous to repair certain manipulations of technology products. So these three points show the importance of knowledge and IT architecture—both of which are needed to build a safe dental practice choosing the path of complete digitalization in dentistry.

Another important aspect for preventing cyber attacks is to educate employees who use the internet to communicate with patients or to order material for the practice. “Phishing” mails are a danger because once you open the attachment, the computer virus is on your server. Hopefully you have an updated anti-virus software program to delete this virus, otherwise you have a problem. Browsing websites which are not directly related to the clinic is also a problem, but even if you advise your team to avoid randomly surfing the web, commonly visited sites could still be infected.

The conclusion for dealing with cyber attacks in the context of digitalization in dentistry is to invest in new IT architecture, to update it from time to time, and to firmly educate the whole team to avoid opening “phishing” mails.

5 Apps and Smartphones

Digitalization in dentistry also affects patient management and communication. The use of apps opens new opportunities for patients and dentists. A mobile app is a software application for smartphones, tablets, notebooks, or personal computers, and offers the user added value through interactivity. Before the age of digitalization in health care there was no possibility for active engagement with patients after they left the dental practice. Now, through apps, the practice can use an online scheduling system, send recall and news messages to the patient, or offer a standardized or personalized app for a better view of the patient’s health situation.

During the corona crisis we have seen a lot of interaction between patients and our dental clinic through digital video software like Zoom, Skype, and Microsoft Teams. We had a few esthetic consultations for patients who were interested in getting a smile design, but also some patients with pain problems called us through those channels or asked if they could chat with us on WhatsApp. These things came along fast, and here we see the corona crisis as a chance to try to implement innovative technologies. It should only be a matter of time until this kind of communication becomes established with patients, because through their experiences of working from home and video-conferencing, the patients also have a higher acceptance of communicating this way—even with their dentist.

Another option is to implement telemedicine services. This could be a future scenario in a dental practice, but as long as dentists drill, cut, fill, or fix, there will be a need to come to the clinic, even with telemedicine. Nevertheless, telemedicine apps open up a field of multidisciplinary communication between dentists, general physicians, and pharmacies, and even insurance companies could participate on a common platform. Usually such scenarios are AI-driven and connected to a cloud, but the legal barriers are high and with the risks of cyber attacks to contend with as well, it will take some time to establish such systems. Aspects like user experience (UX) and user interface (UI) bring new dimensions to dentist–patient interaction. The gamification potential of these apps can motivate patients to brush their teeth, eat healthier food, and attend recall sessions frequently to get some professional dental hygiene services. This could help to prevent caries, periodontitis, and periimplantitis, and would be a long-term strategy. Especially the influence of chronic periodontitis on widespread diseases like diabetes shows the need for patients to have an app where interdisciplinary information and lifestyle data flow together. For that we need high acceptance on the patient side to recognize the value of such an app which collects a lot of health care and additional data. It would be an advantage if doctors for internal medicine could get information through such an app—e.g. if the diabetic patient is ignoring the dental clinic's recall invitations and their dental hygiene situation is very negative. In that case, the physician for internal medicine could motivate the diabetic patient to use the dental hygiene services to avoid further risks to their health. The chronic character of periodontal inflammation leads locally and systemically to a higher number of inflammation molecules, which influence the patient's insulin resistance—this could weaken the impact and effect of insulin (Chen et al. 2010; Demmer et al. 2010). The pre-diabetic risk and promotion of the transition into diabetes are associated with chronic periodontitis (Taylor et al. 1996). To avoid further risks for patients with widespread diseases and a history in chronic periodontitis, such an app where all health data is connected could bring added value to the patient and be part of a long-term prevention strategy. In the long term it would also lead to reduced costs in the health care system.

Ultimately digitalization in dentistry will help to treat patients better, but in the prevention process we still depend on the compliance of the patient and their willingness to brush their teeth.

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Changes in Medical Processes Due to Digitalization: Examples from Telemedicine

Krisztina Schmitz-Grosz

1 Introduction

Healthcare systems which organize the main process of patient care (patient history—diagnosis—therapy) in the classical way, where the patient is treated either in acute outpatient medical practices or in hospitals, are running at their limits. This is seen in overcrowded waiting rooms, long waiting times, less time for examinations and doctor's consultations, and resulting problems affecting the quality of care (Irving et al. 2017). Long waiting times both for planned interventions and for providing acute emergency care are an issue for inpatient care in hospitals that have been known about for a long time, whether due to inadequate resource planning in hospitals or ineffective triage of clinical conditions according to severity (Sammut 2009). "Available statistics show that over 45% of World Health Organization (WHO) Member States report having less than 1 physician per 1000 population" (WHO 2020). Because of the increasing volume and importance of data in the medical field, more and more new tasks are being added to the core activities. These take up more time and, without resource rearrangement, create further pressures and difficulties in the core area (Kim 2015). One approach that has already delivered increased quality while reducing the burden on the care system is physician practices that are members of integrated medical care groups (Mehrotra et al. 2006). As they are networked with each other or with other facilities such as telemedicine centers and radiological facilities, they may have resources to improve quality and guidance for the patient that separate physician practices do not.

During the *core* process of medical care, first the patient's medical history is recorded. A doctor's appointment is made, at which symptoms are described and questions answered. Before arriving at a diagnosis, the patient history is

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followed by a physical examination, sometimes supplemented by blood tests in the laboratory or by certain radiological screenings. After a systematic consideration of the differential diagnosis by the physician, the diagnosis is made and a therapy proposal is provided (Adler and Hemmeler 1992). The information gained results in data, which is accumulated, analyzed, and evaluated in a *secondary* process, for example as part of studies, in order to draw conclusions from the data and to achieve improvements. Such data is no longer simply entered into various patient management systems (PMS). It is increasingly collected through various apps, wearables, and medical devices. The evaluation of health data, the emerging health-related e-learning methods for professionals and for the general population, as well as the important question of how to communicate about health properly through social media, are summarized under the area of e-health (WHO 2016). When the new term telematics is discussed, areas of the *tertiary* process are also addressed: anonymized data for control, planning, and billing (Berger et al. 1997).

Telemedicine has points of interaction with all three areas (primary, secondary, and tertiary process), which are strongly interrelated and have become even more intertwined with the new technologies. Frequently mentioned areas of telehealth include administration and support, public health, as well as research and health education. In the future, these could be included among the competences of telemedicine. Mentionable is that only 27% of European countries have a specific directive or strategy for telehealth (Peterson et al. 2016). Figure 1 shows how the processes relate to each other, work together, and influence each other.

Digitalization has become evident everywhere, including in healthcare processes. Digital technologies can be split into “*digitization*” and “*digitalization*” (Bloomberg 2018). Digitization means the mechanization, automation, and efficiency of the existing processes. Examples in healthcare—insurance card readers in medical practices and pharmacies, electronic patient files or electronically provided

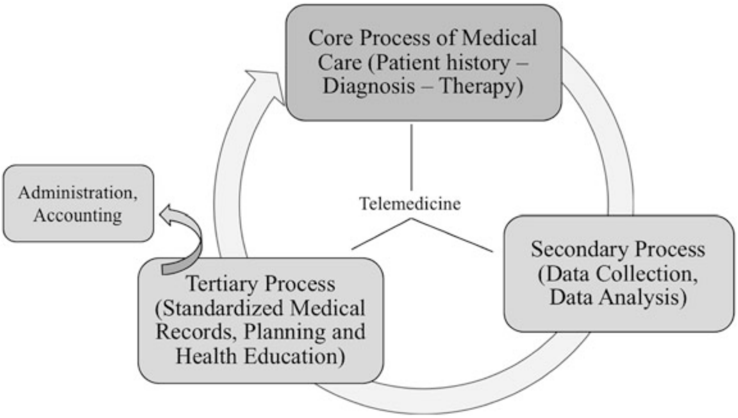

Fig. 1 The continuity of healthcare: the individual processes are connected, create parts of the other areas and flow back circularly into the next area. Source: author

prescriptions—have primarily been developed as part of a general implementation of digital technology. Associated challenges include organizational coordination of the interfaces and achieving corresponding evolution of the previous system. The term “digitalization” refers to the use of newly developed techniques which previously did not exist. Involving sensors of all kinds, tests, and digital applications, these techniques are used primarily for measuring various biological parameters, and secondly for data collection, analysis, and evaluation, increasingly with the help of artificial intelligence (AI). At this level, interface incompatibilities are overcome, systems are integrated, and new services are created. As these changes take place, sometimes in parallel, many different new terms are created. Telemedicine has also become charged with a new, expanded meaning. More and more segments from the areas just mentioned (e-health, telehealth) have now joined the original definition of telemedicine: medical services in the areas of consultation, diagnostics, therapy and rehabilitation, provided over geographical distances or time differences using various information and communication technologies (Bundesärztekammer 2015).

How have medical processes changed in the context of digital technologies? What challenges have to be managed? How can it be ensured that the information and data constantly emerging from the various fields of (tele)medicine is bundled in a standardized, qualified, and cost-effective way, so that it can be actively monitored and used efficiently for the individual and for scientific research?

The following sections give a brief overview of how medical care processes have already changed due to the new technologies. They describe the challenges, potentials, and success factors that have emerged for the future, as well as the kinds of suggestions for improvement that can be derived for the implementation of new digital paths in everyday medicine.

2 A Brief History of Telemedicine

As new technologies have brought about changes, terms such as e-health and telemedicine have become increasingly popular, and are attracting ever greater interest. But the term telemedicine is not entirely new. Where did telemedicine really start? The origins of telemedicine go back a very long time. In the Middle Ages, fire signals or flags were used to communicate information from afar, during outbreaks of leprosy or plague. Technological capabilities have developed rapidly over time. The first medical consultation by telephone was documented in 1879. Since then, this type of communication has been part of patient-centered healthcare. In 2001, the British Medical Association (BMA) classified it as safe and acceptable if—and this is crucial—it is carried out in the correct way (Vaona et al. 2017; Evans et al. 2003). As far as the various communication channels are concerned, radio has been an important means of communication, in addition to the telephone, when medical consultations have taken place on ships. Isolated areas such as parts of Alaska, the Arctic or Antarctica had to open up quickly to the telemedical possibilities that were still very space and technology intensive at that time (Glatz 2020).

Nowadays, computers and the internet are of course the most widely used channels for researching health issues. Besides classical search engines and websites, video consultations are possible and there are applications (apps) that can have a significant influence on our lives. The mobile web and its social platforms are now empowering millions of people to more easily share, communicate, and find applications for almost everything imaginable, including health issues. Since the introduction of smartphones, interaction using software has become even easier and more accepted (Boulos et al. 2014).

Another milestone on the digital highway is the increasing use of microdevices for recording vital parameters and biosignals. Contact centers that process these parameters using various types of communication technology are expected to develop into comfort contact centers providing services to citizens and bridging the gap between the patient's daily signs and their clinical profile. Intervention based on a large amount of such data and information could save thousands of lives every year. Contact centers could effectively use messages, warnings, or reminders to provide information to doctors and patients to help them make the right decisions (Balas et al. 2000).

3 The Main Process of Patient Care (Patient History—Diagnosis—Therapy)

The main process of patient care consists in taking the medical history and carrying out some tests and examinations—which allow various clinical conditions to be excluded or confirmed—in order to recommend an optimal therapy. For this process, it is no longer mandatory for the patient and doctor to meet in person. With the new technologies, it is possible to go through these steps even when the patient is in a completely different place than the doctor, with the process managed by video, chat, special sensors in watches, smartphones or on clothes, or indeed a combination of all of these. Among medical colleagues, too, discussions can take place independently of time and place, in the form of teleconsil. There are already a few examples of these approaches in preventive, acute, chronic, and individual medicine, but no bundled, widely applicable concept has yet been developed. Some of the examples mentioned are discussed below.

3.1 Telediagnostics

In *telediagnostics*, a disease is diagnosed without the doctor and patient being in the same room. Depending on the specialty, examples include teleradiology, teledermatology, telepathology, telepsychiatry, telecardiology, teleneurology, teleoncology, and telesurgery. Telediagnostics is often practiced in the form of *teleconsil*, in which an exchange between two or more specialists takes place using telematics (Telemedizin BW 2020). A successful example of the adoption of teleradiology is the case of the island of Sylt. Since 2002, all radiological examinations on the

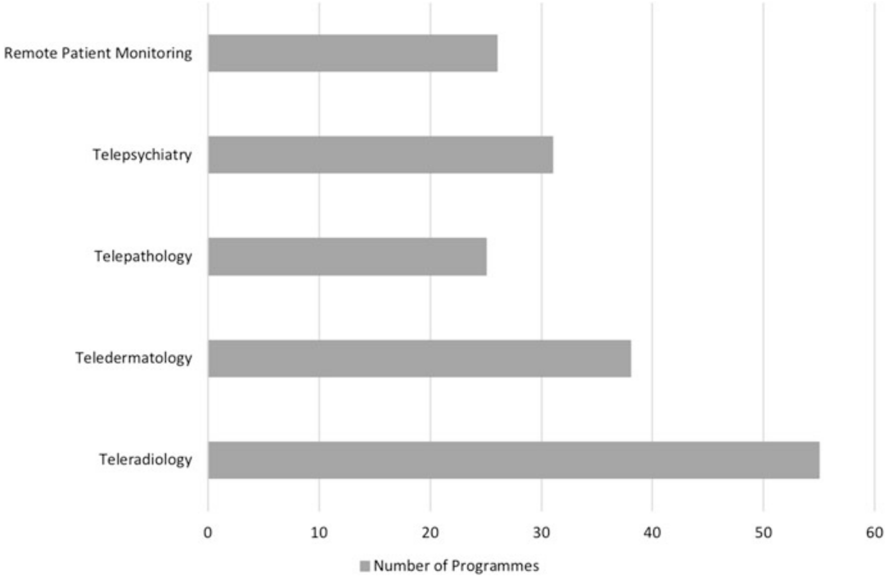

Fig. 2 Telehealth initiatives in the European region depending on the area of expertise. Data from Peterson et al. (2016): Source: author

island have been evaluated by telemedicine. By increasing the speed and actuality of medical findings, and due to the uncomplicated exchange of information among specialists, patient care has been significantly improved (Visus 2009).

Comparing the individual fields of specialists within Europe in terms of the frequency of telemedical projects, teleradiology comes first by far. This is also the area in which established programs exist, rather than just pilot missions or purely informational events without standardized processes (Peterson et al. 2016). Figure 2 shows the initiatives and programs by field of specialization for the European region.

3.2 Telediagnostics with Home Care in Acute Primary Care or Teletriage

This facet of telemedicine is also known as *teleconsultation*. Doctor's consultations unnecessarily carried out in person lead to overcrowding of surgeries and outpatient clinics and promote hospitalization. The resulting pressure influences clinical outcomes as well as important processes and problems in care (Bernstein et al. 2009). By applying telemedical care via teleconsultations in those scenarios where it is possible, 50% of cases can be treated with a high satisfaction rate. Services such as prescriptions, referrals, and certificates of incapacity for work enable care to be completed without the need to visit a doctor's practice or hospital (Stacey et al. 2004; von Solodkoff et al. 2020). The other 50% can be effectively and resource-efficiently triaged to the right doctor at the right time. Patient routes are thus optimally guided throughout the entire healthcare system. The ability for patients to discuss their current health problems with a doctor from home, via telephone or video, is already part of everyday life in European countries such as England, Sweden, and Switzerland (Steiner 2020).

Switzerland has had very good framework conditions for telemedicine and medical care using remote technology for some time. Thus Medgate, one of the leading physician-operated telemedicine centers in Europe, was able to start out in the outpatient primary and specialist care sector with the goal of enabling "360° healthcare" for patients at a very early stage, in the year 2000 (Fischer 2014). With a total of over eight million teleconsultations carried out and with up to 5000 patient contacts daily, Medgate has acquired broad expertise in this field. Medical teleconsultations via the Medgate Tele Clinic are safe and effective, and rated highly by patients (Blozik et al. 2011). For on-site consultations, supporting patients along the patient value chain, they also have access to Medgate Mini Clinics, the doctors and clinics of the Medgate partner network, and various managed care programs. As part of its digital strategy, Medgate has also launched an app with an AI-supported analysis and triage tool.

A national telehealth program in the United Kingdom observed not only cost reduction but also fewer visits to a doctor and a 45% reduction in mortality when using remote technology (Peterson et al. 2016).

The transition between primary and secondary processes is naturally continuous and cannot be sharply separated. The following section puts more emphasis on the secondary and tertiary aspects.

4 Further Processes of Patient Care (Data Collection, Data Analysis, Administration and Accounting)

Where exactly does the data come from? Firstly from the existing PMS that have been around for some time, and secondly from new sensors (Turakhia et al. 2019), input apps such as neotiv, the Alzheimer's disease early detection app (Düzel et al. 2019), AI-based diagnosis tools like ADA (Thurner 2020), complete diagnostic cells like the one in China (Onag 2019), cars (Van Berck et al. 2019), virtual reality (VR) glasses (Gerlof 2019), and also from specialized laboratories (Grünblatt 2014). Accordingly, there has been an explosion in the amount of data. Some examples from these fields are provided below.

Digital, more standardized medical records and invoicing channels have simplified the tertiary sector and made it more efficient. Previously, online appointment booking portals, such as Doctolib, merely enabled better staff and time resource planning. Through the Covid-19 pandemic situation they have expanded their service offering with teleconsultation platforms (Bourdon et al. 2020). The large amount of data, complex models, analyses, and the development of algorithms enable AI to be trained in such a way that causal relationships can be checked faster, more comprehensively and with a higher degree of complexity. The key influencing factors here are the quality and size of the AI data stock, and the training of the AI. Both aspects depend on the primary medical process: the more anamnesis data is entered, and the better structured it is, the more meaningful the calculation models become. Going a step further, the greater the precision with which the therapeutic interventions of the treating physicians are documented, the more causal dependencies, explanations, and even differentiations of therapeutic approaches become apparent, leading toward evidence-based, personalized medicine (Dilsizian and Siegel 2013).

4.1 Home Care

The classical understanding of home care stems from the care sector. Patients are assisted at home in everyday tasks by various means (provision of aids, bandage changing, meal preparation) and receive support so that they can stay in their familiar surroundings and recover there. In a broader and telemedical sense, home care likewise is intended to enable the patient to stay as long and as safely as possible in the home environment, but there are many more technical components, like telemonitoring of indicator parameters for chronic diseases. Telemonitoring means the monitoring of biological values measured via sensors. The resulting data is transmitted to a separate monitoring facility (Telemedizin BW 2020).

Chronic diseases for which telemonitoring and subsequent case management can typically be successfully implemented include chronic heart failure, diabetes mellitus, and chronic obstructive pulmonary disease (COPD) (Peterson et al. 2016). Some projects with other diseases like multiple sclerosis are already showing good results. Key parameters and opportunities for further diseases are being explored (Baker et al. 2020).

Approximately 2.5 million Germans suffer from chronic heart failure, and that number is increasing by 300,000 every year. This disease is the most common cause of hospital admissions. The Fontane study by the Charité University Hospital in Berlin has shown that telemedicine not only helps to reduce hospital stays (frequency and length of stay) but also brings the standard of care for heart failure patients in rural areas closer to that provided in urban areas (Charité 2020).

Much has happened in recent years with regard to diabetes and its telemonitoring. To the great satisfaction of everyone involved, huge progress has been made. One of the best outcomes of recent years has been the development and implementation of a fully “artificial pancreas” (AP) in the form of complex cooperation and coordination between several devices and measured values (continuous glucose measurement, an insulin pump, and an algorithm on a smartphone). The three devices work together smoothly. Blood glucose values measured by a continuous glucose measurement (CGM) device in the subcutaneous tissue automatically control the function of the insulin pump and thus the amount of insulin delivered, according to the principles programmed into the algorithm on the smartphone. Then the loop starts over, just like in a physiological pancreas. The telemedical monitoring of values and a corresponding alarm system have played an important role in patient safety and were essential for the safe application of this research method. Now that studies have shown that the AP system can be used not only under controlled conditions, but also in normal home settings, the system currently faces the challenge of finding appropriate funding to support its adoption in the everyday treatment of diabetes (Heinemann et al. 2016).

4.2 mHealth

mHealth uses mobile technologies to draw attention to, discuss, and teach health-related topics, all with the general goal of improving health. mHealth therefore addresses areas like prevention, health promotion, and well-being, through apps called lifestyle apps. Data on habits and behavior is collected throughout the day via wearable medical devices or sensors. Some 73% of European countries do not have an authority responsible for ensuring the safety and reliability of these applications. On the other hand, the use of these mHealth services has increased by 25% since 2009. It is highly recommended to establish an entity responsible for the quality and regulation of mHealth applications, to evaluate the benefits of mHealth and ensure good quality (Peterson et al. 2016). Aspects such as informed consent, licensing schemes, and liability rules need to be discussed and regulated, given that mHealth services are set to expand and gain a significant role in mainstream healthcare.

Taking a closer look at wearables, an amazing range of advanced technologies is already available. But technological progress has not only enabled the further development of existing devices, it has also helped to realize new detection techniques. In addition to the traditional electrocardiography (ECG) examination, the heart rhythm can also be determined from pulse curves recorded by photoplethysmography (PPG). To achieve the greatest possible accuracy, this method was validated from beat to beat via a simultaneously derived ECG (Vandenberk et al. 2017). PPG is based on changes in blood volume in the observed tissue. The tissue observed may be a finger, wrist, or other part of the body. During measurement, the tissue is illuminated by a light source such as light emitting diode (LED). Since the heartbeat produces wave-like changes in the blood flow and thus changes in light absorption and light reflection, the method can be used to measure heartbeats. The wave-like changes in the blood flow are recorded by a photodetector as a pulsatile signal, displayed and stored as a pulse curve. From this information, the heart rhythm is determined. Various studies have demonstrated a good correlation between the parameters recorded by ECG and PPG (Vandenberk et al. 2017; Koenig et al. 2016). For these reasons, the method was included in the screening recommendations of the European Heart Rhythm Association (EHRA) (Katritsis et al. 2017). The large-scale Apple Heart study with more than 400,000 participants delivered initial results on the ability of a smartwatch algorithm to detect an irregular pulse as a sign of previously undetected atrial fibrillation (Turakhia et al. 2019). Another study (Lahdenoja et al. 2018) presented a smartphone-only solution for the detection of atrial fibrillation. The smartphone's built-in accelerometer and gyroscope sensors are used for the analysis. Signals are taken directly from the thorax without an

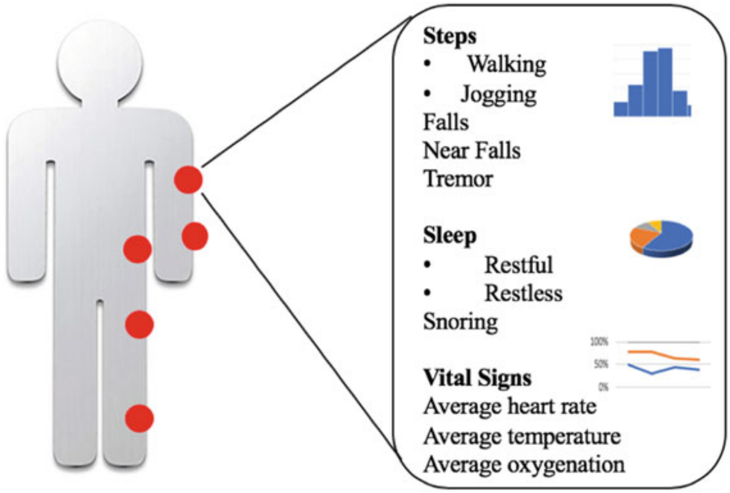

Fig. 3 Parts of the body where sensors can be comfortably worn and some parameters that can be measured, displayed, and recorded by the devices. Inspired by Baker et al. (2020). Source: author

additional external sensor. Accuracy of 97.4% (sensitivity 93.8% and specificity 100%) was observed in the study.

Smartphones can help to diagnose other diseases too and support more precise treatment, as in the case of multiple sclerosis (MS) (Schwab and Karlen 2020). MS is a disease of the central nervous system which can affect the entire brain and spinal cord. Parts of the nerve fibers are destroyed by their own immune cells, thereby disturbing the transmission of electrical impulses and the structure itself. Symptoms include paralysis, an inability sometimes to coordinate muscles properly or at all, and problems at the sensory level. The Floodlight Open app uses smartphone accelerometers and can be applied by people suffering from MS. The app is an innovative step revealing the potential of real-time remote patient monitoring. The associated long-term study, the Floodlight Open study, is intended to build an understanding of how long-term data collection and real-time evaluation of various key parameters such as mobility, motor function of the hand, cognition, gait and posture in people with MS contribute to optimal monitoring and fine-tuning of MS and its treatment (Baker et al. 2020). Furthermore modern medical devices are comfortable and convenient to wear on different parts of the body—wrist, hip, or ankle—and can detect physical activity through the use of accelerometers (Bradshaw et al. 2017). Figure 3 shows the parts of the body where sensors can be worn comfortably and some parameters that are recorded by the devices.

4.3 Highly Specialized Fields

In the fields of *aerospace* and deep-sea shipping, circumstances have meant that telemedicine has already been in use for a long time. Monitoring the condition of astronauts' health—with all manner of derived vital parameters—could only be done from Earth using telemedicine technology. Some of these newly developed monitoring methods then went on to be used in different contexts. Premature babies, as an example, often need to be monitored over a long period. With a special suit, however, all this can happen at home under quieter conditions. Sensors continuously record parameters from the baby such as blood pressure, pulse, and respiration. ECG and oxygen saturation can also be measured. All data is collected and analyzed so that in an emergency, the medical staff can immediately alert the parents or send an emergency doctor (Knapp 2001).

The term *"-omics"* is often used to describe something big: it summarizes parts of life science research such as genomics, epigenomics, transcriptomics, proteomics, or metabolomics. The different omics approaches provide valuable information about risk factors in the genetic background or due to environmental influences. They can be helpful for diagnosis or therapy recommendations. As biomarkers they can be relevant for clinical predictions such as prognosis, risk of relapse, drug response, and side effects (Grünblatt 2014).

4P medicine is also moving in this direction. 4P medicine prioritizes predictive, personalized, preventive, and participatory approaches (Jenkins and Maayan 2013). This allows in-depth biological data to be brought into play: molecular, cellular, and phenotypic measurements, even individual (now easily accessible) genome secretion analyses. Portable devices can be used for monitoring and alerting and can thus make a key contribution to promoting preventive medicine (Khemapech et al. 2016). Another essential component is to provide people with a comprehensive understanding of the many factors affecting their health, so as to be a step ahead before disease develops. The old focus of medicine, based on disease, needs to be shifted and directed toward how to stay healthy. The aim is to identify those at risk before the symptoms of disease appear, so that preventive treatments can be planned (Alonso et al. 2019).

Automotive health combines time spent in cars with health aspects. It considers all possibilities, from prevention to diagnosis and therapy. The willingness to take advantage of health services in the car is high. Health awareness among the general population has changed over recent years. People who spend a lot of time in their cars are able to collect health data while driving by using specific technologies integrated into the car (Van Berck et al. 2019).

Virtual Surgery Intelligence by apoQlar is a software that enables the virtual combination of CT and MRI images with a 3D model. Projected directly onto the patient, it provides exact anatomical guidance for the surgeon, who works with *mixed-reality glasses*. This can speed up the surgical procedure and increase safety (Gerlof 2019).

Ping An Good Doctor is a Chinese company offering specialized services. They have carried out the first pilot tests of various services, such as a one-stop online healthcare platform. This consists of an in-house diagnostic room and a *"smart medicine cabinet"* storing more than 100 common medicines. Patients have access to medical and health advice around the clock at any location, and can even take the appropriate medicine directly from the "dispenser" (Onag 2019).

5 Challenges and Potentials in the Implementation of the Changes in the Daily Medical Routine

Changes brought about by new technologies and emerging new services create some major challenges. These include the financing, legal aspects and required infrastructure, as well as respecting the interests of the various stakeholders. At the same time, medical effectiveness has to be proved, and economic efficiency demonstrated, based on valid clinical and especially health economic studies. The importance of these new services for the future and the possibility of their implementation must also be emphasized politically, so that these systems can receive appropriate financing and thus become practically feasible.

5.1 Challenges

The question of appropriate *reimbursement* is the biggest obstacle slowing down the practical, widespread implementation of new services emerging through recent technical developments, as in the case of telemedicine. In the various reimbursement systems in the outpatient and inpatient sectors as an example of Germany, accounting codes for telemedical services are largely absent. Required cross-sectoral telemedicine solutions are only viable in the long term if they are matched by lucrative cross-sectoral reimbursement. Further obstacles are seen in the lack of economic incentives for a balanced distribution of investments and proceeds. Policymakers need to create not only suitable conditions, but also financially motivating incentives. The *legal conditions* are often crucial when it comes to setting up various new forms of medical care in different countries. Some countries still do not permit purely remote treatment when the patient and practitioner have not previously met in person. In this case, there is no real possibility of establishing a truly comprehensive and broad-based medical digital solution. Other countries are not so strict, but nevertheless there are fields lacking legal certainty where clear rules need to be established (Dittmar et al. 2009). *Data protection* is particularly important in the medical field, as highly sensitive data is involved. Regarding telemedicine in particular, it is important for platforms to be secure under data protection law, and for clear rules to be established for the subsequent processing of the data (Berg 2004). It is beyond the scope of the present chapter to examine this topic in more detail.

Establishing and integrating *infrastructural systems* for the different requirements of new modes of digital health requires an initial investment and considerable effort. Ideally, such systems should be designed to be flexible from the outset, to facilitate combination with other systems and expansion. Maglaveras and colleagues (2005) have shown internationally—with examples from Greece, Spain, and the USA—that a multi-modular and multi-layered medical monitoring and consulting system creates an extraordinarily flexible and expandable structure. This can be established as a toolbox system, giving users access to their preferred applications even as others use different channels. The modular Medical Contact Center (MCC) is cited as an example of how such systems can be successfully used in the monitoring, treatment, and management of chronically ill patients at home. It offers valuable functions for medical personnel and for citizens. Data was input into the system through various established measurement devices (electronic weighing scales, blood pressure and pulse meters, digital thermometers, portable ECG recorders, and electronic glucometers). Interaction was also possible in the form of questions and teaching about the clinical pictures, both in text and audio format. This type of system can also be adapted to users' needs in terms of technological affinity and living conditions. In order to integrate different interfaces, a three-layer architecture is required, with an intermediate layer between databases and customer input. The intermediate layer integrates useful modules, and serves to link and translate between the other two endpoints. The key modules in the middle tier were the authentication module for data security and profile identification, the patient session module, where patient interactions take place, and finally the signal server module. Its task is to receive different signals from the home-monitored patient, which are recorded via the corresponding microdevices used at home. A three-layer architecture provides enhanced security, since client applications are not allowed direct database access. Additional processing modules like the clinician alert tool or detailed ECG processing were also implemented. Figure 4 illustrates the simplified set-up model of a three-tier architecture.

The system has achieved significant successes even just for the patients in this study. The number of hospitalizations per patient was 0.33 for the follow-up period, compared with 1.16 for the period before enrollment, while hospitalization days declined from 5 per patient to 1.5 per patient for the follow-up period. The main finding for the obesity subpopulation was a statistically significant reduction in bodyweight in the group of patients who used the platform as compared to the patients who did not. Home care services offered by the MCC system were well accepted by patients and clinicians, and contributed to a more efficient and higher-quality disease management plan. Following a similar three-tier principle, not only could the care of chronic and acute illnesses be well managed, but also the other potential future areas of modern telemedicine can be integrated in a customer-oriented manner. Solutions like this offer an attractive platform for healthcare delivery for the next generation, who are very interested in their health and in having more information about their health status. Designing telemedical centers in a multi-modular way would enable different facets of telehealth to be combined,

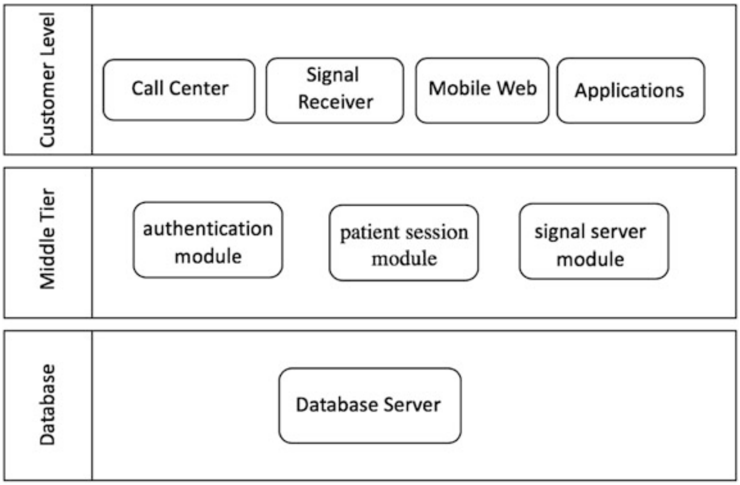

Fig. 4 A three-layer model to establish with the purpose of bundling and effective processing of several different digital input channels. Inspired by Maglaveras et al. (2005). Source: author

creating interfaces and further developing the guiding role according to the needs of individual medicine.

Every *stakeholder* in the healthcare system—whether hospitals or outpatient service providers, policymakers, or the patients themselves—has to some extent differing interests and different ideas and expectations about the new digital healthcare capabilities. Finding the overlaps and using them optimally is essential for lasting success. With increasing specialization, desired shorter hospital stays, more intensive outpatient care, and growing new digital areas, there is a fundamental need for telemedical instruments to cover treatment processes, organizational procedures, and new fields. The aim is to optimize resources, increase quality, and bring the focus of care back to the patients, so that they can also be retained as customers.

The valid cost analysis of a new procedure should be linked to a simultaneous measurement of clinical efficiency (Wohlgemuth et al. 2008). One difficulty in the *health economic evaluation* of e-health lies in its rapid, technology-driven development. The results at the time of publication may already be outdated to a large extent. Underlying applications and features may have been further refined, with an impact on cost-effectiveness, in part due to rapidly falling technology costs. Previous reviews of cost-effectiveness studies of telemedicine also show that accompanying health economic research could only be conducted in rare cases (Whitten et al. 2002). However, well-founded statements on the benefits of telemedicine, taking into account the preferences of patients, are essential for the acceptance of telemedicine. This is true for all sides of the healthcare system, and a requirement for its widespread introduction and reimbursement (Kristiansen et al. 2003). It is not easy to conduct a "value-for-money" or cost–benefit analysis in telemedicine. In addition to often fixed reimbursement groups and various billing systems, there is the problem of individuality. Not only is the patient as a human being different in each case, in terms of preferences within the medically meaningful range of treatment, but individual diseases also manifest themselves differently according to different genetic and environmental factors. Then there is medical freedom in terms of making assessments and the resulting consequences. Despite guidelines and standards, such decision-making also flows into a best possible solution, this is being human. Furthermore, infrastructural conditions such as practice and hospital density, specializations, and equipment are additional factors which influence the best possible decision for the patient. All of this should encourage us to conduct the classical cost–utility analysis on a more individual level. To make processes comparable, the medical and overall picture should perhaps be split into smaller parts and analyzed at the level of the respective medical case.

5.2 Potential and Success Factors

The new digital or remote medical care capabilities such as telemedical services give patients *access* to medical advice or even assessment by specialists, even in areas where medical care would otherwise not be available due to the great physical distance. If some questions can be resolved without real doctor contact, and the remainder can be optimally triaged into acute as well as chronic or preventive care, then *resources* (costs, time, personnel) are best allocated. This contributes to an overall improvement in the *quality* of care, as each party knows exactly what its role is and where the limits are. Feedback data flowing back into the telemedicine loop can help to track the performance of doctors and services and monitor standards.

A study of Switzerland's national influenza surveillance activities has shown that data gained through routine telemedical consultations can help to detect the early stages of an influenza outbreak, as surveillance reports would be available almost immediately. When the barrier to accessing teleconsultation is lower compared to face-to-face consultations, the sensitivity of detection is higher. In summary, the use of data from medical teleconsultations for influenza surveillance is feasible and could be transferred to other disease surveillance systems to support *public health* notification systems (Blozik et al. 2012). Due to larger data volumes with combined implementation of AI, telemedicine also has good potential as a valuable tool for *research*, especially in the field of rare deseases and multimorbidity clusters that are less prevalent.

There are numerous instances of pilot projects that could not be continued after the end of the funding period despite proven benefits. The projects do not succeed in getting into everyday operation, despite statements such as the following by the Commission of the European Communities, summarizing the situation in 2008: "Greater use of telemedicine could bring enormous social and economic benefits" (Paulus and Romanowski 2009). What are the significant advantageous factors that allow a project to continue operating?

The experience of recent years shows that sustainable concepts have become established and have proven to be viable if they were designed in a *standardized* way. Organized processes and bundled experience save time—a resource which is already scarce and valuable in healthcare facilities, where in many cases core tasks have already exhausted reserves. For a high-quality telemedical consultation, a *trained medical staff* with clinical experience is essential. Experience in medical triage (deciding which patient should be sent when and where for optimal care) and very good communication skills are helpful. Telemedical services should be carried out by a doctor or delegated under medical supervision. The most effective services can be provided by all the centers that have established themselves in this special field and can potentially be integrated further into existing healthcare structures (Braga 2017).

In medicine, some requirements and special characteristics are industry-specific. There is a certain natural variation in the course of diseases, as one example. The patient may deteriorate or improve according to circumstances, even without intervention or therapy. So there must be an opportunity for follow-up, to reassess the situation and re-evaluate the patient's condition. The time, attention, and trust to be gained from the patient side as well as the high level of patient safety from a medical point of view reinforce the assumption that a *24/7 service* is an important requirement for long-term success (Charité 2020). Offering consultations with experts in different specialties or longer accompanying programs such as nutritional or weaning advice can increase patient satisfaction.

Without a clear *legal and political framework*, and without an established, suitably attractive *reimbursement* system, which does not predominantly incentivize illnesses and interventions such as operations, but rather more preventive measures and independent consultations, the system will inevitably swim against the tide and the chances of successful implementation will be lower, thus the potential of digitalization in the healthcare system will not be fully exploited (Dittmar et al. 2009).

The *360° view* is essential to realize that one aspect is not enough without the others. In addition to medicine first and foremost, it is important to consider the economic approach, the infrastructure, and patient preferences, and work toward modern solutions (Fischer 2014). This approach will help to identify and constructively use the necessary overlaps between the different stakeholder interests.

6 Conclusion

Processes such as digitalization have fundamentally changed medical processes at all levels—whether the physical presence that is no longer absolutely necessary for making a diagnosis and suggesting a therapy, or the exploding data volumes of new digital applications in the medical field. It became clear that the available digital technologies and the resulting changes in the primary medical process have an enormous influence on the secondary and tertiary areas, as well as a dependency in the sense of feedback from these areas, which play a circular role in shaping the primary process. With effective process design there is great benefit potential in all of these fields.

The sensors of all kinds described above enrich the anamnesis with objective information. The patient history, which otherwise tends to be carried out on a one-time, retrospective, and reconstructive basis, is recorded on a more continuous data level in real time and in context. This creates new qualities and artifacts in the medical processes, which it is still necessary to learn to interpret and handle and requires a high level of resources. Healthcare systems organizing the main process of patient care (patient history—diagnosis—therapy) in the classical way, are running at their limits. These facts, together with the identified essential success factors for optimally managing the changes through new technologies, are an indication that new methods are necessary to cope with these changes. Basic management of collected data (analysis for assessment purposes, identification and categorization of the need for action with support for implementation, an alarm and advance warning function when certain limits are exceeded) as well as a first point of contact function could be covered by well-structured telemedicine centers with high standards.

At the same time, the economic and health policy challenges of an integrative, preventive medicine that goes beyond case-related billing should also be taken into account. First the political and legal framework has to be clarified and established in order to create a setting in which the remaining challenges, such as optimal infrastructural development, can be addressed. The continuity of healthcare established in this way moves the whole medical view of what to do when the person is ill more in the direction of how to stay healthy. The use of personalized medicine and digital technologies is changing our healthcare system and the way we think about health interventions and individual responsibility (Vilhelmsson 2017). With the internet and the active exchange of information among affected people and also with specialists, there is great opportunity to actively shape one's own health (Younesi and Hofmann-Apitius 2013).

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COVID-19 as a Driver for Digital Transformation in Healthcare

Stefanie Steinhauser

1 Introduction

The COVID-19 crisis had and is still having a huge impact on individuals, organizations, and society. Despite all the tragedy it caused, it also created room for learning and change. Previous important contributions to management and organization studies as well as to healthcare research were originally derived from extreme contexts such as wars, chemical leaks, aircraft accidents, nuclear disasters, or healthcare action teams (e.g., Hällgren et al. 2018). In their literature review on extreme context research, Hällgren et al. (2018) emphasized the potential for learning processes and development of new and innovative approaches in emergency contexts such as a pandemic.

Healthcare systems around the world struggle with rising healthcare expenditures, increasing staff shortages, and structural barriers to access (e.g., Christensen et al. 2009; Steinhauser 2019). Digital innovations and digital transformation, however, are perceived as an opportunity to improve the quality of and access to care while at the same time containing costs (Agarwal et al. 2010; Fichman et al. 2011). Yet, despite this potential, healthcare providers were quite hesitant in adopting and using digital innovations in the past. Thus, digitalization in healthcare progressed only slowly (e.g., Agarwal et al. 2010; Steinhauser 2020; Steinhauser et al. 2020; Venkatesh et al. 2011).

However, the COVID-19 outbreak, announced as a pandemic by the World Health Organization on 12 March 2020 (World Health Organisation 2020b), necessitated significant changes in healthcare delivery (see Fig. 1). First, social distancing was introduced all over the world in order to decrease the COVID-19 growth rate

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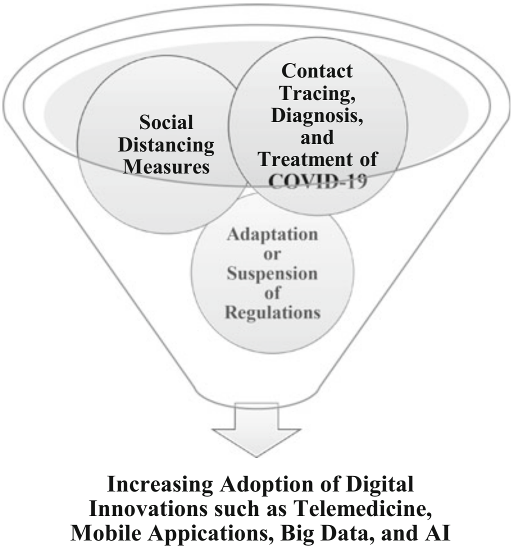

Fig. 1 Factors driving the digital transformation in healthcare during the COVID-19 pandemic. Source: author

(e.g., Courtemanche et al. 2020). As a result, telemedicine experienced a strong increase in many countries. Second, digital technologies were employed to deal with the COVID-19 pandemic: Mobile applications, big data, and artificial intelligence (AI) were employed to trace, diagnose, and treat COVID-19 infections. Third, regulations were adapted or suspended in order to facilitate the use of these digital technologies. Thus, regulatory sandboxes for the adoption of digital technologies were created (Steinhauser et al. 2020; Tsai et al. 2020). The use of digital solutions helped to protect patients, healthcare professionals, and the population at large (Whitehouse and Marti 2020).

This chapter presents a non-exhaustive selection of examples from practice and thus utilizes a practice-oriented perspective to provide an overview of the various ways the COVID-19 pandemic accelerated the digital transformation in healthcare. By doing so, this chapter aims to illustrate paths for facilitating the diffusion of digital technologies in healthcare during the pandemic and beyond.

2 Telemedicine for Remote Care Delivery

Telemedicine is defined as the delivery of healthcare over distance by digital means (World Health Organization 2010). Telemedicine can consist of provider-to-provider as well as provider-to-patient applications and encompasses applications such as teleconsultation, telemonitoring, or teleradiology (e.g., Steinhauser 2020; Steinhauser et al. 2020). That way, telemedicine provides the opportunity to deliver healthcare remotely and thus supports social distancing measures during the COVID-19 pandemic.

Telemedicine solutions offer several benefits during a public health emergency such as the COVID-19 pandemic. Telemedicine can help to reduce the risk of infection for patients as well as healthcare professionals. It allows patients who have non-COVID-19 issues to receive care without the risk of exposure. For patients concerned that they have COVID-19, telemedicine can address questions, coordinate testing, and triage clinical needs. In addition, healthcare professionals who are themselves quarantined can continue to provide care via telemedicine. Furthermore, telemedicine can also free up resources such as hospital beds for patients in urgent need of care and limits the demands on emergency departments (Fisk et al. 2020; Hollander and Carr 2020; Mehrotra et al. 2020; Moazzami et al. 2020; Whitehouse and Marti 2020).

All across ***Europe***, telemedicine applications such as teleconsultations reportedly experienced large growth rates (Whitehouse and Marti 2020): In Catalonia (*Spain*), 70% of healthcare encounters that were previously conducted face-to-face were transferred to digital encounters within a very short period of time. In *France*, healthcare providers and patients were incentivized to use telemedicine services by health authorities and insurers in order to expand its use across the country. The National Institute for Health and Disability Insurance of *Belgium* set a fee of 20 EUR for teleconsultation.

In the *United Kingdom*, the National Health Service (NHS) England issued a notice to health trusts, health service commissioners (procurers), and providers, including general practitioners (GP) services, calling for them to support the provision of telephone-based or digital- and video-based consultations, and advice for outpatients (Fisk et al. 2020; NHS 2020). In Scotland, the telemedicine development in relation to COVID-19 was swifter than in other regions of the UK, presumably built on experience that was driven by the needs of rural, remote, and island communities. Its program included telemedicine applications such as home and mobile health monitoring, videoconferencing, and telecare (Fisk et al. 2020). Before the COVID-19 pandemic, video appointments accounted for only 1% of the encounters of Britain's NHS. This drastically changed in a matter of days. A London-based GP noted: "We're basically witnessing 10 years of change in one week." (Mueller 2020).

In *Germany*, telemedicine platform operators reported growth rates of more than 1000%. There was a drastic increase in teleconsultations. By the end of 2017, only 1.8% of physicians offered teleconsultations via videoconference. In May 2020, a study revealed that 52.3% of the physicians offered this telemedical service and another 10.1% planned to implement it at short notice. The trigger for this significant increase was the COVID-19 pandemic: 94.1% of the responding physicians stated that they introduced teleconsultations as recently as 2020, and 89.7% clearly attributed their adoption of teleconsultations to the COVID-19 pandemic (Obermann et al. 2020). In order to support the adoption of teleconsultations via videoconference, reimbursement regulations have been modified. As a result, teleconsultations were reimbursed on an equal footing with conventional face-to-face consultations by the German National Association of Statutory Health Insurance Physicians (KBV) (Whitehouse and Marti 2020). For the second and third quarter of 2020, the cap for video teleconsultation of 20% of all a physician's cases was lifted. Furthermore, the process for obtaining a license for teleconsultation via videoconference has been temporarily simplified for this period (KBV 2020; KVB 2020).

In ***Australia***, GPs have traditionally only been reimbursed for face-to-face treatment of patients. On 11 March 2020, however, the provision of teleconsultations for vulnerable groups such as elderly people, pregnant women, chronically ill persons, or immunocompromised persons for 6 months was unveiled by Australia's Medicare (Tanne et al. 2020). On 30 March 2020, the rollout of a universal telemedicine model for all Australians started to enable healthcare access through teleconsultations (with or without video) from home until 30 September 2020 (Fisk et al. 2020).

China, where the COVID-19 outbreak presumably started in Wuhan in December 2019, was the first country that had to deal with the new virus. In the Shandong province, for example, a telemedicine platform was initiated to deal with the COVID-19 pandemic. It includes a COVID-19 informational page, remote education for vulnerable individuals, and an online consulting clinic where experts are available 24 h/day. The telemedicine platform targets patients, medical staff, and community residents (Song et al. 2020).

In the ***USA***, COVID-19 also has had a large impact on the adoption of telemedicine. For instance, NYC Health + Hospitals (NYC H+H), a large safety net healthcare delivery system in New York, reported a drastic increase in the provision of telemedicine services (Lau et al. 2020): Before the COVID-19 pandemic, NYC H+H served more than one million patients and provided less than 500 telehealth visits monthly. From March 2020, however, NYC H+H transformed their system by employing virtual care platforms. They conducted almost 83,000 teleconsultations in one month and more than 30,000 behavioral health encounters via telephone and video. In addition, they provided patient-family communication, post-discharge follow-up, and palliative care for COVID-19 patients using telemedicine. In this case as well, the adaptation of reimbursement regulation played a crucial role. The New York State Department of Health expanded Medicaid coverage and reimbursement of a greater range of telemedicine services. The swift shift to virtual care relied on historic regulatory changes enacted at the federal and state level in response to the COVID-19 pandemic. Within only two weeks or less, primary care practices around the country also transformed from in-person care to virtual practices with telemedicine (Mehrotra et al. 2020). Before the crisis, telemedicine played a minor role in many practices, but after COVID-19 hit, the majority of patient encounters were virtual. This transformation was clearly supported in the cases where temporary changes allowed the reimbursement of applications such as teleconsultations. The adoption of telemedicine by NYC H+H and primary care practices was also facilitated by pre-existing digital technologies such as an electronic health record (EHR) system and health information exchange (HIE) functionalities (Lau et al. 2020; Mehrotra et al. 2020; Salway et al. 2020). Thus, this crisis clearly provides support for the argument claiming the importance of digital complementary assets for telemedicine adoption (Steinhauser et al. 2020).

3 AI, Big Data, and Mobile Applications in the Context of COVID-19

3.1 Contact Tracing and Containment of COVID-19

Contact tracing is used to avoid the further spread of COVID-19 by identifying and managing people who have recently been exposed to an infected COVID-19 patient (Lalmuanawma et al. 2020). Contact tracing is an essential public health tool used to break the chain of virus transmission (World Health Organisation 2020a) and can contain the outbreak by increasing the chances of adequate controls and helping to reduce the magnitude of the COVID-19 pandemic. The digital contact tracing process can perform virtually in real-time. As a result, it is much faster than a non-digital system (Lalmuanawma et al. 2020).

Various countries around the world came up with mobile applications that utilize different technologies such as Bluetooth, Global Positioning System (GPS), Social graph, contact details, network-based API, mobile tracking data, card transaction data, and system physical address. These digital apps are designed to collect individual personal data that is analyzed to trace persons, and they use centralized, decentralized, or hybrid approaches. In addition, AI, more precisely machine learning (ML), can be employed for analyzing the data and making sense of big data (Lalmuanawma et al. 2020; Whitelaw et al. 2020). By 01 September 2020, 47 countries had developed COVID-19 tracing applications (O'Neill et al. 2020; Statista 2020). Below, two examples are described, respectively from Asia and Europe.

Singapore, which has maintained one of the lowest per-capita COVID-19 mortality rates in the world, developed a mobile application that records encounters of individuals and stores them in their mobile phones for 21 days. The application employs short-distance Bluetooth signals. Singapore's Ministry of Health can access the data when an individual is diagnosed with COVID-19 and identify contacts of the infected person (Whitelaw et al. 2020).

Germany launched a decentralized mobile application to be used on a voluntary basis. Individuals can decide whether they want to install the app on their smartphones, inform the application about a positive test, and how they proceed when they learn that they have been in contact with a COVID-19-positive individual. The app uses Bluetooth technology to measure the distance and duration of encounters between people who have installed the app. Encrypted IDs (random codes) do not disclose any information about the individuals or their location (Bundesregierung 2020).

However, digital technologies such as tracing applications can potentially infringe on privacy. Hence, government authorities have to balance the need for COVID-19 containment (or any other benefit for public health) with the individual's right to privacy and data security (Whitelaw et al. 2020). COVID-19 tracing applications can establish a basis of information and practical experience that provides insights for the setup of future digital health applications and can thus facilitate their adoption.

3.2 Diagnosis of COVID-19 Cases

Early detection and diagnosis of COVID-19 is critical because early treatment can save lives and limit the spread of the pandemic disease. During the COVID-19 pandemic, AI applications such as machine learning were used to augment the diagnosis of the disease by applying them to medical images such as CT scans and X-rays and to clinical blood sample data (Lalmuanawma et al. 2020).

Already before the COVID-19 pandemic, interest in ML-based technology for medical imaging had increased around the world. Through chest X-rays and CT scans, healthcare systems produced a large amount of data on COVID-19. Huge datasets from China and increasingly from other countries have generated numerous publications where AI applications are applied to COVID-19 (Bachtiger et al. 2020).

Ardakani et al. (2020) suggest a rapid and valid method for COVID-19 diagnosis by applying the ***deep learning*** (DL) technique to images of *CT scans* in order to distinguish a COVID-19 infection from non-COVID-19 groups. The authors used ten well-known pre-trained ***convolutional neural networks*** to diagnose infections related to COVID-19. The best performance was achieved by ResNet-101, which could distinguish COVID-19 from non-COVID-19 cases with an area under the curve (AUC) of 0.994 (sensitivity: 100%; specificity: 99.02%; accuracy: 99.51%). They conclude that the DL technique can be used as an adjuvant tool for diagnosing COVID-19.

Another study applied ***deep neuronal networks*** in order to achieve automated early detection of COVID-19 cases in *X-ray images* (Ozturk et al. 2020). Their DarkCovidNet model can assist clinicians in making a faster and accurate diagnosis by using heatmaps that can help the radiologists to locate the affected regions on chest X-rays. It produced a classification accuracy of 98.08% for binary classes and 87.02% for multi-class cases.

COVNet, an open-source ***deep convolutional neural network*** design developed in China, can quickly differentiate COVID-19 cases from other lung diseases using *chest CT scans*. The DL model can accurately detect COVID-19 and differentiate it from community-acquired pneumonia and other lung conditions (sensitivity: 87%; specificity: 92%; area under receiving operating curve (AUROC): 0.95) (Li et al. 2020).

A study conducted in China extracted *11 key blood indices* (bilirubin total, creatine kinase isoenzyme, GLU, creatinine, kalium, lactate dehydrogenase, platelet distribution width, calcium, basophil, total protein, and magnesium) through ***ML*** (random forest algorithm), which, as a COVID-19-discrimination tool, can assist healthcare professionals in making a rapid diagnosis. The tool achieved a sensitivity of 95.12%, a specificity of 96.97%, and an overall accuracy of 95.95% (Wu et al. 2020).

3.3 Treatment of COVID-19 Cases

In addition to diagnosis, AI can also help to identify patients that may progress into severe conditions. That way, healthcare professionals are able to intervene earlier and thus may save lives.

A study with patients from Shanghai (China) who have been diagnosed with COVID-19 employed ***ML*** (namely support vector machine) to analyze *laboratory features associated with severe/critical symptoms*. It identified a combination of four clinical indicators (age, GSH, CD3 ratio, and total protein) that predicts severe/critical symptoms of patients infected with COVID-19. The model is effective and reached an AUROC of 0.9996 and 0.9757 in the training and testing dataset, respectively (Sun et al. 2020).

ML algorithms, like one developed in China, can predict the likelihood of developing acute respiratory distress syndrome and critical illness among COVID-19 infected patients. As a result, these prediction models can guide clinical decision-making and timely intervention in critical cases. In addition, they can improve resource allocation for COVID-19 treatment (Whitelaw et al. 2020). Thus, AI-based tools can provide objective stratification tools to rapidly assess a patient, assisting healthcare professionals in making difficult decisions about the allocation of scarce resources (Bachtiger et al. 2020).

Furthermore, AI can potentially contribute to tackling the COVID-19 pandemic by supporting the *development of drugs and a vaccine* (Lalmuanawma et al. 2020; Naudé 2020). Beck et al. (2020) used a pre-trained ***DL-based*** drug–target interaction model called Molecule Transformer-Drug Target Interaction (MT-DTI) to identify commercially available *drugs* that could act on viral proteins of SARS-CoV-2, the virus that causes COVID-19. They employed the algorithm on the 3C-like proteinase of SARS-CoV-2 and 3410 existing FDA-approved drugs. The drugs Atazanavir, Remdesivir, and Kaletra were predicted to inhibit SARS-CoV-2. Ke et al. (2020) established an ***AI platform*** to identify potential existing drugs with anti-SARS-CoV-2 activities by using two different learning databases; one consisted of the compounds reported or proven active against SARS-CoV, SARS-CoV-2, HIV, and the influenza virus, and the other one contained the known 3C-like protease inhibitors.

Finally, Ong et al. (2020) applied reverse vaccinology and ***machine learning*** in order to develop an effective and safe *vaccine* against COVID-19, caused by the SARS-CoV-2 coronavirus. They conclude that their predicted vaccine targets (i.e., proteins that were predicted to be adhesins) have the potential for effective and safe COVID-19 vaccine development.

In summary, a crisis such as the COVID-19 pandemic can accelerate innovation, in part by creating permissive environments for collaboration between healthcare professionals and AI experts (Bachtiger et al. 2020). Nevertheless, there has to be a balance between risk and rapidity that helps to find the solutions with the greatest clinical value. In this crisis, governments increasingly advocated light-touch regulation. Together with robust ethical standards, this can help to create an environment for a rapid and ethical approach. As a result, the COVID-19 crisis could mark the beginning of the digital transformation in healthcare through AI.

4 Conclusion

This chapter shows that crises such as the COVID-19 pandemic pose not only threats but also opportunities. As a result of the COVID-19 crisis, digital health solutions will likely present a more important complement to conventional care than before the pandemic. The adoption and usage of digital technologies during the COVID-19 pandemic created practical experience, technological capability, and medical evidence.

The COVID-19 pandemic had an impact on every stakeholder and individual, which got everyone involved in the fight. The rapid adoption of digital technologies during the crisis shows that stakeholders will be motivated to engage in the digital transformation in healthcare if each one can benefit from these digital innovations (e.g., Steinhauser 2019). It also points to the importance of digital complementary assets for a swift adoption of digital innovations such as telemedicine or AI (Steinhauser et al. 2020).

Finally, regulatory bodies and health insurances have temporarily modified long-standing regulations and policies to support the digital transformation during the COVID-19 crisis (e.g., Sinsky and Linzer 2020). In order to sustain these changes, healthcare systems should seize the opportunity to take advantage of the lessons of COVID-19 for the further digital transformation in healthcare.

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The Radiology of the Future

Yaron Rado

1 Introduction

Diagnostic Radiology has always been on the forefront of digitalization and would not be possible in its current form without the extensive use of a digitalized workplace. Nowadays, medicine heavily relies heavily on diagnostic tools in order to make an informed patient management decision and radiological tools have become more and more important in the daily clinical routine. While some have complained about overuse of "Clinical Engineering" versus "Clinical Medicine," there is no doubt that radiology has taken an important part in the clinical management of patients in the first world. As such, significant monetary and intellectual resources have been poured into this field over the last decades.

Radiology is a relatively young part of medicine, with the discovery of X-rays by Wilhelm Conrad Röntgen in 1895 and has been continuously developed at a great speed ever since. Generally speaking, radiology utilizes a range of physical tools for image acquisition: X-ray, CT, MRI, and ultrasonography. Besides very basic X-ray exams, all of these methods basically rely on the use of a computer for image generation, thereby making the field of radiology an ideal candidate for investigating how digitalization has shaped this specialty in the last decades and how it will evolve with new technologies entering the market.

In the following, the impact of digitalization in radiology as well as current and future artificial intelligence applications will be examined on the basis of several key examples.

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The application of non-intelligent image reconstruction algorithms is a powerful tool in radiology. Multiplanar reconstructions producing sagittal and coronal images from an axial image dataset like a CT or MRI exam have been used since the mid-1980s, when first spiral CTs were introduced and computing power started to be usable for 3D volume rendering (Calhoun et al. 1999). The advent of these new scanners resulted in a tidal change in anatomical tissue contrast and resolution and as such in diagnostic accuracy. More and more images were produced in a single patient, which can today easily result in thousands of axial images in a combined CT and MRI study. How should a radiologist cope with this image flood? The resulting improvement in diagnostic capabilities required more and more highly trained personnel. Many developed countries struggle to fill the vacant positions for radiologists (RCR 2019). Thus, although digitalization helped compile more diagnostic information, resources to analyze this information were clearly limited. In the last years, the topic and promise of Artificial Intelligence (AI) has dominated almost every big convention in the field of radiology and has often been praised as the solution to the almost intolerable flood of information that we nowadays can collect during a single radiological exam.

Although the promise of implementing AI to reduce the workload of the traditional radiologist sounds alluring, it can also impact this specialty with regard to making the traditional radiologist in the role of a mere interpreter of images redundant. As such, especially young doctors fear about having a future in this medical field which appears to compete to computers.

Today's use of teleradiology, where imaging studies are sent to offsite radiologists for interpretation, underlines the future possibilities of the onsite radiologist's role. Value added tasks include ensuring cost effective and appropriate imaging, integrating the clinical and imaging information better by having direct contacts to the referring physician and being an integral part of the clinical team. Interestingly, there is no difference in whether images are read by human or artificial intelligence since it does not affect these required tasks.

Although this chapter will concentrate mostly on the field of diagnostic radiology, I want to point out the role of interventional radiology (IR) in this context. In IR, an image-guided approach for therapeutic applications like closing or reopening vascular structures, image-guided placements of drainage catheters and drug or energy depositing probes make the interventional radiologist the truly minimally invasive surgeon. Minimally invasive image-guided procedures performed by IR have made many major surgical procedures unnecessary. In this context, digitalization techniques like subtraction of pre- and post-contrast images, which are then used as a roadmap for catheters. In neurosurgery 3D datasets previously acquired by CT or MRI are fed into a stereotactic program, which allows surgeons to take image guided biopsies or operate in head and spine using a virtual overlay. The overlay of an MRI pelvis dataset to live US images allows urologist to biopsy suspicious prostate areas that could be missed in the classic transrectal ultrasound biopsy (TRUS). This MRI/TRUS fusion biopsy has the advantage of using the superior imaging of the MRI coupled with easier-to-use ultrasound guidance and can even be done in the office setting.

Today datasets are printed on a 3D printer to explain complicated anatomical problems to the referring physicians like orthopedic surgeons or their patients.

2 A Retrospective: Wow the Digital Transformation of Radiology Started

Maximum Intensity projection (MIP) and Surface shaded display (SSD) techniques apply early 3D technology developed for the movie industry to a medical image dataset. The CT research group at John Hopkins collaborated with LucasFilm and Pixar in 1987 to demonstrate a 3D view of a hip fracture. They were using a then state of the art Sun 3/160 computer with 16.6 MHZ processor and 4 MB of Ram 78 showing the results on a "high resolution 1024×768 Barco monitor" (Fishman et al. 1987).

Many early applications were essentially attempting to creatively manage and pre-process the new flood of images and to facilitate the visualization of anatomical and pathological data. In the early 1990s, Virtual Colonography was invented, where a patient had undergone bowel preparation and inflation to produce a "fly through" movie of the large bowel. The data reconstruction at the time took 8 h but the resulting video was first screened with Wagner's Ride of the Valkyries to an impressed meeting of the Society of Gastrointestinal Radiology in 1994 (Dachman 2005). By 2008 Virtual Colonographies were included in the guidelines as a recommended screening test for colon cancer (Johnson et al. 2008; Pickhardt et al. 2018).

3 The Present: Artificial Intelligence, Machine Learning, Deep Learning, and Convoluted Neural Networks

Attempts to use modern computing power and the idea that it would obviously be superior to brain power has been attempted in modern radiology for quite a while. Artificial Intelligence (AI) algorithms to mimic cognitive functions and application of Machine Learning have been used for computer-assisted diagnosis (CAD) for a while. New methods like Deep Learning and Convoluted Neural Networks (CNN) which are biologically inspired networks mimicking brain cortex behavior have been on the rise due to recent advancements in computational power and availability of huge datasets (Pesapane et al. 2018). This data is used to train the computers to find a diagnosis. The largest freely available machine learning dataset available at the time of writing contains 874,035-images and is a multi-institutional, and multinational brain CT dataset. It includes expert annotations from a large cohort of volunteer neuroradiologists for classifying intracranial hemorrhages (Flanders et al. 2020).

3.1 Computer-Assisted Diagnosis

First steps in this approach were done under the name of Computer-assisted Diagnosis (CAD). The R2 ImageChecker 1000 CAD workstation was the first of its kind and was FDA approved for use in mammographic studies in 1998. It included a Pentium II processor, a laser digitizer and listed at US$179,000. Early studies concluded that CAD could improve cancer detection and in 2002, The Centers for Medicare and Medicaid Services in the United States approved reimbursement for CAD usage. "Despite some operational drawbacks to using CAD, radiologists have embraced it in an effort to improve cancer detection. Its use has grown rapidly, and in 2008, it was used in three-quarters of all screening mammographic studies and half of all diagnostic mammographic studies" (Rao et al. 2010). The new technology was quickly embraced in the radiological community. The usage was being payed for, money was invested, and the future of the traditional radiologist job description as a primary reader questioned. But later studies showed that radiologists did not change their diagnostic decisions after using CAD and thus, it did not bring the expected significant changes to their performance. There was no benefit for female patient population (Cole et al. 2014; Lehman et al. 2015). So despite the application of huge amounts of time, material, money, and people to the usage of CAD, in the mammography setting it eventually lacked effectiveness (Kohli and Jha 2018). Overall radiologists mostly disregarded the information delivered by the computer due to the overwhelming false positive markers. Even with the advent of tomosynthesis, a new mammography technology showing slices of the breast instead of a summation image, CAD could not improve the diagnostic sensitivity or specificity but at least seemed to improve speed a little (Benedikt et al. 2018). Your author as an early adopter gave the mammography CAD back to the manufacturer after trying to implement it in his reading routine for a year.

While modern imaging modalities can depict sub-millimeter anatomic structures, faster acquisition times have also allowed to show contrast enhancement curves to depict physiological background. Time is used as the fourth dimension and as such this datasets are referred to as 4D, adding physiological information (what the tissue is doing) to the available anatomical (how the tissue looks like). Both together have widened the field for early diagnosis possibilities. In the breast MRI realm two features suggest malignancy: Firstly, the morphological appearance with cancerous spiculae or linear orientated "string of pearls" pattern. And secondly, the dynamic features of a mass in a 4D dataset. Multiple series after contrast administration are repeated and contrast enhancement dynamics are calculated and offered as a parametric map image, overlying color coded information of different wash out curves of hyper perfused areas on top of normal breast tissue. Again, CAD turned out to be a tool improving the detection rate of the rather more inexperienced radiologist (Dorrius et al. 2011), but your author finds the application quite useful to explain findings to the referring physicians.

3.2 Convoluted Neuronal Networks

With this past experience, why are we today still excited about computer application to patient data? Modern picture algorithms deployed by companies like Amazon and Facebook, can identify thousands of objects and people faster and more reliable than humans. Integrating these technologies into the picture medical field of radiology has shown great promises and starts to find wider usage. Applying the doubling processing power every 2 years rule according to Moore's law has always resulted with advances reflected in radiology applications.

New AI systems using deep learning techniques like convolutional neural network (CNN) processes show new promises, with the latest studies suggesting over 11% better detection than radiologists using a mammography image database of over 80,000 images (Greenspan et al. 2016). Radiological image data is generated and transferred in a digital format which includes patient- and modality data called DICOM. The addition of "structured reporting" to the DICOM standard (DICOM-SR) has added the radiologist's report to the digital available information. Making these huge image databases with structured reports attached available to train CNNs allows AI to teach itself. Many imaging datasets are available for training AI algorithms. Some are proprietary data sets from hospitals or companies, but some are freely available. But the question remains if we can truly rely on CNN's learned features? Applying CNN to CAD has shown some promises with at least slight improvements to previous versions of CAD (Setio et al. 2016).

To reconstruct CT and MRI images, Fourier transformation or iterative reconstruction algorithms of the raw data is performed in order to construct the image that then later becomes a part of the 3D dataset. Latest approaches give CNNs access to the raw data with some success in, e.g. being able to use less information to derive the same information. This in conclusion would allow for faster image acquisition times (Masutani et al. 2020).

When looking at very recent research published, it becomes clear that we are getting closer to the goal of offering deep learning-based systems that achieve parity to board certified radiologists. This has been shown for the detection of pneumothorax, nodules or mass, airspace opacity, and fracture (Majkowska et al. 2020) and even fellowship trained performance in finding and classifying hip fractures (Krogue et al. 2020).

4 The Radiologist's New Job Description in the Age of Digitalization

There seems to be the accepted knowledge that AI will change radiology and the question is not if but when. We seem to be ready for prime time soon as radiologists all over the world are collaborating in bringing datasets together to train AI. As described above, radiology has changed constantly through the early application of the IT driven revolution affecting almost every facet of our daily life. Being a player at the forefront of new developments and bringing the necessary conservative approach of a doctor to the table puts radiologists in a unique position to use the advent of such a new strong tool to good use.

The necessity for a physician to strike the last hammer blow, to finish what algorithms have computed and make it human, will not go away with AI. But the writing is on the wall that the formerly unfulfilled promised computer diagnosis is around the corner.

The radiologist's job has always been on the interface between technology, the referring physician, and the patient.

The field gets more and more specialized and access to this pinpointed knowledge is more and more expected by the radiologist's customers: patients, referring physicians, insurance companies, and the public.

Young doctors who only see the detection and interpretation portion fearing for the future of the radiologist miss the value chain generated in this field. The advent of new powerful tools will enhance the job description, making it more interesting and raising its importance to patient care even further.

5 The Patient's Perspective in Radiological Digitalization

Everything we do in medicine is about the patient. The impression of above achievements might appear tainted in the light of an overall scepticism towards novel scientific discoveries and alleged technology overuse in today's patient care. However the frontline healthcare workers can truly acknowledge how these advancements have impacted and improved healthcare. No accurate diagnosis means no effective therapy. AI promises to bring specialized knowledge to the masses very soon, and the one who directly benefits is always the patient.

6 Conclusion

In summary radiology has throughout the last decades become a more and more important field in medicine by applying new technologies in science, technology, engineering, and mathematics to improve the speed and accuracy of making a diagnosis available allowing for the most effective treatment of patients.

Radiology has been surfing the tidal wave of new information technology for a long time and will continue to thrive even more with the advent of AI. In the above I have tried to give insights to the history of application of this knowledge, the status quo, and the promises of the future. Radiology stays being on the forefront to make use of new technology in the conservative field of medicine, and the radiologist is the pioneer. Exciting times ahead!

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Digitalization of Pneumological Care in the Outpatient Sector: An Inventory

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1 Introduction

The world is currently undergoing digital change. This raises the question of why digitalization has become more widespread in the private sector than it is currently in the healthcare sector. Social networks have become a matter of course, and apps are used to control forms of organization and conduct business. This is not the case to this extent in the outpatient medical sector. Here, digitization has so far been limited to billing processes and documentation. However, various factors have recently necessitated a rethink towards the use of digital products in the context of outpatient treatment of pneumological patients. The leading factor here is an orientation of the doctor-patient contact away from traditional treatment in the practice towards the use of digital contacts in the patient's home environment. This development is accelerated because outpatient pneumologists are underrepresented in Germany. In the outpatient sector there is a ratio of 0.6 pneumologists per 100,000 inhabitants, which represents the lowest pneumological coverage within the European Union. In contrast, Greece, the leader in this field, has a rate of 13.2 pneumologists per 100,000 inhabitants (Barzok 2016). In addition, individual practices are no longer adequately staffed and the pneumological presence will be increasingly lost especially in smaller cities. However, demographic developments will lead to an increase in the number of cases due to the high co-morbidity of the patient group, which means that a pneumological presence can be created through telemedicine especially in rural areas with long distances to travel.

This article deals with the possibilities of digitalization in the pneumologic outpatient setting. The first chapter describes the possibilities and limits of telemedicine in the outpatient sector. The subdivision of telematics into telemonitoring and its

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contribution to intersectoral cooperation using the example of sleep medicine is the topic of the following chapter. Subsequently, the current state of development of digital products and their limitations especially in the area of patient data protection will be shown. Finally the currently existing obstacles to development and solution modalities are discussed.

2 Telematics: Telemedicine and Telenursing

The term telematics defines the use of means of telecommunication for specific purposes, such as the control of systems. Telemedicine is a sub-area of telematics in the health care system which includes both diagnostic and therapeutic bridging of spatial and temporal distances between the participating physicians, service providers (providers, pharmacists), cost units and patients (WHO 2020). Telemedicine is intended to optimize the quality of doctor-patient contact and the treatment outcome. Telemedical interventions can also ensure improved care for patients with chronic lung diseases in particular (Sulaiman et al. 2018). In addition, there is the organizational will and the technical-digital know-how to combine virtual clarification and clarification appointments with further treatment on site. The technical prerequisites already exist for establishing intersectoral cooperation with the family doctor using telemedical possibilities (Merchant et al. 2016). Digital aids will improve doctor-patient contact and will complement personal contact.

2.1 Virtual Consultation Hours

Particularly in pneumological practices with catchment areas of more than 100 km telemedicine services are tested and promoted with the professional political support of the Federal Association of German Pneumologists (Simoni-Wastila et al. 2012). It is possible to create an electronic file card by means of a technical device. After approval by the patient the virtual file can be processed by the treating professions, such as family doctors, specialists, and pharmacists (Häussermann 2020). Additional data such as lung function, laboratory values, and other diagnostic data can be entered via the physician. The patient’s medication or adherence to therapy is digitally documented and entered into standardized questionnaires (Price et al. 2017). This should enable family doctors and pneumologists to analyze the course of asthma and COPD patients at any time and to react quickly and specifically to any problems (Van Boven et al. 2014). Corresponding possibilities (Vitabook) are currently being tested. Telemedical engagement is being accelerated, especially in the context of the Corona Pandemic, where the intensity of a tele-video contact is rated higher by patient groups than a telephone call or e-mail contact (Randerath et al. 2017).

2.2 Digital Training Material

A focus for the implementation of telemedical intervention in pneumology is on patients with unstable asthma or severe COPD (Dekhuijzen et al. 2018). Telemedical concepts are developed to improve the quality of life, shorten reaction times, and avoid inpatient treatment. An example is the successful project of the German Respiratory League, which has developed training videos for improved inhalation therapy (Vestbo et al. 2009). Further illustrative material is to be made available to patients in the simplest possible way via smartphone. One way to ensure the rapid penetration of information and general availability is to make the material available on the video platform You Tube (Sulaiman et al. 2018). Electronic instructional videos from various scientific journals (New England Journal of Medicine) as well as (company-) sponsored knowledge platforms are available within the academic training programs of the medical profession. In the pneumological-German-speaking area, the LehrApp Leila was sponsored by the German Society for Pneumology in order to offer the most up-to-date availability of medical information which is presented in a product- and company-neutral environment.

2.3 Digital Patient Training Programs

There are training programs for outpatient pneumologists to care for asthmatics and COPD patients. These are the National Outpatient Training Program for Adult Asthmatics (NASA) and COPD Patients (COBRA). Both programs show proven positive effects (Van Sickle et al. 2016). In the future digital aids and smart devices will support these patient education programs. This will help especially those patient groups who are unsure how to use digital applications (Black et al. 2008). In this context the employees of the practices , e.g. MFA, must not be disregarded. Because telemedical programs also enable an integrative approach to understanding the training devices (Duiverman et al. 2019). These measures will lead to a sustainable improvement in the care and stability of the patients' health (Barzok 2016).

2.4 Telenursing

Telenursing means the digital integration of medical professions into patient care. In programs such as training within the Disease Management Programme (DMP) COPD or asthma, pneumology assistants (PFA) already play a major role in Germany (Merchant et al. 2018). By including this profession in telemedical projects, decisions on further therapy planning can be made appropriately. In this regard a pilot project exists in Baden-Württemberg involving the associations of physicians and two ministries (Wallenfels 2020). For example, vaccination programs can be controlled, which provide digital information on medical measures. Furthermore, at the beginning of a hypersensitization through telenursing appointments can be made and patients can be checked for adherence (Foster et al. 2014). Telenursing can also be used to monitor treatment with topical steroid therapy. Due to the easy access to implement guidelines these measures can be controlled very well without the intervention of a physician (Dreher et al. 2019).

3 Telematics: Telemonitoring

Telemonitoring is the remote examination, diagnosis, and monitoring of the patient by his treating physician. Randerath et al. have shown the possibilities and limitations of telemonitoring for sleep-related respiratory disorders. After all, the comprehensive care and long-term support of patients represents a challenge for medical care (Taylor et al. 2006).

3.1 Data Processing with the Therapy Device

The rate of sleep-related breathing disorders and their prevalence with clinical symptoms is gradually increasing (Kohler et al. 2015). Today, approximately 13% of men and 6% of women in the USA are affected by sleep-related breathing disorder (SBAS) requiring treatment (Nilius et al. 2016.) In the currently possible digital diagnostics, the data is transmitted to a central sleep medical center. Doctor-patient contact is then established via a digital consultation hour (Bohning et al. 2011). In the future, web-based questionnaires and telephone doctor-patient contact will allow the recorded data to be expanded. This is because checking compliance and improving long-term care for high-risk patients, including professional drivers, is the therapeutic goal of care and treatment (Goldstein and Zee 2010). At present, it is technically possible to read out treatment data from the therapy devices via modem during follow-up monitoring (telemonitoring).

3.2 Sleep-Related Respiratory Disorders and Telemonitoring

Scientific publications on SBAS telemonitoring have mostly dealt with the issue of treatment compliance. Here, a positive effect on the patient’s use of the devices was proven (Isetta et al. 2015). In addition, telemedical care has a positive effect on the physician’s scope of action. Here he prescribes the equipment, but also determines to what extent the provider is allowed to take over the problem treatment. The provider delivers the device to the patient and instructs him or her on its functions, including the possibility of telemonitoring. The provider is responsible for informing the health insurance company about any mandatory data. For telemonitoring, the legal framework of data protection laws applies to the processing of personal patient data. The prescribing physician is responsible for the entire therapy including the telemedical component (Randerath et al. 2017). The telemonitoring of the therapy devices via modem allows a personal doctor-patient contact to take place as soon as abnormalities are measured (Sparrow et al. 2010). Problems related to the therapy compliance of the devices or the occurrence of mask leakages are detected early. It is also possible to close gaps in care because patients in rural regions in particular are reached via telemedicine within the pneumological undersupply (Godden and King 2011). Digital process flows simplify the possibility of standardized quality in follow-up care and avoid unnecessary stays in the sleep laboratory for therapy control (Nasu et al. 2011).

3.3 Real-Time Analysis and Data Protection

The attending doctors are responsible for the entire sleep medicine therapy. Therefore, they also prescribe the extent and type of telemedical processing and collection of patient-related data, after consultation with the patients. The medical aid provider may only store data within the scope of the prescription. A use for third parties or own purposes is not permitted. Real-time analysis or continuous online transmission may not be carried out during use by a provider for reasons of data protection law. In the contractual relationship between health insurance companies and providers all usage data can only be transmitted if the patient has given his consent (Bohning et al. 2011). In summary, the technical possibilities of a digital analysis of the equipment used for SBAS therapy are already available today. However, real-time analysis or even complete transfer and exchange of the measured data between handlers, providers, and health insurance companies is not possible without the explicit consent of the patient.

4 Digital Products: Increasing Adherence

Adherence is defined as the extent of an agreed adherence to a therapy, for example, in the context of taking medication. To improve adherence management, the development of the so-called apps is in the clinical foreground. Apps are programs that fall under the term application software systems. These are sometimes operated by several users and can ideally be processed via smartphone or tablet. In Germany, electronic diaries in the form of apps are available for outpatient settings. In addition, digital inhalation devices (smart devices) are being developed that can document the correct use of the inhaler (Häussermann 2020).

4.1 Electronic Diaries

There are electronic diary functions via App. The course of the disease, medication, and symptoms are documented on the smartphone. In addition, activity parameters such as the peak flow meter and a pedometer can be implemented via the app. An additional reminder function ensures that the medication is taken. Separate data analyses, such as pollen count, can also be switched on (Barrett et al. 2018).

Due to the improved display options and the subdivision of the data into the treatment groups of doctors and pharmacists, the course of the disease and the success of the therapy are decisively influenced and consecutively improved. The integration of relatives into this data world is possible. The measurements within the electronic diary can also be forwarded to the treating physician as a pdf document (Häussermann 2020).

4.2 Apps

Adherence not only means taking the correct medication at the prescribed time, but also the correct use of the inhaler (Lewis et al. 2016). Due to the different ways in which the various apps can be used, adherence can be extended to include nutritional recommendations and other treatment suggestions from the treating physician (WHO 2020).

However, a pure reminder function is not sufficient to increase the success or compliance of treatment (Charles et al. 2007). A significant increase in adherence is only achieved if the correct use of the medication is also monitored (Morton et al. 2017). Some apps for the treatment of chronic respiratory disease have already enabled improvements in inhalation treatment of pneumological diseases with the help of artificial intelligence (Smartphone App CARTA) (Montes de Oca et al. 2017). In addition to learning control, the app includes a reminder function and logs whether the individual steps of the inhalation process have been completed. The patient is informed via images and text whether the active ingredient has reached the lungs (Cushen et al. 2018).

4.3 Adds-on for Inhalation Devices

For a better control of the handling of the inhalation devices (Devices) there are the so-called hardware adds-ons with corresponding App. This can improve adherence (Baddar and Al-Rawas 2012). Triggering processes can be recorded by these products. In the future, add-ons will compete with each other, which can be adjusted to a wide variety of inhalation devices. The devices are connected to the smartphone via Bluetooth and store the frequency of the inhalation maneuver. Furthermore, charging maneuvers, the inspiration and inhalation process of the devices are recorded. A feedback is correspondingly possible. These systems are currently being tested and are not available on the German market (Häussermann 2020).

4.4 Smart Devices/E-Devices

On the US market there is only one product with integrated add on. This so-called smart inhaler records when the patient uses the inhalation device. The recording does not go beyond that of the clip-on add-ons. Nevertheless, the breathing pattern can be displayed as a feature. The German professional associations DGP, Atemwegsliga and the Verband pneumologischer Kliniken (2020) recommend the further development of the E-Devices based on therapy and medication adherence. The use of E-Devices in pediatric and adolescent medicine is particularly interesting as patients become more independent (Westerik et al. 2016). Due to the complexity of the market, the German Respiratory Tract League has created a seal of quality that is independent of company influence. The aim is to create a uniform data format without open interfaces, which can also be used for scientific studies and which takes data protection into account.

5 Challenges

What are the challenges to be met in order to promote the further development of telemedicine in the ambulatory pneumology sector? On the one hand, digital intersectoral cooperation between the hospital and practice institutions must be promoted. This is because the lack of digital communication between the respective software programs means that no meaningful data exchange can take place. In addition, it must be possible to process patient data in accordance with strict data protection regulations. Finally, the reimbursement modalities (EBM) must be quickly adapted to the current needs of treatment partners and patients.

5.1 Intersectoral Cooperation with Standardized Interfaces

The introduction of digital aids or the possibilities of telemedicine is a great challenge in the field of pneumology. In particular, an interlocking of intersectoral cooperation between hospitals and branches is necessary (Dreher et al. 2019). A forced further development is barely necessary, which does not only concern the digital aids and the further development of the so-called smart devices. Rather, standardized interfaces between the individual documentation systems must be created. Without a standardization of the current practice and clinic software, a concentrated development of, e.g. digitalized consultation hours and telenursing as well as telemonitoring will not take place.

5.2 Data Protection

Compliance with the strict German data protection laws as an unconditional criterion has top priority in the treatment of patients. In the case of sleep medicine, there is a field of tension between the providers of therapy devices (providers) and the Internet companies on the one hand, and the patients and their doctors on the other. This is because the generated data can be used economically, especially by provider-respecting internet providers. Therefore, patients must have control over their treatment data at all times. In addition, the companies' handling of data storage outside the EU must be taken into account.

Regulatory frameworks such as the German government's Digital Agenda 2014 to 2017 and data protection laws (DSGVO 2018) must be taken into account when developing digitized products and communication channels. The processing of personal patient data may only be further developed using procedures that guarantee data protection and information security. At present, user groups and graduated user rights are being defined, because data must be processed in the quality appropriate to the purpose of use. The EU is currently planning to introduce a Medical Device Regulation (MDR) in 2021, which will uniformly regulate EU data protection and medical device legislation. This is because it defines the selectivity between, for example, an app and a medical device (Schöbel and Woehrle 2020). With the help of providers, a complete care concept can be guaranteed, but the evaluation may only be carried out with the express consent of the patient. This must also be documented. Currently, the evaluation of medically recorded data in Germany is carried out within the framework of scientific studies and investigations. A comprehensive evaluation by the providers is not possible due to the local data protection laws.

5.3 EBM (Uniform Assessment Criteria of the Federal Association of Statutory Health Insurance Physicians)

A shift of the ambulatory supply happening to the telemedical consultation is necessary in the context of the shortage of the ambulatory active pneumologists. In this way, standardized care can be established for patients who have a stable disease. In this way, the appointments for acutely ill patients can be focused. This development is opposed by the current EBM, which mainly rewards technical services such as lung functions (Heimann 2020). This is because telemedicine is expected to lead to a decline in case values while the number of cases remains unchanged. Therefore, according to the experience of the COVID pandemic, the focus is currently on the evaluation and efforts of outpatient pneumologists. Only after a reorganized reimbursement structure of the EBM will digitalization and all its possibilities be actively integrated into the outpatient care structures for pneumology.

6 Conclusion

We showed that within the pneumological ambulant patient care far-reaching possibilities of digital supply by telemedicine, telenursing, and telemonitoring from the virtual consultation hour up to adhesion improvement are already available today.

In the event that problems such as data protection, digital interface, and reimbursement structures are solved, a completely new supply unit will be created. The promising possibilities of telemedicine and telemonitoring can be fully exploited.

In addition, there is the chance of a reorganization of the intersectoral cooperation. By guaranteeing legal security, a new cooperation of the cost units with the treating parties—doctors, pharmacists, and developers—will be possible. If these aspects combine, an improvement in the medical quality of patients with pneumological diseases can be achieved.

The digitalization of the field of pneumology in Germany has a slowed down dynamic in the ambulatory sector, although the inclusion of telemedicine and its subgroups telemonitoring and telenursing makes it possible to treat a broad group of patients outside the existing practice structures, even with the addition of apps and monitoring of inhalers. The possibility to create professional networks and an intersectoral structure between the outpatient and inpatient sectors is desired and technically possible. Here, the field of sleep medicine is leading, whereby the existing obstacles to the development of data protection, reimbursement structures, as well as company-neutral data networks must be overcome.

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Computer Vision Applications in Medical Diagnostics

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1 Overview of Computer Vision

The field of computer vision has existed since the late 1940s, initially intending to help robots understand the environment they were operating in. The earliest versions of successful computer vision algorithms were largely utilizing pixel-based, statistical analysis methods, like, for example, averaging the gradients in a small area of the picture to detect boundaries of objects based on “sudden changes” of pixel-values. These methods were already good enough to help early robots navigate and were therefore used in experimental designs for video surveillance and self-driving cars, etc. However, these methods were lacking a few key features: They were relatively low-resolution and were not able to recognize smaller differences in objects, see e.g. (Minsky 1961).

These problems became solvable with the relatively recent advent of deep learning methods: Driven by innovations which enabled the scaling of the amounts of data we can create, store, and compute (like, for example, the invention of GPUs—graphics processing units) we are now able to process a much larger amount of correlations then before. This increased performance has enabled deep neural networks (DNNs), to work sufficiently fast to train large networks with millions (and even billions) of variable weights in reasonable times to allow for massive innovation in computer vision and the field of AI at large.

Deep neural networks in computer vision primarily rely on learning correlations of neighboring areas in an image in a hierarchical structure with increasing abstraction: These “convolutional neural networks”, depicted in Fig. 1, have then been able to recognize for example handwritten digits with no prior human input in setting the parameters itself. These are learned through the method of “backpropagation”

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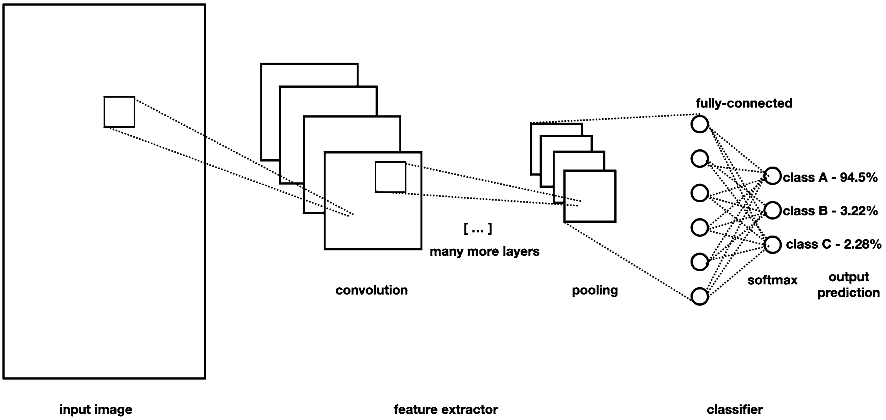

Fig. 1 Architecture of a convolutional network, which served as important part of the foundation for most computer vision work done today. This simplified sample network demonstrates the different stages and layers involved in a CNN: convolutional feature-extractors, pooling layers and finally a fully connected classifier with a softmax output layer. There are many other variations and architectures of CNN networks used today, but most of the underlying principles remain similar. Source: Author

(Rumelhart et al. 1986). This method was then applied to recognizing handwritten characters (LeCun 1986). That achievement unlocked a huge field of research and applications for networks to be trained end-to-end with only limited human input, which is mainly the case for the design of the architecture and learning functions of the DNNs.

Today, computer vision experts all over the world leverage deep learning, coupled with many more recent advances, like hyperparameter tuning, and neural architecture search, which both optimize the hyperparameters (general architecture and parameters like the model's learning rate, etc., which significantly can improve a model's performance if chosen correctly) and therefore allow for rapid scaling and experimentation on large (and small) datasets. Additionally, cloud providers today provide the computing infrastructure needed to train such DNNs very easily and with a limited upfront investment.

Notably, open and free access to data, deep learning frameworks, and pre-trained models is another trend which steadily promotes innovation. With the new platform of massive open online courses (MOOCs), which is largely driven through platforms built by computer vision experts,[1] made learning about computer vision, deep learning, and the skills needed to be active in the field, very easily accessible to anyone, anywhere. Since then, a lot of effort has gone into building frameworks, that simplify the usage of deep learning and other machine learning methods,

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[1] Udacity, founded by Sebastian Thrun. Coursera, founded by Daphne Koller and Andrew Ng.

by providing a sufficient abstraction to the programmer. As these programming frameworks evolve, they become better and more efficient to use.

Today, the most used and most popular deep learning frameworks include Keras.io and TensorFlow (both maintained by Google engineers), PyTorch (maintained by Facebook), and MxNet (maintained by Amazon). These frameworks provide all the necessary tools to get started in computer vision with relatively low effort. One train a computer vision algorithm for Pneumonia Classification on X-ray images with less than 100 lines of code with Keras for example.[2]

Additionally, numerous "model hubs" are now freely available, which allow researchers or engineers to download pre-trained networks and then fine-tune them to specific use cases or automatically leveraging any of the "AutoML"—automated machine learning—frameworks to have their dataset modeled to the optimum performance.

Over the last 10 years, all of these innovations and platforms helped to unlock this field of research and development to hundreds of thousands of enthusiasts, engineers, and scholars. This has led to many interesting and impactful developments around the problems of medical diagnosis as well, some of which we will discuss in detail now.

2 Computer Vision in Healthcare Diagnostics: Applications

The problems of healthcare diagnostics are some of the most interesting, and impactful areas of research and application in computer vision.

2.1 Applying Computer Vision in Practice

When applying computer vision in practice, one often follows the workflow depicted in Fig. 2.

Generally, in computer vision, we categorize into different types of problems:

- Classifications with supervised learning: When you give the learning algorithm all the labels of your training examples to learn from.
- Classifications with unsupervised learning: When you do not have the labels of your training examples when learning, so the learning algorithm tries to identify what classes exist.
- Classifications with semi-supervised learning: When you have some, but not all labels; sort of a mix of supervised and unsupervised learning.
- Classifications with weakly supervised learning: When you try to use the signal from a small, often noisy, labeled dataset to infer the labels of a broader unlabeled dataset, to then use that for supervised learning.

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[2] https://keras.io/examples/vision/xray_classification_with_tpus/

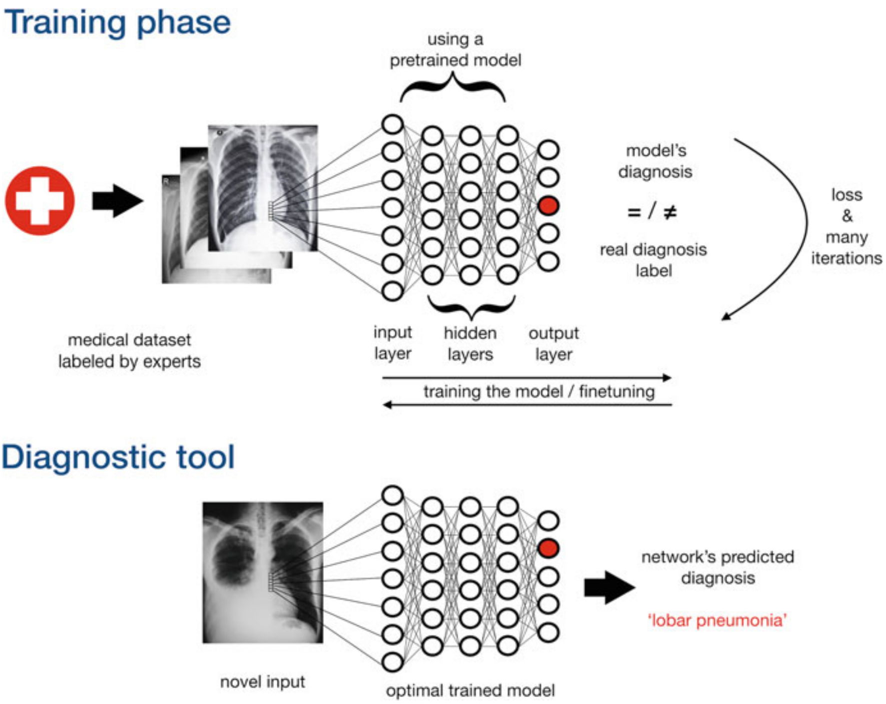

Fig. 2 Common workflow in practice: (1) Get specific training data suitable for the problem at hand. (2) Load pre-trained model. (3) Use problem-specific training data to fine-tune the model. (4) Iterate over the data many times, minimizing the training error. Then use the model as a diagnostic tool by loading the model and running it on new data to get predictions. Source: Katharina Thoene and author

Most study problems one would encounter when learning computer vision methods will be using supervised learning: You have a lot of labeled training data (usually already labeled standard datasets) and you train a DNN to find the optimal mapping from the input vector (your image data) to a probability distribution over the possible labels (your models' prediction). This method works well if it is possible and effective (think about the time and cost it takes to label often hundreds of thousands of examples) to provide labeled training data.

However, in reality, this is very rarely the case: Often datasets are only partially labeled, and also these partial labels will be noisy and have some errors in them, like, for example, when you are getting clinical X-ray data from a hospital where the labels, or diagnosis, are only sometimes provided and then there might be also mistakes in them or errors due to the transfer from one format (often paper notes) to another (digital labels with the images). That is why a pure supervised learning algorithm will rarely be used in practice. The majority of times you will be using weakly supervised or semi-supervised learning algorithms.

2.2 Examples of Applications

Most applications today in medical diagnostics can be classified as one of these following categories:

- Detection of certain abnormal tissue, e.g. cancer detection, etc.
- Detection of (micro-)fractures, e.g. in bones, veins, etc.
- Counting of certain types of cells or tissues, e.g. count of white blood cells in probes, etc.
- Segmentation of certain tissues from the rest, e.g. seeing where and how big a cancer is, etc.
- Guided surgery through (3D) models of the tissue to help perform the surgery higher precision, often using computer vision-assisted robot arms to perform the surgery.
- Functional brain analysis, segmentation, and classification on fMRI data to identify areas of dysfunction.
- Image super-resolution, using generative adversarial networks (GANs) to produce higher resolution images, e.g. for MRI resolution (Sood et al. 2018).
- Classification-based image retrieval, using computer vision to "tag" images and data based on their content to allow for faster easier retrieval, especially with rare conditions and disorders (Müller et al. 2005).
- Substructure segmentation, to assist in identification and examination of different substructures, for example, of blood vessels in the retina which are hard to spot for humans (Fu et al. 2016).
- Motion tracking of human movements to identify abnormalities in movements like, for example, gait analysis to diagnose onset of Parkinson's disease (Kour and Arora 2019).

Early pioneers in this field include Daphne Koller,[3] Kunio Doi,[4] and many more. It is very interesting to go through their early publications to see the evolution and changes in the approaches in the field over time.

Because of the increasing media coverage and hype about AI taking over many jobs, many medical professionals fear that their jobs could be replaced soon. However, the overall goal of using computer vision in medical diagnosis is to help the medical professional to perform better and faster diagnosis, not to replace them.

Over the last few years of research, it became evident that deep learning methods are actually quite complementary to the human strengths. Therefore, there is a lot of emphasis on the idea of human-machine collaboration: Often the skills that are fairly easy for us are the hardest to learn for machines and vice versa. Humans are very strong at "seeing the bigger picture" and taking all different aspects of a patient's condition and symptoms into account when making the diagnosis, while

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[3] http://dags.stanford.edu/publications.cgi

[4] https://profiles.uchicago.edu/profiles/display/13712530

even the best experts sometimes tend to overlook minute details in the vast amounts of available data and are limited in their capacity to compare a single patients case with many others in real time.

In contrast, trained machines detect picture anomalies within milliseconds, but fail to find the context beyond pixels. These are exactly the advantages of deep learning-based systems to help in medical diagnosis, as the machine learning algorithms are much better at using hundreds to millions of examples and other data points to base their conclusion on and can be much more sensitive to very small details in these large amounts of data. The human experts and machine learning systems can therefore form a very powerful "team" to optimize for the best possible diagnosis and outcome for the patient.

Many startups and solutions are already being integrated in today's clinical practice using this human-in-the-loop approach for medical diagnostics. Some notable ones include:

- Smart Reporting: building a reporting tool suite where radiologists are assisted by deep learning.
- Caption Health: using deep learning to help interpret and guide ultrasound examinations.
- Deep Pathology: helping pathologists evaluate their samples using deep learning to count, segment, and classify cell and tissue types.
- CellmatiQ: various products to help dentists and orthodontist identify and classify different types of problems using deep learning.
- Athelas: using computer vision to classify and count white blood cells and Lymphocytes to be able to detect infections earlier and much cheaper than usually done.
- There are many more great startups in the field of medical diagnostics using machine learning, most of which utilize the principles and methods discussed here.

With all of these applications, as well as the many more which are still at the research stage or pending approval from the regulating bodies in their markets, the most common challenge for them is very similar: Getting access to sufficient amounts of clean, well-annotated (at least partially) training data. Accessing, structuring, and assembling these training datasets is often the biggest challenge when developing a new solution using machine learning, due to the cost and time needed to get the data. Another difficulty lies in the approval to use the data for this project, and the domain experts time to label the training examples properly.

Even when that is all done properly and with many good training images, the DNNs still tend to "overfit" (e.g. model too closely to the specifics of the training datasets which were provided) which can lead to problems when scaling the approaches to new sets of information.[5] This can be due to either the equipment used to generate the imaging data might have a small inherent bias (like different color/pixel gradings, etc. which might get picked up by the DNNs) or the underlying patient population has slightly different, which can lead to a significant reduction in the accuracy of the machine learning-based approach, and is often one of the biggest challenges when developing and bringing these applications to market.

3 Computer Vision in Healthcare Diagnostics: Opportunities and Challenges

Since the amount and quality of the available training data for each computer vision task is so critical, this therefore offers one of the biggest opportunities for improvement. There are several (sometimes opposing) forces currently at play to improve the handling of medical imaging data.

On the one hand, to make access to training data harder (by means of privacy enforcing regulations like GDPR, generally increased privacy awareness, etc.), and on the other hand to make it easier to get the right training data (open sharing platforms of anonymized data, conferences pushing to publish data along with the papers, increasing awareness of hospitals to gather and structure data, etc.). Additionally, innovations, like zero shot learning[6] or active learning techniques (Brust et al. 2018) make algorithms much more data-effective, allowing for better results with less data.

Furthermore, the interfaces of human-in-the-loop systems are becoming much better over time, allowing for more effective collaboration—both, in training models and also in the clinical production setting—and therefore higher data throughput.

The biggest challenges, besides ensuring access and quality of training data for each diagnostic problem, are currently:

- Bias: solving for unbalanced features in datasets (e.g. due to the ethnicity or gender of the majority of the patients in a training data set, etc.).
- Robustness: Correcting for overfitting due to characteristics of the individual or the imaging device.
- Scalability and access: Currently most of these advanced methods are only available in the best-resourced hospitals and areas.
- Interpretability of models: When basing the decision about medical treatments on the diagnosis provided, one has to have high confidence in the algorithm. For that, having interpretable (or explainable) algorithms is critical, but this remains one of the biggest challenges to overcome when using deep learning methods.

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[5] https://www.sciencemag.org/news/2019/06/artificial-intelligence-could-revolutionize-medical-care-don-t-trust-it-read-your-x-ray

[6] https://www.learnopencv.com/zero-shot-learning-an-introduction/

- Regulation: ensure proper and appropriate regulation and standards for learning algorithms in diagnostics applications.
- Human–computer interaction (HCI): make the interfaces better and allow for the best possible collaboration (more below).
- Synthetic training data: Using computer graphics and simulations to generate new training data automatically, based on previously known data and principles, in order to make algorithms better and more robust without needing more expensive real-world data.
- New learning paradigm: Overall, the deep learning paradigm has offered a lot of opportunities and improvements over classical computer vision methods, however, it still lacks a few fundamental features which will be needed to enable a lot more applications and more reliability.

  It is currently unclear how exactly this new paradigm will look like, but it has become evident that one is needed beyond deep learning. Personally, I believe it will be developed out of the neuro-symbolic machine learning community.

Some of these challenges will be improved upon by building new model architectures, introducing new learning functions, and better hyperparameter tuning, etc. But some others are more fundamental and teach us a lot about the strengths and weaknesses of both human experts and learning algorithms on these tasks.

It becomes evident that the future most likely will be shaped by the collaboration of experts and machines, leveraging each other's strengths to deliver the best, fastest, and most accurate diagnostics possible. Therefore, the user experience of the interfaces providing such algorithms must be tuned to optimize the interaction between the human-skills (critical thinking, putting the data in context, having the holistic view of the patient) and the machine skills (extreme attention to detail, ability to compare with and learn from millions of other patients, steady or increasing performance with time, etc.). It might make sense to think of "artificial intelligence" as "augmented intelligence," augmenting the human capabilities, such that it becomes a tool for us to become better, just like we use watches as a tool to help us keep the time more accurately.

4 Conclusion

In this chapter, a short history and explanation of the most commonly used methods of computer vision has been given. Afterwards we laid out the most well-developed areas of application for computer vision methods and gave some examples of companies pushing the adoption of these novel techniques to the market. Then we went on to discuss the most important challenges and shortcomings of the current technology and gave some ideas for future directions of development. Overall it became evident, that there are still many improvements to be made and a lot of problems to solve, but computer vision is already a very helpful and impactful tool in the process of medical diagnostics and has contributed to saving and improving countless lives.

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Home 4.0: With Sensor Data from Everyday Life to Health and Care Prognosis

Horst Kunhardt

1 Research Project Home4.0

“Better at home than in a nursing home”—the research project Home4.0 shows how this can be possible up to a higher age. The project demonstrates the intelligent conversion of an existing apartment or house, which remains changeable through intelligent planning and which can be adapted to the needs of the elderly even after decades. All technical-digital aids are to be used there, which facilitate life with restrictions in old age, such as slight to moderate dementia or other restrictions due to chronic diseases. From stair lifts to sensor mats and care robotics, the range is wide. Also nursing staff and relatives can be supported by the use of technical aids (DeinHaus4.0 2020).

1.1 Starting Situation

The German Statistisches Bundesamt reports that only 2% of the 42.5 million homes in Germany in 2020 meet all the criteria for barrier-free living, such as wider doors, level access to the shower, no steps, and doorsteps. At the same time, every fifth person in Germany today already belongs to the 65-plus generation (Destatis 2019a). These statistics show that upgrading existing housing to meet the special requirements of old age is a major social task and challenge. In addition to apartments and houses, many clinics, care providers, and rehabilitation hospitals also have a lot of catching up to do in terms of digitalization and networking right up to the patient or care room. In old age, the preferred form of living is the home of one’s own, the private apartment. Half of the owners and around a third of the

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tenants have been living in their current home for over 30 years. More than half of the households of older people live in residential buildings built between 1949 and 1980.

Since 2000, the development of AAL (Ambient Assisted Living) has made the technology and digital sensor technology in buildings accessible to a wider public. The public health portal Austria defines Ambient Assisted Living (AAL, also: age-appropriate assistance systems for an environment-supported, healthy and independent life) as a technology that uses communication and information technologies to support people's everyday life (AAL 2020). Instead of the term AAL, the term SmartHomes is increasingly being used today when sensors in the house take over certain control and monitoring functions. In the case of the Home4.0 project, these are senior citizens or people with physical disabilities.

However, the term "age-appropriate living" must be expanded and must not only include low-barrier construction methods, but must also be extended to include access to support and assistance systems for different care situations. The goal of older people and those in need of care is to be able to live independently in their own apartments and houses for as long as possible. AAL techniques with networking to regional help and support networks are therefore an important basis for the continued use of existing apartments and buildings in an age-appropriate environment.

Aid and support systems integrated in a regional network in houses and apartments, which are technically easy to upgrade, are not yet available on the market. Although there is a variety of sensor solutions on the market for private households, such as in smartphones, wearables, intelligent light control, motion sensors, voice recognition systems, video technology, the problems are in installation and configuration as well as in the safe and secure handling of solutions from different manufacturers. Different wireless standards and cloud solutions make operation difficult, so many older people in particular are hesitant to use the available technology in their homes. The networking of sensor technology in homes with regionally coordinated support and action chains of actors in outpatient care, support and rescue services, and volunteers with remote relatives has not yet been implemented or evaluated on a regional level (Gast 2013). Even the possibilities of a demand forecast have hardly been implemented so far.

The market for assistance systems in the AAL field has reached a considerable diversity and size. There are a large number of stand-alone solutions from both small and well-known companies, and a unification and standardization of interfaces is still a long way off. In old people's and nursing homes, emergency alarms are standardized by means of a potential-free contact. But when networking several input and output devices, especially in the home, the currently existing diversity becomes a challenge.

The management of social networks requires skills and resources in a region influenced by demographic change, which today are far from being developed and generally available to the care and social care providers, but also to companies and solution providers of technical solutions for improving the living environment.

Technological support is intended to extend the time in which people can live self-determined, autonomous, and safe in familiar surroundings. With the help of age-appropriate assistive technology, the attractiveness of old people's homes and nursing homes for those who are cared for and looked after is also increased. For example, at Technology Campus Cham, a branch of the Technical University of Deggendorf, a universal pressure mat for the bed with several sensor fields was developed. This mat is to be flexibly expandable with a wide range of environmental sensors. At the same time, a coherent system with freely definable escalation levels is to be set up in order to make the conditions for sending emergency messages to relatives and/or nursing staff as individually adaptable as possible. The data integration of the upgradeable sensor technology in the home environment of senior apartments into a regional, IT-supported care file with case-sensitivity prognosis, enables a proactive care scenario with the integration of regional help and support services. This represents a significant relief and offers additional security, especially for care-giving relatives or for relatives living further away.

The lack of evaluation or the purely technical orientation of AAL projects is often cited as a criticism of previously funded AAL projects. In the present project outline, therefore, not only the technical realization, but also the practical experience of smart technology for the users, their relatives and the interfaces to the existing social and nursing service support networks are implemented. Likewise, acceptance and adherence studies are carried out via user surveys in order to determine and plan the specific needs. The cooperation of project partners with different responsibilities and levels of experience is an added value for the project Home4.0, since both politics, science, users, providers, and network partners with great expertise in the operation and organization of care provision as well as the implementing companies and craftsmen for the subsequent technical upgrading of buildings and existing apartments are integrated into the network.

1.2 Relevance to Society

In the future, the competitiveness of rural regions will be strongly influenced by innovative solutions to improve the quality of life in old age. Especially companies with a growing number of older employees will continue to face an increasing need for care and assistance for employees and their relatives.

Within the next years, an increasing demand for apartments appropriate for the elderly with easily upgradeable and inexpensive sensor technology for networking with integrated help and support services is expected. This is also an opportunity for innovative solution concepts from companies for measures to improve the living environment in senior households. Destatis (2019b) reports that three quarters of all people in need of care are cared for at home. 1.76 million people in need of care are cared for by relatives alone.

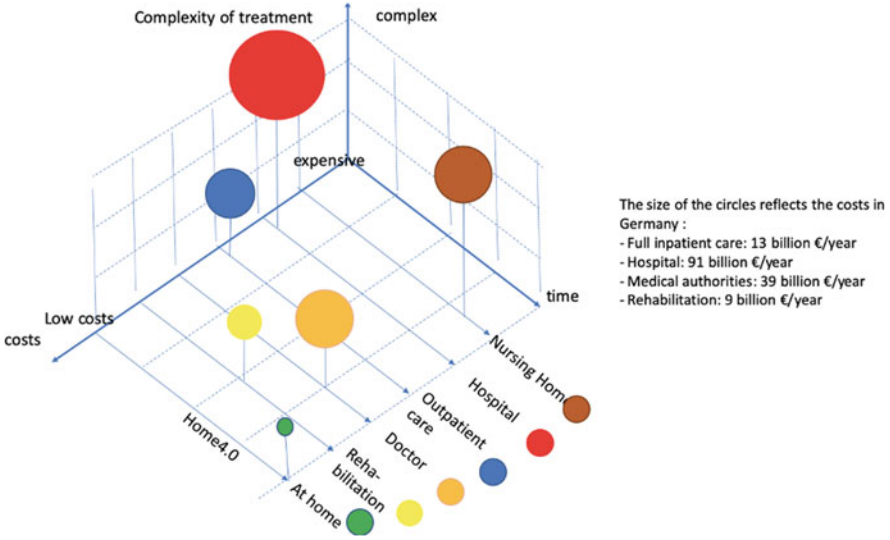
Against this background, projects such as Home4.0 have both a high social and economic relevance, as they can significantly relieve the burden on companies and their employees by offering coordinated assistance and support for their relatives in need of care and assistance. Demographically stable regions that react innovatively and flexibly to demographic challenges will have advantages in the future. The concepts of individual health management and regional health management will work together to provide services of general interest.

The development of proactive sensor technology solutions for homes that can be easily installed without constructional effort and the development of effective, networked help, and support services will also be a future market in view of the demographic development in many regions.

A differentiation of the forms of care by including one's own house or apartment in the care and treatment processes can also make an economic contribution, as shown in Fig. 1. The networking of care services with the inclusion of monitoring data from one's own personal living space can give valuable information for a prognosis of the course of chronic diseases that frequently occur in old age and can trigger rapid help in an emergency.

Social participation and civil engagement in regional aid and support networks offer many opportunities with high social and economic sustainability. Social enterprises in the sense of integrating older employees and social communities will be particularly attractive locations in the future. The project is planned for 5 years. The funding will be used to create structures in the communities and companies that will continue to exist beyond the end of the project and can also be transferred to other regions.

In all project phases, attention is paid to the sustainability of the implemented activities. This is done with regard to local supplier structures, local clients, and environmental resources. At each step of the project, the project partners pay



The size of the circles reflects the costs in Germany :
- Full inpatient care: 13 billion €/year
- Hospital: 91 billion €/year
- Medical authorities: 39 billion €/year
- Rehabilitation: 9 billion €/year

Fig. 1 Decentralization of care. Own addition. Data from Graalmann et al. (2019). Source: Author attention to the applicable legal regulations and the adherence to data protection laws and compliance rules.

2 Research Concept

To make digital technologies perceptible means to be able to adapt quickly to new technologies in a fast-changing environment. Making technologies accessible and tangible to a large number of different interest groups without limiting personal rights and the privacy of the users of these technologies is essential for project success.

Therefore, the concept for Home4.0 must solve three core challenges:

1. Technologies must be experienced in the real environment of an apartment or house.
2. It must be possible to demonstrate the use of these technologies in real life situations without affecting people as users of these technologies in their personal environment.
3. Home4.0 must be able to follow the rapid technological change in order not to become outdated in the near future.

The following technologies are to be used at the different project stages:

- Physical accessibility and implementation of an age-appropriate living situation or embedding in concepts of multi-generational living.
- Fitting out the building with building automation systems to make it easier to use.
- Data collection and subsequent data analysis to record health conditions as a monitoring system.
- Telemedicine services.
- Digital systems for care support.
- Special sensor technology for specific clinical symptoms or different levels of care (e.g. digital floor mats, fall sensors, ...).

The project applies a participatory research approach, in which all stakeholders from the provider of a solution to the user are involved in the design and application.

2.1 Bio-psycho-socio-technical Model

In the Home4.0 project, scientists from various disciplines, such as social and nursing sciences, engineering and computer science, work together. The International Classification of Functioning, Disability and Health (ICF) is a classification of the World Health Organization (WHO), which is a uniform and standardized language for the description of the functional health status, disability, social impairment, and the relevant environmental factors of a person. With the ICF, the bio-psycho-social aspects of disease outcomes can be systematically recorded and described, taking context factors into account (Dimdi 2020).

Basis of the ICF is the bio-psycho-social model. The bio-psycho-social model is a further development of the biomedical model that was the basis for human medicine. The bio-psycho-social model expands the previous purely disease-specific view by the aspect of health and the systemic connections between the individual and the environment. The model of General Systems Theory with its consideration of the complex systemic interrelationships of health, disease, environment, and individual behavior according to Ludwig von Bertalanffy can be regarded as the basis for this model development (Betralanffy 2020).

The bio-psycho-social model is primarily not deficit-oriented, i.e. disease-related. Rather the ICF classifies the components of healthy, thus bodily functions, body structures, activities, and participation as well as environmental factors. The ICF is resource-oriented thereby and takes regarding the etiology a neutral point of view. The ICF can therefore be applied to all people, not only to people with disabilities. It is universally applicable (ICF 2020).

But people cannot be described only in the context of their health/disease, participation and personal factors. People live in their environment, i.e. in their house or apartment, and are surrounded by a variety of technology. People also live in their networked environment, which today is characterized by telephone, Internet, social media, and networked devices such as smartphones, wearables, and home automation. For this reason, the bio-psycho-social model is extended by a technology perspective and is called the bio-psycho-socio-technical model. In addition to environmental factors, personal factors such as health behavior, motivation, and level of education play a role in how people lead their lives. Today, digital skills are required to inform oneself, to find offers of help, to live social participation, and to exchange information. The expansion of the bio-psycho-social model by the perspective of technology is therefore the basis for the project Home4.0.

Figure 2 shows schematically the structure of the ICF and the extension around the technology and environmental dimensions:

Individual-related factors, such as genetic disposition, health literacy, lifestyle, and motivation are not yet classified and would require further research. The environmental and personal factors are closely interrelated. One goal of the Home4.0 project is to record and systematize these interactions in order to create tailored networking offerings in a regional context. The offers in the region and the individual needs of those affected and their special preferences must be taken into account when designing the home environment and its networking with the environment.

For an informed decision about the use of technology in one's own living environment, competence is required to assess the solutions used. Data protection and data security issues in particular are of great importance and are the subject of controversial debate in society. Although many people are already using smartphones and health apps, the topic of data protection and data storage in Cloud

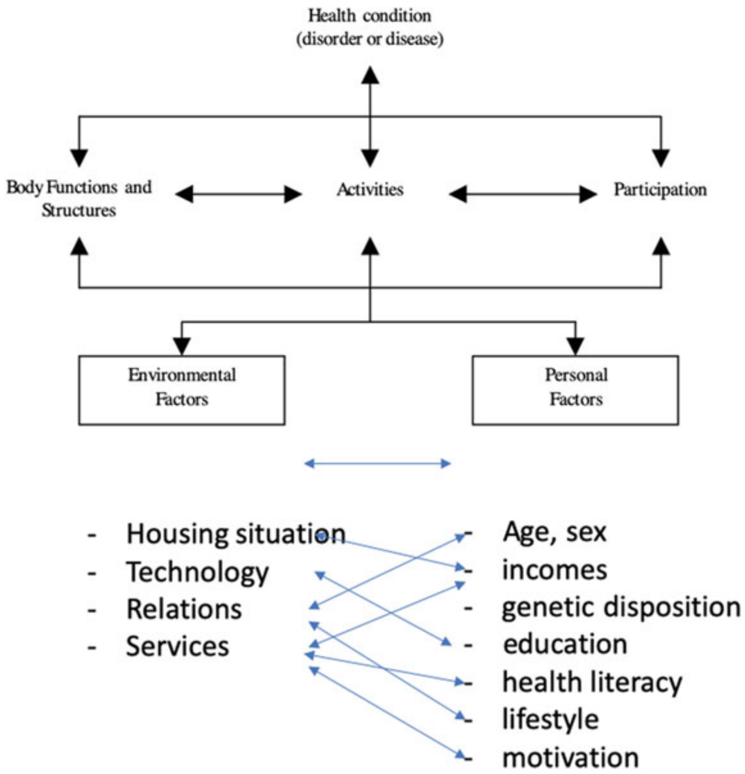


Fig. 2 Environmental factors and personal factors of the ICF. Data from ICF (2020). Source: Author

systems is not fully transparent for many people. The German government's eighth report on the elderly therefore rightly points to a digital divide in society, especially among the elderly. Information, training, and exploring the new digital technologies in the so-called learning and experiment rooms can bring the public and science together to develop the skills needed to make a conscious decision for or against the use of technology in the home.

2.2 Networking in the Region and Community Care Model

Different care situations are a topic that affects the whole society and not only the person in need of care and the family, but also the social environment. The wish of many people in need of care and their families for care at home in their familiar surroundings with their usual social contacts is a social challenge that can only be met by a network and cooperation of different partners in their specific responsibilities and competencies.

The project thus also contributes to regional health management based on a community care model. The integration of modern sensor technology allows not only qualitative data but also quantitative data to continuously monitor and further develop the effectiveness of the measures. Potentials of AI (Artificial Intelligence) can further develop the model into a system that is able to learn as shown in Fig. 3.

Since the publication of the Expanded Chronic Care Model, smartwatches, wearables, and sensor solutions have become widely available at low prices to support individual health management with data. The sensor data from digital scales, sleep sensors, and motion sensors, now enable interested people to manage their health themselves. Web-based solutions based on blended-learning, such as IGM-Campus (Individual Health Management), enable a long-term change in lifestyle towards better health (IGM-Campus 2020). The large number of health apps available on the market in combination with sensors in smartwatches, or in smartphones, allow continuous monitoring of one's own health data. However, it is apparent that these solutions are not accepted, especially by the older population, because of fears in the areas of data protection, data security, and the handling of the solutions.

For all models, therefore, aspects of usability, IT-literacy in the target group and the questions of data protection and data security are to be taken into account and will be implemented and evaluated in the Home4.0 project in a regional context together with the stakeholders.

2.3 Project Evaluation

Quantitative and qualitative factors can be considered as evaluation indicators for the project.

Quantitative indicators are determined by the monetary transfer flows resulting from the accounting and personnel management systems. Key figures of this category are, e.g. number of visitors, number of information events and network conferences, etc.

Qualitative effects can be used to assess topics such as the level of information of the participants, satisfaction with the technical solutions, or satisfaction with the services in the project region.

In order to implement the evaluation, an acceptance and adherence analysis is planned during the individual project phases with the actors involved, which will provide ongoing feedback on the acceptance by the users. This will allow the project to be continuously evaluated and the project partners to be given feedback during the project period, which will enable feedback loops. At the end of the project a health economic cost–benefit analysis for the target area will be carried out. The results will be made available for information of the project partners and the public.

The project evaluation should also serve to determine the cost and revenue-relevant key figures that make it possible to make a statement about the economic effect of a project on clinics and facilities. It is assumed that, following the project,

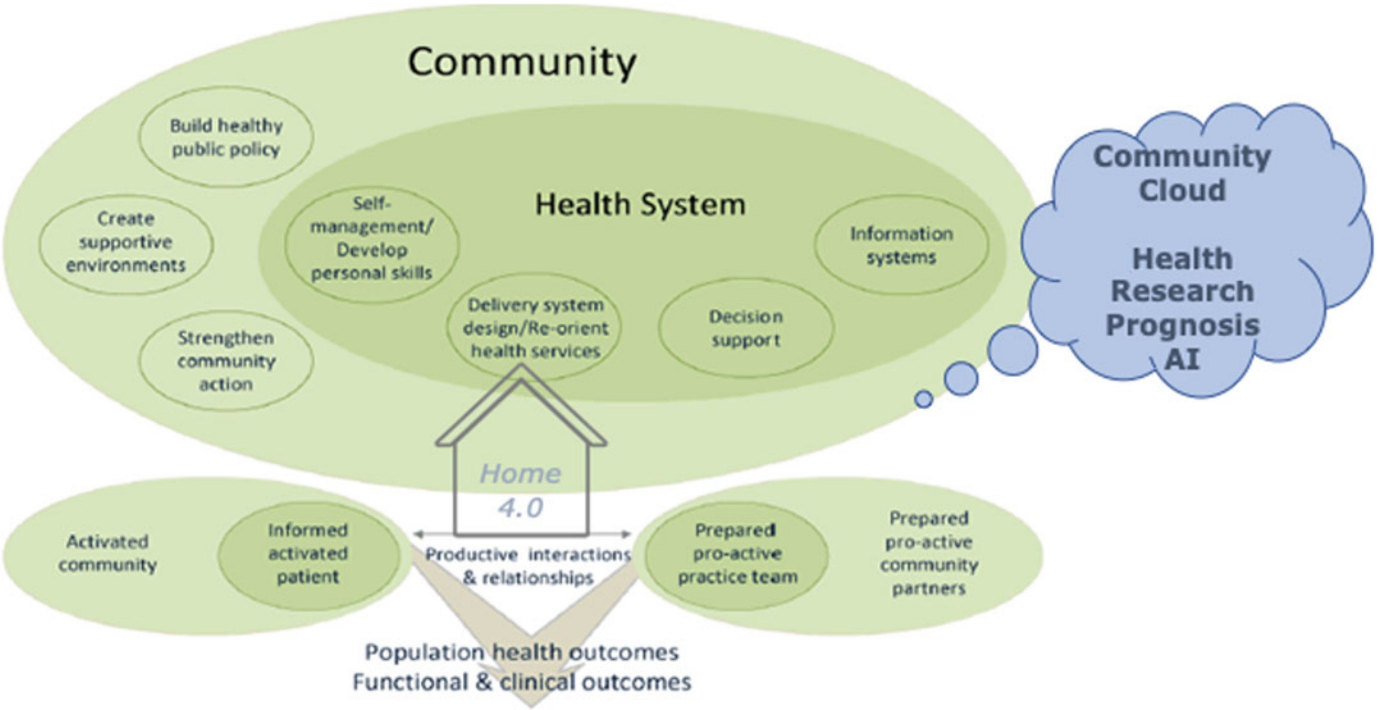


Fig. 3 Expanded chronic care model with own adaption to Home4.0. Data from Barr et al. (2003). Source: Author

sufficient added value for those in need of care and their families and for the economy has been achieved, which can ensure continued financing of the project.

3 Technology and Implementation

At the beginning of the development of AAL, wired networking of sensors was a prerequisite for use in buildings, e.g. for controlling heating, lighting and for functions of security and building protection. With the development of wireless, open technologies based on W-LAN, Bluetooth, enocean, ZigBee, the systems became usable without the need for cabling.

Meanwhile, there is a large, almost endless market for sensor technology in smartphones and wearables and health apps based on them, which makes it possible to provide solutions tailored to individual needs. Often, however, the different, mostly incompatible standards overwhelm the user, especially if the target group is older.

A substantial task in the project Home4.0 is therefore the selection and cross-linking of the system components on basis of the bio psychological socio-technical model with the fulfillment of all requirements to the data security, the data security and the informational self-determination of the target group.

Based on Maslow's pyramid of needs, the following figure shows the assignment of sensors to certain hierarchical levels of the model. The limitations of the pyramid of needs named after Maslow are well known. The representation in this form serves as an understanding and Visualization model for the application possibilities of technology/sensor technology in relation to certain individual needs and motives as shown in Fig. 4.

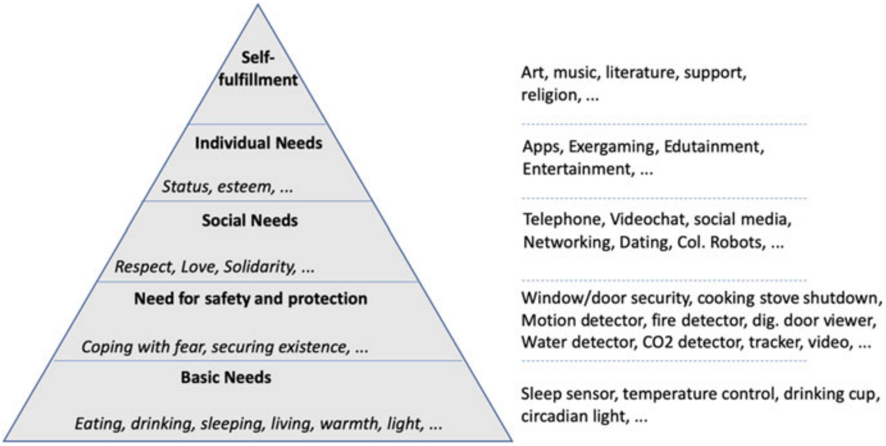


Fig. 4 Hierarchy of needs according to Maslow and mapping with sensors. Source: Author

The model behind the Home4.0 project aims at the selection of readily configured package solutions based on the ICF classification, networking with the respective living environment and environment, and the consideration of personal factors. The data generated in the process is first stored locally in the respective household and then forwarded in aggregated form to a cloud for further care research with regard to the prognosis of disease progression in the home environment. If an emergency or immediate need for help arises, notifications are sent to family members or professional emergency services. Using AI methods, the data streams generated by the home sensors are continuously evaluated, searched for patterns and thus a prognosis of future need for help is made. The aim of the project is to establish the own apartment or house as part of the treatment and care chain by means of monitoring, in order to prepare hospital admissions either with valid history data or with the help of AI.

Figure 5 shows schematically the system connections in the Home4.0 project.

In the Home4.0 project, currently available technology and sensor technology is used and combined with methods of AI. Figure 6 shows the designations from 1.0 technology to 5.0 technology, which are based on the previous technological developments. In the project Home4.0, mainly sensor technology or IoT (Internet of Things) is currently used, based on the technologies of 1.0, 2.0, 3.0. The research aspect of the project Home4.0 also aims at the further development of the

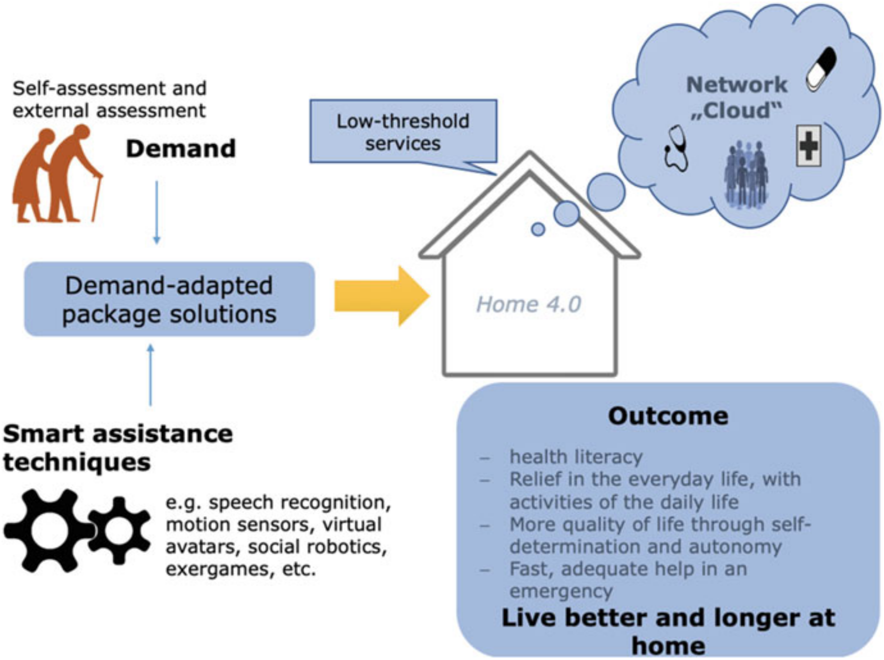


Fig. 5 Overview and interfaces in Home4.0. Source: Author

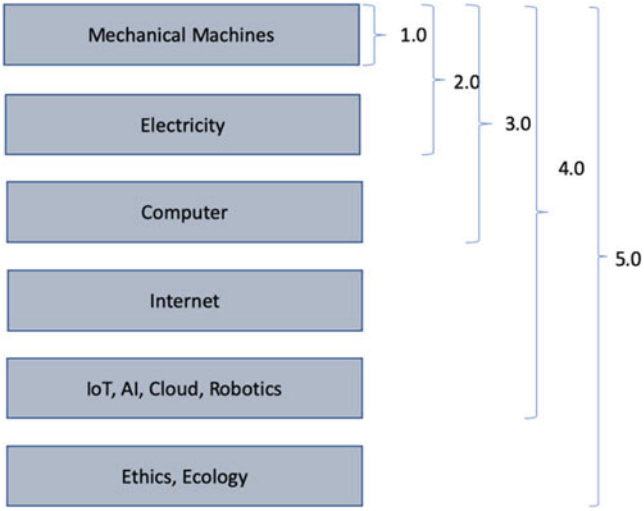


Fig. 6 Evolution from 4.0 to 5.0. Source: Author

currently available technical and informatics solutions, taking into account ethical and ecological considerations. Thus, a concept for Home5.0 will be developed in the course of the project, which will add components to the previous solutions, such as the ethical handling of large amounts of health-related data, the consideration of people's informational self-determination and also the development of a system based on shared data use, which will be administered regionally and used for the benefit of citizens in the sense of a local public service.

It is planned to install selected sensor solutions in up to 100 households by 2023 and to train a database for data analysis and machine learning in one region to enable individual prognosis and recognition of changes in the course of nursing care.

As discussed in (Microsoft 2020), the sensors used in Home4.0 generate a continuous data stream of events and sensor data, which are first buffered and locally analyzed by a home gateway system and then transferred in encrypted form and aggregated form to a cloud service for machine learning. This enables real-time analyses to detect possible emergencies and react accordingly. The aim is to identify patterns in the data streams that indicate a worsening of the state of health or to reliably identify emergencies.

As discussed in Horchert and Stocker (2015), sensors in a SmartHome, e.g. of digital thermostats, produce about 7 Mbytes of data per day and send this data to a cloud. Smart sockets exchange approx. 6 Mbytes per day with cloud systems. W-LAN controlled lamps generate approx. 1 Mbyte of data per day. Sensors therefore deliver data streams every second and send them to the manufacturers' cloud systems. Over a longer period of time, this creates a clear picture of daily life and the behavior of residents in a SmartHome, which could also be used to monitor residents. This personal and personally identifiable data must therefore be protected and encrypted and only be accessible to authorized persons.

It will be essential for the success of the project to transparently discuss and clarify data protection and data security issues with all stakeholders. The privacy in one's own home is therefore under special legal protection. Health and behavioral data are directly related to persons or can be related to persons and may only be used in compliance with strict protective measures or with the consent of the persons concerned. In the project, personal probability statements can be made regarding the deterioration of the health status in the case of a chronic illness or behavioral changes. It is therefore of utmost importance that this research data is only used for the intended purpose and that the interpretation of this data is of utmost importance. In the best case, the data reflect the actual state of health, in the worst case, this will trigger many false-positive alarms and confuse the users.

Holl et al. (2019) developed a framework for public discussion for the Labor Market Opportunities Model (AMS Model) in Austria, which describes transparency and continuous verification of the algorithms used. In this way, violations of standards in statistically obtained personal probability statements should be detected. The basic principle of transparency and participation of the persons concerned was described in the form of standards, which can also serve as a basis for further projects in the field of scoring. The insights gained into correlations based on exogenous data are seen as descriptive and not as causal. The statistical model will be renewed and verified periodically. The persons concerned are given low-threshold access to the stored data. The algorithmically obtained data serve only as a second opinion, since there is always a probability of error. In the meantime, the Austrian data protection authority has stopped the project for automatic categorization of job seekers (Fanta 2020).

With the method of technology assessment, which is also part of data protection impact assessment, the risk for the parties involved can be assessed. Of particular importance is data transparency and low-threshold information of the persons concerned. This is the only way to achieve a conscious decision to participate in the project and to use the technologies in Home4.0.

4 Conclusion

In the future, it will be possible to create a protective home that not only provides security, light, warmth, and entertainment to an optimum degree, but also takes on a care function in health matters through digital assistance techniques and AI-based data analysis as well as package solutions tailored to the residents. With the help of adaptive algorithms, certain critical situations for the health of the residents can be recognized at an early stage and appropriate assistance measures can be initiated. For an aging society and the desire of many elderly people to stay in their own homes for as long as possible, this can open up new perspectives of self-determination and independence. The certainty that the sensor technology in the house will set off an alarm in an emergency and alert family members and emergency services represents a great added value for elderly people living alone.

In addition to the challenge of technology and information technology, the ethical guidance of the project and the basis for data protection and data security is an essential element. By including the ethical and ecological perspective, Home4.0 can develop into Home5.0 and thus contribute to shaping the change in our aging society.

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Digital Healthcare Applications: Marketing, Sales, and Communication

Carsten Schmid

1 Introduction

Digitalization in the healthcare system in Germany has received an enormous growth in 2020, which is due, among other things, to various influencing factors and initiators:

1. The Corona/Covid19 pandemic has ensured that telemedicine applications and solutions such as the so-called video consultation or telemonitoring/remote vital sign monitoring are increasingly integrated into medical care concepts. The background esp. in rural areas with few medical doctors is the bridging of distances and the reduction of personal doctor-patient contacts, where these are not necessary.

   Since the approval of the change in the ban on remote treatment at the annual conference of the German Medical Association ("Deutscher Ärztetag") in 2018, the market for "telemedicine" in Germany has been developing rapidly. In addition to regional providers such as the Teleclinic from Munich, which has been one of the pioneers in the field of remote treatment since its start in 2016, suppliers from abroad are currently pushing into the German and German-speaking markets, which have years of experience and, above all, extensive investment capital. These include, for example, Zava (formerly Dr. Ed) based in London or the Swedish-based provider Kry. But new suppliers from the German-speaking countries have also emerged. This also includes Medgate from Basel, which has been operating as the largest medical telemedicine centre in Europe since 2000 with the Medgate Tele Clinic in Switzerland. Since the end of 2019,

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Medgate and its German partner have been working on the establishment of another telemedicine centre based in Berlin.

While in the past the offer of telemedicine providers in Germany was still directed to private health insurance companies and self-payers for primarily regulatory reasons, this practice is currently changing because first providers such as Teleclinic and Kry are now reimbursed for their service by the GKV—Public Health Insurance ("Gesetzliche Krankenversicherung"), and the market for telemedicine receives additional growth impulses. And the health insurance companies themselves are now recognizing the added value of telemedicine. For example, the TK—Techniker Krankenkasse, based in Hamburg—offers its insured patients the possibility of remote treatment by using a video consultation, which is particularly useful and attractive in rural areas, where doctors are increasingly scarce and the distances between patients and practitioners are long.

2. The Digital Care Act (DVG) (Law for better care through digitalization and innovation) came into force on 19th December 2019 and means that health apps, which have often been used by patients for a long time, can be prescribed by the doctor in the future and the costs of this will be covered by the public health insurance.

   In the meantime, the range of applications is extensive and constantly growing and is aimed at a wide range of patient groups, often focusing on chronic diseases such as diabetes, asthma, COPD, heart failure, hypertension, mental illnesses such as anxiety disorders and depression or chronic pain disorders such as dorsal pain, fibromyalgia, and migraines. In addition, there are also applications which monitor pregnant women or which are generally used for health prevention.

   Since 5th May 2020, applications can be submitted to the BfArm (Federal Institute for Medicinal Products and Medical Devices) to get an app reimbursable from health insurance companies at all, but regardless of whether a corresponding digital product becomes refundable in the end or not, a greatly underestimated aspect in context with the topic "Digitalization of Healthcare" are the marketing and the sale of digital solutions and applications to the respective target group.

3. In addition to these two digital health applications "telemedicine" and "app on prescription" which are currently in focus, there is another area in the healthcare sector in Germany, where digitalization efforts are being started. The Federal Ministry of Health (BMG) has just implemented a draft law in July 2020, that should support hospitals in Germany to be further digitized and has provided a total of 3 billion euros for this purpose through an economic stimulus package. Hospitals that need digitalization can apply for a funding of individual projects. The law names many projects which are going to be supported with the available fund. These include, for example:
   (a) establishment of patient portals for digital reception and discharge management,
   (b) partially or fully automated clinical decision support systems,
   (c) continuous digital medication management,
   (d) concepts for matching the services offered by several hospitals with the aim of creating a comprehensive supply structure.

In addition, another aspect is the improvement of IT and cybersecurity as well as the adaptation of emergency rooms to the state of the art.

Looking at the developments, projects, and strategies as a whole, it can be seen that the "digitalization of healthcare system" offers great potential for solution providers in the various areas, from digital health application for patients with public health insurance to digital applications which established physicians can use to improve the care of their patients, such as telemedicine and e-prescription, to solutions for improving the level of digital expansion in hospitals.

Due to the laws described above, which are intended to advance the degree of digital expansion in the German healthcare sector and the associated growth and market opportunities, a continuous growth and expansion of the product range in this area can also be expected.

To position themselves in this emerging market, suppliers and manufacturers of corresponding solutions can now look for suitable marketing and sales concepts to successfully introduce and position their digital applications and products in the market. A special feature must be considered right from the start that does not make sales and marketing seem less complex:

The *target groups* or *target customers* who are to be addressed and to whom the marketing is to take place!

In contrast to many other solutions and products in the healthcare sector, digital products and solutions are not only aimed at a core target group such as

(a) Patients = consumers/end users, but (b) also at health facilities and health service providers such as practitioners, hospitals, and nursing homes or health insurance companies, both public and private.

So, anyone who wants to develop and implement sales and marketing concepts in the field of "digital health applications and solutions" must deal with both target groups: (a) consumers (B2C) and (b) business clients (B2B).

The starting point for the marketing of products and solutions for the digitalization of the healthcare sector, regardless of whether in consumer goods or industrial goods for business clients, is the so-called 4 P of marketing, with which the market-oriented approach of a company can be combined and structured.

Marketing and sales objectives can be operationalized by various instruments so that companies are able to shape the influence on markets (Bruhn 2013). Still the classic marketing mix that goes back to McCarthy in 1960, is the classification into the mentioned "4 P", which denotes the following four marketing instruments:

- product,
- price,
- promotion (communication),
- place (sales).

The challenge, including the marketing of newly developed and innovative products and solutions, as digital health applications usually are, is to define and implement the optimal combination of marketing instruments.

2 Marketing for Digital Healthcare Applications

Marketing in today's world, especially for digital health applications (DiGa—Digitale Gesundheitsanwendungen), which may in future be prescribed as an "app on prescription," must deal much more closely than before with the permanent social and technological change.

The main driver for this lies primarily in the individualization of society, in the self-image of customers, the increase and fragmentation of sales channels (e.g. eCommerce and online/social media marketing) and in a constantly changing way of information, communication, and consumer behavior.

There is therefore no longer just one single society that can be divided into fixed patterns of life and orientation, but there are many small sub-societies with different needs and requirements of their members.

This also results in a differentiated need for communication and information as well as a different, and in some cases increasingly unpredictable purchasing and consumption behavior. Sales strategies and sales channels must be changed, developed, and adapted in the same way as the individualization of the product portfolio and customer approach (Binckebanck and Belz 2012).

Digital health solutions and applications are now mostly new and innovative products, which in some cases still have few competitors and are therefore still not as interchangeable as products in established markets, but here, too, every marketing and sales manager should be aware that brand loyalty and a lack of loyalty to the provider exist especially among younger target customers at the time of the market launch. Also important is the awareness of the increasing ability to criticize and the associated need to communicate when negative experiences are made with digital health products and applications or if the service quality of the offering company is not right. This is then increasingly shared with others on the internet and by one's own social media activities.

The fundamental challenge for every provider, whether the digital health application becomes reimbursable or not, is to bring it to the patient and thus places special demands on marketing and communication:

- The target groups are heterogeneous. On the one hand, there are business-to-business sales to medical professionals, primarily established practitioners, who are to prescribe an application in the future. For this, it is necessary that they know the application, are convinced of the benefits, and have the willingness to integrate the digital health application into the patient-specific therapy plan.

  On the other hand, there is the well-informed patient, who is also concerned with raising awareness of the application in order to increase the willingness of the doctor to prescribe the app the patient prefers. Patients are not only open and interested in using a digital health application, but also proactively present it themselves to their doctor and advocate a prescription.

However, market communication with patients is then classic consumer goods marketing.

- Doctors need to be experienced in products, gadgets, and services. If you consider the number of general practitioners and medical specialists in Germany, you come to more than 100,000, which is a hardly manageable target group which needs to be clarified in the short term. This must be considered when choosing the appropriate sales and communication tools.
- With regard to the content of the respective digital health application, there is also a correspondingly large target group of patients, which should also be reached, informed, and trained.
- During the entire sales and marketing process, care must be taken to comply with the existing legal regulations, e.g. in the form of the Medicinal Products Advertising Act (HWG—Heilmittelwerbegesetz).
- It should also be noted that communication behavior in the healthcare system has changed increasingly in recent years. The possibility of independent research on the Internet is being used more and more frequently. Both the patient as the application's end user and doctors inform themselves online about health care providers, health offers and treatment options, pay attention to evaluations and experience reports of other patients and doctors and are gaining more and more trust. As a result, online marketing is also gaining an importance to make the existence of (reimbursable) digital health applications visibly on the Internet.

With these environmental factors, the supplier's distribution policy after product development and pricing is of importance. It is necessary to go through successive planning processes that build on one another (Bruhn 2013).

1. *Analysis of the sales situation*

   Both internally and externally, taking into account the sales approach and practices of other market participants/competitors.
2. *Setting sales goals and establishing sales targets*

   These can be described as follows:

   - both economically as well as sales volume and turnover,
   - supply-oriented, such as delivery times and availability,
   - psychologically-oriented such as sales image to be achieved, consulting and service quality, etc.

3. *Development of the sales strategy*
4. *Determination of the sales budget*
5. *Decision on sales/distribution policy measures*

   Here it is necessary to make specifications about the design of the sales systems and sales/distribution instruments as well as the sales channels.

6. *Sales control*

   In addition to the development of comprehensive sales controlling, this also includes the implementation of sales-specific information systems, such as CRM systems.

A possible sales policy measure for the market entry strategy of digital health applications into the German-speaking market can be systematic sales management (SSM), which will be considered in detail below.

3 Systematic Sales Management as a Basis for Market Entry and Sales of Digital Health Applications

3.1 From Prospect to Customer

In the age of CRM (Customer Relationship Management), target groups are no longer decisive for every successful sales organization and for solution-oriented sales, but target persons, after all, every consumer or purchasing decision-maker wants to be targeted and addressed as an individual and not through permanent mass communication.

When selling products, solutions, and applications for the digitalization of the healthcare system, the heterogeneity of the target groups and target persons must be considered:

- Hospitals with classic buying center structures and decision-making processes for the purchase of digital health applications (B2B).
- Established medical practices and medical supply centers (MVZ—Medizinische Versorgungszentren) without taking into account buying center structures (B2B). This group is particularly important when it comes to the prescription of digital health applications (“app on prescription”).
- Patients, and thus private end users, who ultimately use the digital health applications (but are also key providers of demand and should be stimulated to position their needs with the doctor, so that they can integrate a digital health application analogous to medication into the therapy plan).

Especially with expensive capital goods, which inevitably include digitalization software for hospitals, but also with many services such as an “app on prescription” it is a long way to develop a buying customer out of a prospective sales lead.

Therefore, continuous dialogues are necessary throughout the entire marketing communication but also throughout the entire sales process to

- deepen the interest of a potential customer after the first identification as a prospect/lead,
- convince him and persuade him to buy,
- make him less vulnerable to approaches from competitors,

- motivate him to make further purchases and long-term cooperation as part of customer loyalty measures and through service concepts (cross- & up-selling).

Classical mass media are at least in the consumer goods distribution (B2C Business to Consumer) quite suitable to generate attention and awareness for the product but are generally strained with the task of continuous dialogue.

On the other hand, the personal dialogue by sales representatives, as is classically realized in the sales and distribution of medical technology or in the marketing of medicines by pharmaceutical representatives, is not the appropriate instrument in all phases of the sales and marketing process from a cost perspective.

The success in marketing is only guaranteed by a systematic approach and continuity in addressing target customers and target persons and take care of all interested parties. Therefore, for the marketing of “digital health applications” to hospitals, medical practices and finally also to patients as end customers, “dialogue-enabled” measures and tools for personal and individual addressing and a “systematic sales management (SSM)” are necessary for implementation.

SSM is to be seen as a dynamic concept for a systematic and yet individual support over all phases of the sales cycle, from prospective customers to regular customers.

The use of this sales system is not only limited to the healthcare sector, but can be considered across all industries and is used to support companies at every stage of market development, to communicate systematically with their target persons and identified decision-makers—from the identification of prospects to customer loyalty.

In the individual sales phases, however, different communication content, phase-specific goals and the respective customer and prospect status require different types of approach.

The individual instruments of the SSM

- Direct Mail (analogue and electronic)
- Telesales/Inside Sales/Sales Support as well as
- Field Sales Force (mobile sales)

achieve an outstanding success within the framework of an overall concept and in systematic and coordinated use.

3.2 Sales Instruments in Concerted Interaction

For systematic sales management, different sales tasks require different types and measures or instruments:

- Personalized direct mailings (as analogue print mailings or as electronic mail) are suitable for regular contact refreshes and for a wide spread of information. For example, when it comes to informing the prescribing doctors about innovations and new features of an app, the target group can very quickly include several thousand target physicians—depending on the specialist medical field. Based on this size, the target group cannot nevertheless be informed as quickly, cost-effectively, individually and personalized without using this instrument.

- A Telesales department or a proactive Inside Sales Support is always useful if a personal dialogue is necessary, but a visit to the field is either too expensive or psychologically too intensive in the current phase. The advantage of using the "telephone" as a sales and distribution tool for the marketing of "digital health applications" is that the telephone can be used to conduct personal dialogues too, but more cost-effectively than through a Field Sales Force.
- However, the personal visit by the Sales Force becomes necessary when larger specific deals are pending or complex problems must be solved or if a personal relationship needs to be deepened or refreshed.

3.3 Lead Generation and Qualification with Systematic Sales Management

Systematic sales management begins with the finding and the identification of prospects. To be able to address them specifically and tailored to their individual needs, target persons must first be identified and then selected as precisely as possible. Here again it is important to ensure that the lead generation for digital health applications involves the heterogeneous target groups such as doctors, hospitals, and patients.

Triggers are, e.g. mailings or "classic" advertising such as advertisements in general interest magazines (health magazines for patients such as "Apotheken-Umschau", etc.) or special journals for doctors. Also, editorial press articles on PR activities by the companies are to be mentioned as an effective communication tool in this context.

In addition to these "non-digital" communication tools, other digital communication tools are particularly suitable in connection with the marketing of a "digitalization" product. In addition to own website or company-owned social media profiles such as Facebook, LinkedIn or Xing, this also includes display advertising on external websites or in mobile apps, search engine advertising, advertising in social media and partner networks in the form of affiliate marketing. Also positive for the generation of interested parties are user and experience reports in external blogs, user posts on social media as well as online recessions (Meffert et al. 2018).

The qualification of the prospect's response and reaction (usually in a personal dialogue on the phone or via e-mail dialogue and live chat on the Internet) enables a potential-oriented and target-specific classification and further processing. Depending on the reaction to the initial trigger, follow-up measures and offers can be adapted to the respective demand potential and individual customer needs.

Increasing the use of the relatively cost-effective sales instrument “Telephone” for the marketing of digital health applications results from the constantly changing conditions in the health market:

- The products in competition, also in the field of “health applications,” will become interchangeable from a certain point in time. This can be seen, for example, in the topic “Mental Health,” where a variety of applications (such as Novego, Mind-Doc, Selfapy, Deprexis or Moodpath) are now supposed to support the treatment of depression, anxiety disorders, and other mental illnesses.
- Competition and cost pressures on providers are also growing in the healthcare sector at the moment.
- Sales work is increasingly focusing on promising customers.
- Field sales workers focus on signing the contract.
- The support of interested parties, especially in the mass market, is neglected.
- Frequency of contact and the intensity of contact to customers and prospects decrease.
- The personal connection and the bonds to many (especially B- and C-) customers and interested parties are lost.
- Subjective assessments of the market exclusively by the field sales force lead to “inaccurate” customer potential assessments.

Especially about the worthiness of sales support and care during the sales cycle, misjudgments often occur for both customers and prospective customers. It is not the realized turnover, but the existing and feasible sales potential that expresses the worthiness of customer support. And in the case of interested parties, it is not the mere expression of interest that should control the current and future measures of support, but the situation of the customer, which is defined and outlined by clearly qualified requirements.

In order to qualify prospective customers, in particular as a basis for further prospect/lead management as well as for downstream sales activities, the following procedure should be chosen:

- collection of relevant questions that express the situation and needs of customers or interested parties,
- definition of operational requirements,
- definition of demand categories,
- scaling the demand categories of each individual characteristic of requirement,
- definition of classes to form the ABC analysis.

The qualification and potential classification of interested parties does not only take place within the framework of incoming contacts, e.g. in the context of incoming enquiries as a result of (direct) marketing campaigns but can also be carried out proactively via the conception and implementation of a telephone market analysis. This is also used for the collection of demand data as a basis for a systematic sales management.

The process of a telephone market analysis is structured as follows:

1. Detailed concept and coordination,
2. Target group definition, organize, and provide addresses,
3. Conceptual and administrative pre-organization of the project "Telephone Market Analysis,"
4. Information/process workshop with sales staff,
5. Provision and pre-training of employees for telephone market analysis,
6. Training, project start-up, and implementation of the market analysis,
7. Evaluation of the interview results,
8. Performance of an ABC analysis.

The entire prospect qualification is therefore used to collect and verify the exact market and customer potential with the following focus:

- Identification of responsible contact persons and decision-makers,
- Potential analysis regarding demand, distribution of demand across products/applications and competitors,
- Generating of interest through product and service presentation,
- Answering questions, objections, concerns,
- Agreement on further sales measures as required, such as visits of the sales force, recall, provision of written information,
- Initiation of the systematic sales management program.

The basic prerequisite for active, systematic customer support is:

- Knowledge of the overall market potential,
- Knowledge of the temporal distribution of the potential (short term vs. long term and medium term),
- Calculability of the potential for each individual customer and prospective customer,
- Customers and prospects weighed and classified according to potential,

This is the only way to ensure continuous market exploitation by providing the right information to the right recipient at the right time using the right instrument. This process is depicted in Fig. 1.

3.4 Management of Prospects/Leads

In the phase of prospect management, the focus of the systematic sales management is on strengthening the willingness of the interested party to buy and consume.

Through targeted information and offers in the context of personalized mailings or actively and passively conducted dialogues on the phone, the interest can be deepened in several phases up to a definitive willingness to buy. If it is necessary

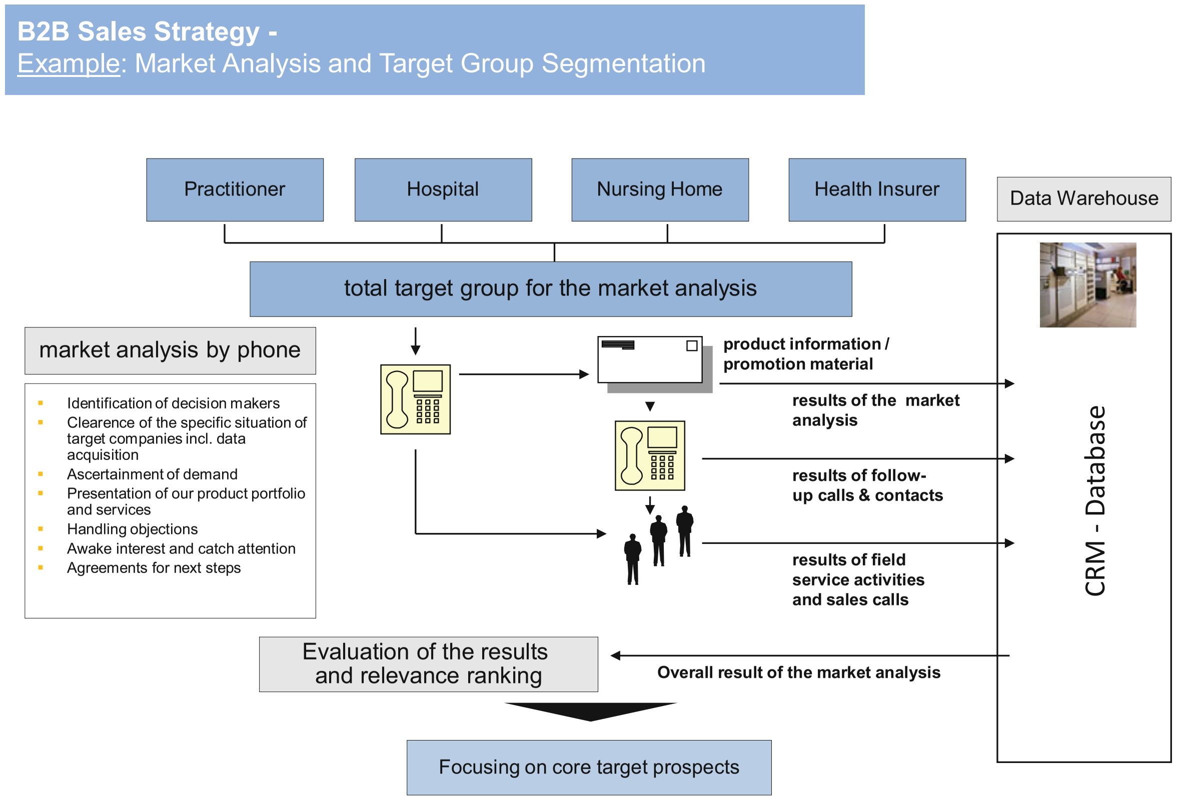


Fig. 1 Market analysis and target group segmentation by telephone. Source: Author

and reasonable to make a field service visit to finalize the deal, it can be scheduled at the end of the process.

The contact frequency depends on the individual level of interest and customer-specific objections.

In this context, the question of the selection of a suitable communication tool also arises, because the aim is to give every potential customer at every stage of the sales process the feeling that his/her interest and questions or objections are given sufficient importance and space without overdoing him/her by too much on-site presence, e.g. by too many and too early visits.

It is important in this phase to increase the contact rate to previously acquired prospects as well as to intensify the loyalty of interested parties through more personal contacts and more personal support without directly recognizable sales intention.

This means that the continuous collection and maintenance of information about customers and interested parties and their systematic use are of central importance.

However, consistent personal market support in the phase of prospect management exceeds the capacity of the sales force, whereby pure contacts of support service by the field sales staff would also be uneconomical at this stage.

The transfer of all tasks in prospect management and customer acquisition to the field service would also lead to potential conflicts with interested parties, because a visit to the field too early is not desired by many people, as it unnecessarily builds up a "psychological buying pressure" and, moreover, not every person is equally "worthy of care" due to the existing purchase volume.

Thus, in the process of managing prospects for the marketing and sales of digital health applications, it is necessary to decide which role the individual instrument "direct mail," "telephone," and "field service" should take on and how they should be coordinated. The decision should depend on which function and task the respective instrument can perform:

Direct Mail:
- Keeping a broad target group informed,
- Create attention,
- Generate response,
- Remind regularly and provide up-to-date information to a broad target group.

Phone:
- Gaining information about customers and prospects,
- Answer current and individual questions quickly and in a targeted manner,
- Takeover of direct sales tasks,
- Exploitation of up- and cross-selling opportunities,
- Create personal closeness between customers/interested parties and companies.

Field Service/Sales Force:
- Targeted, comprehensive, and personal advice to customers and interested parties,

- Product presentation and explanation,
- Obtain a purchase decision,
- Create a personal bond with the sales force as a representative of the company.

In addition to deciding when to use which instrument in the different stages of the sales cycle, there is also a question of which topics and occasions should be contacted with a prospective customer. Different categories can be distinguished, such as

- Product- and performance-oriented events such as the introduction of new products and services, changes in price and conditions policy, promotional activities and special sales offers, etc.
- Event-oriented occasions. This includes, for example, specialist events such as trade fairs, congresses, symposia, and workshops, as well as employee-oriented training and further education courses.
- other topics and events.

In the entire phase of prospect management, topics, and occasions as well as the respective instruments must be planned in the long term within the framework of comprehensive contact planning. This process is depicted in Fig. 2.

3.5 The Method of Systematic Sales Management

Systematic sales management is based on three basic parameters:

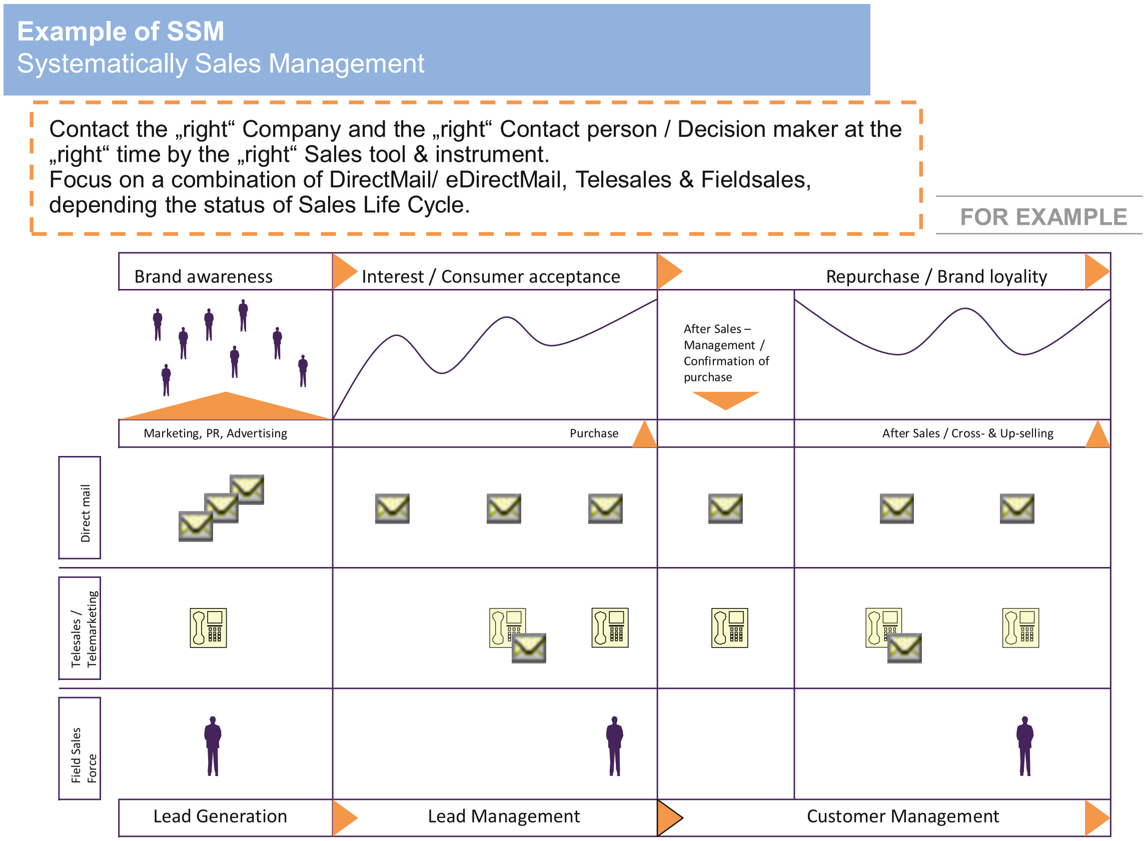
1. Target segmentation, in which an initially unmanageable mass of potential target clients is divided into groups with the same need for care,
2. Planning of measures in which the available instruments (e.g. Direct Mail, Telephone, etc.) can be used according to the respective support and care needs, and
3. Contact frequency planning with the question, how often a potential customer should be contacted.

To organize and realize the required sales processes and workflows, the establishment and use of a CRM database is sensible and necessary.

This enables the flexibility within and between the respective parameters and a needs-specific and individual support of the respective target persons based on their customer history.

Complementing every sales activity and every reaction and response, the CRM database represents the entire history of the sales process from interested parties to regular customers.

This provides an overall view of all information, influences purchasing and can be the basis of sales controlling and forecasts.



Example of SSM
Systematically Sales Management

Contact the „right“ Company and the „right“ Contact person / Decision maker at the „right“ time by the „right“ Sales tool & instrument.
Focus on a combination of DirectMail/ eDirectMail, Telesales & Fieldsales, depending the status of Sales Life Cycle.

FOR EXAMPLE

Fig. 2 Example of systematic sales management (SSM). Source: Author

The sales database therefore plays a special role within the systematic sales management, as it is the only way to look after each individual interested party and customer at all stages of their interest, but also to ensure the profitability of all measures (results in relation to sales costs) and to be able to control at any time.

4 Conclusion and Outlook

For the sale of digital health applications to doctors and patients as well as for the sale of products and solutions for the necessary digitalization of hospitals and the nursing sector, the offering companies need innovative products and attractive and competitive prices. Structured and systematic sales processes and concepts are just as necessary for market entry and continuous market cultivation, as for continuous communication with potential target customers via different, target-specific communication tools.

Even if the market is growing due to the advancing digitalization of the healthcare sector and the legislator also ensures general market growth through framework parameters (such as the Law for Better Care Through Digitization and Innovation) applications, solutions, and products will not sell themselves automatically. The solution providers are required to be proactive and to develop their sales and marketing concepts.

The "Systematic Sales Management" can be used as an integrated building block in multi-channel sales, especially in the first phase of market entry, which is very much about . . .

- creating perception/brand awareness,
- generating interested parties,
- converting prospects to customers, and
- ensure successful market entry, continuous sales growth, and adequate market positioning.

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Ethical Implications of Digitalization in Healthcare

Guido Lerzynski

1 Introduction

The digital transformation is profoundly changing healthcare, medicine, and nursing. Whether it is the storage of personal health information in electronic health and patient files, the creation and networking of medical databases, the use of artificial intelligence in diagnostics and therapy, or the deployment of health-related apps, the digital transformation is all-encompassing and rapid, with a significant impact on patients and the healthcare system. However, this transformation is inherently neither ethically good nor problematic. Rather, an ethical evaluation of each digital application is required, which relates to its specific utilisation (Mittelstadt et al. 2016; Wagner et al. 2017: 12). This evaluation must be based on certain parameters, as shown in Fig. 1. The evaluation of digital applications based on these parameters results in individual opportunity and risk profiles.

1.1 Responsibility of Patients

With regard to the patient, two questions arise when considering these parameters:

1. What is then ethically permitted or prohibited?
2. What rights and obligations does the healthcare system have towards the patient?

Conflicts of interest can arise at this point. For example, patients can only benefit from improved therapies if they disclose parts of their private data in return. The health of the patient may thus be at odds with their privacy and individual self-

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Fig. 1 Core ethical principles. Data from Jannes et al. (2018). Source: Author

determination. In this respect, all parties involved in the healthcare system must weigh up which of the patient's rights are affected, and to what extent an impairment is justifiable. Healthcare professionals have a responsibility to respect the above-mentioned ethical principles towards the patient.

1.2 Responsibility of Institutions

Not only individuals are stakeholders in the development of the digital transformation in the healthcare system. Institutions such as data protection supervisory authorities must ensure that sensitive information is protected against unauthorised access. These institutions are responsible for creating framework conditions in which health-relevant data is processed appropriately and used in the best interests of healthcare. In many cases, they are faced with ethical challenges that cannot be overcome by a single stakeholder. However, in order to enable individual stakeholders in healthcare to deal with ethical challenges appropriately, institutional framework conditions are essential.

The increased use of digital technologies will lead to fundamental changes in the professional and activity profiles of medical professionals (Amarasingham et al. 2016). Wherever digitalisation can achieve better results than humans using traditional methods, corresponding tasks will be delegated to such systems. If an algorithm, e.g. for the analysis of images for the early detection of lung disease, achieves better results than human experts, it doesn't seem to make much sense to train and employ corresponding professionals in the current form. In the development of training occupations in the healthcare sector, they must in future aim to train professionals to use algorithm-based systems and to interpret and check the automatically generated results (Wang et al. 2016).

Institutions in the healthcare system should explicitly implement ethical principles and design structures in such a way that appropriate action by employees is encouraged. These structures can be designed to respond well to ethical challenges, because there is a high degree of mutual trust and competence, or in such a way that the individual can hardly hope for support within institutional healthcare structures (Jannes et al. 2018). This becomes important when it comes to questions of responsibility in case of mistakes. Can the healthcare worker be held responsible for an error of an algorithm or more likely the software designer? To eliminate uncertainties, legally relevant questions must be reconciled with ethically acceptable approaches.

1.3 Responsibilities of Society

Ultimately, the digital transformation must be viewed in the context of social challenges. One of the aims of digitalisation in the healthcare system is a general improvement in healthcare and the early detection of diseases (Wilder et al. 2018). Therefore, digital applications can increasingly link and analyse data from different areas of life. This can result in both advantages and disadvantages for specific groups in society. For example, discrimination against marginalised or disadvantaged groups is possible. This is to be feared if algorithms are used to investigate the influence of lifestyle on the development of specific diseases. People who lead a lifestyle associated with an increased risk of disease could also be identified by the algorithm and excluded from certain medical services (Lippert-Rasmussen 2016). Linking the advantages and disadvantages with individualised insurance conditions can be highly problematic and ethically reprehensible. Therefore, core ethical principles must provide guidance for stakeholders and—more broadly speaking—for societies.

2 Pitfalls of Digital Applications

When selecting data to be processed for digital applications, standards and values should underlie the design of algorithms, which all have an ethical dimension (Kraemer et al. 2011; Mittelstadt et al. 2016). Algorithms are trained to process specific types of data. A set of basic data is used as a reference. This reference may already contain a bias, e.g. in the form of a prejudice, which determines the overall performance of the algorithm. An example is the malfunction of face recognition in a photo app provided by Google. The algorithm used there had been trained on the basis of image data which mainly included photos of people with fair skin. As a result of the limited data set, the programme was not trained to recognise people with dark skin colour as human beings. Instead, the automatic keywording function referred to them as gorillas (Jannes et al. 2018; Kasperkevic 2015). The discrimination against people associated with such a false classification is ethically unacceptable in any way. In the field of medical applications, it is not only hurtful, but also dangerous to health. When it comes to issues of mutual respect and security, neither individuals nor institutions alone can provide a solution to problems. Social discourse and political solutions are required here (legal regulations). Above all, there is a need for socio-political debate on the goals and purposes to be pursued. Should algorithms be used with the primary goal of reducing healthcare costs?

May algorithms developed in the healthcare sector also be used for commercial purposes? These and other questions are of a socio-political nature and require corresponding discourses and solutions. Further questions arise with regard to the possible effects of technology on future socio-cultural developments. Will there be health-related obligations in light of new technological possibilities? Will there be an obligation to record one's individual vital signs data, in order to make potential risks of illness recognisable at an early stage, and thus more cost-efficient to treat? These questions also require a broad public discourse, in which an awareness of possible developments is created. Responses to current and future challenges must be found, which meet the ethical requirements for observing the above-mentioned core principles. They should help to promote the ability to make decisions, to protect against potential harm and discrimination, and to distribute scarce resources fairly.

3 Opportunities and Challenges

3.1 Opportunities

There are many hopes and expectations associated with the use of algorithms in healthcare. Numerous current reports on projects for the development and use of algorithms in healthcare convey the impression that the realisation of fully digitalised healthcare is imminent.

In reality, many ideas and projects still have a long way to go before they can be realised and used on a practical level in healthcare, on a quality-assured basis. As in other areas, it must be expected that not all expectations will be met. The following description of the opportunities and challenges of algorithms in medicine and healthcare is to be understood as a description of expectations, wishes, and hopes. It also highlights the challenges that can be associated with the various applications. The aim here is neither a prognosis of the future nor an evaluation of the convictions and assumptions associated with the opportunities and challenges formulated. The use of algorithms in healthcare is associated with many expectations, some of them very high: a considerable increase in the speed with which health-relevant knowledge is gained in research and introduced into healthcare; a considerable broadening of the knowledge base and the range of medical services based on it; an increase in the precision of diagnoses and treatment recommendations, and associated with this, the medical safety of healthcare services (Dörn 2018: 352; Wired 2017; De Witte 2017). The automatic processing of a large set of health-related personal data is also associated with the hope of developing individualised medicine and reducing costs in the healthcare system (IBC 2017: 7; De Witte 2017).

The above-mentioned expectations of digitalised health research and care are primarily linked to the possibility of processing large amounts of data from different sources. However, the mere availability of a considerable amount of data by no means guarantees its meaningful evaluation. With regard to Big Data, experts criticise that in current applications the usual principles of science are often not observed, and the principles of evidence-based medicine are violated (Antes 2016). The main criticism is that too little attention is paid to theory formation in data evaluation (Mayer-Schönberger et al. 2013: 70).

To be able to meaningfully analyse the data that will become available in the various fields of medicine with the ongoing digitalisation, it is necessary to edit and curate the data. This task can only be performed by human experts. However, they can receive valuable support from algorithms. Algorithms can be used to facilitate data analysis by training and using them to process precisely and exclusively the data that is necessary to achieve a specific goal, such as the prognosis of a complex disease. The use of algorithms thus promises to make it easier to handle an ever larger and more diverse set of different data generated in medical contexts.

Improvements are expected in particular from the ability of algorithm-based systems to automatically match a large amount of data in the shortest possible time. Here, the mechanical capabilities clearly exceed the corresponding capabilities of human stakeholders. Based on such data matching, algorithms can achieve the same or even higher accuracy than human experts. Especially in the case of rare diseases, they are even superior to humans in terms of diagnostics (Esteva et al. 2017; Rajpurkar et al. 2017). Algorithm-based image analysis methods allow, for example, an automatic quick check for potential skin diseases.

Moreover, algorithms are already being used to automatically detect drug interactions and side effects based on the evaluation of information from digital patient files and medical articles (Dörn 2018: 651). The number of inadequate or unnecessary treatments could also be reduced by improving findings. The use of algorithms can counteract possible errors caused by overworked employees. Algorithms thus contribute to increased security in healthcare. In addition, they can generally reduce the workload in medicine and care. They also open up new possibilities for automation processes in other areas. Many routine tasks, for example, in laboratory medicine, cardiology and radiology, could be taken over by algorithms in future (Rasche 2017).

3.2 Challenges

Given their high speed and their ability to process even the largest amounts of data, the performance of algorithm-based systems could easily be overestimated. Machine systems are indeed systematically superior to humans in the storage and management of data, and this superiority is likely to increase in the future. But when it comes to evaluating information, they are systematically inferior to humans. Human judgement is required in many, if not most, areas of medical/nursing care and research. If there are several diagnostic or therapeutic options, an algorithm can at best have a supporting function (Rasche 2017). This cannot replace human judgement. With algorithm-generated recommendations, it is therefore important to clearly distinguish between recommendations and decisions: digital assistance systems could make recommendations, but they cannot yet make a decision (Rasche 2017). Decision-making always falls to a human being. This also applies to the use of algorithms in systems that, for example, automatically administer medication, trigger electrical impulses or send notifications to medical or nursing staff. One example is sensors implanted under the skin that record the blood values of diabetics in order to automatically release insulin when required.

Ethically and legally problematic implications may arise in connection with the programming, use and settings of the system, particularly with regard to the attribution of responsibility. Obviously, an algorithm can cause damage through poor-quality or even faulty programming or application. However, it would be nonsensical to claim that the algorithm is literally responsible for damage. Even highly developed algorithms are not able to assume responsibility. They do not make morally responsible decisions. Only humans can do that. So if damage occurs as a result of an algorithm application, those who were involved in the programming and application decisions are responsible. However, in view of the often-large number of people involved in such decisions, the question arises as to who is ultimately responsible for which factors and possible errors (Mittelstadt et al. 2016). Is it the programmer, the institution offering the system, the attending physician or the patient? The problem of attributing responsibility is exacerbated by technical aspects. Different types of algorithms sometimes raise different questions. In order to make decisions, people must have sufficient relevant information and practical decision-making knowledge. However, the different modes of operation of algorithms are sometimes hardly comprehensible, and sometimes not at all, even for computer scientists (European Group on Ethics in Science and New Technologies 2018).

Partially supervised or unsupervised machine learning poses the most problems. The individual steps of the respective processes are often no longer comprehensible, even for computer scientists and programmers. If the algorithm works incorrectly, people cannot recognise which step is the cause. Even with supervised learning algorithms, questions arise about transparency and the allocation of responsibility, e.g. between individual programmers and users. They are used to filter and process information. Thus, they influence human decisions. As a result, a mistake in data processing can lead to wrong human decisions, for example, if information relevant to the decision is classified as irrelevant. If experts rely on the performance of such an algorithm, decision-relevant factors can easily be overlooked. In the worst case, the awareness that decision-relevant information can be overlooked by an algorithm is lost (Mittelstadt et al. 2016).

Further challenges are associated with the so-called bias phenomenon. Bias means that the processing rules of an algorithm lead to a systematic distortion or bias. Algorithms are used to automatically analyse and group cell samples with regard to certain disease markers (Kraemer et al. 2011). In many cases, such grouping will be unambiguous. In other cases, however, the classification may be unclear. In such cases, a threshold value must be defined that determines whether a cell sample is marked as disease-relevant or not. Such a limit is a norm, and when determining it, it must be weighed up which consequence is more likely to result: a possibly more frequent false positive alarm or a possibly higher proportion of samples marked as false negative (Kraemer et al. 2011). A bias can also result from an algorithm operating on an insufficient data basis. This may be because the algorithm, as in the above-mentioned example of Google's image recognition algorithm, was trained with insufficient and above all one-sided data sets. But it can also be due to the incompleteness or inconsistency of data sets in the process of applying a learning algorithm. Health-relevant data has often been recorded incompletely so far. Data in patient records is often coded insufficiently or inconsistently and information is incomplete. Such shortcomings have an impact on the performance of algorithms, which often cannot evaluate such data or can only do so inadequately. Further imbalances in the database can also be caused by the fact that there is a particularly large amount of data available from certain groups of people, but only little from others. Patients in hospitals that already work digitally produce more data than those in less digitalised hospitals. Such an imbalance can also lead to a bias (De Laat 2017). Bias-related failures can significantly affect the reliability of systems in practical use. The analyses generated are inevitably either incomplete or even incorrect. The above-mentioned chance that the use of algorithms can significantly improve the safety and reliability of health services is therefore currently only limited.

It remains to be seen whether the problems caused by the various types of bias can be remedied in the future. Automatic or semi-automatic processing of digital content can ultimately only work if a sufficient degree of interoperability of different systems is ensured. It is therefore important to develop and establish common standards for data exchange (cf. Chap. 2). At present, however, there are sometimes considerable deficiencies in this area.

4 Conclusion

It is indisputable that digital algorithms can contribute to improving care, but their use also raises ethical questions: about distributive justice and protection against discrimination, about liability for algorithm-based decisions, about the upcoming changes in the relationship between doctor and patient, and about trust in the healthcare system as such. A broad understanding is therefore needed about which developments we as a society should support and demand on the one hand, and where boundaries must be drawn on the other. One of the tasks of digital ethics is to establish the effects of digitalisation on society and the individual, and to develop consistent justifications for moral action and normative standards. Furthermore, it can serve as a navigational tool for questions of values and norms associated with new technologies and the resulting social-communicative practices. Its aim is to promote value-based digital literacy, in order to develop a better understanding of how algorithms work and behave.

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Efficiently Delivering Healthcare by Repurposing Solution Principles from Industrial Condition Monitoring: A Meta-Analysis

Ulrich Hutschek, Thomas Abele, Philipp Plugmann,
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1 Introduction

Societies around the world are aging. In the next few years, more old people will be treated and cared for. It is also getting more difficult to hire qualified staff and to motivate and keep them in the healthcare industry. Whether to succeed under these circumstances and how to succeed in a humane way will depend on automation, digitalization, and AI in order to meet the key results for the quality standard we want to preserve. The management and implementation of novel technological solutions requires integrating people from IT, engineering, and robotics. Managers who execute services in home care and hospitals also need to become more proficient in technology in order to make this happen.

In this context, a general perception might come in handy: Most technologies can provide benefits in a multitude of applications (Gruber et al. 2008; Penrose and Penrose 2009; Teece 1982). Thus, instead of reinventing the wheel, existing technological solutions might be applied in order to fill the current technology gap. In particular, patterns from industrial condition monitoring—as a leading sector regarding this application—appear to be usefully transferable into the healthcare and care service sectors.

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The main contributions of this work are: We provide concrete and conceptual impulses to those who have or want to improve effectiveness and efficiency in the care sector, i.e., R&D executives, managers of care facilities, and entrepreneurs. We also demonstrate the methodological approach of transferring technologies and solution principles from different domains to the care sector.

2 Methodology

The data of our analysis comprises the papers in the Web of Science Core Collection[1] that were published between 2016 and 2019 and whose title includes the term "condition monitoring." This has resulted in 1206 papers. To identify the different research trends in this basic population, we conducted an AI-supported cluster analysis. We employed tf-idf—"term frequency-inverse document frequency" (Rajaraman and Ullman 2011), a numerical statistic that reflects the importance of specific terms to a document relative to a collection of documents. We then identified concise terms in the respective papers, and on this basis, we modelled similarities between the papers.

The terms identified by tf-idf were next used for cluster naming, as well as names of papers with a small betweenness, i.e., a short distance to the respective cluster core. For each of the clusters, we then examined important research topics and the underlying functional principles. These principles should serve as a basis for the transfer of the respective conceptual idea to the care sector. Last, our interdisciplinary team identified potential benefits of the principles in the healthcare sector.

3 Results

Our study identified the 15 clusters depicted in Fig. 1.

One of the key problems in condition monitoring is that critical components are often difficult to access and therefore difficult to monitor. As a consequence, a lot of research deals with the question of which proxies can best be used to draw conclusions about the actual system states. A relatively simple approach is to make an input–output comparison that identifies efficiency losses, as is done for example with energy converters (cluster 3). Alternatively, wearing parts (cluster 4) or operating materials (cluster 11) can be analyzed.

An important proxy for the assessment of operating conditions is the emitted sound. By using microphones (or sometimes even radar systems; cluster 2), acoustic signals are detected from machine tools (cluster 5), gearboxes (cluster 9), roads (cluster 13), or diesel engines (cluster 14). Not only, but especially with acoustic analysis, AI approaches are used to identify faults by pattern recognition, e.g., in

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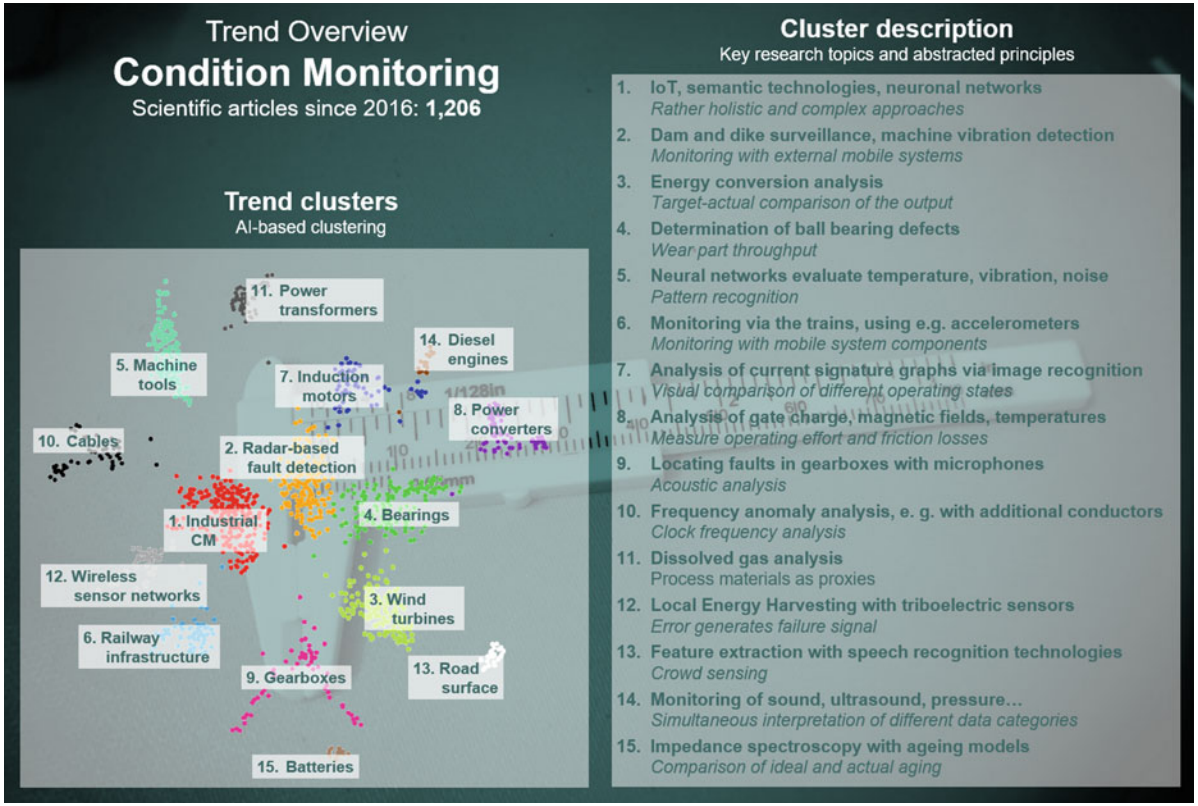
[1] http://apps.webofknowledge.com.



Trend Overview

Condition Monitoring

Scientific articles since 2016: **1,206**

Trend clusters

AI-based clustering

Cluster description

Key research topics and abstracted principles

1. **IoT, semantic technologies, neuronal networks**
   Rather holistic and complex approaches
2. **Dam and dike surveillance, machine vibration detection**
   Monitoring with external mobile systems
3. **Energy conversion analysis**
   Target-actual comparison of the output
4. **Determination of ball bearing defects**
   Wear part throughput
5. **Neural networks evaluate temperature, vibration, noise**
   Pattern recognition
6. **Monitoring via the trains, using e.g. accelerometers**
   Monitoring with mobile system components
7. **Analysis of current signature graphs via image recognition**
   Visual comparison of different operating states
8. **Analysis of gate charge, magnetic fields, temperatures**
   Measure operating effort and friction losses
9. **Locating faults in gearboxes with microphones**
   Acoustic analysis
10. **Frequency anomaly analysis, e. g. with additional conductors**
    Clock frequency analysis
11. **Dissolved gas analysis**
    Process materials as proxies
12. **Local Energy Harvesting with triboelectric sensors**
    Error generates failure signal
13. **Feature extraction with speech recognition technologies**
    Crowd sensing
14. **Monitoring of sound, ultrasound, pressure…**
    Simultaneous interpretation of different data categories
15. **Impedance spectroscopy with ageing models**
    Comparison of ideal and actual aging

Fig. 1 AI-generated condition monitoring research topic clusters with abstract principles. Source: authors industrial contexts (cluster 1), machine tools (cluster 5), induction motors (cluster 7), gearboxes (cluster 9), cables (cluster 10), road surfaces (cluster 13), or diesel engines (cluster 14).

In addition to the question of which proxy data to use for condition monitoring, the position of the sensors, their power supply, and the transmission of the measured data is often not trivial either. Thus, in addition to the radar systems already described (cluster 2), mobile system components are used, such as accelerometers in trains to monitor the rail infrastructure (cluster 6). Furthermore, triboelectric sensors are applied in the analysis of vibration data, where the power for data transmission is generated from the vibrations themselves (cluster 12).

A monitoring concept with a lot of potential is the use of sensors that are equipped with computing power for evaluation and communication options and that are mobile and often already available, e.g., in smartphones. For example, road surfaces can already be analyzed if there is simply a smartphone with speech recognition in the passenger seat (cluster 13).

3.1 Proposed Use Case: Comprehensive Home Care Monitoring

As home care patients are at home alone most of the time, they are particularly vulnerable and may not get help in time. For example, they may fall, suffocate from vomit, or die from a lack of fresh air (Komiya et al. 2013). We therefore suggest a comprehensive home care monitoring system that combines different sensors, such as motion sensors on patients, audio sensors for breath sounds monitoring, and air quality sensors. The sensor data needs to be constantly monitored for anomalous behavior. We suggest a deep neural network (Goodfellow et al. 2016) for this kind of task. (Artificial) neural networks are machine learning models that are loosely inspired by how the human brain works. A neural network is depicted in Fig. 2.

Deep neural networks consist of multiple layers of nodes (neurons) and are thus particularly suitable for learning hidden correlations in input data. There are already a number of related works in condition monitoring that can be adapted, e.g., an anomaly detection approach using wavelet transform and neural networks for condition monitoring of wind turbines' gearboxes (Cui et al. 2018) (cluster 3) and a neural network-based automated feature extraction method for anomaly detection in on-line condition monitoring (Roy et al. 2018) (cluster 4). Once anomalous behavior is detected, the system informs a nurse who can go to the patient's home and

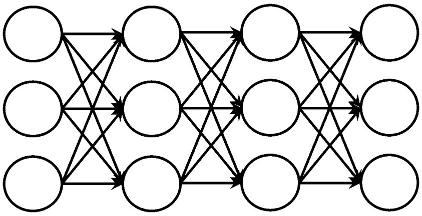


Fig. 2 Neural network connecting input nodes (left column) to output nodes (right column). Source: authors

provide assistance. We see great business potential for monitoring health of home care patients, as future healthcare will likely include more hospital-at-home models (Gebreyes et al. 2020).

3.2 Further Proposed Use Cases

In addition, further conceptual ideas derived from the condition monitoring domain that have the potential to bring benefits to care applications could be:

1. Mini drones at home that can fly to the head of patients and take probes of the sweat to analyze it in a miniaturized home laboratory (*derived from cluster 11*).
2. Monitoring the health of the staff in hospitals and private practices in order to check that they drink and eat enough, given their long working hours and work intensity (*derived from cluster 4*).
3. Intelligent mattresses that control the time spent in bed and monitor sleep quality and detect anomalous patterns, such as no use of the mattress for 24 h or not leaving the bed for 12 h. This would result in earlier alerts, earlier emergency services, and higher recovery probabilities (*derived from cluster 5*).
4. Predictive alert systems through combination of all data on an AI platform that is based on a cloud-based service with all data of the individual (*derived from cluster 14*).
5. Documentation of personal contacts of elderly people. This allows family members to do identity checks and history reviews (*derived from cluster 13*).
6. Laser screenings of eyes to detect problems at an early stage (*derived from cluster 7*).

Additional ideas that lead to a synergy of principles from the production industry, AI, and condition monitoring could be:

1. Self-driving (hospital) beds and chairs. As a consequence, care workers have more time for interaction with patients.
2. Drone-supported drugs delivery in hospitals through AI-driven mini drones that use the climate system infrastructure for transportation. As a consequence, care workers also have more time for interaction with patients.
3. Robotic arms that feed patients at home.
4. Condition care of mental capabilities through gamification implementation in tele-medicine.
5. Avatar interaction, similarly to tea time at home through a screen with an artificial partner.

4 Conclusions and Outlook

In this meta-analysis, we have pursued two main goals. First, we proposed novel and interdisciplinary impulses for decision makers and entrepreneurs in the care domain. In this vein, we provided the care community with the vitally needed use case on "comprehensive home care monitoring" as well as six further repurpose ideas. Second, we summarized the essence of industrial condition monitoring, i.e., 15 clusters of technological solution principles. We demonstrated that these look promising for transfer into and repurpose in the care domain. Future R&D work might use these insights by addressing further domains and transfer respective technologies and solution principles to the care sector. This will further make it possible to quickly and cost effectively deliver new products and services.

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Microservices as Architectural Style

Annegret Junker

1 Why Microservices

Microservices are talked about since 2012 as M. Fowler and J. Lewis described it (Fowler and Lewis 2014). They are an answer to increasing complexity and cloud technologies. Microservices are a technology, where a collection of loosely coupled services build up an application (Jamshidi et al. 2018). Usually one microservice represents one function of the application. Multiple microservices represent an application, which are coupled loosely together using lightweight protocols.

With such an approach it is possible to build up flexible and scalable applications which can be easily enhanced and adapted.

1.1 Example: Pharmacy

To get a better imagination how a microservice architecture could work, a quite simple sample of a pharmacy is used. The pharmacist has to order medicines or to create them by himself using according ingredients. He or she has to manage the stocks in the pharmacy, and to check if certain medicines are due because of their best before date.

In the following, we will use this sample to explain why a microservice architecture style can be better applied to those software applications than a monolithic style. A monolithic style would present all necessary functions in one application, which cannot be separated without effort anymore.

The sample is quite simplified to get the essence of the microservice architectural style. A real pharmacy management system would be much more complex. But even

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then, the additional functions could be implemented as microservices and easily enhance the system presented here.

2 Discussion of a Microservice Approach

2.1 Event Storming of the System

To get a better overview about the pharmacy system, we want to break down the already mentioned functions via a methodology called "Event Storming" (Brandolini 2020). Event Storming is a lightweight method to get information about a system to be built. In a first step "Events" are collected, which occur along the process at hand. Events are written in past. Figure 1 shows the events of the pharmacy system.

The events, which could occur, are discussed and brought in some kind of order. The events are marked with that small flash.

1. Stock checked.
2. Ingredients ordered.
3. Medicines ordered.
4. Ingredients received.
5. Medicines received.
6. Stock updated.
7. Order received.
8. Ingredients selected.
9. Medicine prepared.
10. Medicine selected.
11. Medicines delivered.

In a further discussion along the event order, the events are enhanced by belonging commands, processes, entities, user roles, views, and probably certain open issues and risks. Each category is marked with an according icon, as shown in Fig. 2.

Fig. 1 Events of a simplified pharmacy system. Source: Author

Fig. 2 Categories to enhance events in an event storming process. Source: Author

The process before is enhanced by those categories. Figure 3 shows the result of the event storming.

- **Stock checked**
  The pharmacist checks the stock. Stock means here a specific view to the medicines and ingredients directly available to the pharmacist.
- **Ingredients ordered**
  Based on his or her experience, the pharmacist orders the necessary ingredients, whereas an ingredient is an entity.
- **Medicines ordered**
  In same manner and even parallel to the ordering of the ingredients, the pharmacist can order necessary medicines.
- **Ingredients received**
  The pharmacist receives the ordered ingredients.
- **Medicine received**
  The pharmacist receives the ordered medicines.
- **Stock updated**
  The receiving of medicines or ingredients starts a process to update the stock. The stock is again the view on the medicines and ingredients in the stock.
- **Order received**
  The pharmacist gets an order for one or more medicines. He or she checks if the medicine can be delivered directly or if the medicine has to be prepared.
- **Ingredients selected**
  If the medicine needs to be prepared, the pharmacist needs to select the necessary ingredients. To do so he or she needs to find the according formula.
- **Medicine prepared**
  The pharmacist has prepared the medicine so that it can be delivered.
- **Medicine selected**
  If the medicine is available as product, it can be selected directly.
- **Medicines delivered**
  If the medicines are prepared and/or selected, they can be delivered. The stock list needs to be reduced by the medicines and/or ingredients which were used for the delivery.

Additionally, to the already found events, a risk has been found during the discussion.

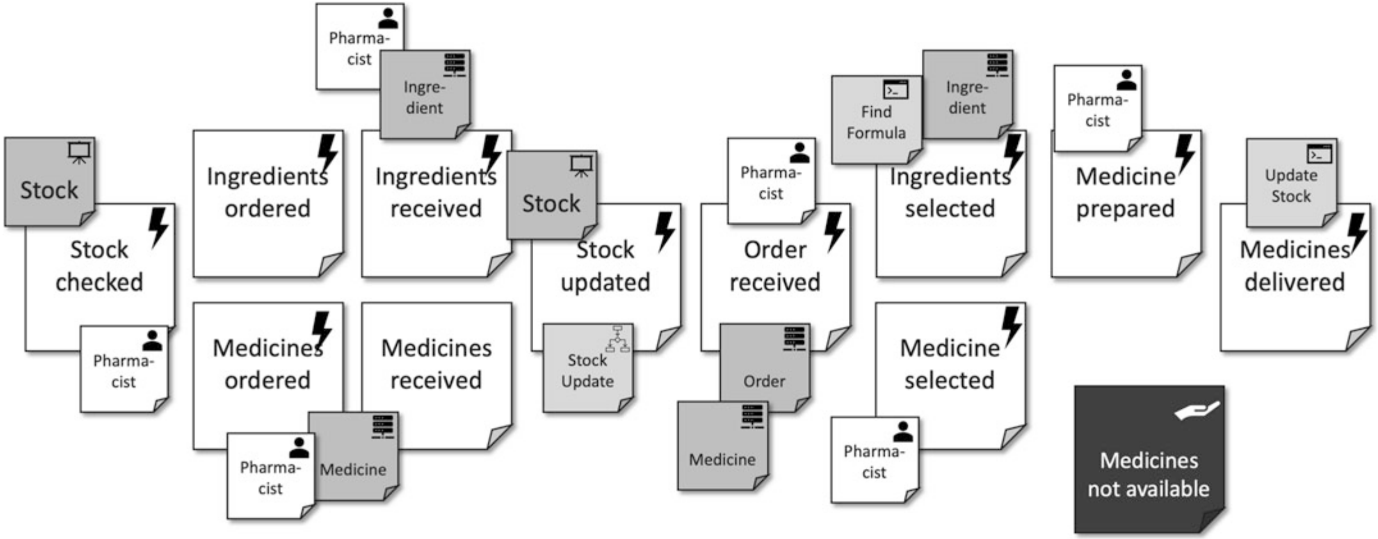

Fig. 3 Event storming of a simplified pharmacy system. Source: Author

- **Medicines not available**
  There is a risk that medicines or necessary ingredients for an order are not in the stock, because the purchasing process relies only on the experience of the pharmacist. Further development has to handle such a risk.

2.2 Domain Boundaries

In the next step, domain boundaries can be determined based on the result of the event storming. Domain boundaries are introduced by Eric Evans (2003).

A domain is an isolated area of responsibility in the business process, where an expert group can develop their ubiquitous language. That language needs to be defined inside of the boundary. Outside of the boundary in another domain, another ubiquitous language has to be developed. Anyhow on domain gates, where data from one domain to another domain need to be transferred, contracts have to be developed to ensure that transferred data can be understood. For example, in the stock domain a medicine is a product. In the delivery domain a medicine can be a product or a medicine prepared by the pharmacist according to the order. Inside of the domain the language is clear, outside of the domain terms need to be defined.

Anyhow, it is not necessary to define all terms over all domains, only those terms need to be defined, which are the base of a contract. Figure 4 shows the boundaries of the system.

- **Stock Management**
  Stock management handles the medicines and ingredients in the stock of the pharmacy. To do so the view “Stock” is used.
- **Purchase**
  The Purchase domain handles the ordering and receiving of medicines and ingredients. It handles the entities ingredient and medicine. If a purchase has been done, an event to the Stock Management has to be sent to update the stock.
- **Order Management**
  Order management handles the incoming orders and the selection and preparation of medicines. A selection is obviously some kind of a subdomain of the order management.
  - **Preparation Management**
    Preparation management handles the formulas to prepare medicines using according ingredients. Preparation management is subdomain of order management.
- **Delivery Management**
  The delivery management handles the delivery of the medicines according to the order. Moreover, it starts the process to update the stock based on the withdrawn ingredients and medicines.

The domain boundaries define in a first step the microservices of the system.

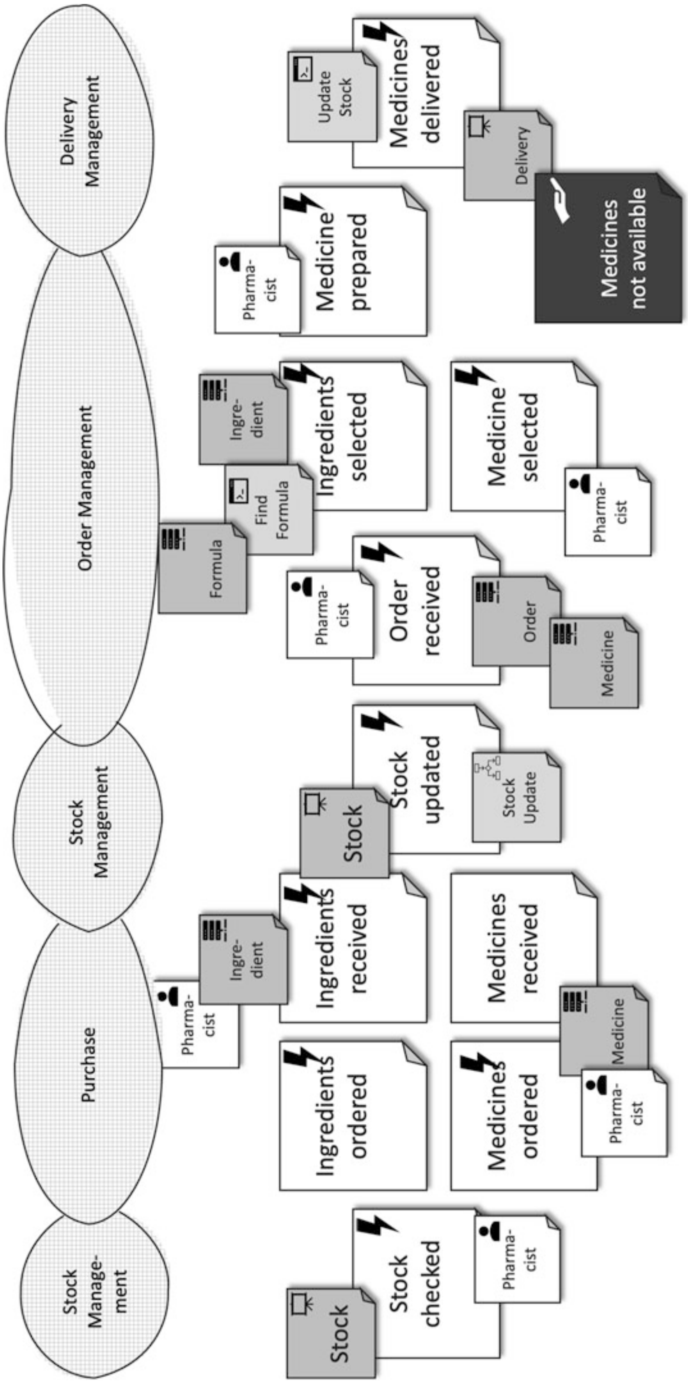

Fig. 4 Selected domain boundaries of the simplified pharmacy system. Source: Author

2.3 Services and Contracts

Figure 5 shows the resulted services out of the modelling based on domain boundaries and event storming. The microservices are represented by boxes. The domain objects are taken out of the event storming model and are shown next to the according microservice box.

It even shows the necessary contracts. Necessary contracts are shown as arrows.

2.3.1 Services

Stock Management

Stock management handles the medicines and ingredients in the stock. It shows via a specific view which medicines and ingredients are available. It can deliver requirements to the Purchase microservice if certain stock items are going low.

Purchase

Purchase handles the ordering of medicines and ingredients based on the requirements coming from Stock Management. Those are bundled to purchases. If medicines or ingredients are received, an update event is sent to Stock Management.

Delivery Management

Delivery Management handles orders which are delivered to the address given in the according order. Delivery is then a specific view on the medicines to be delivered. Medicines here are either products or prepared medicines. When the medicines are delivered, the delivery management sent an update event to the Stock Management about the withdrawn medicines.

Order Management

Order Management handles the orders for medicines. Medicines here can be products or medicines to be prepared by the pharmacist. The order as a specific view can contain multiple of them and needs to include a delivery address. The pharmacist can decide if he or she uses a product for the medicine or if he or she needs to prepare it.

Preparation Management

If the pharmacist decides to prepare a medicine, he or she needs a formula about it in Preparation Management. An according event is sent to Preparation Management if the according formulas and necessary ingredients are known to it. If the medicine is prepared an according event is sent back to Order Management and an update event is sent to Stock Management containing the withdrawn ingredients.

2.3.2 Contracts

Requirement

A requirement means a medicine or an ingredient, which needs to be ordered to fill up the stock again. The contract exists between Stock Management and Purchase.

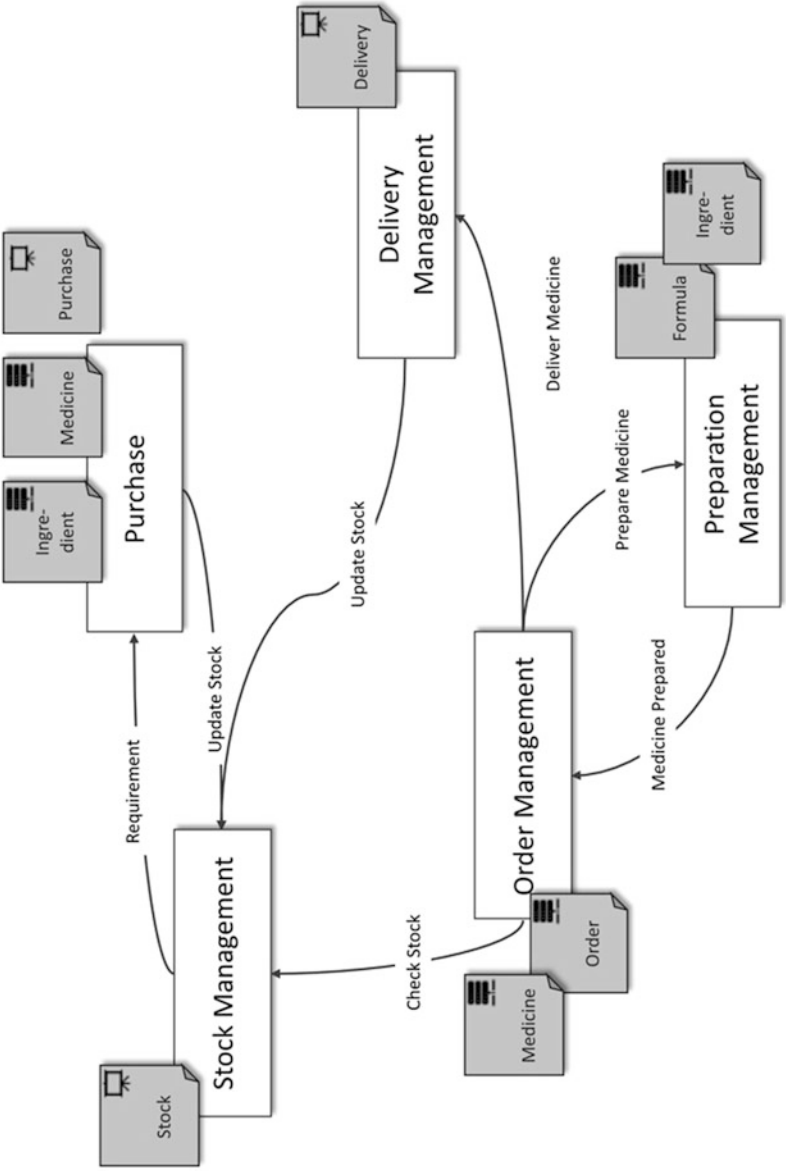

Fig. 5 Services of a simplified pharmacy system. Source: Author

Update Stock
Event to update the stock if medicines and/or ingredients are either withdrawn or added to it. The contract exists for withdrawing between Delivery Management and Preparation Management, and between Delivery Management Stock Management for adding.

Deliver Medicine
When an order is analyzed and all necessary medicine is either selected or prepared, it can be delivered. The contract exists between Order Management and Delivery Management.

Prepare Medicine
When a pharmacist decides to prepare a medicine, an according event is sent to Preparation Management.

Medicine Prepared
If the necessary medicine is prepared, an according event is sent back to Order Management.

2.4 Technical Architecture of the Sample

Figure 6 shows the technical architecture. The services are implemented as microservices.

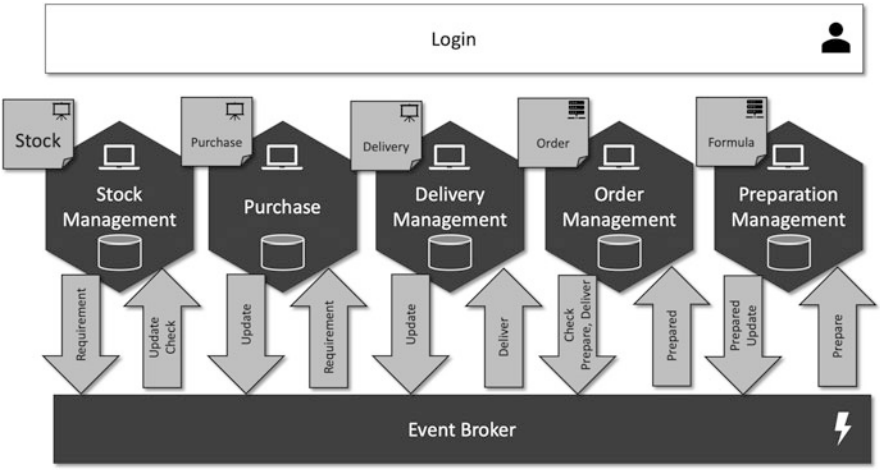

Fig. 6 Technical architecture of the simplified pharmacy system. Source: Author

The microservices shown as hexagons contain a persistence layer shown in the figure as small database symbol and a user interface shown in the figure as small computer symbol. Each microservice owns a specific domain object.

- Stock Management owns Stock object.
- Purchase Management owns Purchase object.
- Delivery Management owns Delivery object.
- Order Management owns Order object.
- Preparation Management owns Formula object.

Each of them has a particular implementation of medicine and ingredients which were represented by the ubiquitous language of the according domain. For example, ingredients are represented by their volume, weight, place of stockage in Stock Management. Whereas ingredients are represented as a dose in formula objects in Preparation Management. In Delivery Management, ingredients do not appear at all, because Delivery Management only knows medicines to be delivered independent if they are products or prepared.

Contracts are technically represented by events which were exchanged by an event broker. Those events need to be synchronized by the producer of the event, e.g. Delivery Management, Preparation Management, and Purchase for the Update event and the Consumer of the event, e.g. Stock Management for the same event.

Technically, additional supportive services are necessary. They are represented by the event broker, which receives events from the producers of those and which provides events to the consumers, which can read the events from it. Event Brokers are used to decouple the microservices from each other so that they can be developed and deployed independently.

In addition to the event broker, some security components are necessary. So only authenticated users should be allowed to access the system. Therefore, a login service is necessary to authenticate the users. The microservices themselves are responsible to authorize the users to access the particular domain objects as the Purchase object based on the provided identity of the user.

The technical system represents the detected services and domain objects as they were found in the event storming session, but it does not handle the identified risk.

2.5 Enhancement of the System

During the event storming sessions as described in Sect. 2.1 Event Storming of the System, a risk was determined what should happen if the ordered medicine or necessary ingredients were not in stock. A solution of that risk could be a partner management. If a medicine or an ingredient is not in the stock, it could be ordered via a Partner Management. Figure 7 shows the variation if the system is enhanced by a Partner Management service.

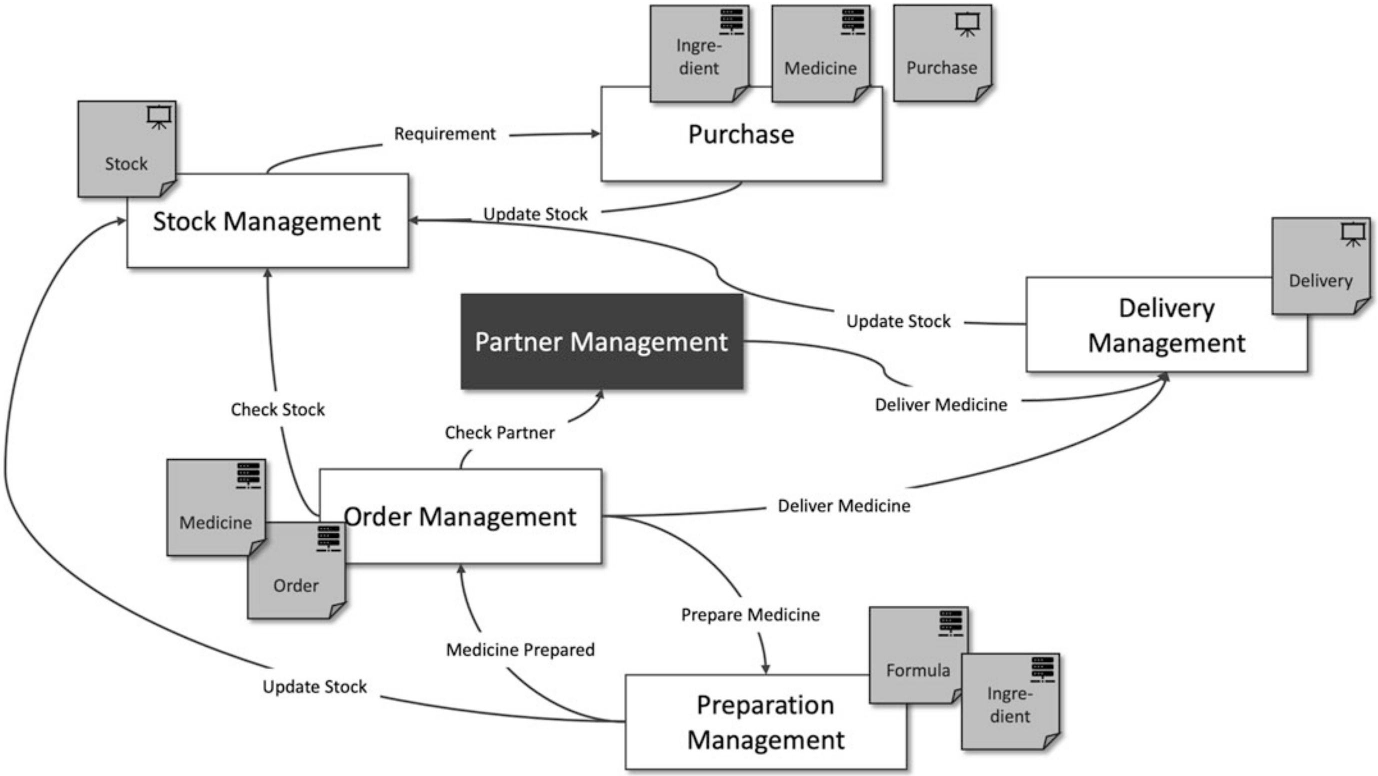

Fig. 7 Services and contracts of simplified pharmacy enhanced. Source: Author

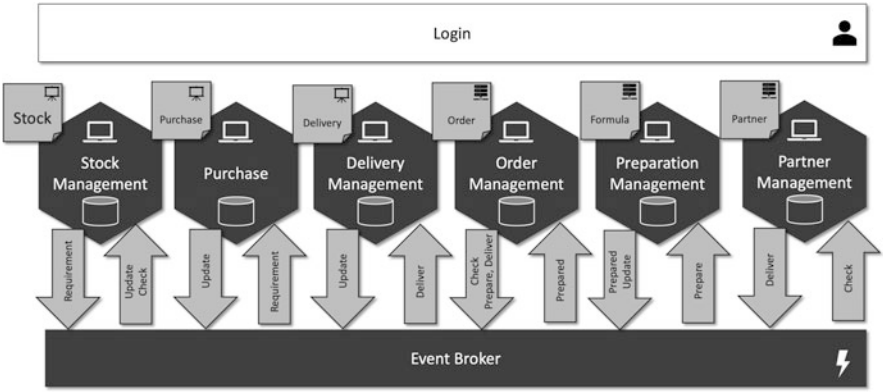

Fig. 8 Technical architecture enhanced by Partner Management. Source: Author

Order Management sends an event to Partner Management for a missing medicine. Partner Management takes over and sends the according event that an according medicine can be delivered to Delivery Management.

Figure 8 shows the regarding architecture.

An additional service appears. The events Check Partner and Deliver Medicine appear additional on the event broker. Contracts for both of them need to be synchronized. Out of a domain approach the contract Deliver Medicine coming from Partner Management and coming from Order Management might contain the same structure.

3 Discussion of a Layered Monolith

In the 1990s years of the last centuries, complexities of software architectures were tackled by the so-called layered architectures. Those architectures were divided to a layer of user interface, business logic, and persistence layer. In the end those layered architectures lead to monoliths were several functions are provided by one service. Those functions cannot be divided without effort. Usually they cannot be even tested separately.

Figure 9 shows the technical architecture of the system as a monolith. There are several issues to be detected.

An often to be watched issue in such layered architectures are entities, which overarch several domains. For example, medicines and ingredients are not restricted to one domain. They appear in the same manner to each component in the business logic, which access them in the same persistent layer. Therefore, the persistent model (e.g. a database model) for it is the same even for different domains. For each change, every component has to be synchronized and tested.

When the system is enhanced by the Partner Management function, each layer has to be changed: user interface, business logic, and persistence layer. The

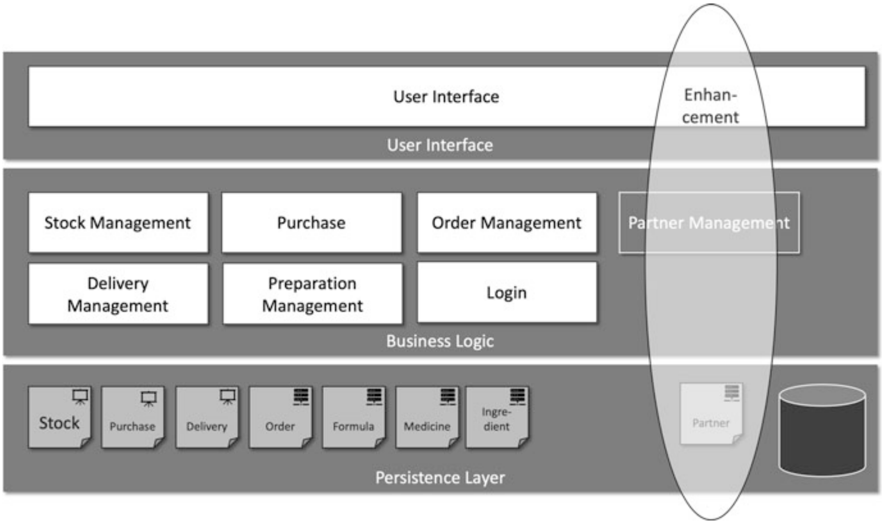

Fig. 9 Technical architecture of a simplified pharmacy system as monolith. Source: Author

persistence layer has to be enhanced by the entity Partner. But the entity Medicine has to be enhanced as well by the Partner Management specific attributes. But those changes require a retesting of the entire system.

In case of the microservice approach only the microservice Partner Management and the according contracts Deliver Medicines and Check Partner need to be tested.

4 Advantages and Disadvantages of Microservices

As shown microservices are an architectural style, which provides an application by a collection of loosely coupled services.

Because microservices provide functions in single services, they are easier to test and better to understand. Because they are better to understand, they can be better maintained. There are fewer synchronizations between teams necessary, because changes are only done inside of a service. Usually contracts are not changed. But if contracts need to be changed, they can be changed along a period; and a consuming team can do the necessary changes later on.

Those advantages come with a couple of disadvantages. Because microservices only provide one function, it might be difficult for a single microservice team to understand the entire application. In a monolith, the team has to understand the entire application to detect the according implications going with a change. For a microservice team that is not necessary in such a regard.

Microservices communicate via network. Peer-to-peer communication is quite difficult because of unreliable networks, latencies, unsecure networks, or even changing network topologies. Therefore, certain decoupling infrastructure components are necessary. In the presented sample, an event broker takes over that decoupling function.

Even though testing of a single service might be easier, as mentioned before, the end-to-end testing of the entire application might be more complex as the end-to-end testing of a monolith. But usually the number of end-to-end tests is much smaller than the number of integrations or even unit tests. So that disadvantage weighs less than the advantage of the good testability of a single service.

Though those disadvantages are serious, microservice approaches bring so many advantages with them that they cannot be ignored. If a new project is setup, a microservice architectural style should be applied. In a migration scenario, the ideal approach can serve as a vision. So for each service can be decided how the microservice approach can be applied. Microservice approaches are the more sustainable and maintainable way to create and migrate modern software applications.

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Value-Added Process Design for Digital Transformation in Hospitals and Medical Networks

Ralf-Joachim Schulz and Martin Schönheit

1 General Thoughts

Today's health care is increasingly caught between financial resources, high service requirements, and continuously regulating quality levels in an increasingly professional and automated value-added process.

1.1 Clinical Data and Participations

First of all, a few basic thoughts on the structuring of digitally-supported medical care in the regional area are allowed. The development is moving towards a recognized center oriented according to competencies at a real and virtually networked location. This competence center will be an interface for referring physicians and care providers. It communicates values to be achieved together and makes joint progress visible by means of quality indicators. The basis of all actions and measures is a digital documentation and storage of medical information in a center, combined with direct but regulated access to existing data and examination results of defined partners. The outpatient and inpatient care system communicates via the same medium and integrates the patient as customer and "co-administrator" in the data exchange.

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1.2 The Partners and Their Particular Interests

The patient as a decisive and co-determining customer and owner of digital information is increasingly coming to the fore and has a greater say. The role of the competence center in (previously still called a hospital) is increasingly limited to that of a diagnostic and therapy initiating center. The referring physician in the form of an external clinic or practicing doctor or, in the future, also as an insurer (special individual treatment contracts) will become more important in his function and task. The insurer will be increasingly involved in the procedures and quality-forming processes as a financing and contractual partner. This is made possible by a digital platform that is enabled by IT providers in the form of network providers with management of data and access rights. With the IT provider, a professional group is created that works individually and highly specialized on the health care system with partners such as the practice/family doctor's practice, medical care centers, primary and maximum care clinics, and outpatient care services. What is new, however, is that patients themselves are increasingly transmitting data on health parameters and lifestyle, which, through artificial intelligence, enables a new form of diagnostics and therapy monitoring.

A further group is the pharmacy structure, which up to now has often operated independently, which is needed in the supply systems to ensure the provision of medical care in outpatient and sometimes remote rural areas.

Here, the field of activity of the pharmaceutical service must be redefined.

1.3 Current Digital Networks in Field Test

The Federal Republic of Germany has a very complex and decentralized medical care system. In contrast, Sweden, Great Britain, and Switzerland have more clearly definable care structures, which is why uniform digital networks entered the test phase years ago.

These networks are very complex and require not only uniform bases in data availability, uniform data protection and rules for the protection of personal rights. They also require a powerful data transfer and storage system that allows the implemented partners to access a form of a digital patient file at any time.

1.4 Devices for Digital Data Acquisition and Documentation

In the last 5 years, an astonishing number of digital measuring instruments have reached series production readiness in everyday clinical practice. Data acquisition and data networks in clinics and outpatient medical facilities are also increasingly gaining substantial improvements and a high proportion of data storage. For this reason, a whole new world of continuous recording of vital parameters and behavioral patterns in patients undergoing therapy and in follow-up care is opening up.

This includes completely new data platforms, which bring together measuring devices placed close to or on the body itself in their data acquisition and enable a profile of the activity and health status of a person without the data evaluator (doctor or nurse) having to be physically present. Not only tele-medicine with its possibilities for a virtual consultation hour but also the continuous recording and evaluation of vital parameters generates a completely new quality in medical care. Above all, this does not take place in short visits with monitoring breaks of days or weeks as in the past, but continuously online.

1.5 The Patient as Customer

By placing the patient at the center of future care networks and technical innovations, it will be possible for patients to receive medical care in less and less time. Thus, consultation hours with waiting times of several hours will soon be a thing of the past. In other words, a patient will no longer tolerate such time delays. The consultation and diagnostic interventions will be expected directly by the patient and will require consultation hours that will exceed the current regular working hours of the current outpatient clinic or consultation service.

Patients will increasingly question the quality of medical care, base their decision on the choice of physician on this, and external service providers will also advise them on which medical services offer the highest medical quality and safety for them as patients at that time.

Only facilities with high technical and qualitative standards and the ability to provide patients with data on demand will survive on the market in the future. The documentation on patients' own data carriers will quickly make redundant repetitive services transparent and easier to control not only for the patient but also for the cost unit. In the current insurance system in Germany, costs currently play only a limited role for the patient, as he or she is only rewarded to a limited extent for avoiding illness or avoiding therapy. But with digitization and the increasing number of treatment contracts and conditions offered by individual insurers, these aspects will nevertheless come to the fore in terms of health insurance contributions and the assumption of services by the insurer. In the future, the patient, as a customer, wants to be the focus of attention and be involved in the decision-making processes as to who will carry out which intervention, diagnosis, etc., when and where.

This is not contradictory to the fact that the patient nevertheless wants to be guided and advised directly, even in view of the large amount of data and the difficulty of getting the data right in detail, but can also be involved in decisions at any time.

2 Practical Examples

The above-mentioned fundamental considerations are now illustrated in the following examples, which are only exemplary and reflect only a small selection of the current developments.

They come from the field of geriatric medicine, which is particularly challenged by the complexity of multimorbid patients and their fragility and can particularly benefit from digitized structures.

In addition to the fact that there will be an increase in this patient group and its obligation to intervene and treat, the problem is also faced with a decreasing supply of care and physician density.

For this reason, care for this patient group in particular must be reconsidered and innovative trans-sectoral care networks must be created.

It is therefore assumed that this patient group is functionally limited, often disoriented and often unable to provide information about themselves in emergency situations.

Which constant, which reference points are then leading as parameters in the decision-making processes and lead to the triggering of courses of action and supply chains? If one translates the multimorbidity, which is complicated in this case, then one can compare the situation with a pilot in a cockpit under bad weather conditions during a landing approach.

Two basic groups with regard to decision-relevant data can be formulated.

1. surrogate parameters in the form of functionality recorded by a standardized, process-related clearly structured geriatric assessment, and a defined sensor system for recording vital parameters.
2. surrogate parameters in the form of quality-of-life states which are based on special assessments independent of the body condition parameters previously considered in medicine.

Diseases that are mostly chronic are thus brought into a new functional relationship with clinical parameters and known diagnoses that determine quality of life.

The 12 illnesses that exist on average in an 85-year-old person are summarized in the so-called geriatric syndromes and transferred into logical relationships. This is currently still done according to medical experience and following medical guidelines for defined individual diseases (Schulz 2012).

The emphasis here is on “still,” since there is an increase in artificial intelligence (AI) supported diagnostics.

This clinical situation requires a maximum of prioritization of the problems taking into account the organic and functional reserves. The multitude of data and clinical correlations must be evaluated visibly but also in terms of quality of life in an overall perspective.

Multimorbidity thus means that it often results in multiple medication, which requires multiple interactions and intolerances to be taken into account.

The fact of multimorbidity, however, also means that multi-organ insufficiencies in a labile equilibrium have to be considered simultaneously during therapy.

The result of these considerations is therefore the question when is or becomes which parameter leading and decides on further diagnostics and therapeutic measures?

When in which period of time is which functional or organ-dependent problem so dominant that it endangers the goal of a good quality of life and results in a continuous high need for care? (Rummer and Schulz 2012).

Which factors are first or second order preventive relevant with regard to complications, hospital admissions, and avoidance of permanent inpatient nursing care.

The decision for the choice of specific therapy concepts depends on data from digital networks at the time of geriatric therapy, the joint therapy of patients with outpatient physicians and the geriatric care options.

At present, valuable human resources are being consumed for data collection in the absence of existing data storage facilities. There is also the additional disadvantage that there is a high risk of errors in the collection of information. Likewise, everyday life is made more difficult by incomplete documentation due to lack of personnel, limited time resources, and different documentation media.

The goal must be to obtain medical and biometric data digitally in real time and to integrate them into result-oriented learning intervention models with the support of artificial intelligence.

The question is therefore how can digital data be prepared and supported in the future so that the scarce personnel and time resources can be used as effectively as possible?

At the St. Marien-Hospital in Cologne (Germany), a unit for cognitive insufficiency has been investigating for several years in a kind of space lab situation the obligation to document new parameters in patients suffering from dementia who are unable to provide information. Under the realization that currently this cognitive impairment cannot be significantly improved by drug interventions, new concepts for the therapy of the emotional peculiarities of the disease are being investigated. In contrast to intensive care units, where patient data are connected to a monitoring system through body-fixed electrodes, this is not possible with patients who are often very mobile. For this reason, new approaches to WLAN-based sensor technology are being tested.

Therapeutic concepts instead of drug interventions can be realized, for example, by means of novel architectural structures of a hospital unit and the resulting positive changes are documented. These findings, in turn, will then be integrated into the special and individual design of the personal domestic environment.

This experimental building structure is clearly structured, structured with defined color accents, takes haptic and visual stimuli into account, such as haptically distinctive wallpaper, certain surface structures on the walls and the so-called *Snooze units*.

But new elements such as a humanoid robot can also be used for emotional therapy approaches.

For the hospital of the future, special rooms are being tested for a special sensor technology to accompany emotional activity states, which will enable room monitoring with regard to movement, patient activity patterns, air quality, temperature, and noise development.

Especially the continuous documentation of the sleep rhythm and other activity patterns allow important conclusions to be drawn about drug therapies. The dosage for very elderly patients with organ insufficiency is often imprecise and only very roughly possible. Especially the digital feedback on therapies with psychotropic drugs seems to be very promising in terms of avoiding complications with prolonged hospital stays. Currently, there is no system that adequately supports this complexity in the form of digital medical interventions supported by sensor technology and artificial intelligence.

One example for the use of smart material.

The VulnusMON project, funded by the Federal Ministry of Education and Research of the Federal Republic of Germany, attempts to identify intelligently selected monitoring parameters of body states without a great deal of personnel effort. The aim is to develop a wound plaster that records wound conditions in terms of moisture, body temperature, and other parameters in real time and to transfer the data into a digital care network. This would mean that less care effort with less manipulation of the wound would be an important parameter.

The time required to treat the wound should be more targeted. But also the now required documentation effort could be reduced significantly. Also the error rate of not being able to treat wounds at the decisive moment for therapy should be reduced. The wound cannot be continuously monitored for healing in the currently existing treatment concepts. It is also being tested how a wound care network can be formed around this digital wound plaster. This includes surgeons, general practitioners, outpatient nursing services, and other specialists such as wound dressing manufacturers. All these partners need to be provided with data that they must receive in real time and be able to plan their interventions accordingly.

The already mentioned technology concerning a simple ceiling sensor system in a room with monitoring of the activities of patients under psychotropic drug therapy is investigated in the experimental approach “Technology and Analytics.” The imaging of drug effects and side effects in real time can be a great opportunity for cognitively impaired patients. Avoiding overdosage saves large diagnostic loops with a very complex differential diagnostic checklist. In addition, such systems can be expected to avoid the number of falls with life-threatening fractures and intracranial bleeding. An essential therapeutic approach from the above-mentioned circadian room lighting is documented by such ceiling sensors with documentation of a resolved day-night rhythm and corresponding sleep disorders. In other words, it is possible to detect with appropriate sensor technology how, for example, a disturbed sleep rhythm can lead to concentration disorders and depression. Due to low structural and constructional effort it will soon be possible to monitor rooms in which patients are staying in stationary care facilities and hospitals but especially in the home environment. Especially for the home environment, this promises to maintain a high quality of life by keeping the patients in their own rooms.

A further therapeutic application is the digital control of light scenarios that are subject to the bio-rhythm with the maintenance of a corresponding metabolic rhythm. The digital control of light in rooms for conditions similar to daylight. This is not only possible in defined hospital rooms, but is already being introduced into the everyday life of private users and their living environment.

It has been scientifically proven that this leads to an improvement in emotional stability. The aim of the project at St. Marien-Hospital is to document the reduced psychotropic drug dose in patients. Also the avoidance of liberty-taking measures for the protection of patients is the goal of this digital light control and composition of light frequencies and their intensity.

Among other things, the human bio-rhythm is subject to two already well-studied bodies own hormones. Namely the cortisol level and the melatonin level. Both hormones control the sleep behavior and metabolic activity and thus the mental activity of every human being.

All these considerations are currently being evaluated internationally in digital assessments. These assessments ask for the so-called prognostically relevant, functional and laboratory medical parameters which are summarized in a so-called Multi Prognostic Index (MPI).

These parameters do not necessarily have to be recorded by medical personnel, but can also be determined by *Artificial Cognitive Systems*.

For example, we are currently investigating to what extent humanoid robots can not only improve the emotional state through standardized interaction and entertainment programs, but can also document parameters such as temperature and pulse via appropriate camera systems in addition to recording the emotional state by means of facial mimic analysis. The goal is to record actions and reactions in connection with patients free of human judgements and evaluations.

These parameters can not only influence therapy concepts significantly in the future, but also determine the degree of care required in further patient management. Not only the pure functional possibilities of the patients and abilities supported by aids are included in the analysis, but also the co-factors in the home environment that determine the quality of life. These quality-of-life factors must be recorded in new types of assessments, documented digitally in patient-related media, and communicated to the care networks. New parameters have recently been published for this purpose (Bordne et al. 2020).

The documentation and digital storage of subjectively perceived quality of life improvements and the associated interventions point to the new development according to which very old patients evaluate their satisfaction with medical care, nursing care, and social ties. The realization that functional improvement does not necessarily improve the quality of life has not yet been taken into account in the considerations that determine therapy. Unfortunately, however, it is also so complex that it will only be possible to store certain “patterns” in patients’ own documentation media and integrate them for further concepts.

The 360° overall concept from hospital care to home care with as preventive an intervention as possible is the future. These concepts are only possible through digital care networks and will be able to meet the demand for real-time interpretation of health changes and biometric parameters.

3 Conclusion

The conclusion to be drawn from the above-mentioned examples is that IT platforms are the key to an effective care network. These networks, as they are being tested, for example, in Sweden, Switzerland, Great Britain, and other countries like Denmark, have a future. Artificial intelligence can support decision-making processes in the collection and direction of data and, in the best case, prevent patients from having to be regularly transferred to inpatient care facilities (Rummer and Schulz 2012). However, it is essential that the hospital architecture and room conditions adapt quickly. In the next decade, *Future Hospital 4.0* will have to combine biometric and laboratory chemical parameters in real time without great technical effort and support the interpretation of disease states during medical visits.

Data protection must be improved for these care networks and ensure that this data is only compiled and stored at the patient's location. The current interweaving of medical topics and consumer-dependent parameters does not necessarily have to be a disadvantage, but it does lead to considerable data protection and legal problems. It is clear, however, that the definition of medical parameters and consumer-related parameters are difficult to separate from each other and can be used in the future in a supportive manner, such as movement profiles, intensity patterns with regard to certain topics, areas, etc. The question remains to what extent and to what depth supply networks can be supported or coordinated by artificial intelligence.

There is currently no lack of technical innovations in data management and networking. The advantages, such as increased patient well-being, improved quality of diagnosis and treatment, and reduced medication errors, are convincing and will significantly support future digital documentation and sensor technology. However, further research is needed to combine data quality with higher data security.

Facilitating communication between healthcare providers and, above all, in remote, decentral coordinated communities is a particular challenge. It becomes clear that due to the lack of qualified nurses and physicians, the adoption of redundant data acquisition using sensor technology and artificial intelligence represents a great opportunity for the healthcare system of tomorrow. Parameters such as body temperature, weight, recording of medication intake and its immediate effect profile, but also the recording of over- and under-dosage, the care and playful recording of emotional states and thus quality-of-life parameters will have a decisive influence on the future with regard to the amount of care required and the satisfaction of a health care system. The evaluation of image material and biographical data play a special role, especially for multimorbid very elderly patients, and form a special focus of the project.

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Digital Pharmacy

Tamim Al-Marie

1 Introduction

2020 is really not the year to criticize the German healthcare system as a whole. I'm still glad about how great we handled the COVID-19 pandemic and, to be honest, a little proud to be part of such a great healthcare system.

After I repeatedly criticized how little digital our healthcare system is in comparison to the rest of the world (Thiel 2018), it is time to acknowledge how above average our healthcare system still is when it comes to actually treating patients. Nevertheless, there is still much room for improvement: "Up to EUR 34 billion could have been saved in 2018 if the German healthcare system had already gone digital. This corresponds to around 12 percent of the actual total expenditure of an estimated EUR 290 billion this year. This is a new record, and the momentum is unbroken: German healthcare expenditure is growing at a nominal annual rate of 4.5 percent due to the aging population and more expensive treatment methods" (Hehner 2018).

Thinking about a better way should not be strictly correlated with thinking badly about the current process. Rather, we should appreciate the good things in our health care system and not be blind to the potential for improvement in so many areas.

I do not pretend to be able to say what is the right way and what is the wrong way. I am more interested in pointing out challenges and suggesting possible solutions—whether they work, well, that's something we can discuss, but in the end we have to try them out.

The following will not be a quantitative study of the digitization potential in the pharmacy sector. I leave that to external strategy consultants. As part of my pharmaceutical education I worked in a pharmacy myself. I would like to describe

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the most typical patient enquiries in everyday pharmacy life that I have noticed. Since I had already worked with digital business models before, I couldn't help but think about digital solutions. Therefore, I will also start to sketch digital solution concepts as a basis for discussion, but they all still need to be tested. You can now take this as either an interesting impulse for thought or as an invitation to test it together. That is fully up to you.

Disclaimer By pharmacist I mean all people who work in pharmacies. Just to reduce the complexity of reading, I will not distinguish between the different roles in a pharmacy. Furthermore, it shall be clear that in addition to the three cases described in the following, a lot of other areas of responsibility are covered by pharmacies. In order not to go beyond the scope of this chapter, I will limit myself to the most important and interesting cases in my opinion.

2 Patient No. 1: Self-Medication Request

Of course, the relative frequency of the different patient cases depends strongly on the type and location of the pharmacy they are looking at, so it should be mentioned at this point that I worked in a pharmacy in central Berlin with very long opening hours.

Patient no. 1 simply asks for quick relief of his trivial complaints (e.g. cough, runny nose, or a simple vaginal infection). They do not ask for a specific product. They have a rather typical problem and want to know which of the hundred available products is best suited for them.

Since this type of patient typically has no concomitant diseases, the answer to the question of which drug is the right one for him is very general. If they do take medication regularly, it is usually only the classic headache tablet. In addition, the medications used for such complaints are (not always!), but for the most part very well tolerated and have few interactions. This is often due to the fact that the drugs are only used locally. At least the interaction is usually so low that it only plays a role in pharmacology lectures, but not in practice. In addition, many cold medications are plant-based and extremely well tolerated.

It remains to be examined whether the trivial symptoms in their combination, appearance, or duration are perhaps signs of a more serious disease. The questions that need to be answered are defined in standardized guidelines and are comparatively simple to apply (Bundesapothekerkammer 2019).

The answer as to which drug is the right one is often the same and theoretically easy to answer, whereas the problem is often that the data available on some over-the-counter drugs is comparatively thin. To give an example: While the importance of expectorants in cough therapy in pharmacy practice can hardly be denied, the data available on them is sometimes questioned. The drug telegram says the following about this drug group: “There is a lack of meaningful clinical evidence that the course of lung diseases can be favourably influenced by expectorants. (...) The therapeutic benefit of expectorants is therefore still doubtful" (Arzneimitteldatenbank, atd arzeni-telegramm 2020).

In my observation, it happens way too often that the pharmacist's recommendation follows personal preferences and habits instead of the latest therapy guideline.

3 Patient No. 2: Simple Request of Prescription Medicines

Patient no. 2 comes with a prescription and wants the medication the doctor has prescribed. He tends to react annoyed when he is overwhelmed with too much information, because he is usually on his way to the next appointment or even more understandable, he is feeling bad and wants to get back to bed as soon as possible.

Apart from the discount contracts, which we will talk about later on, the cases we are going to deal with here are—from a pharmaceutical point of view—not the most complex: we are talking about patients who do not take any other medication apart from the medication the doctor has just prescribed for them, no comorbidity and no chronic diseases. Typically, these are antibiotics or similar therapies that are only used for a limited time.

If the basic conditions are trivial (no comorbidity, etc.), the patient cases who have been prescribed the same medication usually differ only slightly from one another.

The questions about the drugs and their use or the important aspects the patient needs to know about are therefore almost exclusively dependent on the drug and the disease for which it is prescribed (e.g. some antibiotics are taken at different frequencies depending on the type of infection), so that there are only a handful of cases per drug that differ, but are almost identical from patient to patient. The really exotic requests are rather rare.

In addition to the core pharmaceutical issues, the discount contracts already mentioned must also be taken into consideration: Now comes a little bit of detailed knowledge from everyday life in a pharmacy: In the majority of cases, the corresponding discount contracts must be checked for this. In theory, this happens automatically. In practice, there are often little pitfalls and problems for the patients.

For all those who do not know the discount contracts: These are concluded between health insurance companies and pharmaceutical manufacturers and lead to the pharmacy being obliged, depending on the health insurance company to which the patient belongs, to give the patient the medication that is most economical for his health insurance company. These can change from time to time and then a patient gets the yellow pack instead of the blue one. Theoretically, of course, these are the same drugs, but from different manufacturers.

It is far beyond my competence to evaluate discount contracts, but let us keep in mind that, even if it is sometimes difficult in the pharmacy everyday life, it is one of the few measures with which we have managed to reduce our health costs dramatically (Rohrer 2020).

Which seems very important to me in the light of demographic change and the like.

On the one hand, the challenge lies in stock-keeping, which means that instead of having one drug in the appropriate dosages and pack sizes, the whole range must now be available from a large number of manufacturers so that all patients can be served as quickly as possible and does in the best case not has to come to the pharmacy a second time to pick up his or her medication. But experience shows that the colleagues managing the inventory are doing a great job. Of course, the bigger the pharmacy, the better it works.

On the other hand, the pharmacist's challenge is to empathetically deal with the related fears of the patient. In principle, of course, drugs would not simply be exchanged if they had different effects. But the devil is in the details: some tablets are harder to swallow than others; the patient should only take half a tablet and the new tablets are no longer divisible and of course—especially when we think of psychotropic drugs—the patient is sometimes simply afraid if the tablet suddenly looks different, no matter how it is supposed to work in theory.

4 Patient No. 3: Complex Request of Prescription Medicines

I met patient no. 3 relatively rarely in my pharmacy, which is probably mainly due to the location and type of pharmacy I worked in. The patient for whom new solutions are urgently needed: a multitude of medications, so that he is overstrained by the correct intake, the prescribing doctor does not know about all the medications that are also taken, so it comes that diseases are treated doubly, interactions occur that could be avoided and, which is not to be underestimated, the patient, who may also have problems swallowing, must take unnecessary many medications. Side effects occur which could be avoided and so on. In fact: "23% of all adult German citizens (15 million) take three or more drugs on a permanent basis" (ABDA—Bundesvereinigung Deutscher Apothekerverbände 2019).

The time and resources that we can save on simple cases like Patient No. 1 (Self-Medication Request) and Patient No. 2 (Simple Request of Prescription Medicines), we should urgently invest in patients like case number 3. I am talking about the big field of medication management, which I think urgently needs to be established.

I am uncomfortable to say that pharmaceutical education in general is not up to the task of sophisticated drug management, although I am convinced of this, but I am not aware of any data on this. Therefore, I approach it from the other side: Imagine a team of about 20 pharmacists specializing, for example, in neurological diseases and concentrating only on these. Every day they do nothing else but work on medications in these therapeutic areas (which of course have their overlap with other therapies), then it is quite plausible (to put it cautiously) that consulting and medication management can take place on a much more sophisticated level than if a pharmacist simultaneously sells cough medicine, deals with antibiotics and cardiological medications, and also has to stay up-to-date on the latest developments in the field of neurological diseases, isn't it?

5 Let Us Try to Be Naive

It is our statutory responsibility to provide the population with the medication they need and we are happy to do our best to find a way to get any medication a patient wants (of course, only if it is allowed) and that as soon as possible (§§ 1 und 2 Bundes-Apothekerordnung, Bundesapothekerkammer 2016).

In addition to the increasing number of available drugs, we can already observe how the patient is becoming more and more a "responsible health customer." Thus, pharmacists no longer advise patients only on the few options they most like to recommend to their patients, or which they consider to be the best, but also on products that patients have read about online (Carl 2018; Kinch 2014).

Sometimes, and some of my colleagues will certainly judge me for this, working in a pharmacy has something of a specialized logistics provider: We arrange even the most exotic medicines for the patients as quickly as possible. You will never hear in a good pharmacy: "That's not in our inventory." There is no such thing as a limited inventory in the everyday life of a pharmacy. The inventory is almost everything that has anything to do with health.

The second major part of our statutory responsibility is to advise patients on the medicines we supply them with (§§ 1 und 2 Bundes-Apothekerordnung, Bundesapothekerkammer 2016).

But, if you want to give profound advice on a nearly unlimited range of products, you need nearly unlimited knowledge. It is self-explanatory how well this can work in practice, isn't it?

I have already seen pharmacists giving their patients perfect advice on cosmetics, talking to them for half an hour to find the perfect sun protection for them and their children before the vacations—great work in preventing skin cancer.

I have also seen how pharmacists have analyzed the medication of comorbid chronic patients in a depth that left me speechless. Not only do they find problems, but they also suggest solutions to the doctor, and this results in patients actually taking less medication with better outcomes and fewer side effects—fantastic.

Last but not least, I have also seen how pharmacists have given a perfect answer to the patients' questions about their colds. Not only did they recommend the products that best fit the patients' needs, but they also responded sensitively and caringly, so you could see how patients were already feeling better when they left the pharmacy.

But here is the problem—it was never the same person. In our age of knowledge expansion, we need to specialize more and more to be able to offer the best possible service. "The knowledge about how the human body works, its strengths and weaknesses doubles approximately every 4 years. This poses unexpected challenges not only to medical students, but also to experienced physicians and finally to the entire healthcare industry" (Carl 2018).

How can a human being be able to handle all this at the same time?

Let me be clear: My colleagues are doing a great job! It's not a question of whether we do it well or badly today, it's a question of whether we could do it better tomorrow by using the full potential of digitalisation.

As I already mentioned, I am not claiming that my ideas are right or that they work. It is merely an invitation to try out new concepts with me in an industry that has been talking about the need to renew itself for longer than I have been in the sector, which admittedly is not too difficult to achieve.

If you refuse to participate, just take a seat and observe. Watch us fail with ridiculously foolish ideas. Watch us closely so that you can learn from our mistakes, and who knows, maybe through all this failure we will learn enough to come up with ideas that actually make sense and even have the power to change the industry to provide even better care than we can already provide to all our patients today. After all, that's what all innovation and start-ups are all about, right? Having the courage to fail often enough until you have created something beautiful.

We need a discussion between people who know the problems and realities of everyday life, why certain ideas cannot work and people who are naive enough (like me) to believe that new ways are actually possible.

And only if we combine this discussion with the willingness to be stupid enough to try these ideas—taking into account all patients concerned and their safety, of course—only then will we have a real chance to find answers to the question of how we can make our great healthcare system even better.

6 Just Brainstorming Here

The discussion about online pharmacies often ends with a discussion about online stores that sell packages. I am not talking about replacing structures with complex tasks and responsibilities with a simple online store. On the contrary: I am talking about adding digital areas to complex structures that allow for even more sophistication, instead of reducing the pharmacy to simply selling packages.

After we have divided the majority of patients of a public pharmacy into the three categories described above, it is difficult not to think about using technological innovation to slim down processes for handling cases 1 and 2 in order to have more resources available for case number 3.

How young pharmacists would spend the extra money: Sometimes innovation comes not from outside and new competitors but from inside—from the own new generation: Pharmaceutical services such as medication management for the care of polymedication-patients are strongly advocated by the BPhD (Bundesverband der Pharmaziestudierenden in Deutschland e. V. 2019).

Apart from the discussion who will pay whom how much for that kind of services, I would like to see the discussion start about how it could be done on a highly efficient way.

As it is common for providers of telemedicine, it is time to introduce automatic pre-filtering mechanisms in the pharmaceutical world as well and to forward only specific problem cases to appropriate experts, who can then contact the patient and his doctor through various channels to solve their complex problems. Human capacity is limited so there is an urgent need for greater specialization: For me, the question is whether a pharmacist who is in charge of medication management has to be present in a pharmacy as we know it? Does he at the same time have to know about discount contracts and be able to sell cough medicine empathically? Or would it perhaps be more beneficial for the patient if this pharmacist were to sit at a computer in an office and do nothing but optimize medications all day long? Drug management is only one area that could be expanded if resources were freed from routine tasks. New services could be introduced, but most of them require a certain reach to function efficiently, which typically can only be achieved digitally. Back to the automation of simple cases, which I will focus on below: For patient no. 1, most inquiries are, as described above, simple and often the same—ask any pharmacist you know how many patient cases are the same on any given day. We should seriously consider ways to automate this process. Automating does not mean skipping out consultation and thus reducing the pharmacy to an online store. As I have already explained, the goal is to improve services: It is almost too obvious why, for example, medical chatbots can save a lot of resources that we can then put into better care for patients whose cases are more difficult (Hehner 2018).

But quite apart from that, why do I think that for simple cases, digital solutions can increase the quality of consultation? The following are my thoughts, the validity of which still needs to be tested.

6.1 Find the Right Medication/Product

Digital, patient-centered consultation tools can raise the quality of consultation to a constant level. Instead of sometimes being based on the pharmacist's personal preferences, the products are then recommended purely according to guidelines and the currently available data on the active ingredients.

My point is not that pharmacists give bad advice, but that pharmacists are people and people sometimes have a bad day, algorithms do not.

In the test, only 3 of 21 public pharmacies tested ended with "good." Many mistakes could have been easily avoided: For example, pharmacy software warns of interactions between the drugs entered. Online pharmacies seem to use these programs more often than locale pharmacies (Stiftung Warentest 2014).

This is something I can confirm from personal experience. At this point you can probably already guess that I am actually a fan of digital tools. Nevertheless, it is difficult to integrate them into the personal conversation and furthermore, it feels as if the need for software support is questioning the competence and thus damaging the patient's trust in the consultation.

Firstly, it shows that despite the generally very good health care, we still see significant potential for improvement. Secondly, it suggests that it will be very difficult to integrate the potential of digital technologies into a personal consultation. I'm not saying that it is impossible, nor am I saying that the quality of consultation can be improved by digital, patient-oriented services. Both have yet to be tested.

Concerning patient no. 2, we talked about discount contracts. Since the selection of the right product is, apart from technical implementation problems, already automated, I will focus in that chapter on the part of answering the patient's questions about discount contracts (see Sect. 6.3 Consultation).

6.2 Safety Issues

Even if an above-average number of self-medication inquiries can be solved trivially, by no means all of them are. Therefore, especially when these are processed automatically, it is important to filter out the more serious cases and to forward them to a personal consultation, e.g. via tele-pharmaceutical solutions. This could be done, for example, by means of integrated security queries in the automated consultation. The security questions required for this are clearly defined in the relevant guidelines and would have to be queried during every consultation: both online and offline. Unfortunately, some of these are sometimes forgotten in the heat of a personal conversation (Stiftung Warentest 2014).

I can understand this very well based on my personal experience, too. And here, too, I am convinced that it can be implemented digitally more consistently—and that, too, still needs to be tested.

The problem in a personal conversation in a local pharmacy is often that patients number 1 and 2 react quickly in an annoyed manner because they are naturally in a hurry in everyday life and on their way to the next errand. The fact that health comes first, and that people like to take a lot of time for it is more true in theory than in practice. In my opinion it could help to give the patient the opportunity to deal with the safety questions when he has the time and not when he is near the pharmacy: e.g. when he lies relaxed on his sofa on Saturday evening and not Wednesday afternoon when he has to pick up the child from soccer training next.

6.3 Consultation

With tips for the correct intake it behaves in my eyes similarly: For the patient these do not play the largest role, if he stands in the pharmacy. The main question here is whether he can still catch the next bus or if he has to wait 15 min for the next one.

In my opinion, the questions about the correct intake would mainly be asked when the patients are at home and are about to take the first tablet. The questions about side effects become particularly relevant when considering where the itching comes from the next morning. At the time the medication is administered, the urge to be back home to rest is often stronger. This is understandable if you imagine that the patient with a severe cold has only left home to buy a remedy to feel better and wants to get back on his couch—because he is sick.

Also, the consultation with information about the food dependence of the intake, application duration, and possible side effects can be displayed automatically. As described in Sect. 3, the necessary information about the same medication differs only marginally in different patients.

Furthermore, I am convinced that if the patients can read the most important information always available, e.g. in their pharmacy app, it is even more effective than if it is said once in a one-time personal consultation. Since the detailed situation of the patients in these cases make only a small therapeutic difference, the instructions can be presented in a few standard cases. I see the whole process within the realm of possibility. As always in this chapter, all claims and suggestions are to be verified.

Now we will talk about the discount contracts: In practice, almost every time medication is dispensed, it must be explained again why it is a different tablet this time. In my experience, confusion on the patient side is mainly caused by the fact that the contracts in different pharmacies and by different employees in a pharmacy are adhered to with varying degrees of accuracy and—even worse—are explained in different ways.

In my opinion, digital, standardized information on the subject, for example, in the form of explanatory videos, can help here and provide the patient with more clarity in the long term than having to listen to a new/different explanation every time a patient goes to the pharmacy to get a drug. As always, there must of course be the possibility of receiving individual explanations if there are further questions or individual factors to be considered in the selection. As already mentioned, the devil is in the detail here.

7 Conclusion

The first part of this chapter categorizes the majority of patients in a local pharmacy on the basis of real-life experience. We then presented various problems within each of the categories and described the situation in pharmacy's everyday work. In the second part we presented innovative concepts to provide medicine to the patients in a beneficial way. Finally, we pointed out ideas on why digital services in some aspects are superior to personal consultations, and as a result I hope that it became clear where untapped potential for technology exists and maybe this chapter even motivated you to invest resources and test new patient-oriented services.

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Smart Contracts in Healthcare

Michael Schnitzbauer

1 Introduction

In a digitally transformed world, the whole ecosystem including business, economy, legal, and political systems can be managed by digital ledger technology (DLT) with smart contracts (Mohanty 2018).

Contracts need approval from authorities and a successful transaction can be prevented by inefficiencies caused by individuals, groups, businesses, or laws. In comparison smart contracts are executed on the digital ledger without the need of a middleman for authorization. “A smart contract is a computerized transaction protocol that executes the terms of a contract” on the blockchain (Szabo 1994). A vending machine is an example in the real world how smart contracts work. The insertion of money into the machine enforces a contract to sell a good at a given price without a shop clerk (Yano et al. 2020). The automation of all these smart contracts can be done on a blockchain/DLT. The DLT framework provides the currency to fuel the execution of smart contracts.

The blockchain/DLT was invented by Satoshi Nakamoto for the first cryptocurrency Bitcoin (Nakamoto 2009). Data can be stored on the digital ledger transparent, immutable, and with a consensus mechanism to allow secure, non-anonymous or anonymous transactions. DLT with smart contracts could lead to a fully automated digital world in the future. Smart contracts are coded and stored in the digital ledger, being transparent, can be shared, and are protected from deletion, tampering, and revision.

The lawyer, broker, or banker as middleman will no longer be needed (Yano et al. 2020). The smart contracts are self-executing coded contracts which are coded, for example, on the Ethereum blockchain with Solidity, Vyper, and LLL. “The terms of the contract between the buyer and seller [are] directly written into the lines of

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code. Smart contracts permit trusted transactions and agreements to be carried out among disparate, anonymous parties without the need for central authority, legal system, or external enforcement mechanism. They render transactions traceable, transparent, and irreversible" (Mohanty 2018). Smart contracts can be developed and run on the DLT as decentralized Apps (DApps). They interact with the DLT and facilitate on-chain storage (Johnston et al. 2014). Antonopoulos and Wood provide a detailed description of smart contracts development with solidity on the Ethereum blockchain (Antonopoulos and Wood 2019). The number of DApps is increasing and DApp.com gives as a cross-chain platform an overview about current and future developments (DApp.com 2020).

2 Decentralized Digital Ledger Technology with Smart Contracts: A Chance for Healthcare

Digitalization could help to transform the current centralized healthcare ecosystems via a partly centralized and decentralized system to a fully interoperable decentralized system. In the transformation process centralized IT systems should coexist with decentralized IT systems. The operability of the healthcare system could be ensured in the transformation phase. Profits could be directly invested in the transformation process.

Decentralized IT systems could leverage patient-centered care on a national and global scale. The patients own their health data in these systems and decide who can access the data, powered by smart contracts.

To start the transformation process towards a more efficient and effective decentralized infrastructure a change in IT strategy in Germany is necessary. It is a major problem that in Germany IT strategy is not aligned with business strategies or IT strategy does not even exist. The IT investment budget can be very low and in around 66% of hospitals in Germany, supported by a study from Deloitte, chief information officers (CIO) reported that the IT budget is only 3% of the total budget. The other 33% have an IT budget of around 6%. New technologies are not sufficiently supported and therefore IT departments lack a lot of funding (Deloitte 2018). The law for the future of hospitals in Germany (Krankenhauszukunftgesetz) will support the healthcare ecosystem to build up a digital infrastructure with 3 billion euros and this could also help to establish decentralized technologies in the future healthcare system in Germany (German Health Ministry 2020a).

A decentralized integrated DLT with smart contracts provides the technologies to carry out authorizations and identifications. Therefore it could help to achieve the transformation of patients' health data to electronic health records (EHR). Many countries started their own initiatives to digitalize their health care ecosystems on a national level. Estonia is very successful in this transformation and they even implemented a system with a full blockchain environment to manage EHR (Estonia Health Ministry 2020).

The German "elektronische Gesundheitsakte" will be introduced in 2021 and insurance companies for healthcare in the public and private sector have to offer an EHR to their customers by law which will lead again to many solutions without interoperability (German Health Ministry 2020b). The USA started its initiative in 2009 and still has not succeeded to introduce a complete national EHR system and a high number of data breaches happened in the EHR system since 2009 (ARRA 2009; Liu et al. 2015).

In Germany a EHR with interoperability will not be introduced in the near future, but the investment of 3 billion euros could help to start the transformation and implementation of higher IT budgets. The IT strategy decisions in the next 5 years will show whether Germany will transform its healthcare system to an interoperable system with a decentralized infrastructure powered by smart contracts. There are many prerequisites to do before this transformation can successfully happen. The following sections should give an idea which key tasks need to be accomplished to switch in the direction of decentralization and the potent role of smart contracts could play in this scenario.

3 Privacy Laws to Secure the Patients' Data: HIPAA and GDPR

Two privacy data laws shall provide the example how privacy laws guarantee the secure transaction of health data within the healthcare ecosystem.

In the USA the Health Insurance Portability and Accountability Act (HIPAA) was introduced to manage patients' privacy. HIPAA privacy regulations ensure that health information of the identifiable individual is managed confidential and the individual person is protected when healthcare data is transferred, received, handled, or shared by healthcare stakeholders, for example, organizations and healthcare professionals. It guarantees that only the minimum necessary health information is used or shared when operating a business. A prerequisite for digital health apps and other systems used in healthcare is that they must be HIPAA compliant when they share personally identifiable information (PII) (HIPAA 2020).

In Germany the General Data Protection Regulation (GDPR) protects health data as special categories of personal data. Sector-specific provisions need to be observed, i.e. provisions of the social code, the German E-health Act, federal state laws on hospitals, or the professional codes of ethics for physicians and pharmacists. Additionally, medical secrecy has to be protected under the data protection regulations. Efficient data protection concepts have to be implemented in all entities processing health data (GDPR 2020).

These regulations require law advice when you want to develop a DApp as an entrepreneur for the European or American market and they have to be followed to publish the DApp on those markets.

In case of the US system any PII to be accessed by a DApp or which is written on a digital ledger when it is public must be encrypted and the interaction parties have to manage the secure interaction with the DApp and any other software solution or system created to collect and add data to an EHR (Zhang et al. 2017).

4 What Is Interoperability in Healthcare?

In an interoperable healthcare system, clinics can exchange their healthcare information without any boundaries and they also can optimize their healthcare processes (Geraci et al. 1991).

There are three types of interoperability:

1. Foundational interoperability: data exchange between multiple healthcare institutions. Data interpretation is not required by the responder.
2. Structural interoperability: data exchange mediated by structured data formats. Data interpretation guaranteed by the usage of these standardized data formats.
3. Semantic interoperability: data interpretation enabled at the level of semantics which allows the interpretation of data meaning.

The three interoperability types allow different IT architectures and integrated data acquisition devices, i.e. mobile devices for blood sugar acquisition or mobile health tracking devices for blood pressure, pulse, etc. to deliver their structured data with quality, security, and in a cost-effective way. Foundational and structural interoperability are prerequisites for the achievement of semantic interoperability which is high in demand for quality of care and the future implementation of new technologies like decentralized DLT frameworks with smart contracts and future technology integration of artificial intelligence (Zhang et al. 2017).

Additionally, chief medical officers are needed to communicate clinical domain knowledge to data scientists and more sophisticated data standards are necessary for the preparation of unstructured acquired data into the EHR, i.e. acquisition of mobile health data by tracking devices for preventive or personalized medicine.

Key in the future will be to integrate clinical domain knowledge and integrated standards who communicate this knowledge, because the myriad sources of health care information cannot be easily interpreted with information systems (Zhang et al. 2017).

Health Level Seven International developed the fast healthcare interoperability resources (FHIR) as an interoperability standard to facilitate the transfer of healthcare information between healthcare stakeholders, like patients, caregivers, healthcare providers, payers, researches, etc. FHIR can directly share specific and well-structured data in comparison to a document-centric approach like PDF-file storage which stores a wide-range of unstructured data with a high security risk. A modern healthcare app like DApps should support data standards like HL7 FHIR which is the blueprint for a standard application programming interface (API) and also is a step towards semantic interoperability (HL7 2020).

5 The Step Towards Patient-Centered Care as a Modern Healthcare Model

Patient-centered care gives back autonomy to patients and gives them full access, decision, and control to their health care data. This prevents data fragmentation, communication inaccuracy, and transmission delays (Oates et al. 2000; Reynolds 2009; Ash et al. 2004; Zhang et al. 2017). In patient-centered care three components are critical to the process: health promotion, communication, and partnership (Constand et al. 2014). We owe the patient a fourth component in a decentralized world: health data sovereignty (see Fig. 1).

DApps should allow data view in real time and patients should be notified when new data is added to the EHR, e.g. in a COVID-19 test, when results are directly transmitted to the EHR. Current health systems have limitations that prevent and further refine a fully patient-centered model:

Patients have a lack of data access control in the conventional system.

In the conventional health system patients cannot easily change or cancel a health provider’s access to their data. Providers own the patient´s data permanently after they get access. Patients move between many providers during their life when they have medical issues or just visit their general practitioner for a recipe. In their life time many providers get access to their data. The more parties have stored your patient’s data, the higher the risk of data theft due to the increasing probability of data security breaches. In the conventional health care system the access to stored health care data from a specific patient is a challenge. Patients cannot cancel access to their data by the providers, nor can they share data with other providers. The lack of interoperability between providers prevents secure patient-centered health data management. Patients have to register at every provider with communicating their health data and they have to fill out registration forms every time they seek medical treatment at a hospital, clinic, etc. Their data is stored in centralized silo databases at every provider in their own data processing center (Zhang et al. 2017).

Fig. 1 Patient-centered care builds on the three critical components: communication, health promotion, and partnership. For a decentralized world we have to add a fourth one: data sovereignty. Source: Author

6 The Whole DApp Workflow Must Be GDPR or HIPAA Compliant

The protection of PII against confidentiality breach is a main proposition of HIPAA compliance. A healthcare app data processing workflow from accessing to processing and then distributing the data necessitates HIPAA compliance. In centralized healthcare systems data servers are encrypted and data is protected behind firewalls. In a DLT environment data is publicly available and it is complicated to securely store and manage sensitive health information on the digital ledger (Zhang et al. 2017). In GDPR the patient must give explicit consent that his sensitive personal data can be processed (GDPR 2020).

Currently, DLT cannot be used to store encrypted health data on the ledger. The storage costs and operation expenses would be high to manage the data. Another problem of a public ledger is that the stored sensitive health data would be publicly accessible as long as the ledger is running. Private blockchains could revolutionize this challenge in the future when storage gets cheaper and faster access technology is broadly available, i.e. 5G.

The encryption mechanism of the DLT/blockchain used to protect stored data is critical. It could lead to large data loss when the algorithm is corrupted. New algorithms could damage the algorithm and higher computing power, for example, by quantum computing could solve the cryptographic puzzle and make the stored data vulnerable for hackers. Technology in DLT/blockchain can be updated by hard forks and also if the encryption algorithms are updated frequently maximum protection can only be guaranteed if any temporary breach is prevented (Zhang et al. 2017). Healthcare DApps should be designed well and the storage of encrypted sensitive information should be avoided on the DLT/blockchain. In the future new promising technologies will allow to store data in decentralized cloud systems.

A current approach to connect the DLT/blockchain to patients' health data is to store and point at non-identifiable or encrypted metadata. The metadata refers to the actual patient's health data. Another possibility is to store a small data package which is necessary to transfer sensitive data via a trusted channel, like Chainlink that allows a smart contract on the DLT to search and call a data source off-chain. "[Chainlinks'] smart Contracts provide the ability to execute tamper-proof digital agreements, which are considered highly secure and highly reliable. In order to maintain a contract's overall reliability, the inputs and outputs that the contract relies on also need to be secure. Chainlinks provide a reliable connection to external data that is provably secure end-to-end" (Chainlink 2020).

7 Future Decentralized DLT Frameworks Should Support Turing-Completeness

Bitcoin was the first cryptocurrency and it was designed to buy and sell commodities on a crypto exchange securely and pseudo-anonymously (Nakamoto 2009). Cryptocurrencies are not designed to mediate the transfer of healthcare data models.

Health care systems with interoperability should mediate both the transfer of sensitive patients' data and communications between different stakeholders in the system. In this scenario DApps with decentralized DLT/blockchain as a backbone should be Turing-complete and have implemented programming features which can solve any computation problem. Ethereum as an open-source blockchain platform with smart contracts is ready for Turing-complete DApp development (Ethereum 2020; Zhang et al. 2017).

8 User Identification and Authentication Is a Key Support Prerequisite of DApps

Two stakeholders in healthcare need identification and authentication: patients and healthcare professionals, i.e. physicians, pharmacists, administrators of clinics and insurance companies. Generally, to forget or misplace PII is more prevalent among patients which is the bigger group compared to healthcare professionals. Exposition to healthcare information and continuing education material is higher with healthcare professionals. DApps have to support user identifiability and authentication in addition to strategies to mitigate lost PII (Zhang et al. 2017).

9 DApps Need to Have Structural Interoperability Integration

Vendor-specific data models are used in conventional health systems and apps and those models need to be upgraded and organized to a common standard which is a complex task. DApps need to provide at least structural interoperability and in ideal circumstances semantic interoperability which allows the interexchange of clinical information and the interpretation of received data when similar data models have been implemented. For standardization popular healthcare standards, e.g. HL7 FHIR, DICOM, etc. should be used (Zhang et al. 2017).

10 DApps and Its DLT Framework Must Have High Scalability to Manage a High Number of Patients in the National/Global Healthcare System

Healthcare is a ubiquitous good everybody needs sooner or later. The healthcare systems worldwide have many customers and DApps need to provide their services to millions of users and have to comply with scalablity. It is important to assess a DApp's feasibility by analyzing how it manages high amounts of traffic on the DLT/blockchain, e.g. How much information can be stored on the ledger of the blockchain until the blockchain platform terminates operation from the app to prevent it from being a malicious attack. Another example is how a DApp will track and route operations to the right party within a high number of users? In that case interoperability of the blockchain should be enabled by the DApp and the same service quality should be provided when users or components of the DApp scale up (Zhang et al. 2017). Scalability for a blockchain environment is still a concern, because when there is a high number of participants in the DLT the system also has an increase in the need for computational power for the whole blockchain ecosystem (Roehrs et al. 2017; McGhin et al. 2019). Sensors or smart devices make the challenge of scaling even greater, because the computer power of the devices is smaller than that of the average computer, to circumvent this problem resources can be offloaded to edge devices of the cloud (Hou 2017; McGhin et al. 2019).

11 How Can Decentralized Systems with Smart Contracts Be Cost-Effective in Comparison to Centralized Existing Approaches?

In the DLT/blockchain network the network nodes who are managed by operators are rewarded cryptocurrency as an incentive for their contribution to sustain the decentralized system with the necessary data integrity and agreement mediated by the fault-tolerant consensus mechanism. DLT/blockchain users have to pay the price for the operator's incentive with respect to storing data and performing computations.

How high will be the costs to pay for the services provided by the decentralized ledger for a healthcare DApp? Can those costs compete with existing centralized systems?

This cost estimation gets important when the services of a DApp are provided to a high number of patients/health provider populations.

Is a healthcare system with DLT and improved interoperability with a patient-centered model more cost-effective that current centralized solutions? What will be the costs for network maintenance and for upgrades to new technology implementations and new versions of the system?

What impact will the implemented DLT/blockchain have when operational costs are directly related to the native cryptocurrency of the employed blockchain? Will fluctuations in price affect cost estimations? Will special tokens be tailored to fit these needs with a token economy approach (Zhang et al. 2017)?

12 Support of Patient-Centered Care Model

The on-going acceptance of a patient-centered care model could help to switch from a centralized healthcare system to a decentralized DLT-based healthcare system where the patients get health care data access, health care data control, and can share their health care data for treatment, for research, in patient support groups, in training groups, etc.

The change from centralized health care systems to decentralized health care systems allows many questions to be asked:

How do we efficiently change the centralized system to a patient-centered decentralized system? Do we need to bridge the introduction of decentralized systems with a centralized/decentralized solution? How can we store health care information on the cloud securely with the help of new decentralized cloud technologies?

In the end we have to decide whether DApps with smart contracts on the digital ledger can overcome the conventional centralized systems with the introduction of patient-oriented features (Zhang et al. 2017).

13 Potential Benefits and Examples of DLT with Smart Contracts in Health Care Ecosystems

In a patient-centric health care system all stakeholders, like patients, doctors, researchers, insurers, clinics will benefit from a DLT system with smart contracts (Carson et al. 2018; Kuo et al. 2017; Khatoon 2020; Skiba 2017).

The decentralization of health data would enable full interoperability: First between health stakeholders at a national level and later at a global level. Borders between different healthcare systems could become blurred and payment between different systems could be leveraged by standardization of payment methods and the use of smart contracts.

Health data exchange could be possible worldwide and security will be provided by the DLT. To solve the problem of scalability faster telecommunications, i.e. the 5G standard which will be introduced soon could provide the necessary coverage around the world and speeds up to 10 gigabits per second will be possible. As a consequence a faster deployment of decentralized networks could happen (Li 2019).

The storage of data in decentralized cloud systems could move centralized data silos to the cloud. The distribution of data and the way data is stored in those systems have to be adapted. Current decentralized cloud technologies divide data in small data chunks which is called sharding. In the next step these chunks are distributed over the decentralized network which is called swarming. This allows to store data in a decentralized “torrent” architecture. A problem which has to be solved is that health data cannot be openly distributed in a public blockchain. A partly decentralized and partly centralized approach could solve the step towards decentralization in the beginning: Encrypted meta data could be stored in the DLT and the health data itself in centralized data silos until better solutions are developed (Siacoin et al. 2020).

DLT would benefit research, preventive medicine, personalized medicine, and artificial intelligence, because the health data would be stored structured in a decentralized health data ecosystem and could easily be analyzed. Personalized data could be tracked in real time and patients would give the permission to access their data (Randall et al. 2017).

The access of health data from a decentralized health data network where patients have to give their permission by smart contracts as a starter could change research.

It could be advertised by multi-center-studies by generating a smart contract for the specific study. The EHR could recommend potential studies from the study trial register and list them for suitable patients in their health record. The patient could give his authorization by simply signing the smart contract of the study. The researchers then get access to the clinical data, radiological data, etc. A foundational change could happen for study population acquisition, because a global decentralized health data ecosystem also would include patients from small- and middle-income countries. Non-university hospitals would also be able to have an incentive to participate in multicenter studies nationally and globally, because a decentralized EHR provides the infrastructure. The smart contract system manages all study relevant management tasks predetermined by the study protocol.

Studies could be adapted to race, religion, and society requirements (Brennan 2017; Radanovic and Likic 2018).

The management of studies by smart contracts could also lead to new ways of research funding. Participating centers could be given study tailored research grants by the appropriate multi-center-study backed by a research foundation with their own side chain, like the German Research Foundation, the NIH, etc. Research money spending could be reduced, because smart contracts do not need any third parties. A more open policy in research could lead to critical voices around study protocols.

Another application in healthcare is pharmacovigilance for the pharmaceutic industry. Smart contracts can write the different produced medication batches into a blockchain. Medications of patients can be identified via the connected side chain from the pharmaceutic company to the EHR and all batches are personalized to the treated patients which is mediated by a smart contract. When the batch cannot be verified in the pharmacovigilance blockchain, then it is sure that a fraud batch was sold to the drugstore and must be stopped from distribution. A fraud solving smart contract could help to solve this problem by informing the patient and the logistics distributor. All are connected by a DLT sidechain and communication is mediated by the appropriate smart contract. The logistics partner could then be stopped automatically to distribute the batch of this fraud medication. The patient is informed that he has a wrong batch, asked to dispose it and the smart contract also orders a new batch of the medication.

Patients could also directly report side effects of a medication by their HER in a patient reported outcome. All pharmaceutical companies must be connected by side chains to the health care DLT framework. Then a special smart contract could report of side-effect to the vendor, producer, and the scientists and improve drug surveillance.

Global health data exchange could accelerate the future of healthcare and personalized medicine. This allows the treatment of patients based on their personal imprinting influenced by their own genetics, epigenetic, life habits and environment. (Kshetri 2018).

The decentralization of data will prevent patient's data loss, because everything is written in the same archive and a chronological life time record is generated (Dimitrov 2019). The decentralization of data management for patient records will offer accessible infrastructure which allows low- and middle-income countries to connect without having to establish a cost intensive own infrastructure. A lot of data of this under-served and often underestimated group is just waiting to be added (Boulos et al. 2018).

Interoperable structures could also allow doctors to fill out more flexible roles from home by telemedicine or from different locations around the world, because a decentralized system can establish new opportunities which still have to be developed further by experience and try out scenarios. The increasing connectivity and standardization in healthcare could lead to new economic possibilities which can easily be managed by smart contracts and integrated into the decentralized ecosystem by side chains. Another important integration is the direct connection of wearable data to the patient's record which are already collected by step counters and devices for blood glucose management and blood pressure management.

The future will create a new type of smart health care stakeholder powered by a smart contract blockchain environment which will thrive new possibilities to work together interdisciplinary and puts aside grudge.

Currently we are not prepared to go the step beyond our current system. I am curious to follow the next step and some examples I depicted are chosen to be provocative, but I just try to encourage people to start thinking over one's horizon. Hierarchies prevent our system from thriving beyond the point where we only try to tailor our research after grant proposals (Kuo and Oncho-Machado 2018; Greenberger 2019). A patient-centric approach could even more strengthen the patient's position and further will give the doctor the opportunity to build up cooperative relationships, provide extensive information about diagnosis and treatment (Stawicki et al. 2018).

14 Conclusion

Decentralized future DLT frameworks with high transparency, immutability, implemented DLT side chains, and smart contracts could provide the structural IT backbone for a future global health ecosystem and be the key requirement for the realization of healthcare interoperability. Future developments will implement additional layers to the ledgers that allow data storage on decentralized cloud solutions directly connected to the DLT framework with given privacy and security.

Future technology with decentralized cloud solutions, better cryptography tailored by quantum computing, and the 5G communication protocol could start the future health care economy by providing scalability for DApps.

Currently the number of DLT and smart contract developers is rising, because decentralized ledger technology is implemented in every industry besides healthcare. More books are published by pioneer programmers to guide interested programmers towards DApp development on the blockchain and also about smart contract development.

New micro- and macroeconomic solutions could arise by integrating DLT with current healthcare protocols and the usage of smart contracts as a support could solve healthcare's interoperability problem, get a decentralized EHR which can be used from all stakeholders and future smart contracts could automate healthcare payments, enhance patient admission with home preparation of the hospital stay, automated quality management on structured EHR data, data structuring in a decentralized EHR, national and global comparison of hospitals, structured data in the EHR for artificial intelligence analysis, and the support of clinical-decision-support-systems, multi-center-studies with tailored, automated patient acquisition through the blockchain.

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Evaluating the Ethical Aspects of Online Counseling

Agnes Nocon

1 Introduction

Digital health technologies are more and more frequently employed in a variety of psychosocial and mental health care environments, even in fairly complex fields of activity such as counseling or psychotherapy. New technological applications for counseling and psychotherapy in fact nowadays appear regularly. Today, care providers not only use telephone or e-mail to supplement face-to-face interaction, but also make use of real-time chat, video-consultations, and even chat-bots and avatars. There are manifold potential benefits to be gained from these new technologies. But there also comes, along with the digitalization process, a variety of challenges and potentially problematical effects that even regard the core functioning principles of counseling.

2 Psychological Counseling

The term "counseling" means in common parlance a form of advice given with reference to practical problems. In the health sciences, however, counseling refers to a process of professional guidance of an individual or a group in need of psychological assistance without giving advice. It designates a practice similar to psychotherapy. The counselor uses psychological methods with the aim of supporting a client to help him- or herself. The client, who is the person in need, engages in the process consciously and willingly and receives a treatment that follows clear aims and a clearly defined set of rules.

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2.1 A Brief Introduction to Psychological Counseling

No specific, clear and consistent definition of counseling has yet been established. One often-used conceptualization is to distinguish it from psychotherapy. Whereas a number of professional associations use the term “counseling” synonymously with “therapy,” due to the fact that many countries do not regulate the delivery of psychotherapy, in a number of other countries the boundary between the use of the two terms is firmly and clearly set by law. The meaning of the term “psychotherapy,” as for instance determined by the German Law on Psychotherapy (PsychThG), is restricted to “activities to diagnose, cure or alleviate disorders of clinical significance by the application of scientifically recognized psychotherapeutic procedures” (PsychThG 1998/23.05.2020, c.1, s.3). The same regulation further specifies that psychotherapy needs to be an indicated intervention to treat the respective disorder. This definition of psychotherapy explicitly excludes “activities that intend to work out or overcome social conflicts or other purposes that lie beyond the realm of medical science” (PsychThG 1998/23.05.2020, c.1, s.2). It is just these activities that fall into the sphere of counseling. Counseling, in this respect, is a mild form of psychological support: the mildest and lowest possible threshold intervention in the area of mental health services. It is directed to people who want to solve and overcome personal and social problems or conflicts and intends to promote their psychological and behavioral competence, activate or develop new personal resources, remove disturbing factors and thus help the clients to empower themselves. Since it is directed toward people with only mild psychological impairments it is often carried out as an ambulatory short-term intervention.

Psychological counseling is applied in almost every area of health care. It constitutes one of the central working methods in the field of mental health, and in many disciplines, like clinical social work, for example, is one of the major modes to connect with clients or patients in need of assistance. Therefore, experts from a variety of disciplines are involved. Counselors come from very diverse background. They can have received an education as psychologists, social workers, theologians, nurses and other disciplines besides, and bring along diverse levels of qualification, as the type of education and the amount of training required to become a full-time counselor differ between countries and often are not regulated.

Where counseling is not specifically medically indicated, health insurance systems tend not to cover the service and the clients have either to come up with the fee themselves or take advantage of one of the services that are provided at no charge by non-profit organizations. In this case, the financial coverage is provided by public or private operators. Even so, clinical counseling can use the same methodology as psychotherapy does, depending on the training and education of the practitioner. Some of the established counseling approaches, such as, for example, the person-centered approach developed by Carl Rogers, at the same time constitute effective psychotherapeutic methods. Practitioners and clients can choose from a large number of psychotherapeutic approaches available, many of which have thoroughly been studied. However, the reasons for their mode of action are not yet fully understood, although considerable research has been done into whether, and how, they actually work. Factors that account for a positive outcome fall into various groups (e.g. characteristics of the client, characteristics of the counselor, specific psychotherapeutic techniques), and among the most potent ones turns out to be the relationship between client and counselor.

This relationship is first and foremost a cooperative one. Both, counselor and client, are of equal value and try to clarify problems together and find solutions for them. Since they often discuss sensitive and deeply personal topics, counselors are expected, and usually legally bound, to respect client confidentiality. This principle bolsters the therapeutic alliance and forms the basis of an environment of trust, and it is only in exceptional cases that confidentiality can or must be breached. Examples, however, of when it is typically accepted include: when the therapist has knowledge that a child or elder is being physically abused; or when there is a direct, clear and imminent threat of serious physical harm to the client him- or herself or to some other specific individual.

2.2 Counseling Ethics and Regulation

The specific legal regulations are complemented by ethical principles of the profession, and it is the professional associations who express them in their codes of ethical practice. However different the codes may be, they all include foundational principles, which (Forester-Miller and Davis 2016) have verbalized in their Guidelines to Ethical Decision Making for the American Counseling Association:

1. *Beneficence* refers to the counselor's effort and responsibility to contribute to the welfare of the client and to prevent harm.
2. *Autonomy* refers to the freedom of choice and action of the client. A counselor will encourage clients to make their own decisions and to act on their own values, and even abstain from bonding to a client beyond the professional relationship.
3. *Non-maleficence* is the concept of not causing harm to others and not engaging in actions that risk harming others. A counselor will abstain from any activity that may cause harm to the client, and not take any advantage of the relationship.
4. *Justice* does not necessarily mean that a counselor treats all individuals the same. Instead, it usually is necessary to treat unequal clients unequally in order to meet their individual needs or capabilities. The counselor should, however, be able to explain why she or he treats somebody differently.
5. *Fidelity* and honesty are essential to permit clients to trust their counselor and to develop a therapeutic relationship that enables them to grow personally. The legal bond of confidentiality falls under this ethical principle.

Counselors seek to carefully put these principles into practice in their everyday work, but the emerging new communication channels demand more caution to accomplish them. Whether it is a new dimension of autonomy of the client, who can choose to stay anonymous, or the challenges that the new communication channel poses on fidelity and trust between client and counselor: media-based interaction changes the parameters that both need to adapt to. The following section highlights some of the new issues that come along with digitalization processes in counseling.

3 Digitalization in Psychological Counseling

Media-based counseling is nothing new. The telephone has been an important instrument of remote contact in many countries for decades. For years, crisis hotlines have, usually through trained volunteers, dealt with suicidal and emotional crises as well as a number of other adverse situations. They enable clients to open themselves up because they can stay anonymous, and allow them to talk about their problems even if they might not have done so in other circumstances. Telephone counseling obviously shares the same ethical and methodological principles as counseling in its face-to-face (f2f) form. But spatial distance, diversity of the counselors, and anonymity on both sides have brought new challenges into the counseling process. Counselors need additional competences when they are providing counseling by indirect contact (e.g. when all information regarding facial expression and body language is lacking). Furthermore, they need to establish a time to provide reliable answers, and the service needs to be embedded in a professional local health care network, in order to be able to assist clients who need personal contact or to refer them to some more adequate treatment (Wenzel 2008).

As digitalization processes are introduced into counseling the possibilities for remote counseling services expand. The advent of the Internet and the increasing penetration of broadband have resulted in the continuing growth of online therapy, blogs, self-help sites, and a growing number of professional mental health counseling services are provided through the Internet, sometimes instead of, or in addition to, f2f meetings. Services are also offered via e-mail, real-time chat, and video conferencing. The new communication channels continue to change the communication process: they fragment it not only in terms of space but also in terms of time, and both, the client and the counselor do not immediately get an answer or reaction. They increase the degree of anonymity, when, for example, the sound of somebody’s voice is missing through text messaging, and require new and amplified competences in media-based communication. It is more challenging to express or decode somebody’s feelings when the usual nonverbal information is lost.

However, digital technologies are highly promising in a number of ways. Since they complement traditional services beyond crisis hotlines, they can reach a wider public than the usual real-life contact. People with psychosocial problems often find it easier to engage in low-threshold Internet services such as chatrooms or online counseling. Online services have the potential to overcome a number of obstacles, too. They can provide support in areas with few local mental health services, across great distances, and even in politically fragile situations and during pandemic events. They have the potential to support people who are too ashamed or afraid of being stigmatized, or people who had previously had only limited access to services because of physical or mental health issues. In this way, online services can improve participation, promote integration, and equalize differences in the accessibility or attractivity of mental health care. Some population groups (e.g. the Internet-raised generation) might not be reached by traditional services. The younger generation communicates in everyday life in a way which accords a massively important role to digital communication. This group, for example, can be reached more easily by virtual services. Other clients (e.g. adult refugee populations) are so used to remote communication with their friends and families that this has become a fundamental way of communication and cannot be disregarded in keeping contact. For those with language barriers, written text can be of help and give them more time to understand, as interpreters are scarce. Online services can also supplement f2f counseling as they shorten waiting time, provide additional information, and allow communication with other professionals and clients.

Case example Mrs. S. is 70 years old. She lives in the countryside in Germany, and lost her husband 2 years ago due to a brain tumor that had not been discovered. During the operation which aimed to remove the tumor, he slept into a coma and did not wake up any more. Since he passed away, Mrs. S. has been grieving. Most of the time she longs for her husband, she wishes to die, has been wearing her husband’s bathrobe every day and sits in her husband’s armchair. Her only son and her granddaughter live far away in town. Two or three glasses of white wine help her to fall asleep at night. But for some weeks she has started to walk slower, feels insecure, and is afraid to fall.

Counselors could support the client in her grieving process, help her to establish new contacts and assistance, and find new ways on how to relax and sleep. Under which circumstances would an online service be meaningful for this client?

4 Ethical Evaluation of Online Counseling

As fast as digital technologies establish new standards, vigilance with respect to their potential negative consequences must also be increased. The promises of digitalization come with new risks and challenges and it is not always clear how the ethical principles of counseling are affected by the new modes of communication. Practitioners require vigilance and resilience in order to navigate the risks and opportunities of this digital landscape.

There have been a number of efforts made to provide some guidance through the field of potential adverse consequences arising from digitalization. Several instruments have aimed to facilitate ethical evaluation here. Among the various ethical evaluation models that have been proposed, one of the most renowned is MEESTAR, developed by Manzeschke et al. (2015). MEESTAR aims to structure and systematize sensitivity to ethical issues and realms of action, and in this way helps to generate solutions to omit them. The following section gives a brief overview of the model and applies it to online counseling.

4.1 A Model for the Ethical Evaluation of Socio-technical Arrangements (MEESTAR)

MEESTAR has been developed as a result of a validation study with clinical professionals in the field of age-appropriate assisting systems (AAAS). It is an instrument to evaluate socio-technical arrangements, and addresses a range of ethical issues with the aim to analyze and structure them, to identify additional problematical points, and thus, to promote the finding of ethically sound solutions. The model includes three reference points of reflection: the ethical dimensions that need to be considered, the perspectives of affected stakeholders, and the level of ethical caveats. It aims to generate questions: questions about potential negative consequences of a given technology, where all critical points of view are respected and "blind spots" omitted. In this way it helps to evaluate an actual scenario, enhances communication about ethical problems, and can guide a process that involves the affected people and finds solutions for ethical problems.

The three levels of reflection are represented in the form of three axes, all of which need to be taken into account during the evaluation. Seven ethical dimensions form the x-axis of the model: care, autonomy, safety, justice, privacy, participation and self-conception. Along the y-axis, problems are allocated between four levels of ethical sensitivity. Since the minimum ethical requirement is that AAAS incur either little or no harm, the MEESTAR instrument only exhibits one neutral and three negative levels, but no positive one. The z-axis provides three points of view (individual, organizational, social). For every scenario the central stakeholders should be identified and the ethical caveats from their perspective considered.

Evaluators can use this structure to identify and allocate ethical issues in an actual scenario. Using the three axes, ethical issues can be detected in a number of ways. Some issues may arise at one specific point, like, for example, a system that is not safe enough. Others can be conflicts between two ethical dimensions, when, for example, a socio-technical system collects personal data to properly assist its user, and security at this point comes in conflict with privacy. Other scenarios can rise conflicts between two perspectives, when, for example, the question on a socially just distribution of the economic burden of a service and the right for the individual to be cared for do not match. In addition to these conflicts, the model calls the attention to the possibility of so-called tipping points where technically positive effects and morally beneficial aspects of AAAS tip over into their opposite. Some such "tipping points" are characterized by a change in the nature of the assistance offered from being supportive to being something more forced and coercive, like, for example, a care-giving system that turns into something patronizing when the technology inhibits a person in making his or her own decisions.

The identification of ethical conflicts thus initiates the search for possible solutions and a discussion about whether a technology is acceptable at all. In cases where benefits exceed the negative effects, the decision to introduce the technology, even despite these adverse effects, should be taken with the consent of the stakeholders.

Can MEESTAR be useful in analyzing ethical issues in online counseling?

4.2 Ethical Evaluation of Online Counseling

As in AAAS, MEESTAR can structure the reflection process on the critical issues of online counseling as another example of socio-technical arrangements. The following section applies the model to highlight some of the critical issues. Starting from a consideration of possible stakeholders, it raises questions that need to be taken into consideration when evaluating and designing online services.

Online counseling affects clients and practitioners. However, the organizational level also includes the service provider and the software/hardware companies. At the societal level a vast number of stakeholders at various levels are all involved, including, for example, municipalities, who may pay for the service, or provide health service networks, specific health services or health service structures, and the society itself. Taking into consideration their perspectives—which critical issues should be addressed when designing an online counseling service?

Care: Care in counseling means that a professional person provides help through talking, with the aim of enabling the person in need to return to their original state—or at least to some more appropriate state—and to become once again capable of helping themselves in accordance with their own needs and values.

- Is online counseling effective at all? Is it as effective as f2f counseling?
- Is it possible to adapt the process to the specific needs and capabilities of the client group?
- How can qualification of the counselor be established? And how can it be monitored?
- Will direct contact in social counseling become less frequent as online counseling develops?

Autonomy: Counseling respects and fosters the autonomy of the client and online counseling can even grant anonymity.

- Even immobile clients have easy access to online counseling. However—will they not receive f2f counseling then?
- How should the practitioner deal with clients who quit the communication in a moment of crisis? Does autonomy come into conflict with privacy here? How can the professional guarantee care in cases where there is a risk of self-harm or of harm of others without having access to personal information?
- Is there a possibility of mis-operation of the system and how do providers deal with it?

Safety: Safety comprises safety for the client, safety for the professional, and safety for the provider. Safety in the personal dimension, technological safety, a safe operation mode, data safety, safety in the sense of reliability.

- What can be done at the organizational level to build a reliable connection? Which software is data-safe? Should there be monitoring at every institution to make sure that data is safely stored?
- What kind of protection do we need for specific client groups (young age, old age, vulnerable groups)?
- Should certification and monitoring of the providers be installed to prevent fraud and help to identify trustworthy services?
- Do we need a monitoring of technical safety? How do we guarantee a data-safe Internet connection?
- How can we install an international legal framework for online health services?
- What level of digital literacy will be expected from the client? Can this be provided for all (at school?)

Justice: The ideal aim is to provide access to counseling independent of income, age, gender, educational level and technical affinity, i.e. an access which is just and without barriers.

- Can people with low technical affinity access the service?
- Is it possible to reach a specific group through online services?
- What technical equipment do people need to use it? Will new risks of exclusion of certain groups emerge?
- Do online services place an additional burden (time, work-load) on the practitioners? Do they receive the necessary support, training and supervision?
- How can services be designed in order to be barrier-free?
- Does the technical infrastructure (network coverage) guarantee equal access for everybody?
- How are online services embedded in a regional healthcare network?
- How can the financial burden for online services be distributed socially just?

Privacy: Privacy in online counseling refers to the protection of somebody's identity and personal data.

- How can control over personal data be granted/given to the client?
- And how can it be granted to the practitioner?
- Does anonymity come to conflict with the principle of care in cases where the client needs additional or intensified assistance?
- How does the provider deal with anonymity in case of an emerging risk of harm to others?
- Who has access to private data? How is data security established?
- Does the provider apply certified technology?
- How does the software company guarantee data security and who is in charge of checking and monitoring this? How can it be prevented that a company collects personal data?
- Is the existing legal framework to protect private data sufficient and effective?
- Should there be an international regulation of digital monopolies?

Participation: Participation means providing people with access, rights, services and assets that enable them to live together with other people in society.

- Are clients and practitioners involved in the development of technical solutions?
- Do the solutions facilitate communication or do they complicate it?
- Who is in possession of the know-how needed to develop and evolve the software?
- Does the urban-rural divide result in different services? Do we get a two-class system of participation?

Self-conception: Self-conception describes the way in which somebody evaluates and perceives themselves.

- Do online services turn from a service into a requirement for clients to be able to deal with the technology?
- Will online counseling (or f2f counseling) turn into second-class counseling?
- Does the occupational profile of counselors hereby change for good?
- Will digital services only complement f2f contact or will they replace it altogether?
- Should counselors be replaced by technology (artificial intelligence)?

5 Conclusion

MEESTAR can structure critical ethical issues in the field of online counseling just as it does in AAAS. Only if we combine education in the principles of information technology, creative adoption and use of digital transformation processes, and critical reflection on their meaning for people and society can we develop holistic services which really empower the individual and strengthen his or her power to act.

In spite of the great potential of online counseling, training is scarce. In Germany only a few colleges include online counseling in the curricula of social work or psychology courses. The training concentrates rather on classical f2f formats and misses the opportunity to qualify the graduates for the new occupational field. Moreover, up to now the development and implementation of technical solutions has largely occurred outside of the traditional professional community. If the health professions decide to shape the process according to their needs and ethical principles, the professional associations should get involved in this process.

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Machine Learning as Key Technology of AI: Automated Workforce Planning

Nadine Rischmeyer

1 Introduction

In recent decades, the digital revolution has increasingly penetrated our lives. As a result, digital information and data are omnipresent. This change brings with it the opportunity to make sensible use of the ever-increasing volumes of data. In the healthcare sector in particular, there is substantial potential in the realization of responsible technological progress. The promising fields of application for innovative technologies are contrasted by increasingly complex staffing requirements, a shortage of skilled workers and a predominantly inadequate IT infrastructure. Thus, health care institutions and leaders are increasingly facing essential challenges in this dynamically economic world. Since the focus of health care systems is on service delivery, staffing cost is one of the largest factors. For instance, it is useful to answer the question of what optimal staff deployment planning can look like in order to efficiently compensate for bottlenecks.

As an interdisciplinary science, AI can be a solution to this question. AI consists of several sub-disciplines, which are useful for different tasks. The core of AI is always the imitation of intelligent behavior, which, as experience shows, is accompanied by increases in efficiency. This technological singularity usually begins in the sub-discipline of machine learning.

Therefore, this chapter will first outline the basics of machines capable of learning and then, identify the elementary prerequisites of the technology. This will be followed by requirements and challenges for automated workforce management, which include the areas of resources, society, and legislation as well as data and interfaces. We then discuss possible components and advantages of an automated

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solution. Finally, a roadmap will be presented to support the implementation of machine learning in practice.

2 Machine Learning

One of the most important areas of AI is the development of machine learning methodologies. But what does learning mean and how can we distinguish the learning ability of computers and humans? Learning describes the acquisition of skills and knowledge. It is an individual process, sometimes based on experience only. For example, while most people usually find it difficult to learn a foreign language, computers are able to store and apply the relevant data very quickly. The only limiting criteria are computing power or storage capacity. During bionics, attempts are made to model the principles in the field of brain research on computers. Artificial neural networks are being developed which are intended to simulate human neural connections in an abstract way (Ertel 2016).

2.1 Data Mining

Progressive digitalization and automation result in large amounts of data. While a few years ago, experts described data as the gold of the twenty-first century and highlighted its enormous potential, there is still a long way to go. This is often explained to the complexity of high-dimensional input data, which results in limitations of manual statistical data analysis. Therefore, generating usable knowledge from large databases must have a positive cost–benefit ratio. Machine learning methods can derive structures or forecasts from high-dimensional input data (Richter 2019). With this assistance, knowledge can be extracted from data and used sensibly. It should be noted that the learning ability and success of algorithms depend in particular on the quality and quantity of existing data.

2.2 Learning Methods

Machine learning, the development of powerful algorithms, can be differentiated into different teaching methods. Decisive for the choice of method is whether predefined target values are already known and a teacher should be consulted or similarities be recognized independently.

In the case of *Supervised Learning*, both input and output data must be marked by a teacher. Thus the algorithm knows the pre-structured data and is trained accordingly. The goal is to find possible connections or patterns between known input and output values. Therefore, the AI uses methods of linear regression, linear discriminant analysis, and the decision tree method (Kreutzer and Sirrenberg 2019). Imaginable Scenario is a machine that is trained with extensive medical knowledge to recognize the symptoms of appendicitis. The task of the AI system can be to diagnose whether the patient is suffering from appendicitis or not (Das and Neelima 2020).

If undefined target values are present and similarities and patterns are to be recognized independently from the existing input data, the learning form *Unsupervised Learning* is used. Due to the complexity and quantity of data, the goal of the algorithm is to independently gain new insights and identify data groups with similar characteristics. The performance of the algorithm improves with increasing data volume (Kreutzer and Sirrenberg 2019). Linked to the above scenario, unspecified patient data, symptoms, and diseases are transmitted to the machine. In the course of the learning process, the algorithm independently establishes relationships. For example, it assigns typical symptoms to appendicitis and provides a basis for deciding whether the patient might suffer from this disease.

Reinforcement Learning can lead to an acceleration of the learning success (Huss 2019). The method is strongly oriented on the human learning process, which can be described as learning through experience. Tom Mitchell already made the following statement in 1997:

> Machine Learning is the study of computer algorithms that allow computer programs to automatically improve through experience.

With Reinforcement Learning, neither training data nor optimal solution are available. The AI iteratively runs through a trial-and-error process in order to independently try possible solutions. For good decisions required for the goal being achieved, the AI receives a “reward,” for bad decisions a “punishment.” The algorithm optimizes the solution strategy again independently. The goal of the algorithm is to learn an optimal strategy, which results from its experiences made (Ertel 2016). The classical field of application of reinforcement learning is robotics. Since tasks of robots are usually complex and no training tasks are available, it is necessary to learn from experience. As an example, the company Adlatus works in the development of self-sufficient service robots for automated room disinfection of hospital staff and patients from COVID-19. The integrated advanced navigation concept is based on an algorithm-based measurement to optimally detect obstacles in the room. With the combination of sensor data and image processing the functionality of deep learning algorithms is also used.

2.3 Deep Learning and Neural Networks

As early as 1943, McCulloch and Pitts laid the foundation for Deep Learning. They developed a mathematical model of a neuron, which was presented as the basic switching element for brains. Since then, humans have faced the task of modeling neural networks in order to solve regression and classification problems by artificially emulating neurons. These are high-dimensional problems that are accompanied by high-dimensional input layers. This results in AI systems for which computations are very time-consuming and involve well-trained developers who can take on the demanding task (Kruse et al. 2015).

Deep Learning is also known as expert system. For a positive learning success, a sufficient amount of training data is needed for the simulation. As the machine becomes safer and faster with increasing experience (used data memory), it develops into an expert system. Since the brain structure of a human being adapts to environmental influences, science today no longer aims to reproduce the human brain. Rather, the new goal is to create a human-like adaptive capacity (Goyal et al. 2020).

Computing power of such AI systems can already beat humans in chess or in the game “Go,” which has 361 board positions and a total of 2.08×10^{170} valid game positions. Why should not AI have the intelligence to take over the optimal staff planning of a hospital?

3 Requirements for the Use of AI Systems

Although the requirements for automated staff scheduling in hospitals are very similar, certain conditions should be met before considering implementation of an AI system. According to Topohl, three requirements are relevant in this regard. First, the course must be set to obtain elementary information about each individual patient involved. This includes patient data, as well as data of hospital staff, both are subject to special protection. Furthermore, an understanding of the positive influences of AI in the health care system must be created. AI systems will not only find their way into pattern recognition to support diagnosis but a variety of other fields of application can be experienced and improved by new technologies. Lastly the relationship between patients and physicians must be mentioned. The time factor is increasingly becoming a scarce commodity. Greater demands are being placed on doctors, while the calculation of operations is increasingly based on time. Only when the potential of AI has also been recognized by the hospital staff and a basis of trust has been created it will be possible to use smart solutions as a effective working aid (Topohl 2019).

4 Challenging Aspects

Before intelligent support can lead to a reduction in workload, the requirements and challenges of AI-based workforce planning must be analyzed. In order to ensure a combination of workflow management, duty scheduling, resource planning, and time recording, high quality data availability must be ensured. Only then can planning and forecasting be carried out according to requirements. In addition to the classifiable requirements of resources, society and legislation as well as data and interfaces, general requirements must be mentioned (Fig. 1). On the one hand, planning-related conflicts should be avoided. On the other hand, a clear and flexible solution should be created (Bent et al. 2016). The overriding goal is to minimize the organizational effort in order to relieve skilled workers and increase their job satisfaction with a user-friendly solution. In contrast to this, there are business

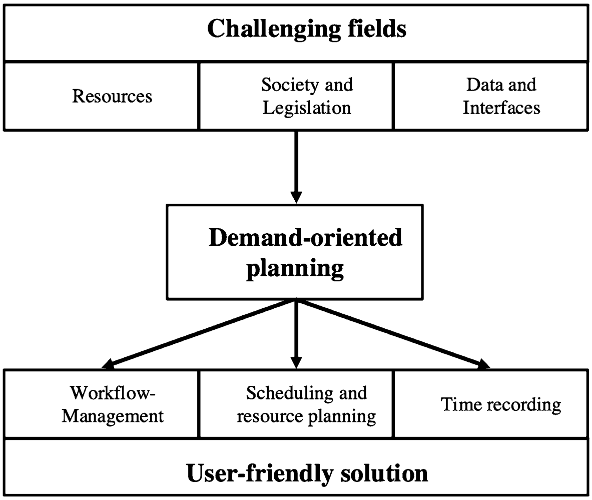

Fig. 1 Correlations of challenges. Source: Author

management conditions as well as short-, medium-, and long-term goals of the health care institution.

4.1 Resources

Key function and at the same time the main challenge relates to the required resources. Due to the shortage of skilled workers, staffing resources are particularly at risk. Especially health care facilities tend to be chronically short-staffed with qualified employees. The emergence of scientific research and results leads to the additional difficulty for specialists to stay up to date. A modified capacity building in medical education is becoming increasingly necessary (Klein et al. 2018). It is essential to impart basic knowledge in the areas of machine learning and information technology (Budde et al. 2019). This is one of the only ways to create the basis for human acceptance to use algorithms in the future, to support decision processes, and to consider AI as a modern working partner.

The fulfillment of requirements that administrators have for AI-based staff planning is also essential. These include user-friendly operation and the expression of service requests. In addition, existing service structures and staffing strengths and competencies must be included.

4.2 Society and Legislation

Besides the challenge of extrapolating past scenarios to future periods, country-specific legislation also shapes the respective framework, such as compliance with working-time laws. Furthermore, AI systems are almost always accompanied by ethical questions, especially in the medical environment. Not least because of the influence of politics and society, a superior strategy for the use of AI is needed. This includes, for example, adjustments of funding conditions. These have a significant influence on the innovation process of a country. National digitization strategies also have positive effects at the sector level (Frederking et al. 2019). In health care institutions, the integration of the use of AI into strategy development and implementation is equally effective.

4.3 Data and Interfaces

The performance of an AI heavily depends on data quality. Moreover, greater success can be achieved when data from many different sources is available and networked at the same time. Here the connection between Big Data and AI becomes clear. If one thinks about linking data from other research fields, the benefit can increase exponentially. However, medical data is now particularly sensitive. In some countries, data protection issues are therefore increasingly arising, which must first be resolved and integrated into the considerations (Budde et al. 2019). Only then can further requirements be analyzed. Furthermore, IT infrastructures are usually very heterogeneous. It would be helpful to homogenize the environment in order to establish a uniform basis for AI systems. This results in the necessity of developing standards and norms, which are laid down in guidelines. An example is the use of HL7 standards (Frederking et al. 2019).

In order to be able to automatically determine process times in the near future or to forecast the end dates of tasks, functional interfaces to budget planning and working time documentation are recommended. Integrations and smooth information transfer help to save planning time and reduce error rates. Due to the complexity it is important that IT departments of health care facilities receive sufficient support.

5 Automated Workforce Planning System

The following describes the components of an automated workforce planning and the advantages of such a solution can work. Moreover the conception of a directional implementation plan will be presented.

5.1 Components

The goal is the automated creation of a staffing deployment plan taking into account all relevant parameters and requirements. AI is able to take over this task by applying a combination of already described procedures and further approaches. This is already possible today. Here, the components of real-time staff planning, user-friendliness, and security can be highlighted (Fig. 2).

Intelligent workforce planning is done in real time. The medical environment is subject to constant change. Risks and disruptive factors characterize the daily work routine. This requires not only short-, medium-, and long-term staff planning, but also a short-term update of the occupancy in hospitals. An AI system is able to carry out spontaneous service changes, taking into account the lower staff limits and adherence to quality of care. In addition, it is possible to forecast difficulties on the basis of past data and to configure plans differently as a preventive measure. The plans can then be tracked by staff in real time, anytime, and anywhere. The integration of additional software, for example, accounting solutions, leads to further useful adjustments throughout the system and thus to a reduction in workload.

Intelligent workforce planning is user-friendly. The retrieval of information in real time can be carried out by staff with desktop computers as well as mobile devices. User-friendly dashboards with the optional creation of a report or an invoice can be integrated. The staff can express vacation requests via the digital infrastructure, which shortens official channels and makes approvals/rejections faster. Despite an intuitive user interface, it makes sense to integrate training environments.

Intelligent workforce planning is safe. Since data storage is subject to country-specific regulations, individual precautions must be taken. Regardless of this, data must be backed-up continuously. With intelligent solutions, regular updates should also be carried out.

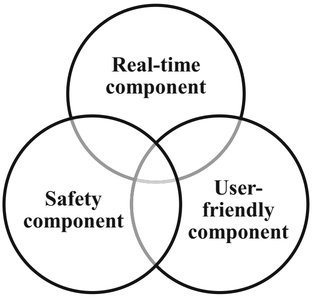

Fig. 2 Components of automated workforce planning. Source: Author

5.2 Advantages

Since human beings should always be in the center of attention and gain advantages when supported by AI, the opportunities are viewed from the perspective of the clinic staff. Basically, automated staff planning can lead to knowing the right person with the necessary qualifications at the right time and in the right place. In the best-case scenario, taking into account individual wishes of each person. Simplified, positive effects on clinic management, clinic staff, and planners are considered.

The exhaustion of the potential of the AI leads to the fact that in the future, clinic managers will find an optimal utilization control. Dominant regulations of the legislation are fully complied with. Interfaces to staff management open up the possibility of effective career management. The predominant gain for the clinic management is economic efficiency, combined with increased employee satisfaction.

Clinic staff have online access to relevant schedules and can easily enter service requests. In addition, they are immediately notified of any changes. Easy access to contacts is ensured in order to be able to consult with colleagues faster. A decisive advantage for the staff is the absence of overload due to incorrect planning.

Planners are almost completely relieved. They only check the fully automated plan for remaining errors. Manual entries are still possible at any time. Furthermore, it is possible to give only authorized users access to specific tools. Since planners are mainly performed by senior physicians, automated staff planning can be very attractive.

5.3 Roadmap for Implementation

Due to social conditions, AI solutions still face a certain skepticism. On the one hand, this is accompanied by the necessity to conduct a comprehensive requirements analysis. On the other hand, the stakeholder analysis is of great importance. In addition, AI projects require a sufficiently pronounced project management competence. Social, organizational, and methodological competence are thus bundled within one responsibility.

The procedure for initiating and implementing AI projects should include four phases: *Analysis, Design, Test, Monitoring* (Fig. 3). These are all subject to different requirements that must be taken into account.

In the *Analysis phase*, the first delimitation and collection of relevant parameters takes place. By implementing an environment analysis, both the social environment (stakeholders) and the factual environment (risks, processes and regulations) can be identified. This is followed by analysis and documentation of project requirements. In this context, it is important to formulate criteria that are as specific as possible in order to ensure traceability. In order to integrate synergy effects but also different perspectives, a workshop should be initiated for the delimitation, in which relevant

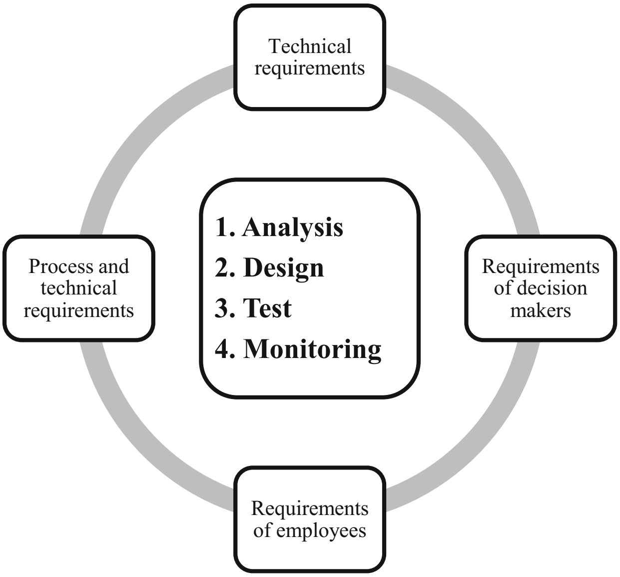

Fig. 3 Phases of AI projects. Source: Author

parties of the project participate. The aim of this phase is to provide a first rough outline of project contents.

The goal of the subsequent *Design phase* is to gain a detailed view of requirements. Interviews with potential users will be conducted and the affinity to technology will be determined (Schiller et al. 2019). Subsequently, further information is compiled in a detailed conception. Accordingly, the validation of the first technical concept is carried out and a prototype is developed.

In the *Testing phase* the participation of potential users should lead to optimizations. The prototype will be tested and optimized for usability and functionality.

The final phase combines constructive feedback on the prototype and the development of the alpha version. In the *Monitoring phase*, the influence of important stakeholders provides a further opportunity to adapt the technical implementation to existing conditions.

6 Conclusion

Machines are able to work 24/7. They do not need vacations, do not suffer from overload, and do not complain. To date, the end point of technological progress has not yet been reached and may in fact never be reached. We are only at the beginning of the digital transformation and the exhaustion of possibilities. New perspectives and tools regularly open up. But the use of AI is always tied to the fulfillment of certain conditions. Technology is not always the best solution to a problem. Those willing to innovate should therefore always first weigh the cost-benefit ratio and evaluate possible risks. Nevertheless, the hurdles are getting smaller and any technological progress is becoming increasingly important. AI systems hold an enormous potential. Our demand for support is growing, while machines can satisfy it. Ultimately, the overarching goal of all AI-based projects should be for the benefit of patients and physicians, and in fact for the whole of humanity.

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Six Areas of Healthcare Where AI Is Effectively Saving Lives Today

Cordula Bauer and Alexander Thamm

1 Introduction

Advancements in technology have always been key to improving our lives and especially our health. Within the last century, inventions like the X-ray machine, the microscope, or the ultrasound machine have contributed significantly in diagnosing, treating, and preventing diseases. One of the most significant technological leaps of humankind in this century is the adoption of artificial intelligence (AI). From intelligent assistants to autonomous driving AI is changing our daily lives both in business and in private. Luckily, there is a large field of applications in healthcare for artificial intelligence in further contributing to our well-being by smartly supporting patients, doctors, healthcare workers, hospital managers, drug producers, and scientists.

1.1 Overview of Status-Quo in Both Science and Industry

The applications of AI in healthcare are vast and the number of scientific papers, research initiatives of large corporates, startups, and blog articles seems to be exploding since a couple of years.

A recent bibliographic analysis of the 100 most cited papers in that field shows that medical informatics is the field which has received most attention by researches in the past years. Medical informatics is the management and use

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of patient healthcare information in applications such as precision medicine and diagnostics. Then follow radiology, oncology, and non-radiological medical image analysis. They also find that only 11 of the 100 most cited papers are clinical studies (Sreedharan et al. 2019). Consequently, 89 of the 100 scientific papers in the top 100 are not supported by clinical studies, indicating further potential for the adoption of AI in healthcare. Conversely, there are a vast amount of companies with appealing offerings in the field of medical artificial intelligence receiving a lot of attention from venture capitalists. The market analysis platform CB Insights—specialized on tech trends and relying on AI technology themselves—show that funding in healthcare AI has multiplied since 2015 by factor eight (CB Insights 2020a), see Fig. 1.

Despite the large amount of activities and recent advancements in AI-driven healthcare, there are still very few productive AI applications deployed in healthcare institutions. In Germany, the main reasons for the low adaptation rate are seen in trust issues, which result from questionable data quality, data protection concerns, and insufficient verifiability and explainability of AI algorithms. The latter is problematic if an algorithm recommends or even takes a decision that is ethically complicated, such as deciding upon who gets the last available emergency care bed. In addition, IT infrastructure challenges, such as interoperability with other healthcare information systems and the lack of standards for data exchange and interconnection of multiple AI systems, are hindering adoption by the industry further (Frederking et al. 2019). Within various sections of this article, we will come back to some of these hurdles and also see first promising approaches of how to overcome them. Let us now have a quick look at the main ingredients in AI applications: data and AI methods.

1.2 Nothing Works Without Data

What is true for human intelligence is true for artificial intelligence, too: Good decisions or meaningful predictions are only possible if relevant and good-quality input data is available. Thus, digitization is a prerequisite for AI to do a good job. The degree of digitization is different between healthcare sectors. The pharma industry leads the way with its large molecule databases contrasted by small medical care centers or single doctors in private practices where most medical data is recorded on hand-written paper files. Another issue when it comes to data, especially sensitive personal data as in patient records, are data privacy and data security issues that need to be taken seriously. Many healthcare institutions fail with their digitization efforts, as there is neither a secure legal basis nor a secure yet affordable way for them to store and process patient data.

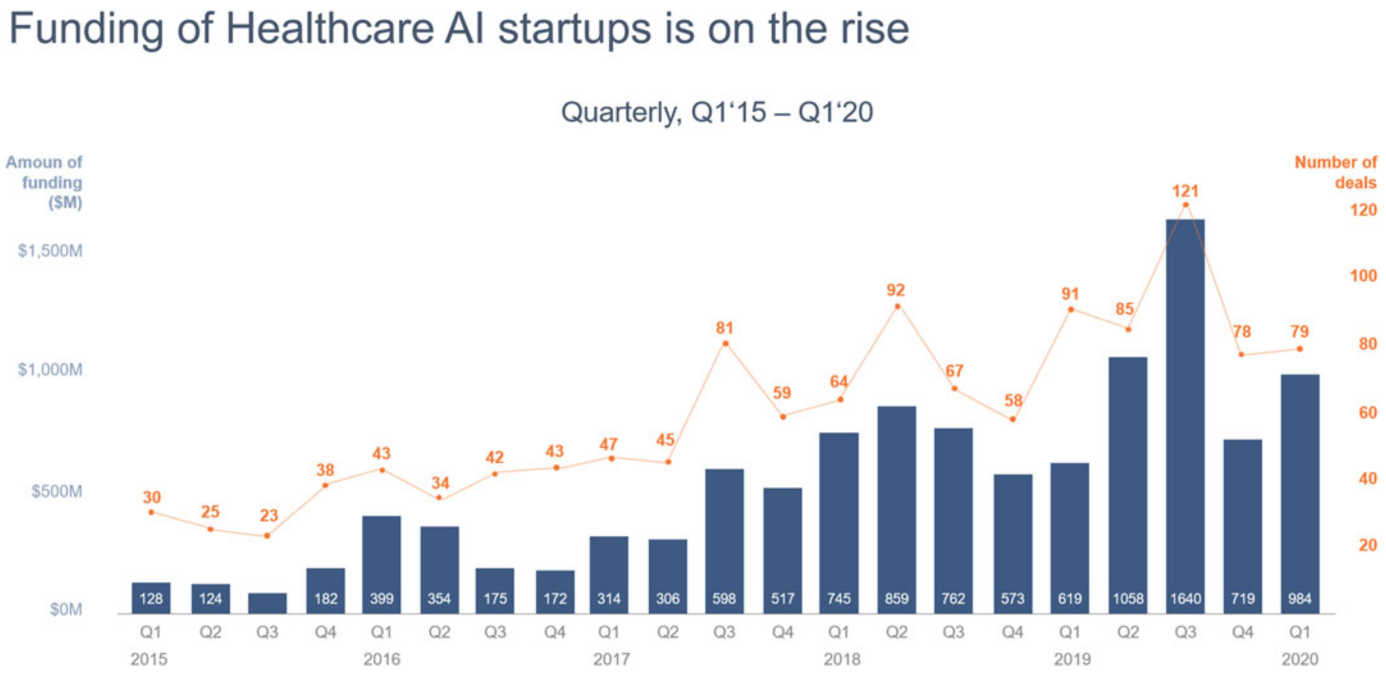


Fig. 1 Healthcare AI funding from 2015 till 2020. Source: Authors, Data by CB Insights

1.3 Quick Introduction to AI Methods

AI can be defined as the ability of a machine to perform tasks normally requiring human intelligence. In order to be capable of performing those tasks, a variety of AI technologies and algorithms exist. Those algorithms can be distinguished into three different categories: Traditional AI, weak AI, and strong AI, see Fig. 2.

Traditional AI, also called expert systems, are knowledge databases combined with hard-coded if-then rules that have been programmed by humans. In healthcare expert systems are known since the 1970s and are used within medical diagnostics for analyzing symptoms or clinical decision support systems (Davenport and Kalakota 2019). Robotic process automation (RPA) can be considered a sub-field of traditional AI that is quite present at the moment. RPA is used to automate simple and repetitive tasks like updating patient records, filling out claims, scheduling appointments, or billing. Despite its name, RPA does not involve real robots, but is rather a renaissance of scripting and macros to mimic the work of an administrative employee. When rules become more complex and interdependent or are subject to frequent change, expert systems become overstrained and therefore create less reliable results. Machine learning comes into play.

Weak AI or narrow AI represents the most exciting and relevant field of AI nowadays—not just in healthcare but across all industry sectors. In contrast to traditional AI, weak AI leverages machine learning (ML), meaning the machine learns rules and parameters from patterns in the (digital) data we feed it. Most common applications of machine learning are the so-called supervised learning methods (Ng 2019), in which both inputs and outcomes (e.g. onset of disease) are observable in the data. The machine uses (often large) amounts of the so-called training data to learn where the outcome has already been determined and is labeled accordingly. During this process called training, the machine comes up with its own inference of input data to outcomes. In many methods this is a black box, not interpretable by humans (which can raise ethical concerns as mentioned in Sect. 1.1). After the learning is done, the model is tested and validated against known outcomes to assess its predictive quality.

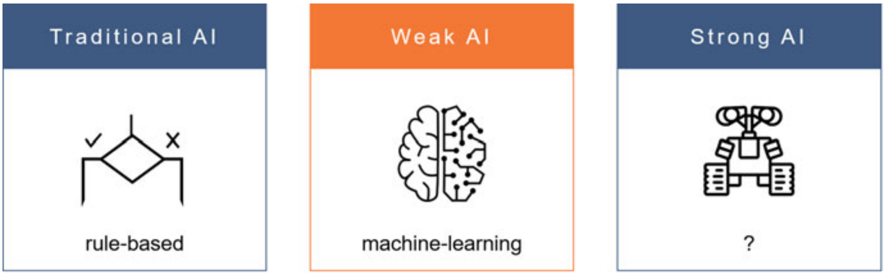


Fig. 2 Three categories of AI. Source: Authors

Many forms of ML are being successfully applied in medicine, as the following sections will depict. They range from statistical algorithms like regression and survival analysis (Sarstedt et al. 2010) to random forests and neural networks (NN). The latter are derived from basic functionality of the human brain and have been present within healthcare research for several decades (Sordo 2002). Neural networks that consist of several deeper level represent what is called deep learning (DL) or deep neural networks (DNN). Deep learning is computationally much more complex than other machine learning methods but its rise is catalyzed by faster computing power with graphical processing units (GPUs) and vast capacity within cloud architectures. Deep learning can be considered the most promising field of application for healthcare as it can progress unstructured data like text, sound, and images often better than humans. Especially in combination with computer vision, DL is used a lot within radiology to fight diseases like cancer (Vial et al. 2018). We will see some examples in Sect. 2.1.

The second largest field of DL is natural language processing (NLP), which makes sense of human language either in the form of speech or text. NLP has a huge potential that has just been tapped, since most medical data is available in form of medical documentation like patients logs or medical research studies like clinical trial documentations.

Another great development in the area of neural networks are generative adversarial nets (GAN) aiming at generating new data. These networks consist of two artificial neural networks that perform a zero-sum game. One of them creates candidates (the generator), the second neural network evaluates the candidates (the discriminator). The goal of the generator is to learn to generate results according to a certain distribution. The discriminator, however, is trained to distinguish the results of the generator from the data of the real, given distribution. The goal of the generator is then to produce results that the discriminator cannot distinguish (Goodfellow et al. 2014). They find their application in healthcare when it comes to creating new drugs as we will see in Sect. 4.2.

For a further deep dive into machine learning techniques, the data and AI guide is a good reference (Thamm et al. 2020).

Strong AI or artificial general intelligence (AGI) represents the idea of a machine being capable of understanding and learning everything a human being can and for some researchers this means having a consciousness. This would ultimately mean that doctors get replaced by superhuman robots, but despite the hype about AGI in media and science fiction movies, it is more fantasy than fiction (Bradley 2019).

2 Diagnostics

A correct diagnosis is often more than half the battle when it comes to fighting a disease. It is thus no surprise that diagnosing diseases has been one of the first applications of AI in healthcare dating back to the 1970s. A rule-based expert system developed at Stanford University successfully diagnosed blood-borne bacterial infections (Buchanan and Shortliffe 1984). However, it never found its way into clinical practices as it did not outperform human doctors and integration with other healthcare information systems was poor.

Today we see many AI approaches in the area of diagnostics, most of them relying on machine learning methods rather than expert systems. First, it is an unmanageable task to keep them up-to-date with all the medical research going on and data exploding (Davenport and Kalakota 2019). Second, machine learning techniques have experienced a quantum leap due to recent breakthroughs in deep learning and can perfectly be used in healthcare, too, with the most obvious field being image analysis in radiology.

2.1 Radiology

There is a lot of research going on in the area and both tech giants such as IBM and Google as well as startups frequently present promising results. Still, there is no extensive use of these practices in medical care centers, yet.

In early 2020, Google Health presented an AI system that surpassed human experts in breast cancer prediction in an experiment. They used two datasets with breast cancer images, one from the UK and one from the USA. They also show the system's ability to generalize from the UK to the USA (McKinney et al. 2020).

Reducing time-to-treatment is key, also in preventing death and disability from a stroke: over 90% of patients who are not treated in time end up severely disabled. San Francisco based, tech company viz.ai uses machine learning algorithms to analyze CTA scans and automatically detect large vessel occlusion strokes triggering alerts if needed. They claim to have found evidence in a study with a Healthcare Center in New York that with the introduction of viz.ai's system both the time-to-treatment and the outcome of a stroke situation were improved: they found the median initial door-to-intervention being significantly faster in the post-viz cohort (21.5 min vs. 36 min; $p = 0.02$) and the measured degree of disability being significantly lower, too (Morey et al. 2020).

As of today, experts agree that AI will not replace radiologists, but augment their workflow and reduce simple tasks like prioritizing patients for immediate screening or standardize reporting, so that they can concentrate on the difficult cases and patient care (Reardon 2019).

A major challenge in AI-driven radiology is building datasets, which are large enough so that results have statistical significance. There is no common practice to share radiology images between clinics and most commercial AI products are built on proprietary datasets. Still, there are a couple of open access databases with medical images from CT scans, MRI exams, and other radiographs. Aylward provides a list of such databases on his website (Aylward 2020).

Another big challenge is still the integration of an AI-enhanced diagnostic system into the major healthcare information system operating within a medical institution. The University Medical Center Utrecht has taken initiative and launched their own AI workflow platform, called IMAGR, which integrates diagnostic capabilities from several radiological units. Their infrastructure is vendor agnostic: First, they do not want to deal with the burden of incorporating multiple vendor-specific AI solutions. Second, they want to be able to incorporate every new algorithm from the large research community in this field as fast as possible and not wait for commercial third parties to do so. Furthermore, IMAGR has the potential to become a standard for medical centers and also for commercial vendors of specific AI solutions to add their algorithms to the platform via licensing or a pay-per-use model (UMC Utrecht 2020).

2.2 Non-image Based Diagnostics

When it is not images that serve as input data for detecting diseases, it is other medical data, mostly laboratory findings that are analyzed and the likelihood of a diagnosis is calculated.

San Francisco based startup Freenome, with a stunning funding of $500 million until August 2020 (CB Insights 2020b) engages in early cancer detection through blood samples. Blood plasma is analyzed for fragments of DNA, RNA, proteins, and other biomarkers. A machine learning model is trained on a large number of these samples where the outcome is already known. The model thus learns which biomarker patterns correlate to a cancer's stage and type. The model can then predict the affinity for a cancer type for each new blood sample and thus support physicians in detecting cancer at a very early stage.

In primary care, general diagnostic systems based on a description of symptoms by the patient or easily observable symptoms have never really found their way into primary care centers as physicians are skeptical about the added value. However, self-service symptom checkers enjoy a rising popularity among patients and can still support physicians. They are described in more detail in Sect. 3.2.

3 Individualized Healthcare

Healthcare as we know it today in our modern world is a system that has been more or less the same for many decades. You are sick, you go and see a doctor, he comes up with a diagnosis and suggests a treatment that is known to cure whatever you have, you go and get it, and you hopefully get better soon.

What if the treatment was tailored not only to the diagnosis but to your individual organism, metabolism, and medical history? And what if you did not have to go to a doctor at all, because you could get useful individualized help from home? And would it not be great if you would not get sick in the first place because you get just the nutrition and fitness advice that your body needs to stay healthy based on its individual characteristics? Individualized healthcare, powered by AI makes all of this possible.

3.1 Personal Nutrition Advice

Food is the engine that keeps our organisms going and still western medicine has put surprisingly few efforts into looking at the role that nutrition can play to prevent and cure diseases. AI is about to change this and has already helped to come to some mind-blowing conclusions.

In their break-through study Zeevi et al. have continuously monitored week-long glucose levels of 800 people and measured blood-glucose levels after approximately 47,000 meals. The machine learning algorithm they used integrates blood parameters, dietary habits, anthropometrics, physical activity, and gut microbiota and accurately predicts personalized glycemic responses to meals. They found high variability in the response to identical meals, suggesting that universal dietary recommendations may have limited utility (Zeevi et al. 2015).

Another study has found that even identical twins respond differently to the same food and the machine learning model they used predicts both triglyceride and glycemic responses to meals and claim their findings to be useful for developing personalized diet strategies (Berry et al. 2020). They develop their own program and app to provide personal nutrition assistance based on user data, called ZOE^{TM}.

The deal in such applications is: you provide your data (what you eat, what you weigh, your blood-glucose level, data from your last stool sample, etc.). In return, you benefit from all other users providing their data, plus AI algorithms that find relations between nutrition data and medical conditions and provide individualized nutrition advice to you.

3.2 Symptom Checker Apps

Symptoma, Babylon Health, Symptomate, Your.MD, and Ada Health are five prominent examples of apps available today for symptom checking. They officially do not replace a diagnosis by a doctor and avoid the wording “diagnosis” as they are not allowed to use it by law in many countries. Instead, they provide “symptom evaluation” and derive “probable medical conditions.” Still: Ada Health found in a trial run with primary care physicians in the UK that 14% of patients that completed an Ada assessment in the waiting room said that if they had used Ada at home they would not have felt the need to come to see the doctor that day (Lewin 2019).

So how do these apps work? The core is a combination of AI methods deriving probabilities of medical conditions—potential diagnoses—from the checked symptoms. Many of them primarily rely on expert systems with extensive knowledge bases provided by physicians. The community-based ones further use machine learning algorithms learning from the data of all the users of the app. Further, natural language processing is used in chatbots that enable the interaction via voice with the user.

The digitization of the symptom analysis process is debated controversially. On the one hand, 1.5 million people die every year due to a misdiagnosis according to a statement made by Jama Nateqi, Co-Founder of Symptoma (2020). On the other hand, a human doctor sees, hears, and somehow “feels” the patient on many additional levels and thus might come to better conclusions. Also he is a human being who can be made responsible for errors. But what if you live in rural Africa and the next doctor is hours away and you cannot even afford the visit? Is not the probability of a false diagnosis better than none?

3.3 Precision Medicine

Nutrition advice and symptom checker apps are tools that are mainly used by individuals for self-service health.

Precision medicine is the term healthcare professionals use for their efforts of predicting the most suitable treatment plan for an individual patient. It is based on the same idea and uses similar data, for example, dietary and lifestyle information, but it typically includes more data collected during whatever examinations were conducted; it can even include DNA analysis. As it comes to play in a clinical context, expert knowledge from physicians can optimally add to the AI-based recommendations. Precision medicine also refers to the research efforts of tailoring treatments to subgroups. The AI framework for precision medicine is depicted in Fig. 3.

Lee et al., for example, presented promising findings when it comes to treating acute myeloid leukemia (AML), a malignant blood cancer. Cancer is well known for responding differently to the same drug regimen. Patients thus can highly benefit from methods, which match patients to drugs better. The researchers used data from 30 AML patients including genome-wide gene expression profiles and in vitro sensitivity to 160 chemotherapy drugs. A machine learning method was applied to identify reliable gene expression markers for drug sensitivity. The method outperformed many state-of-the-art approaches in identifying molecular markers and in predicting drug sensitivity. They also identified a particular marker to be a main driver of sensitivity to certain common substances in chemotherapy drugs (Lee et al. 2018).

Precision medicine can also be a paradigm shift for cardiovascular diseases (CVDs) as they are complex and heterogeneous, according to Krittanawong et al. (2017). CVDs are influenced heavily by both external and internal variables of the patient like, for example, the lifestyle and diet of a person but also her genes. AI gives cardiovascular doctors the possibility to extract patterns of the huge amount of available information, which the human brain would never be capable processing.

However, here often lies the risk and limitation of AI, not just in medicine: if the underlying use case or medical challenge is ignored and not represented in the data, even the best AI method cannot do its job properly. Physicians and data scientists need to work closely together and discuss medical and statistical assumptions in order to leverage AI to patients’ benefits.

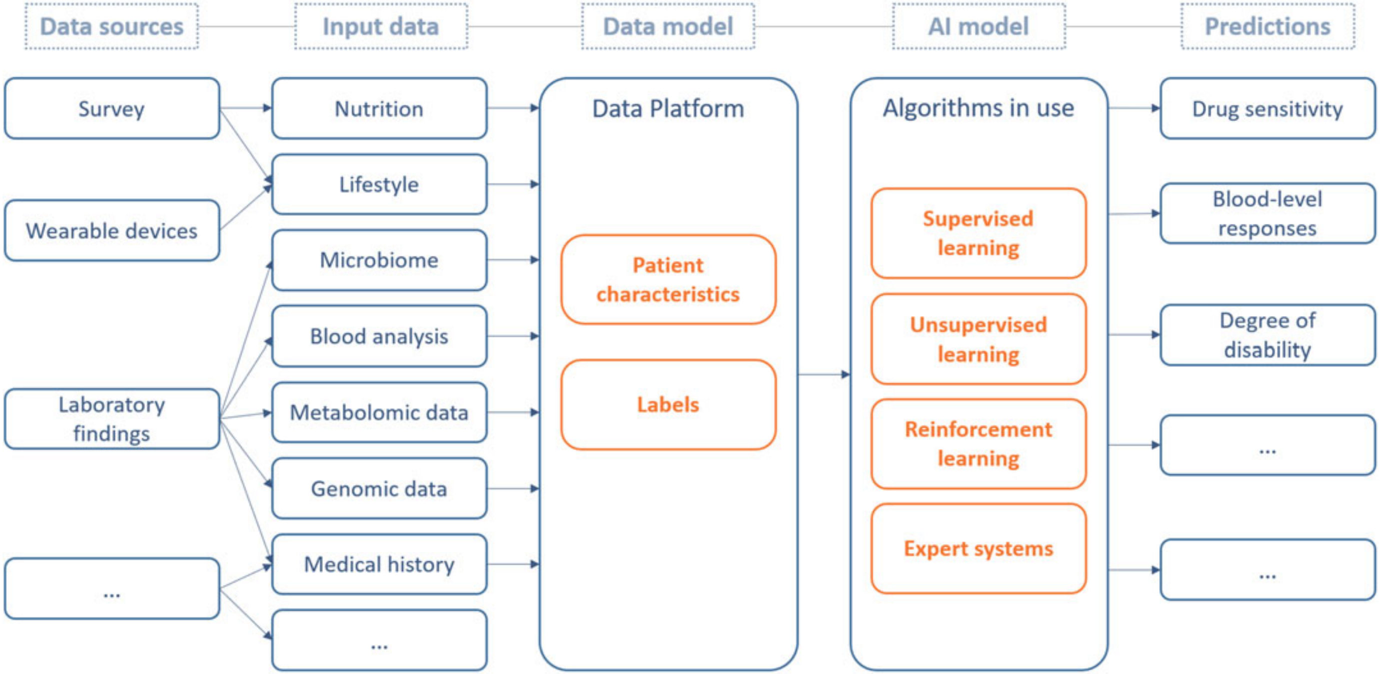


Fig. 3 AI framework for precision medicine. Source: Authors

4 Drug Discovery and Development

It is an expensive and long process to go from early-stage research into providing a drug ready to be used. AI has tremendous potential to decrease both time and cost by speeding up tasks along every step during the process. AI application during the stages of the drug discovery and development process is depicted in Fig. 4.

The following sections explain the application and benefits of AI within exemplary phases of the drug discovery process.

4.1 Lead Identification: Target-Based Virtual Screening (Step 2)

During the lead identification phase, AI technologies can help to speed up the screening process for lead molecules that can potentially be the base for a new drug. We will have a look at how AI can support within the so-called target-based virtual screening (TBVS).

TBVS attempts to predict the best interaction between a protein target (a molecule associated with a disease) and a ligand (a molecule which binds reversibly to a protein in order to serve a biological purpose, e.g. incapacitate a protein). It involves virtually docking candidate ligands into the target—represented by a 3D structure—followed by applying a scoring function to estimate the likelihood that the ligand will bind to the target with high affinity. Ranks are calculated based on scores and other criteria and the most highly ranked molecules are typically selected for further experiments (Yang et al. 2019).

Supervised machine learning methods can support here and either classify a ligand into potentially being “active” or “inactive” with a target (binary classifier) or a degree of affinity for binding with the target (numeric classifier). Input data consists of features representing molecule data and the determined class or affinity value with respect to the target. A common and free available dataset for research purposes is the directory of useful decoys enhanced (DUD-E) containing 22,886 active ligands and their affinities against 102 targets (Mysinger et al. 2012).

This data-driven research approach saves researches a lot of time and money by narrowing down the huge number of potential ligands to a much smaller one. Only for this subset, they then perform much more costly in vitro experiments.

Machine learning based TBVS depends heavily on the accuracy of the representations generated for the ligand–target complexes and on the quality of the corresponding activity data. Deep learning can help here with the feature extraction. Pereira et al. presented such a deep learning model, called DeepVS, claiming to have achieved the best predictive model reported until that time for virtual screening using the 40 receptors from DUD-E (Pereira et al. 2016).

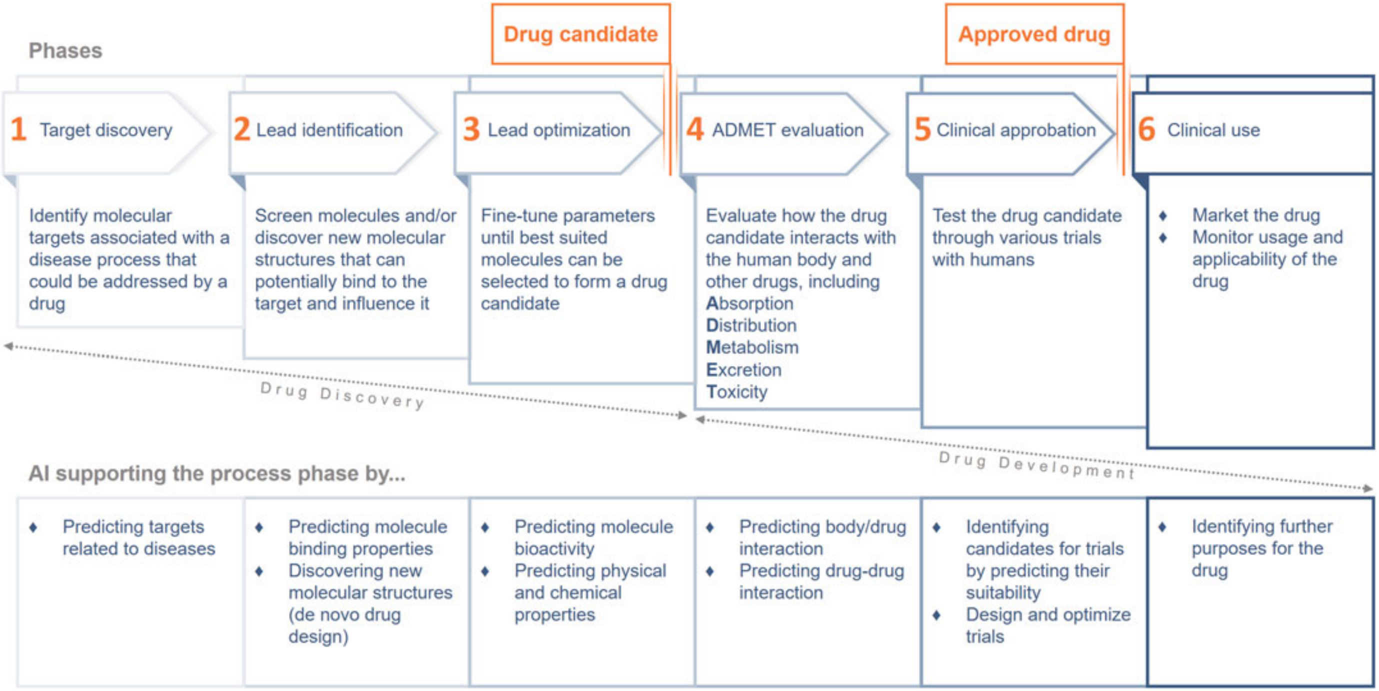


Fig. 4 AI applications during the stages of the drug discovery and development process (inspired by Ekins et al. 2019). Source: Authors

4.2 Lead Identification: De Novo Drug Design (Also Step 2)

The screening method described in the previous section is discriminative: given a ligand, we can forecast whether it will bind or not. But what if we would like to design a molecule that has certain properties? The space of potential molecules is incredibly large and a different approach is needed.

The art of creating novel (previously unknown) chemical entities with desired properties to serve a medical purpose is called "de novo drug" design. Zhavoronkov et al. have developed a generative model based on the principles of generative adversarial nets, their so-called generative tensorial reinforcement learning (GENTRL) approach. GENTRL optimizes synthetic feasibility, novelty, and biological activity. They used the model to discover potent ligands for the discoidin domain receptor 1 (DDR1), a target implicated in fibrosis and other diseases. They did so in only 21 days. Four molecules were active in biochemical examinations, and two were validated in cell-based assessments. One lead candidate was tested and it demonstrated favorable pharmacokinetics in mice (Zhavoronkov et al. 2019).

4.3 Prediction of Drug/Body Interaction (Step 4)

Insufficient ADMET properties (= absorption, distribution, metabolism, excretion, and toxicity characteristics of a drug) are a common source of late-stage failure of drug candidates and have led to the withdrawal of approved drugs. AI techniques can help to determine ADMET properties of a molecular structure early in the drug discovery process. AI algorithms can, for example, predict solubility of a drug, metabolic reactions, or the concentration of certain substances as a reaction to the consumption of a drug.

An example in this field is the prediction of lipophilicity, an important measure of the absorption of a drug by the human body. It is primarily measured by the octanol–water partition coefficient which has proven to be effectively predictable by using neural networks. The ALOGPS program described by Tetko and Tanchuk has been proven to reliably predict the coefficient for low molecular weight structures based on an associative neural network combining elements of the feed-forward network and the kNN approach (Tetko and Tanchuk 2002). According to Yang et al. it has been applied by several drug research groups since then (Yang et al. 2019).

5 Robotics

Robots in healthcare can be considered old hat. Since 1985 the idea existed to turn industrial robots into precision machines for assisting human doctors and there are indeed many applications today. However, with the help of AI, robots are becoming more autonomous and capable of augmenting human doctors' natural limitations. The real magic though can happen when robots learn so much that they can outperform human doctors not just in terms of precision and stamina, but also knowledge and decision making by combining all existing knowledge across multiple medical databases. While there is a vast variety (and fantasy) of leveraging robotics within healthcare, two major fields of application are standing out today: AI robot-assisted surgery and AI care robots.

5.1 AI Robot-Assisted Surgery

According to Davenport and Kalakota, the most common fields of robotic surgery include gynecologic surgery, prostate surgery, and head and neck surgery (Davenport and Kalakota 2019). It has been shown that robotic surgery can shorten hospital stays, allow surgeons to perform more accurate tasks in comparison to traditional approaches, and thus decrease complication rates of surgeries (Hussain et al. 2014).

One of the pioneers in the field is the company Intuitive from Sunnyvale, California, with their da Vinci platform. They were founded 25 years ago and their platform was one of the first robotic-assisted systems to get FDA approval for general laparoscopic surgery. With its surgical machines featuring robotic arms, cameras, and surgical tools for minimally invasive procedures, da Vinci has assisted in over 5 million operations.

A similar, yet newer to the market, company from the USA is Vicarious Surgical. They combine virtual reality with robotics and have raised $31.8 million from tech icons like Bill Gates or Marc Benioff.

Another company from Sunnyvale, California named Accuray developed their CyberKnife system to precisely treat cancer tumors with stereotactic radiotherapy. They leverage AI computer vision methods to sense motions of the cancerous cells in real-time and spare healthy tissue. The precision of the first stereotactic surgeries was based on a rigid frame which was firmly mounted to the patient's head. Fortunately, this painful procedure is not needed anymore, since AI-based motion-sensing can correct the radiation focus in real-time.

Located in Eindhoven, Netherlands MicroSure develops "MUSA," a robot with superhuman precision for microsurgery, which is the first of its kind to be clinically available CE-certified. Surgeons benefit from staying next to their patient, like in conventional microsurgery, but it scales down motion seamlessly and filters out tremor or unsteady movements.

Mazor X is a spine surgery platform, created by Mazor Robotics in Israel, who got acquired by Medtronic end of 2018 for a stunning $1.7 billion. The platform visualizes surgical plans like a GPS system and leverages AI to recognize anatomical features of patients' spines. It further provides robotic guidance and live navigation feedback to allow for a more precise spinal operation.

A last example that sounds truly like science fiction is Heartlander, a miniature mobile robot developed by Carnegie Mellon University. The mini robot is just a few centimeters of size and can enter the chest through a small incision. It then navigates autonomously on the epicardial surface of the heart to the specific location and administers therapy.

5.2 AI Care Robots

Fortunately, we are living much longer now than in previous generations. However, age-related diseases such as dementia or osteoporosis have increased also in their duration. Furthermore, many elderly people but also people with disabilities are suffering from lost independence as well as from loneliness and lack of social interaction. According to reuters.com, the USA is set for a severe shortage of paid direct care workers of 155,000 by 2030 increasing to 355,000 by 2040 (Miller 2017). Similar or worse situations are present in other countries like Germany or Japan. New generations of robots will support humans with a variety of partially or fully automated services. Such flexible and mobile service robots cooperate with humans or even act completely independently.

A team of Irish scientists spun-off the company Akara.com and developed "Stevie," a robot that assists care personnel in elderly care facilities. Stevie watches over residents, runs group based social activities like bingo-nights, and even writes activity reports to reduce manual work for humans (Akara 2020). Similar robots are already in use within elderly care facilities supporting to fight against labor shortage, social isolation, and dementia.

Another example for AI care robots is "S3," a German government supported project with the goal of developing a 3D environmental sensor system for service robots that can reliably differentiate between objects and persons as depicted in Fig.5.

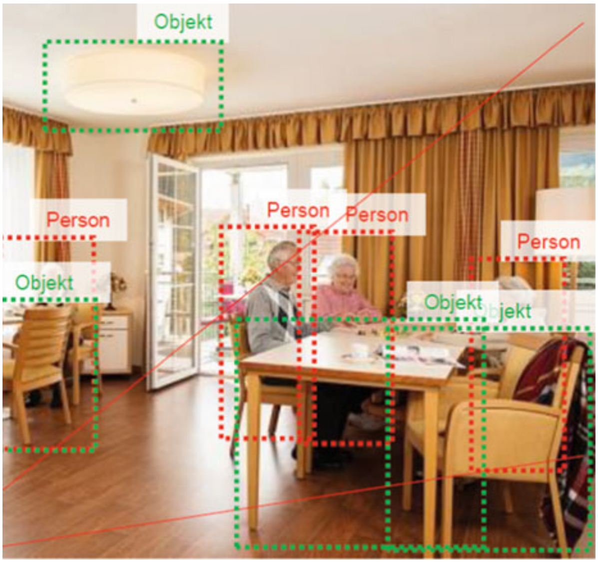


Fig. 5 Exemplary scene showing object–person distinction in elderly care facility. Source: Authors

In addition to the sensor hardware, an AI-based computer vision technology is being developed, which can recognize objects and people in the environment and evaluate situations—such as a person lying on the ground or spilled liquids. This enables the robot to intervene according to whatever situation. Munich-based data and AI consulting company Alexander Thamm is developing the deep learning capabilities of the AI together with industry partners and research institutions (BMBF 2020).

In addition to the core functionality of care, robots could in the future also interact with elderly people, talk to them, play games with them, and thus make a valuable contribution to keeping their minds sharp. Robots can potentially support elderly and disabled people to stay independent longer and reduce the need for nursing homes. Ethical implications are of course debatable with one central question being: is not a robot better than no support at all?

6 Process Efficiency of Medical Care Centers

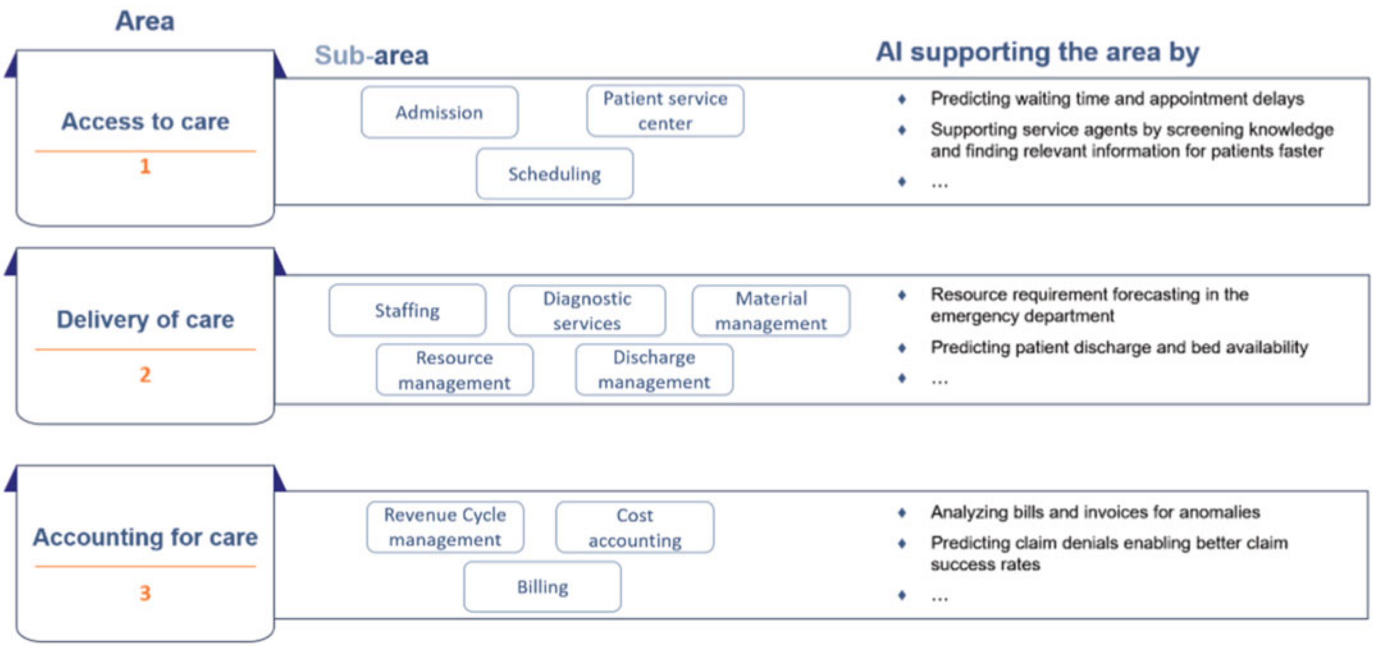
The larger the medical care center, the more likely it is to suffer from inefficiencies like crowded waiting rooms, patients staying longer than necessary, staff being overloaded and unfriendly, costs exploding because they are poorly managed, and in worst cases treatments being delayed or cancelled due to staffing problems. Figure 6 explains some of the most common use cases.

6.1 Delivery of Care: Patient Flow Optimization

Primary data source for prediction efforts in patient care use cases are electronic health records (EHR) with one data point representing one patient or one case and features such as patient age, gender, medical history, etc. In order to build predictive features for AI, thorough data preprocessing is necessary. Since patient data is often unstructured and textual, nature language processing methods are used to extract the relevant information. Medical device monitors in the hospital or wearables worn by the patient can also deliver valuable data.

In their retrospective study Hong et al. used data from all adult ED visits during a period of 3 years from three emergency rooms. 972 variables were extracted per data point and they were labeled as either admission or discharge. Nine binary classifiers were trained using logistic regression (LR), gradient boosting (XGBoost), and deep neural networks (DNN) on three dataset types: one using only triage information, one using only patient history, and one using the full set of variables. Best accuracy was achieved—not surprisingly—by using the full set of variables with all three methods. This shows that AI can indeed robustly predict hospital admission and help for better planning of staffing emergency departments (Hong et al. 2018).

One example for patient flow optimization platforms powered by AI being actively used is the one from Qventus, a Silicon Valley based startup partnering with Emory University Hospital. Qventus claims to have reduced the length of stay



- Predicting waiting time and appointment delays
- Supporting service agents by screening knowledge and finding relevant information for patients faster
- …

- Resource requirement forecasting in the emergency department
- Predicting patient discharge and bed availability
- …

- Analyzing bills and invoices for anomalies
- Predicting claim denials enabling better claim success rates
- …

Fig. 6 AI applications in medical care process efficiency. Source: Authors of patients at the hospital by 0.7 days across eight medical units. They further state to have generated a 23% reduction in length of stay at the hospitals' postanesthesia care unit (Qventus 2020).

6.2 Accounting for Care: Optimize Claim Submissions and Prevent Denials

The denial of submitted claims to public or private payers such as insurance companies is a major cost driver for medical care centers. Reworking and resubmitting a denied claim is time-consuming and costly. According to Change Healthcare, a technology provider for revenue and payment cycle management in healthcare, AI can calculate denial probability of a claim and support to put more effort into these claims, in a two-step approach (Change Healthcare 2019):

In step 1 a machine learning algorithm is fed with a medical center's historical remittance data and thus identifies the patterns associated with denied claims. Future claims exhibiting these patterns are then flagged to let staff know there is a potential issue. In a second step another machine learning algorithm conducts a root cause analysis across subcategories. Staff can then use this information to edit the claim before the submission to the payer.

Error-free claims lead to fewer denials that lead to faster payments and more revenue and of course a more efficient use of staff's time.

6.3 Access to Care: Service Delivery Support

Healthcare specific processes can also benefit from the numerous AI-driven innovations that are available today in general process and service management software. And not only medical care centers but also other entities involved in healthcare can profit from AI-driven process optimization such as healthcare system providers and insurance companies. Serviceware's industry agnostic solution for process management, for example, supports agents of service providers, e.g. an insurance company, in handling incoming requests, claims, or questions more efficiently by automatically searching for similar requests from the past and in the knowledge base. It is a combination of several natural language processing methods doing the job—far better than convenient search algorithms relying only on the matching of key words (Serviceware 2020).

7 Fighting Epidemics and Pandemics

COVID-19 has shown us how vulnerable we are as humankind towards viruses and also how fragile our healthcare systems are. Ever since the early reporting on the virus at the beginning of 2020, there has been a tremendous effort of researchers around the globe to fight the pandemic leveraging medicine, biotechnology, and of course data science and AI.

Efforts include initiatives from all the subsections of AI in healthcare mentioned above: Early diagnosing of the disease based on symptoms, identifying risk factors for a severe disease course, discovering new drugs or repurposing existing ones to alleviate symptoms, and of course finding an effective vaccine. Furthermore, AI can prevent the spreading of an infectious disease by a location-based prediction of infection rates and setting alarms accordingly.

7.1 Better Understanding the Virus

ZOE, the startup we got to know in Sect. 3.1 when talking about personalized nutrition plan, together with some allied research institutes was among the first ones to establish the combination of symptoms most likely to predict COVID-19. They did so by collecting data from over 2.6 million people with and without symptoms in the UK and the USA through their COVID Symptom Study app and applying machine learning techniques to the data collected. They also claim to be the first one to have identified loss of taste and smell as symptoms for COVID-19 (Menni et al. 2020).

OpenSAFELY is another success story in how leveraging data and statistical methods are helping to better understand the virus fast. The team who is working on behalf of National Health Service (NHS), England created OpenSAFELY—a secure health analytics platform holding patient data within the existing data center of a major vendor of primary care electronic health records. They linked primary care records of approximately 17 million adults pseudonymously to approximately 10,000 COVID-19-related deaths. In addition to high age and the presence of underlying medical conditions, they found that being of Black or South Asian ethnicity were among the main risk factors for mortality (Williamson et al. 2020).

Whereas the initiative from Zoe was relying on people voluntarily providing their data, the second one used patient data already existing. Williamson et al. state that only two authors accessed OpenSAFELY to run code, no pseudonymized patient-level data was removed from the vendor's infrastructure and only aggregated, and anonymous study results were released for publication. Nevertheless, this raises the need for guidelines on data governance and data privacy (Williamson et al. 2020).

7.2 Forecasting Spread

On December 31, 2019 the Canadian BlueDot AI platform sent an alert to its customers reporting about a cluster of "unusual pneumonia" cases happening around a market in Wuhan. BlueDot had spotted COVID-19—9 days before the World Health Organization released its statement on the matter. BlueDot uses an AI-driven algorithm that screens news reports in multiple languages, animal and plant disease networks, and official announcements. Natural language processing is thus an important AI method they use extensively. The system for example flagged articles in Chinese that reported 27 pneumonia cases associated with a live animal market in Wuhan. According to its founder, BlueDot does not rely on social media postings since they found the data to be too messy. But they use global airline ticketing data that can help predict where and when infected people are heading next. It correctly predicted that the virus would spread from Wuhan to Bangkok, Seoul, Taipei, and Tokyo in the days following its first appearance (Niiler 2020).

There are many more initiatives now where institutions try to forecast new virus hotspots. Munich's university LMU is working together with data scientists of Alexander Thamm GmbH to improve their so-called nowcasting services for the German government. Nowcasting means predicting the actual spread of the virus, corrected for unrecorded cases. According to Goeran Kauermann, dean and professor of statistics, "the aim of the joint project is to provide local authorities and health authorities with statistically processed information and valid predictions about local infections, as well as to automate the flow of information to them" (Tiedemann 2020).

As we have learned before, an AI-based system is only as good as the data it uses. And that is the tricky part with a new virus: as humans we can only feed the AI with what we know and with data we have. If we know little about a new virus and if we do not have relevant and well-structured data at hand, yet, the machine cannot do its, job properly, either. If there is one thing to learn from COVID-19 regarding AI for fighting a pandemic, then it is to do our homework in terms of digitization, data governance, and data industry standards in healthcare—in order to be better prepared for the next healthcare crisis.

8 Conclusion

The effectiveness of AI approaches within the healthcare sector has been clearly demonstrated in a large variety of examples throughout multiple applications ranging from radiology and drug research to self-service healthcare, medical center process efficiency, surgery, and care. Also in less obvious subsectors which were not mentioned here, such as psychology and veterinary, AI can certainly play an important role.

AI has the potential and most certainly will change the healthcare sector as we know it. The technology is ready, but are we as humans? There is still a way to go and some fundamental things have to change: First, we need to put effort into digitization, data collection, and data quality assurance, as data is the fuel of AI. We need to set standards, too, in order for institutions to be able to exchange data easily and to do so in a safe legal environment that people support. Second, we need to agree as a society on how to deal with the responsibility question when a machine is taking tough ethical decisions such as in a triage situation. Third, we need to embed AI into our healthcare system so that the technology can work hand in hand with health professionals and train these appropriately.

And yes, AI has the potential to replace some of the healthcare jobs. But it is up to us to shape the future. Freed-up resources can either be fired or spend more time truly caring for patients. When machines take over analytical tasks, we as humankind need to focus even more on the areas where we still outperform machines: empathy and compassion. If we can get more of these human qualities into the healthcare sector, AI can definitely said to be a real benefit for healthcare.

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Human–Robot Interaction for Rehabilitation Robotics

Yao Guo, Xiao Gu, and Guang-Zhong Yang

1 Introduction

According to the *World Population Ageing 2019* published by the United Nations, there is almost 703 million persons aged 65 years or over and this number will be projected to double to 1.5 billion in 2050 (United Nations 2019). The aging of the population brings unprecedented challenges in healthcare since elderly people are at high risk of cardiovascular diseases and neurological and musculoskeletal disorders, thus leading to the high potential of impaired cognitive and physical functions.

Rehabilitation robotics represent the development of robotic systems with the purpose of either providing assistance for individual's Activity of Daily Living (ADL) or improving the recovery of physical functioning through automatic therapeutic training (Dellon and Matsuoka 2007), which involves multidisciplinary research on robotics, bioinformatics, anatomy, mechatronics, material science, control theory, and human–robot interaction. In general, there are two main categories of rehabilitation robots, i.e., assistive robots and therapeutic robots. In Fig. 1, we demonstrate several popular types of rehabilitation robots for providing either assistance or therapeutic training.

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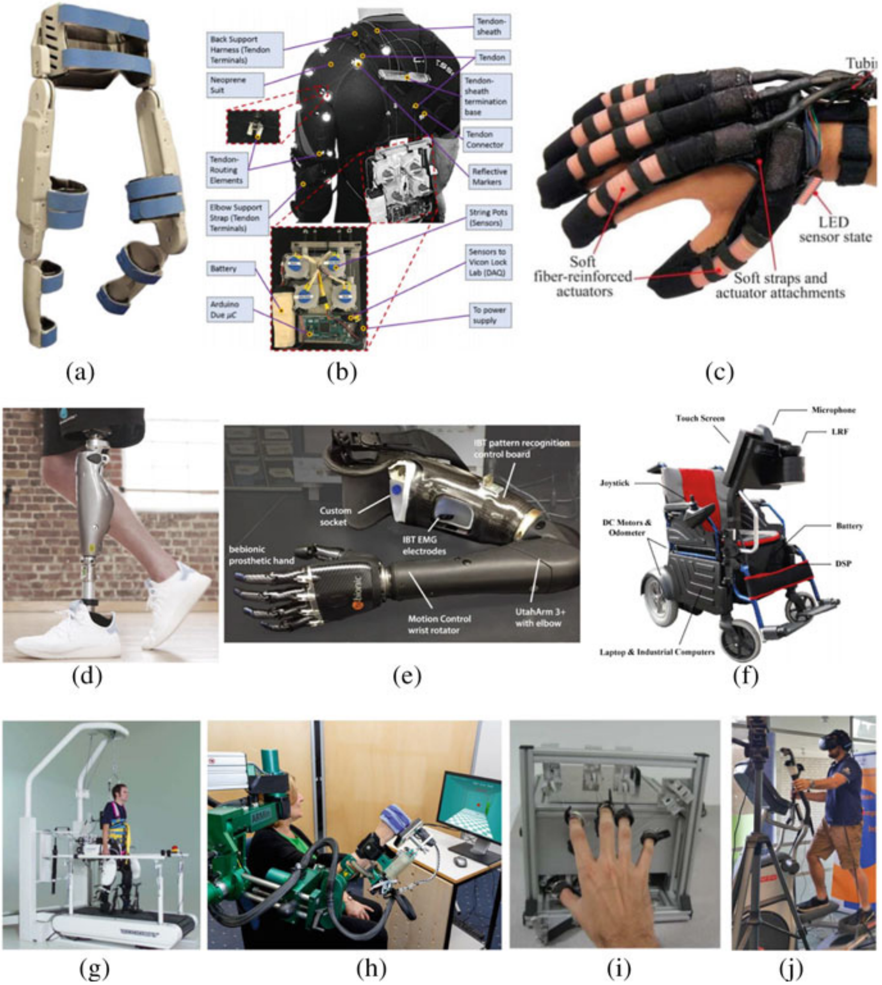

Fig. 1 Different types of rehabilitation robots. (**a**) Vanderbilt lower-limb orthosis (Farris et al. 2011), (**b**) bio-inspired kinematic sensing soft suit (Varghese et al. 2020), (**c**) soft robotic glove (Polygerinos et al. 2015), (**d**) C-Leg 4 lower-limb prosthesis (Ottobock 2020), (**e**) upper-limb prosthesis with neuromorphic multilayered e-dermis (Osborn et al. 2018), (**f**) Jiaolong smart wheelchair (Wang and Chen 2011), (**g**) Lokomat for gait training (Bernhardt et al. 2005), (**h**) ARMin rehabilitation robot (Keller et al. 2015), (**i**) robot-assisted rehabilitation of hand functions (Dovat et al. 2008), and (**j**) VR-based immersive gait training (Hamzeheinejad et al. 2018). Source: authors

1.1 Assistive Robot

Assistive rehabilitation robots are aimed at assisting patients with impaired physical functions to complete desired movements through continuous human–robot interactions (Beckerle et al. 2017). They have come into several forms in terms of the specific practical needs arising in different populations, such as exoskeletons, prostheses, wheelchairs, etc. With the help of assistive robots, users can restore or augment the functional movement in ADL, such as walking, object manipulation, typing, etc., thus improving their quality of life.

Wearable exoskeletons are comprised of joints and links aligned with anatomical axes of the human body. Through the control of fingers and wrist, robotic gloves can augment patients' hand movements with functional grasping pathologies (Cheng et al. 2020; Polygerinos et al. 2015). Upper-limb exoskeletons are designed to assist or resist the movement of the elbow and/or much complex shoulder joint (Goldfarb et al. 2013; Varghese et al. 2020). Lower-limb robotic exoskeletons typically include actuated joints at the hip, knee, and ankle to improve the walking and running locomotion function of patients with spinal cord injuries, stroke, and other impaired walking ability (Young and Ferris 2016; Wang et al. 2020).

In addition to wearable exoskeletons, prostheses refer to the artificial substitutes that can replace missing body parts and restore related motor functions. Through the integration of advanced mechatronics and sensing and control technologies, robotic prosthesis allows for a natural range of motion through receiving online commands from amputees (Osborn et al. 2018; Niu et al. 2021). With recent advancements in material sciences and robotics, soft exoskeletons and protheses are rapidly growing (Cianchetti et al. 2018). Compared to the conventional rigid countermeasures, the compliant nature of soft robotics enables safe interaction with human and minimizes the restrictions of the alignment with anatomical joints (Walsh 2018).

Furthermore, the integration of assistive robots with mobile platforms (e.g., smart wheelchairs) enables automatic navigation in the free-living environment (Wang and Chen 2011). The development of these mobile assistants places emphasis on perceiving the status of the surrounding environment (i.e., mapping and localization) as well as the interactions with the surroundings, based on the information collected from a collection of sensors.

1.2 Therapeutic Robot

In order to gradually improve patients' physical functions, effective rehabilitative therapies are needed for helping patients recover from stroke, spinal cord injury, cerebral palsy, etc. However, conventional therapeutic methods mainly depend on intensive and frequent intervention provided by skilled therapists. By comparison, therapeutic robots showing superiority in endurance and efficiency can automatically aid patients in practicing specific functional movements as well as provide the quantitative assessment on the rehabilitation performance, which can bring new insights into therapeutic training (Lo et al. 2010).

Generally speaking, existing therapeutic robots can be categorized into end-effector and exoskeleton (Veerbeek et al. 2017). End-effector-based robots aim to guide the movement of the most distal segment of limbs, which are easily set up but may lead to undesired movement of other joints. On the other hand, exoskeleton-based robots are integrated with complicated mechanical design to control the movement of joints/links. Compared to the end-effector countermeasures, exoskeletons are wearable robots that fit well with human anatomical axes. For the upper extremity, rehabilitation delivering mainly focuses on the recovery of reaching and grasping functionalities of patients, while standing, walking, and balance training are usually performed for lower-limb rehabilitation. To arouse patients' engagement in rehabilitation, robots are expected to detect human movement intention and provide informative biofeedback through various human–machine interfaces. Meanwhile, therapeutic robots need to quantitatively assess the movement quality by capturing various kinematic and kinetic parameters, as well as biosignals from patients.

Except for improving physical functioning, increasing attention has been paid on the development of wearable robotics systems for patients with mild cognitive impairment (e.g., Alzheimer's disease and dementia) (Hayhurst 2018). In specific, interactive games are designed for memory exercises, and they can assess the individuals' short-term memory and spatial memory, the dysfunctions of which have been proven as the main symptoms in AD and dementia patients (Vovk et al. 2019).

1.3 Human–Robot Interaction

Human–robot interaction (HRI) is a multidisciplinary field that aims to understand the capabilities of both human and robots and then form the effective interaction between them. Especially for rehabilitation robots, HRI plays an essentially important role due to their close collaboration with human partners. In specific, with the help of HRI, the control of rehabilitation robots is enabled through receiving online commands or detecting levels of motion intention from users (Beckerle et al. 2017). Meanwhile, robots can provide various sensory feedbacks to patients to enhance the engagement of patients as well as provide quantitative assessment of movement quality (Nordin et al. 2014). As there are numerous types of rehabilitation robots, in this chapter we focus on two successful and promising applications of HRI in robot-assisted rehabilitation: upper-limb prosthesis and therapeutic robot for stroke rehabilitation.

2 HRI for Upper-Limb Prosthesis

Upper-limb prostheses are aimed at assisting amputees or paralyzed patients to perform ADL by executing the online commands provided by their users (Farina and Amsüss 2016). The functional rehabilitation offered by such assistive tools could potentially exert positive effects to the patients in their psychological, emotional, and functional statuses. Among the prosthetics, passive artificial limbs/hands supported by simplistic stump–prosthesis interfaces are mainly for cosmetic or simple hooker-like functional purposes, while active prostheses are driven by external powers and can subsequently perform more complex and multi-functional operations following the intention of the users (Ribeiro et al. 2019).

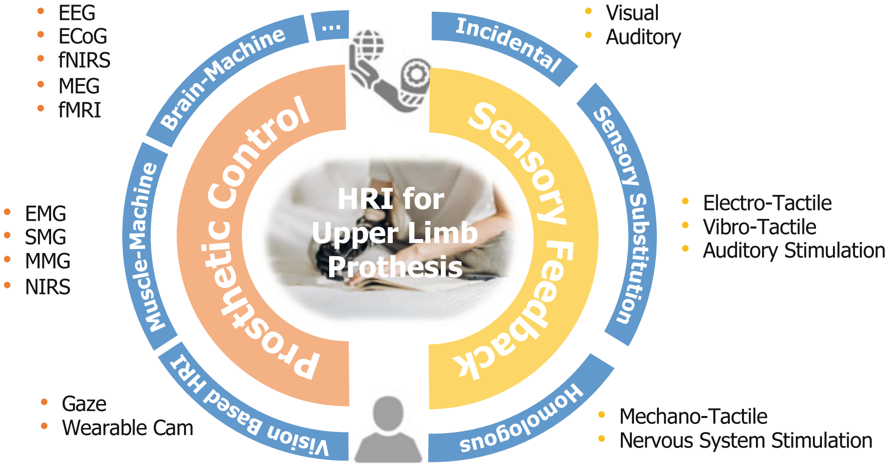

Fig. 2 Bidirectional HRI in upper-limb prosthetic control, which includes forward prosthetic control (from the user to the prosthesis) and sensory feedback (from the prosthesis to the user). Source: authors

Recent advances in mechatronics and materials have allowed anthropomorphic and dexterous upper-limb prosthetic design (McMullen et al. 2013), such as Hero Arm, Michelangelo Prosthetic Hand, and i-Limb Hand. They upgrade prosthetic limbs/hands with limited degrees of freedom (DoFs) to multi-articulated ones driven by electrical motors, as well as supporting multiple assistive functions. Although some of them have been commercialized, it remains open how to develop a natural, reliable, and continuous control for these modern tools (Farina and Amsüss 2016).

To achieve this goal, increasing attention has been posed on the human–machine interfaces embodied in upper-limb prostheses. Normally, a complete active prosthetic system represents a motor control loop enabled by bidirectional HRI, comprised of prosthetic motor control driven by movement intention signals of users, as well as in turn transferring sensory information perceived by the tools to the users, as shown in Fig. 2. In the following, current sensing, control, and feedback techniques are discussed with an emphasis on HRI.

2.1 Multi-Modal Sensing Techniques

In this section, several sensing techniques in terms of different interfaces are discussed, which are summarized in Table 1. They have been utilized as the input for prosthetic control and are also important perception sources for other categories of assistive or therapeutic rehabilitation robots.

Table 1 Multi-modal sensing information for interfacing rehabilitation robotics

Interfaces	Modalities	Noninvasive	Encoded information
Muscle–machine	sEMG	✓	Muscle action potential
	iEMG	✗	Muscle action potential
	SMG	✓	Muscle ultrasonic morphology
	MMG	✓	Muscle oscillation
	NIRS	✓	Muscle tissue oxygenation
Brain–machine	EEG	✓	Neural electrical activity
	ECoG	✗	Neural electrical activity
	MEG	✓	Electromagnetic fields (electrical activity)
	fNIRS	✓	Hemodynamics
	fMRI	✓	Hemodynamics
Vision	Wearable cam	✓	Egocentric/robot-mounted vision signal
	Gaze	✓	Visual attention

2.1.1 Muscle–Machine Interfaces

Electromyographic (EMG) or myoelectrical signals generated by the contraction of residual muscles have been widely applied in prostheses with a long-term development history (Geethanjali 2016; Samuel et al. 2019). Due to the accessibility and noninvasiveness over the course of surface EMG (sEMG) acquisition, sEMG has been the primary source of active prosthetic control with electrodes directly attached to the skin surface. Attempts have been made on sEMG-based control with different configurations in terms of the channel number, sensor positions as well as the amputation level (Fang et al. 2015). The main drawback of sEMG is its sensitivity to cross-talk effects, sensor displacements as well as noises from the surroundings (Zhai et al. 2017). One alternative solution is to utilize intramuscular EMG (iEMG) recorded from implanted devices (Smith et al. 2014). It ensures stable connections between the muscle sources and electrodes and can acquire signals from the deepest muscle level with minimal cross-talk effects. However, due to the invasiveness, iEMG is less favorable in clinical practice compared to sEMG. On the other hand, recent work Stachaczyk et al. (2020) has successfully applied high-density sEMG (HD-EMG) devices into active prosthetic control, spatially acquiring multiple recordings with a two-dimensional electrode array that comprises tens to hundreds of electrodes. With a higher resolution, HD-EMG signals have been proved capable of more effectively extracting spatio-temporal parameters relevant to muscle activation. Based on acquired EMGs, a further discussion of utilizing EMG for myoelectric control is given in Sect. 2.2.1.

Apart from EMGs, other modalities indicating muscle contraction activities have also been explored to control prostheses, including Sonomyography (SMG), Mechanomyography (MMG), and Near-Infrared Spectroscopy (NIRS). The ultrasound imaging-based SMG extracts muscle contraction intensities by analyzing morphological changes in recorded ultrasound images. It can detect deeper muscle activities with the help of advanced signal processing and computer vision technologies, and studies have successfully utilized SMG to predict dexterous individual finger movements (Sikdar et al. 2013). However, the applicability of integrating SMG into prostheses is limited due to current cumbersome scanning devices. The MMG measures the mechanical vibrations of skeletal muscles by using microphones or vibrometers and has been used to estimate forces, kinematics, and hand gestures (Fang et al. 2015), which however is prone to movement artifact and ambient noise. On top of SMG and MMG, the NIRS technique quantifies the muscle oxygen level and is characterized by good spatial resolution. It has been used as supplementary information for EMG-based prosthetic control (Guo et al. 2017).

2.1.2 Brain–Machine Interfaces

The brain–machine interfaces or brain–computer interfaces (BCIs) decode the intention of the users from brain signals, and till now a variety of brain sensing techniques have been employed to establish effective interfaces (Tam et al. 2019). BCI-based active prosthetic control contributes to the interfaces for the so-called mind-controlled prostheses. Existing sensing approaches are either invasive or noninvasive. One representative technique for invasive BCI is the electrocorticography (ECoG) (Yanagisawa et al. 2012), which implants electrode arrays onto the exposed surface of the cerebral cortex and measures the electrical activities on the surface. ECoG is advantageous in spatial resolution, signal-to-noise ratio, and effective signal bandwidth compared to noninvasive methods and has shown promising performance in the interactions of prosthetic finger motion control. Another sensing method is to record intracortical neural signals, with needles or electrodes penetrated into the brain tissues. Those invasive sensing methods allow higher-quality signal acquisition yet are less accessible and pose greater risks due to associated implanting surgeries, compared to noninvasive BCI.

Regarding noninvasive BCI, the most commonly employed modality is the electroencephalography (EEG) due to its mobility and convenience. The recorded EEG signals from scalp surfaces encode cerebral electrophysiological activities and can be translated to human intentions that drive prosthetic movements during the interactions (Khan et al. 2019). A further discussion of utilizing EEG for BCI-based prosthetic control is given in Sect. 2.2.2. Another sensing modality is the functional near-infrared spectroscopy (fNIRS), which detects brain oxygenation level coupled with functional brain activity. Although the inherent delay in the hemodynamic response limits the application of fNIRS on real-time prosthetic control, its advantageous high-spatial resolution feature has led to hybrid EEG–fNIRS-based study to improve classification accuracy (Naseer and Hong 2015).

Magnetoencephalogram (MEG; measuring magnetic fields associated with neural electrical activity) and functional magnetic resonance imaging (fMRI; measuring hemodynamics coupled with brain functional activity) are two other neuroimaging methods that have been applied to interface prosthetic control in the literature. However, they are limited in their accessibility in the context of free daily living. It has received reasonable attention to overcome such limitations by developing wearable or portable scanning devices (Tam et al. 2019).

2.1.3 Vision-Based Human–Machine Interfaces

Thanks to recent advances in sensing and computer vision technologies, studies have been done to employ vision signals as direct or complementary intention interpretation sources. They either provide intuitive control signals based on intentions perceived from high-level image sequences or help to generate more natural and dexterous manipulations based on the shape, pose, and usage of observed objects.

Among explored vision signals, gaze information obtained from eye tracking devices has been widely used in the HRI domain. The visual fixation point provided by human gaze data indicates the locations of the object that the user wants to reach (McMullen et al. 2013). However, eye tracking is prone to false positives, and in daily practice, not all objects posed visual attention needs manipulation. On the other hand, the egocentric vision provided by wearable cameras can also help perceive human intentions. Kim et al. (2019) utilized an ego-centric camera to coordinate the grasp and release operations of a wearable hand robot, with the help of deep learning to estimate users' intentions from first-person-view videos. Zhong et al. (2020) placed a camera on the forearm to recognize the grasping objects in cluttered environments and subsequently generate relevant commands to manipulators, ensuring fluent prosthetic control when reaching the target. Some commercially available wearable intelligent glasses such as Tobii Pro Glasses support the recordings of both gaze behaviors and first-person-view videos and have been applied to enable multi-modal hybrid control (Cognolato et al. 2020).

2.2 Prosthetic Control Approaches

2.2.1 Myoelectric Control

As mentioned above, the most commonly used prosthetic hand is based on myoelectric control. Different schemes have been proposed for such kind of control, such as direct control (DC), pattern recognition, kinematics or postural regression, etc. (Geethanjali 2016). The DC scheme directly links the measured EMG amplitude to the controlled DoFs, mostly based on signals from antagonistic muscle pairs, referred to as dual-site control. The simplistic form of DC applies threshold activation strategy to determine the directions of one DoF. The motor speed can be controlled proportionally by considering the intensity of EMG signals. To control additional DoFs, such as an artificial wrist or elbow, switching mechanism is needed, which is mostly realized by the co-contraction of muscle pairs. These control schemes based on direct EMG amplitude input are not intuitive and need considerable training for the adaptation of the users, adding cognition burden.

Compared to DC schemes, pattern recognition-based control allow more dexterous manipulations with the interactions of multi-articulated and multi-functional prosthetics. Pattern recognition approaches are mainly based on feature engineering, and a considerable amount of features have been proposed in existing studies, including those from time domain (e.g., root mean square, zero-crossing, etc.), frequency domain (e.g., power spectral density, peak frequency, etc.), or the combinations with the help of time–frequency transformation (e.g., short-time Fourier transformation, Wavelet transformation, Hilbert–Huang transformation, etc.). A comprehensive review and comparison of these features have been conducted by Khan et al. (2019). With the extraction of relevant features, machine learning algorithms (e.g., Linear Discriminant Analysis, Support Vector Machine, Bayesian Classifier, Hidden Markov Model, Artificial Neural Network, etc.) are applied to classify different expected patterns. Some recent work also attempted to convert the paradigm from feature engineering to feature learning by incorporating deep learning algorithms (Côté-Allard et al. 2020). Although high classification rate has been reported for pattern recognition-based approaches, they are mainly sequential control based on discrete motion classification, whereas a simultaneous and proportional control is preferred in practice. To realize this, numerous regression models (e.g., Linear Model, Artificial Neural Network, etc.) have been applied to directly predict the postures or forces of controlled DoFs.

On the other hand, with the availability of multi-channel EMG acquisition techniques, spatially related features representing muscle synergies have been derived for complex motor control with multiple DoFs. Blind source separation (BSS)-based decomposition methods, such as non-negative matrix factorization and independent component analysis, have been proposed for quantifying muscle synergies. More advanced, with iEMG and HD-EMG technologies, the discharge activities of motor units can be identified based on EMG decomposition algorithms. The decoded motor unit activities have shown the potentials of addressing the challenging kinematics prediction tasks for prosthetic control (Kapelner et al. 2019).

2.2.2 BCI-Based Mind Control

Among aforementioned neuroimaging methods, EEG has been the most popular source signal for enabling prosthetic control due to its portability and accessibility. The pipeline of mapping brain activities to prosthetic control is similar to myoelectric control, where a diversity of features (frequency, time, spatial) has been developed for EEG-based pattern recognition, together with numerous machine learning algorithms (Khan et al. 2019).

Existing BCI-based control methods are based on either motor imagery (Intention driven/Synchronous) or external stimulation (Stimulus driven/Asynchronous) (Abiri et al. 2019). Motor imagery (MI)-based control investigates the relationship of imagined movement with associated brain activities, thus issuing commands to execute the real movement of prostheses. One of the most commonly reported line of research is investigating the sensorimotor rhythms (SMRs) related to the imagination of kinesthetic movements of amputated body parts. The rhythmic activity amplitude within SMR decreases with movement imagery, while it increases during relaxation, which is referred to as event-related desynchronization (ERD) and event-related synchronization (ERS) modulations, respectively. Many studies have validated the feasibility of utilizing ERD/ERS as features for MI tasks (Abiri et al. 2019). Recently, Edelman et al. (2015) have proposed a novel EEG source imaging algorithm to decode four different MI tasks rather than solely observing the global event-related potentials. However, SMR-based BCI is limited in offering intuitive and natural control due to its low capability of predicting kinematics. To address this, recent work also explored to infer imagined movement kinematics in multiple dimensions from brain activity. Although promising results on kinematics estimation have been reported (Kim et al. 2014), integrating it into prosthetic control is still under investigation.

On the other hand, stimulation-based BCIs utilize external stimulus, such as vision and auditory, to track the event-related potentials. For upper-limb prosthetic control, the most popular one is steady-state visually evoked potential (SSVEP) paradigms. In the SSVEP context, visual stimulation, such as flickering targets, is projected to the subject, while the subject has to shift gaze to choose the right target displayed in the visual stimulus. Different flickering targets flash with distinct frequency rates, and the simultaneously collected EEG signals would show a strong correlation with the frequency of the selected target. For instance, Muller-Putz and Pfurtscheller (2007) applied the SSVEP to control a two-axis hand prosthesis by mounting the flickering lights on the prosthesis surface. Horki et al. (2011) also attempted to combine MI and SSVEP to better control an artificial upper limb with 2 DoFs. Although stimulus-based control does not need large user training compared to MI-based BCI, it could increase the fatigue of the user due to cognition burden.

Apart from the control paradigms mentioned above, in a closed-loop BCI control, error-related potential (ErrP)-based BCI has been used to detect the mismatches between the real intention of the user and the actions decoded from intention- or stimulation-driven BCIs. The detected ErrP signals can be used to correct the real-time control signals to command accurate actions or reinforce the motor learning of the prosthetic controller, as proposed by research on robotic arms (Bhattacharyya et al. 2014). It would be promising to integrate ErrP into prosthetic hands/limbs control, with the goal of improving closed-loop BCI systems (Abiri et al. 2019).

2.2.3 Hybrid Control: Sensor Fusion

A promising research scenario is to integrate multiple sensing modalities to facilitate more intelligent and intuitive control of prosthetic hands by overcoming the disadvantages of each individual sensing modality. Although few technologies are available in markets till now, recent years have witnessed numerous attempts in the literature on investigating complementary information from multiple sensing sources. For instance, McMullen et al. (2013) demonstrated a hybrid prosthetic control system, combining ECoG, gaze, and wearable cameras. The system could reduce false positive errors in motion initiating and help complete complex operations with minimal training for the subjects. Guo et al. (2017) combined EMG and NIRS to pursue synergistic effects on monitoring muscle contraction activities, and the explored hybrid EMG–NIRS myoelectric control scheme improved the results of both offline motion classification and real-time control of a virtual hand. Zhang et al. (2019) combined EEG, EMG, and electrooculography to control a soft robot arm and achieved better performance than each individual modality for offline movement classification. However, existing studies mainly focus on acquiring multi-modal data for offline training and evaluation on health subjects. The challenges associated with practical online operations of patients, such as computational cost and adaptive sensory fusion, should also be addressed in the future.

2.3 Sensory Feedback

Effective real-time sensory feedback plays an important role in restoring motor functions for rehabilitation purposes, contributing to the co-adaptive and mutual learning for both the prosthetic controller and its user in a closed-loop control context (Antfolk et al. 2013b). Normally, for the prosthetic user, the intrinsic feedback provided by vision or audition can supply information on the velocity and position of the prosthesis. Moreover, the prosthesis can be equipped with delicate sensors that are able to measure the state of the system (e.g., joint angles, tendon stiffness, etc.) and the interaction with the environment (e.g., grasping force, tactile, etc.), imitating the sensations of a real hand. These interfaces are then transmitted to the user, facilitating the restoration of their sensory functions. A summary of sensory feedback approaches in upper-limb prostheses is provided in Table 2.

2.3.1 Incidental Visual or Auditory Feedback

As far as most current commercially available prostheses are concerned, explicit somatosensory feedback scheme has not been integrated. However, it has been investigated that, even under the absence of explicit somatosensory feedback, human subjects can voluntarily exploit some incidental sensory information, such as visual and acoustic cues Wilke et al. (2019); Markovic et al. (2018). The user can observe the movement of the prosthesis and its interactions with the surroundings as well as can listen to the sound of the motor. It has been demonstrated that such kind

Table 2 Summary of sensory feedback approaches in upper-limb prostheses

Feedback	Methods	Noninvasive	Descriptions
Incidental	Visual	✓	Observe hand movement and its interactions
	Auditory	✓	Listen to the motor movement
Homologous	PNS stimulation	✗	Direct electrical stimulation to peripheral nervous system
	CNS stimulation	✗	Direct electrical stimulation to central nervous system
	Mechano-tactile	✓	Tactile information → Forces exerted on residual limbs
Sensory substitution	Electro-tactile	✓	Tactile information → Electrical stimulation
	Vibro-tactile	✓	Tactile information → Vibration stimulation
	Auditory stimulus	✓	Tactile information → Sound stimulation

of implicit feedback facilitates better grasping control by helping the subject to identify the state of the prosthesis (Wilke et al. 2019) or scale the grasping force level (Markovic et al. 2018). However, it needs systematic investigation on the control quality of making use of incidental feedback alone; such control is still be viewed as a baseline "open-loop" control, compared to those with supplementary feedback conveyed by sensory substitution or homologous mechanical/electrical stimulation.

2.3.2 Modality-Matched Homologous Feedback

Homologous feedback conveys the stimulation as the same modality of the information received by the prosthesis. Among existing technologies, neural interfaces, such as peripheral nervous system stimulation and central nervous system stimulation, apply direct electrical stimulation to corresponding nervous systems. They are both invasive, requiring surgical intervention to implant electrodes or needles for stimulation generation. For instance, Collins et al. (2017) performed electrical brain stimulation that is synchronized with the touches sensed by an artificial hand, to the hand section of the somatosensory cortex, inducing the ownership of the artificial hand. For peripheral nervous system, both extraneural (Schiefer et al. 2015) and intraneural (Oddo et al. 2016) electrodes have been used to facilitate tactile sensations. Although neural interfaces can directly provide modality-matched sensations, it is a common concern about the potential damages to the nervous systems caused by invasive electrical stimulation.

Apart from neural interfaces, mechano-tactile stimulation is another type of homologous feedback, which exerts a pushing force normal to the stump surface when a force is sensed on the prosthetic fingertips. Antfolk et al. (2013a) proposed a noninvasive mechano-tactile feedback paradigm by matching the tactile stimuli on the stump with that displayed on the screen, and both the amputees and healthy subjects were able to discern different stimuli locations, pressure level, and grip categories after training. Recent research has proposed targeted sensory reinnervation techniques, which transfer nerves losing their targets after amputation to residual muscles via surgeries, allowing muscles to be employed as biological amplifiers of nerve activities (Bergmeister et al. 2017). Marasco et al. (2011) exerted proportional pressure and transients to the reinnervated skin of the amputees, and after training, the embodiment of the prosthetic limb was augmented.

2.3.3 Sensory Substitution Feedback

Sensory substitution transmits sensory feedback in the form of a different sensory modality, such as electro-tactile and vibro-tactile feedback. Electro-tactile feedback delivers electric currents via skin interfaces to stimulate afferent nerve endings. The elicited sensations can be modulated by current amplitude, plus rate, etc. (Xu et al. 2015) improved the grasping performance by electro-tactile simulated slip and pressure feedback. Vibro-tactile stimulation utilizes the vibration signals to symbolize touch sensations, and the signals are modulated by the variations in frequency, amplitude, duty cycle, pulse duration, etc. (Aboseria et al. 2018) employed discrete vibro-tactile feedback, and it successfully prevented the object from slippage in grasping tasks. On top of the aforementioned tactile feedback, auditory stimulation is also exploited as a substitute for touch sensation. The users could be trained to interpret different acoustic stimuli and associate the discern with specific surfaces and textures of the objects touched by artificial hands (Lundborg et al. 1999).

2.4 Challenges and Future Directions

Robust and Flexible Wearable Sensing In prosthetics, numerous sensing technologies have been embodied to interface prosthetic hand/limb control, covering from brain, muscle, to visual signals, and increasing attention has been posed on developing noninvasive sensing modalities, such as EEG and sEMG, to satisfy the need for using prostheses in free-living context with minimal harm to the subject. However, these signals are mostly prone to motion artifacts, low signal-to-noise ratio, and electromagnetic interference. It is promising to integrate novel flexible sensor design technologies (Chen et al. 2018) to ensure comfortable and reliable interfaces, minimizing the negative effects mentioned above. For some noninvasive signals such as SMG and MEG, the design of portable and small-sized wearable scanning devices is a fundamental step for integrating them into prostheses for daily use.

Seamless and Intuitive Prosthetic Control Advances in machine learning algorithms have benefited the development of prosthetic control. However, most cognition and decision algorithms embedded in the prosthetic controller are based on offline training, and they require training or calibration before the usage. This problem is evident in myoelectric control, as EMGs are of high variability in terms of electrode configurations, sensor placements, and inter-subject variance. Moreover, the fatigue caused by long-term use and accumulated cognition burden would also affect signal characteristics. To mitigate the bias and facilitate seamless control, taking into account online adaptive algorithms, such as meta learning and online transfer learning, can be a promising solution. Making use of modalities less prone to subject-dependent variations such as egocentric vision would also help.

On the other hand, the combination of complementary information extracted from multiple modalities could enhance the precision and intuitiveness of prosthetic control. It could also potentially facilitate a more natural control of dexterous and complex movement. Several hybrid attempts such as EMG–NIRS (Guo et al. 2017), EMG–BCI (Ruhunage et al. 2017), BCI–Vision (McMullen et al. 2013; Parr et al. 2019), and multi-modal BCI (Abiri et al. 2019) have been reported in relevant fields. However, most existing work solely conducted offline training and evaluation based on pre-acquired data, and it is worth exploring the performance of the proposed algorithms under online testing.

Clinical Validation and Practical Incorporation of Sensory Feedback Although considerable efforts have been devoted to investigating different sensory feedback paradigms, they are far from being commercialized for practical usage since there remain several challenges, such as the long-term training for adapting to noninvasive sensory substitution stimuli, and the damages associated with direct neural stimuli. Furthermore, since most studies were conducted within intact subjects or small groups of amputees on simple grasping tasks and the knowledge of human hand–brain communication is limited, it still needs further investigation to understand the role that sensory feedback plays in the closed-loop control.

3 HRI for Robot-Assisted Stroke Rehabilitation

Stroke has already been the third leading disease to cause disabilities, and over 80% of stroke survivors live with functional and cognitive deficits, which significantly diminish their quality of life. Therefore, there is a pressing need for improving their movement capability through multidisciplinary treatments such as physical therapy and occupational therapy. However, the conventional recovery after stroke heavily depends on the high-dose intensity and repetitive training for a specific functional task. Instead of the labor-intensity rehabilitation process assisted by therapists, robot-assisted rehabilitation has demonstrated great potential in providing automatic training and motor function assessment.

In the past decades, numerous end-effector-based and exoskeleton-based therapeutic robots have been developed to train the physical functions of impaired body parts of stroke patients (Chang and Kim 2013). The most intuitive robot-assisted strategy is targeted at guiding patients to complete the predefined movement. In this manner, the robot can switch between a follower role and a leader role by changing the impedance of the system, which can be regarded as “patient-in-charge” and “robot-in-charge” modes. However, with these two basic modes, stroke survivors only passively repeat the movement guided by the robot, lacking active engagement and interaction with robots. With the recent advancement in HRI technologies, the development of therapeutic robots has transformed this passive training to an active, natural, and intelligent style. In this chapter, we summarize three fundamental requirements of HRI in robot-assisted stroke rehabilitation as shown in Fig. 3. First, the movement intention detected from patients’ either muscle/brain activities or gaze behaviors can be used as the online commands to control rehabilitation robots. Next, robotic systems are desired to capture the biomechanical and physiological behaviors from patients and deliver such biofeedback to patients via visual, acoustic, or somatosensory way, which encourages patients to adapt/correct their movement patterns. Another requirement of HRI in therapeutic robots is to perform automatic quantitative assessment on rehabilitation by kinematic/kinetic parameters indicating the quality of the movement and various biosignals correlating with clinical scales.

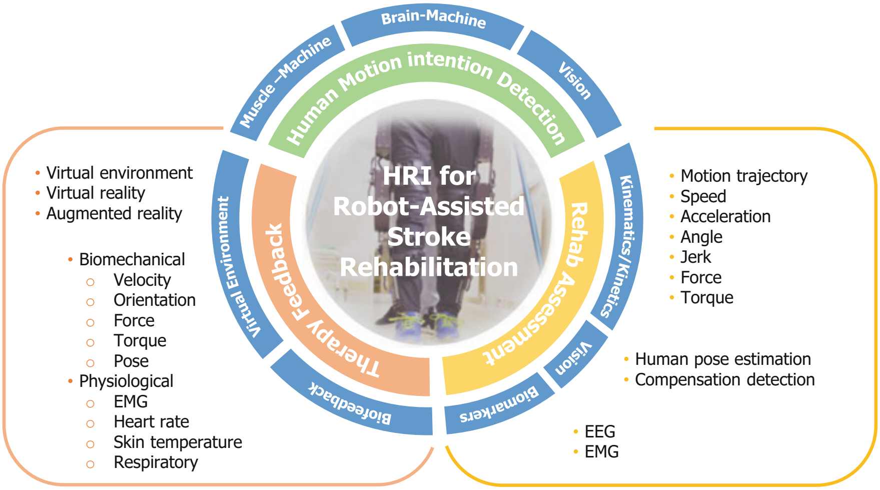

Fig. 3 Requirements of HRI for active, natural, and intelligent robot-assisted stroke rehabilitation. Source: authors

3.1 Intention Detection for Active Rehabilitation

Recent works have paid extensive attention to the development of human-in-the-loop control strategies by detecting human movement intention via different human–machine interfaces. Similar to the prosthetic control as mentioned above, the detected intent can be further used to trigger the actuation of the robotic systems, thus delivering a more natural HRI in therapeutic training. Such an intention-driven actuation mechanism not only arouses the active engagement of patients during a single therapy but also facilitates neuroplasticity in a long-term session.

3.1.1 Muscle–Machine Interfaces

The myoelectric control scheme also plays a significant role in robot-assisted stroke rehabilitation (Stein et al. 2007). The most commonly used strategy is to detect the movement intention from the hemiplegic side of patients, thus assisting them to complete specific functional tasks (e.g., hand open, hand close, reach a point, grasp an object). Through the EMG-driven exoskeleton hand functional training, Ho et al. (2011) reported that the hand functions of stroke patients had been significantly improved according to Fugl-Meyer Assessment (FMA) scores. On the other hand, the mirror rehabilitation therapy strategy detects the movement intention captured from the healthy side, and then the therapeutic robots reproduce the movement on the hemiplegic side (Cai et al. 2019). Such a strategy allows the rehabilitation exercises dominated by patients, which certainly arouse their engagement.

To improve the accuracy of movement intention detection from EMG signals, extensive works are focused on the development of advanced machine learning and deep learning algorithms (Ye et al. 2017; Ren et al. 2019). Also, some works compared the performance on motion intention decoding with sparse EMG and HD-EMG (Li et al. 2019). With a dense spatial distribution, HD-EMG signals are advantageous in extracting spatio-temporal parameters relevant to motion intent.

3.1.2 Brain–Computer Interfaces

For those patients with negligible residual motor function, motor imagery (MI)-based BCI is studied to generate contingent sensory feedback for stroke rehabilitation (Frolov et al. 2017; Berger et al. 2019).

For EEG signals, ERD and ERS are two indispensable EEG patterns highly related to the motor imagery and actual movement, which are typically used as indicators for rehabilitation assessment and motor intention recognition. Cheng et al. (2020) detected the motion intent through the ERD/ERS patterns raised by MI and then was used to initiate the soft robotic glove with preprogrammed actions. They conducted a 6-week intervention and reported that the group with BCI-controlled robotic glove had shown improvements in FMA and Action Research Arm Test (ARAT) scores. Another popular method in noninvasive BCI-based therapy is to use SSVEP signals, which can be detected by fewer electrodes and requires less training than the ERD-based systems. Sakurada et al. (2013) leveraged SSVEP signals recorded from the visual cortex to trigger two hand movements. Except for extracting discriminative EEG patterns, there is increasing popularity for intent detection directly from raw EEG signals (Frolov et al. 2017). More recently, a deep Convolutional Neural Network (CNN) was designed for the binary classification of intent from raw EEG signals to initiate a goal-oriented movement as well as for the discrimination of the movement reaction time (Kumar and Michmizos 2020).

Furthermore, increasing interests have been raised on the use of fNIRS during stroke rehabilitation, due to its robustness to motion artifacts and usability. For instance, fNIRS data was used to detect the left and right hip movement intention (Rea et al. 2014) and the self-paced walking intention (Li et al. 2020), which demonstrated the feasibility of fNIRS-based BCI in robot-assisted gait training for stroke recovery.

3.1.3 Vision-Based Interfaces

Eye gaze detected from either head-mounted or remote eye-trackers forms the vision-based interfaces for HRI in robot-assisted rehabilitation, which characterizes the interactive intention with the real-world (Li et al. 2017) or virtual environment (Novak and Riener 2013). By detecting the gaze point of patients, robotic systems are able to understand where a patient is looking at, then the gaze information can be translated into the movement intent for interaction, and finally the intent will trigger the robot to move the impaired limb to a desired position.

3.2 Therapy Feedback in Rehabilitation

To further encourage the motivation of patients and facilitate the effects of rehabilitation, studies have shown that providing real-time feedback during therapy training leads to a better rehabilitation outcome (Giggins et al. 2013; Stanton et al. 2017). On the one hand, the frequently used biofeedback including biomechanical and physiological signals can be translated into visual, acoustic, or somatosensory signals and then delivered to patients and therapists. By observing the real-time feedback, therapists can provide further guidance and patients are able to adapt their movement patterns by themselves. On the other hand, rehabilitation training in a controlled virtual environment provides additional visual feedback on real-time guidance and task performance, thus encouraging the rehabilitation in a home-based scenario. Unlike human intrinsic sensory feedback processing self-generated information, such biofeedback within HRI offers the supplementary information measured from external sensors, which can be regarded as the extrinsic feedback.

3.2.1 Biomechanical and Physiological Biofeedback

In the past decades, biofeedback has shown great potential in stroke rehabilitation by measuring biomechanical/physiological variables and then delivering them concurrently to patients in various perceptive modes (Giggins et al. 2013). The most common way is to translate the biofeedback into a visual display, which offers intuitive indication and real-time intervention. After receiving the biofeedback, patients could gain their engagement through the automatic adaptation of their movement patterns (Stanton et al. 2017). According to Giggins et al. (2013), biofeedback can be categorized into two groups: (1) biomechanical biofeedback on position, postural control, and force measurement and (2) physiological biofeedback that mainly measures the changes of neuromuscular and cardiovascular systems.

Previous works mainly examined the effectiveness of biomechanical biofeedback in conventional rehabilitation rather than robot-assisted scenarios, which leverages the measurement from the inertial, force, pressure sensors, or external camera-based systems (Giggins et al. 2013; Fern’ndez-Baena et al. 2012). The raw sensing signals are typically converted into a more intuitive representation. In terms of robot-assisted gait training (RAGT), Lunenburger et al. (2004) calculated the weighted force function of the knee and hip joints as the biofeedback during the gait training. Results on both healthy and stroke survivors showed that the proposed biofeedback values correlated well with the subjects of different activity levels. However, it may not be easy for patients to understand the meaning of each sign immediately. Stoller et al. (2012) found that the progress with biomechanical biofeedback such as joint torque, walking speed, and time duration cannot be observed from the patients after RAGT.

For physiological biofeedback on neuromuscular systems, transmitting EMG data that indicates the changes of muscle activities into visual signals provides more intuitive feedback in rehabilitation. Extensive works have demonstrated its effectiveness in the motor function improvement after training with EMG biofeedback (Doğan-Aslan et al. 2012). Moreover, Tamburella et al. (2019) compared the EMG-based biofeedback with the conventional biofeedback on joint torques (Lunenburger et al. 2004) in RAGT with Lokomat system, where the EMG-based group showed significant improvement in muscle force at the lower limb as well as the effective reduction of spasticity. On the other hand, cardiovascular biofeedback (e.g., heart rate and blood pressure), skin temperature, and respiratory biofeedback can also be transmitted into visual signals during rehabilitation. Delivering such physiological biofeedback to patients allows them to control these numerical values within a range, thus enabling a more safe and efficient therapeutic training.

3.2.2 Virtual Environment, Virtual Reality, and Augmented Reality

Recently, Virtual Environment (VE), Virtual Reality (VR), and Augmented Reality (AR) have been integrated with the rehabilitation robots to provide informative visual feedback, which can increase patients' interests and guide them to practice a specific task in a controlled environment (Hamzeheinejad et al. 2018; Mubin et al. 2019). It has been proven that the combination of therapeutic robots and VE can achieve better rehabilitation outcomes than solely using robot (Wagner et al. 2014), and the skills learned from VE can be transferred to the real scenarios (Holden 2005). Wagner et al. (2014) examined the impact on interactive feedback in VE during RAGT. They found that the EEG power in premotor and parietal areas was significantly increased compared to the group without feedback, emphasizing that VE can promote the motor planning and visuomotor processes of patients during rehabilitation.

For upper-limb rehabilitation, most of the previous works explored the use of VR and AR to perform reaching (Acosta et al. 2011) and grasp/release tasks (Archambault et al. 2019). To enable force and tactile information in the virtual environment, haptic feedback is commonly incorporated with the AR/VR systems. With additional haptic information, Broeren et al. (2004) found that there are significant improvements in grip force, fine dexterity, and motor control of the hemiparetic arm, and Acosta et al. (2011) demonstrated that the rehabilitation performance of a reaching task was superior to that with a solely VR system.

3.3 Robot-Assisted Rehabilitation Assessment

During the conventional training, the stroke recovery is typically quantitatively evaluated through the use of well-defined clinical scales, such as Fugl-Meyer Assessment (FMA), Chedoke–McMaster Stroke Assessment (CMSA), Modified Ashworth Scale (MAS), etc. However, such assessment heavily requires intensive labor from therapists, and the scores would be affected by their subjective decisions. Consequently, the objective and quantitative assessment of rehabilitation is another fundamental requirement for HRI in robot-assisted stroke rehabilitation.

3.3.1 Kinematics and Kinetics for Assessment

Therapy robots equipped with inertial sensors can directly measure the kinematic parameters such as motion trajectory, speed, and acceleration of a specific task performed by patients. For instance, an ear-worn inertial sensor was designed to capture the abnormal gait kinematics that indicate injury or impairment (Atallah et al. 2011). Nordin et al. (2014) provided a comprehensive review of the existing kinematic parameters for evaluating upper-limb rehabilitation with an end-effector-based therapeutic robot, including movement, accuracy, efficiency, efficacy, range of motion, inter-limb coordination, and so on. Besides, the kinetic measurements of force and joint torque can also be used as assessment indices of abnormal synergies for stroke patients (Kung et al. 2010).

Extensive studies explored the use of kinematic and kinetic parameters for quantitatively evaluating the movement quality of stroke survivors. These parameters have demonstrated a strong correlation with clinical assessment scales, which could provide a better understanding of stroke recovery by choosing suitable ones for assessment. However, most previous works using kinematic and kinetic parameters were applied on end-effector-based therapeutic robots, while they may fail to detect the compensation of patients by analyzing the movement of endpoint.

3.3.2 Vision-Based Assessment

Patients with severe impairment would compensate for their movement by involving extra degrees of freedom. Relying heavily on compensation impedes the recovery progress and leads to undesirable limb movement synergies or inefficiencies in limb use (Alankus and Kelleher 2012). However, such compensation cannot be well-detected through the kinematic/kinetic parameters captured from the end-effector-based robotic systems.

Although marker-based vision systems can assess the compensation of patients and provide feedback for correcting their movement, they are typical with complicated setup and limit the applications in hospital or lab-based environment (Fern’ndez-Baena et al. 2012). Alternatively, recent progress in vision-based markerless human pose estimation has enabled the real-time posture assessment and compensation detection during the therapy. Taati et al. (2012) used the Kinect sensor and its embedded skeleton tracking algorithm to estimate the pose of stroke patients and then designed a multi-class classifier to successfully recognize the most common types of compensation.

3.3.3 Biomarkers for Assessment

To enable the ubiquitous assessment clinical translation of the advanced robot-assisted rehabilitation technologies, there is also a pressing need for robotic therapists to evaluate the motor and neurological recovery of stroke patients from informative biosignals. Among previous works, EMG is most widely used for assessment together with kinematic and kinetic parameters (Dipietro et al. 2005). Commonly, the EMG activation and co-contraction levels were investigated as the motor functional recovery indexes. During a robot-assisted wrist training for chronic stroke patients, Hu et al. (2009) found that both EMG activation and co-contraction indexes were highly associated with the clinical scale—MAS scores. Similarly, Kung et al. (2010) used the co-contraction of elbow and shoulder muscles to assess the synergy patterns in upper-limb rehabilitation.

On the other hand, the assessment from brain signals also gained increasing interests, especially for the development of quantitative EEG measures to evaluate motor recovery. For chronic stroke patients with robot-assisted rehabilitation, Trujillo et al. (2017) found that the power ratio index and delta/alpha ratio were negatively correlated with the motor improvements, which can be potentially served as a meaningful index for measuring rehabilitation outcomes. In a pilot study on chronic stroke patients with robot-assisted bilateral arm training, Gandolfi et al. (2018) showed that ERD/ERS patterns were significantly correlated to the clinical scales while performing bimanual motor tasks. These studies have demonstrated the capability of EEG measures in the evaluation of motor recovery; however, the clinical clues on the recovery of neurological systems have not been well-studied.

Apart from serving as the quantitative metric for evaluating motor recovery, biosignals such as EMG and EEG can also serve as the quantification tool for mental engagement and fatigue assessment. de Oliveira et al. (2019) showed that the voluntary effort derived from EMG signals could reliably evaluate the patients' contribution to the movement, and Park et al. (2014) explored the feasibility of the assessment of mental engagement from single-trial EEG data. Besides, Foong et al. (2019) suggested that the EEG relative beta power correlating well with the BCI accuracy may indicate the mental fatigue in MI-BCI training.

3.4 Challenges and Future Directions

Accurate Intention Detection from Multiple Modalities Although movement intention detection has been successfully incorporated in robot-assisted stroke rehabilitation to arouse patients' engagement, previous works mainly focused on the patients with physical impairment and performed the predefined training process after detecting human intent. Moreover, the current results showed that it is still challenging to distinguish the fine motor intent, such as the movement of an individual finger. Therefore, similar to prosthesis control, recent advances in multi-modal sensing technologies and artificial intelligence will open opportunities for the seamless therapeutic robot control that depends on a more accurate and real-time intention detection on fine movement. Furthermore, the research effort on movement intention detection of patients with cognitive impairment is required.

Diversity of Biofeedback in Robot-Assisted Rehabilitation By leveraging various feedbacks, extensive work on conventional rehabilitation has demonstrated superior performance compared to the group without feedback. Therefore, it is urgent to incorporate biofeedback with therapeutic robots, thus promoting the effects of robot-assisted stroke rehabilitation. Another point that needs to be addressed is the selection of the appropriate biofeedback values. Although brain signals have been successfully used for movement intention detection and rehabilitation assessment, the capability of brain activities as the biofeedback has not been well-explored.

Mental States Assessment In addition to the motor recovery assessment, previous works may overlook the assessment of patients' mental states. Especially for patients with cognitive impairment, they would suffer a higher mental/cognitive workload while performing the same task, which could significantly influence the effect of rehabilitation. Moreover, with recent progress in computer vision and deep learning, there are substantial opportunities to develop vision-based assessment methods.

4 Conclusions

To enable human-in-the-loop rehabilitation, human–robot interaction plays a critical role in the development of rehabilitation robotics, by providing reliable and intuitive assistance, informative feedback, as well as convincing and quantitative rehabilitation assessment. Several key components/techniques in the human–robot interactions have been discussed in the case of upper-limb prostheses and therapeutic stroke rehabilitation robots. Generally speaking, for the human-to-robot session within rehabilitation robots, forward control of robots is supported by perceiving intentions from information acquired by a variety of sensing modalities. Real-time, intuitive, and reliable control is expected for both assistive and therapy robots, where robust sensing and intelligent learning technologies play an important role.

On the other hand, for the robot-to-human feedforward session, the robot agent aims to transmit the perceived information back to humans. For assistive wearable robot control, especially for prosthetics, sensory feedback has been explored to add to the embodiment of these wearable devices, and a further understanding of its role in HRI should be done. For therapy robots, real-time feedback could augment the engagement of the patients as well as provide appropriate guidance during rehabilitation training. Furthermore, the objective assessment conducted by the rehabilitation robots could potentially convert the way assessment is conducted now to an automatic, precise, and personalized manner.

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