

Future of Business and Finance

Pantea Pape · Guido Lerzynski ·
Patrick Glauner · Julia Plugmann ·
Philipp Plugmann *Editors*

Transformation in Health Care

Game-changers in Digitalization,
Technology, AI and Longevity



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Future of Business and Finance

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Foreword

Imagine a world where your smartphone is as integral to your health as your doctor, where AI algorithms predict medical conditions before symptoms appear, and where remote consultations are as common as in-person visits. Welcome to the dawn of a new era—Digital Transformation in Healthcare.

Healthcare, once rooted in traditional practices and paper records, is undergoing a seismic shift. This transformation isn't just about adopting new technologies; it's about reimagining the entire healthcare ecosystem. From the way we diagnose diseases to how we manage patient care, digital innovation is breaking down barriers, democratizing access, and setting new standards for efficiency and accuracy.

One of the most pressing challenges in healthcare today is the global lack of healthcare access and a significant shortage of medical staff. Digital solutions are stepping in to fill the gap and help mitigating their negative effects. Telemedicine is no longer a futuristic concept but a lifeline for millions, especially in remote or underserved regions, providing access to care without the need for physical presence. Remote technologies, together with AI, for diagnostic and therapeutic modalities enable a whole new medicine.

AI and machine learning are revolutionizing diagnostics, making them faster and more accurate, thereby easing the burden on overworked healthcare professionals.

Wearable devices continuously monitor our vital signs, empowering us with real-time data to make informed health decisions and reducing the need for frequent doctor visits. This empowers people to be more health conscious before they become patients.

The pharmaceutical industry will be benefitting significantly from drug discovery with ultra-fast Quantum Computers, a new disruptive technology which will affect the entire human sphere.

However, this transformation is not without its challenges. Large consultancy found that only 25% of all digital transformation projects have met their goals. Integrating digital technologies into established systems requires thoughtful navigation and robust strategies. Privacy concerns, data security, and the digital divide threaten to slow progress. But the potential rewards—a more personalized, accessible, and efficient healthcare system—are too significant to ignore. Such transformations need to be considered as larger change management projects with all related implications. Instead of modelling existing, analogue processes, it is important to think digital from the get-go.

In “Digital Transformation in Healthcare,” it is explored how technology is reshaping the patient experience, revolutionizing medical practice, and redefining the future of health services. Through deep expert insights, and forward-looking analysis, this book envisions a healthcare system where technology and human touch converge seamlessly. It also guides through important new technology standards and regulatory implications. This book uncovers in an impressive way the transformative power of digital innovation in healthcare and its profound impact on our lives.

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Quantum Computing: Foundations, Opportunities, Challenges, and Applications in Healthcare

Patrick Glauner

Abstract

This chapter provides a comprehensive overview of the foundational principles of quantum computing, its theoretical and practical developments, and its potential impact on the healthcare sector. It begins by introducing the core concepts of quantum computing, such as qubits, superposition, entanglement, and quantum algorithms and explains how these principles differ fundamentally from classical computing. The chapter discusses both the opportunities and challenges of quantum computing, highlighting recent advancements, like new quantum architectures and error correction methods, and addressing concerns around exaggerated expectations and the current limitations of the technology. In the context of healthcare, the chapter explores several promising applications of quantum computing, including accelerating drug discovery, advancing genomics, and personalized medicine, optimizing healthcare operations, and improving clinical trial design. It concludes with an outlook on the future of quantum computing in healthcare, acknowledging the significant challenges that remain but also emphasizing the technology's transformative potential as it matures.

1 Introduction

Quantum computing, a field once confined to the realm of quantum mechanics, is emerging as one of the most exciting technological advancements of the 21st century. Its potential to revolutionize industries is immense and healthcare stands out as a sector poised to benefit profoundly. The ability of quantum computers to

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process and analyze vast amounts of data at unprecedented speeds holds the promise of transforming medical research, diagnostics, and personalized treatment.

The journey of quantum computing is rooted in the early 20th century, when pioneers like Niels Bohr and Werner Heisenberg laid the groundwork for quantum mechanics (Bohr et al., 1928; Heisenberg, 1927). However, it was not until the late 20th century that the idea of using quantum phenomena for computation began to take shape. Visionaries like Feynman (1982) and Deutsch (1985) proposed and laid the groundwork for the concept of quantum computers, sparking decades of research that has gradually transitioned from theoretical exploration to experimental implementation.

Recent advancements have brought quantum computing to the forefront of technological discussions. Major technology companies and research institutions have made headlines with their progress in building and testing quantum systems. The announcement of Google's "quantum supremacy" milestone in 2019, where a quantum computer performed a specific task faster than any classical computer could, marked a significant moment in the field (Arute et al., 2019). These developments have fueled both excitement and speculation about the near-term impact of quantum computing on various industries, including healthcare.

This has also led to lots of hype and wrong claims, such as that quantum computers would replace all traditional computers. Therefore, it is crucial to temper this enthusiasm with a realistic understanding of the current state of quantum computing. While the potential is enormous, the technology is still in its infancy. Many challenges remain, from hardware stability and error correction to the development of quantum algorithms capable of solving real-world problems. The gap between current capabilities and the ambitious promises of quantum computing has led to a dichotomy between hype and reality.

It must also be noted that quantum computing is only a subfield of a much larger field of applications of quantum mechanics (Akenine, 2020). These include quantum networks and quantum sensors (Degen et al., 2017) as well as other applications.

This chapter aims to make quantum computing tangible and relevant for a wider audience, including healthcare professionals and stakeholders. In order to separate hype from reality, this does require an understanding of the foundational principles of quantum computing, as well as the opportunities and challenges that lie ahead. This chapter first introduces the essentials of quantum computing. In order to fully understand this chapter, readers should be familiar with linear algebra and complex numbers.¹ Next, it discusses challenges as well as opportunities and recent developments when building quantum computing applications. Last, it examines how this cutting-edge technology could eventually be harnessed to address some of the most pressing challenges in healthcare. By bridging the gap between potential and practical application, we aim to provide a comprehensive overview that is accessible to a broad readership, from clinicians and researchers to policymakers and technology enthusiasts.

¹ See our lecture recordings at www.glauner.info/teaching for an introduction or revision.

2 Foundations

This section discusses the theoretical foundations of quantum computing, in particular the fundamental units of quantum computers, operations, algorithms, and architectures of quantum computers. An excellent and elaborated introduction to these topics is provided in Yanofsky and Mannucci (2008). A more holistic view on quantum mechanics as a generalization of probability theory and its impact on computing is provided in Aaronson (2013).

2.1 From Bits to Quantum Bits

A bit is the fundamental unit in digital computers. Bits are either “0” or “1,” meaning “*off*”/“*on*.” However, other representations such as “*false*”/“*true*” or “*no*”/“*yes*” are also commonly used.

In contrast, a quantum bit (often referred to as “**qubit**” or “qbit”) is the fundamental unit in quantum computers, which can be in both states “0” and “1” at a time. Concretely, a qubit is a two-state quantum-mechanical system that allows it to be in a coherent **superposition** of multiple states simultaneously (the term “superposition” will be elaborated on in Sect. 2.2).

Qubits are represented as **vectors** and often denoted in the bra-ket notation: $|a\rangle$, which is pronounced “*a* ket.” A qubit is composed of two components $|0\rangle$ and $|1\rangle$:

$$|a\rangle = \alpha|0\rangle + \beta|1\rangle = \alpha \begin{bmatrix} 1 \\ 0 \end{bmatrix} + \beta \begin{bmatrix} 0 \\ 1 \end{bmatrix} = \begin{bmatrix} \alpha \\ \beta \end{bmatrix},$$

where α and β are **complex² probability amplitudes** of the qubit, meaning how strongly $|a\rangle$ is in $|0\rangle$ and $|1\rangle$, respectively. In order for $|a\rangle$ to be a valid qubit, the following constraint must hold true:

$$|\alpha|^2 + |\beta|^2 = 1,$$

where $|\alpha|$ denotes the **modulus**, or **absolute value**, of complex number α . This constraint is a consequence of the definition of more general quantum states.

Example 1 (Modulus of Complex Number) For $\alpha = 4 - 3i$, $|\alpha| = \sqrt{4^2 + (-3)^2} = \sqrt{16 + 9} = \sqrt{25} = 5$.

Example 2 (Valid Qubit) $|a\rangle = 0.6|0\rangle + 0.8|1\rangle$: $\alpha = 0.6$ and $\beta = 0.8$ are complex numbers that only have a real part, respectively. $|\alpha| = \sqrt{0.6^2 + 0^2} = 0.6$ and

² **Complex numbers** extend the real numbers. A complex number has two components $a + bi$, where a and b are real numbers. a is called the **real part** and b is called the **imaginary part**. i is the so-called **imaginary unit** satisfying $i^2 = -1$.

$|\beta| = \sqrt{0.8 + 0^2} = 0.8$. Since $|\alpha|^2 + |\beta|^2 = 0.6^2 + 0.8^2 = 0.36 + 0.64 = 1$, $|a\rangle$ is a valid qubit.

Example 3 (Invalid Qubit) $|b\rangle = 0.5|0\rangle + 0.5|1\rangle$: $\alpha = 0.5$ and $\beta = 0.5$ are complex numbers that only have a real part, respectively. $|\alpha| = \sqrt{0.5^2 + 0^2} = 0.5$ and $|\beta| = \sqrt{0.5^2 + 0^2} = 0.5$. Since $|\alpha|^2 + |\beta|^2 = 0.5^2 + 0.5^2 = 0.25 + 0.25 = 0.5 \neq 1$, $|b\rangle$ is not a valid qubit.

Operations on qubits are described in terms of **unitary matrices**. A matrix U is unitary if $U^\dagger U = U U^\dagger = I$, where I is the identity matrix, holds true. U^\dagger is pronounced “U dagger” and refers to the **adjoint matrix**, or conjugate transpose, of U , which is obtained by transposing U and calculating the complex conjugate of each entry.

Example 4 (Adjoint Matrix)
$$\begin{bmatrix} 6 - 3i & 2 \\ 9i & -2 + 4i \end{bmatrix}^\dagger = \begin{bmatrix} 6 + 3i & -9i \\ 2 & -2 - 4i \end{bmatrix}$$

Example 5 (Unitary Matrix for the Hadamard Operation) $\frac{1}{\sqrt{2}} \begin{bmatrix} 1 & 1 \\ 1 & -1 \end{bmatrix}$ is unitary, as
$$\frac{1}{\sqrt{2}} \begin{bmatrix} 1 & 1 \\ 1 & -1 \end{bmatrix}^\dagger \frac{1}{\sqrt{2}} \begin{bmatrix} 1 & 1 \\ 1 & -1 \end{bmatrix} = \frac{1}{\sqrt{2}} \begin{bmatrix} 1 & 1 \\ 1 & -1 \end{bmatrix} \frac{1}{\sqrt{2}} \begin{bmatrix} 1 & 1 \\ 1 & -1 \end{bmatrix}^\dagger = \begin{bmatrix} 1 & 0 \\ 0 & 1 \end{bmatrix}.$$

Quantum computing requires that all operations be reversible. Unitary operations are inherently reversible, allowing the entire computation process to be undone if necessary, which aligns with the principles of quantum mechanics. The fundamental operations of quantum computers are beyond the scope of this chapter and are discussed in detail in Yanofsky and Mannucci (2008).

2.2 Quantum-Mechanical Effects in Quantum Computing

Quantum computing harnesses quantum-mechanical effects that distinguish it fundamentally from traditional computing. At the heart is **superposition**, which allows qubits to be in multiple states simultaneously, rather than being confined to the binary states of 0 or 1 as in classical bits.

This ability to represent and process multiple possibilities at once underpins **quantum parallelism**. It enables quantum computers to perform many calculations at once and vastly increases their computational power for certain tasks.

Example 6 (Quantum Parallelism) Eight qubits together is called a qubyte. It can represent in total 2^8 states. Any operation on the qubyte will be performed on all 256 states at the same time.

Furthermore, **entanglement** is a phenomenon where qubits become interconnected such that the state of one instantly influences the state of another, regardless of distance (Yin et al., 2013). In quantum computing, entanglement leads to speedup of algorithms. It is also essential for quantum teleportation, error correction and secure quantum communication, making it a foundational resource for the functionality and potential of quantum systems.

Quantum measurement is a process that extracts classical information from a quantum system, collapsing the qubits from their superposition or entangled states into a definite state of either 0 or 1. This collapse is probabilistic, with the outcome determined by the quantum state's probability distribution at the time of measurement. Measurement is a crucial yet delicate step, as it inherently disturbs the quantum state, meaning the information gained is limited and the original quantum state is lost.

Together, these quantum-mechanical effects provide the foundation for the extraordinary potential of quantum computing to solve problems far beyond the reach of classical computers.

2.3 Quantum Algorithms

Quantum algorithms leverage the unique properties of quantum mechanics, such as superposition and entanglement, to solve specific problems that are intractable for classical computers. During the last decades, dozens of quantum algorithms have been proposed (Aaronson, 2022). While most are purely of academic nature, two algorithms have become popular: Shor's and Grover's.

One of the most celebrated quantum algorithms is **Shor's algorithm** (Shor, 1994), which efficiently factors large integers—an essential task for cryptography. Classical algorithms struggle with factoring large numbers, making it a computationally hard problem. Today's encryption relies on that challenge. However, Shor's algorithm reduces the complexity of this problem and comes with a (near-)exponential speedup. In the future, this could potentially undermine widely used encryption systems like Rivest-Shamir-Adleman (RSA).

Another significant quantum algorithm is **Grover's algorithm** (Grover, 1996), which provides a quadratic speedup for searching unsorted databases, also referred to as “black-box search.” While classical search algorithms require linear time, Grover's algorithm can find an item in a database of n entries in roughly \sqrt{n} steps, offering a substantial efficiency gain, especially for large datasets.

These quantum algorithms significantly reduce the complexity of certain computational tasks, transforming problems previously considered practically unsolvable into ones that can be tackled more efficiently. While Shor's algorithm is constrained to integer factorization, Grover's can be applied to many search or optimization problems. In contrast, Shor's comes with a much larger speedup than Grover's. Furthermore, quantum algorithms specific to machine learning have been proposed (Schuld & Petruccione, 2021).

2.4 Impact on Computational Complexity

It must be highlighted that quantum computing will not revolutionize all computing. Rather, quantum computing affects a niche of specific computational problems. In theoretical computer science, problems are often categorized by their complexity classes, such as **P**, the problems solvable in polynomial time, and **NP**, the problems verifiable in polynomial time but not necessarily solvable in polynomial time (Aaronson, 2008). Quantum algorithms challenge this classification by offering solutions that fall into new or modified complexity classes, such as Bounded-Error Quantum Polynomial Time (**BQP**). **BQP** includes the problems that can be efficiently solved by a quantum computer.

Furthermore, **NP-complete** problems are a class of problems in computational complexity that are particularly challenging because they are both in **NP** and as hard as any problem in **NP**. This means that if a polynomial-time solution is found for one **NP-complete** problem, it would effectively solve all problems in **NP**. These problems, like the traveling salesperson problem, are widely believed to be intractable for both classical and quantum computers.

Example 7 Example problems in **P**, **NP**, **NP-complete**, and **BQP**:

- **P**: Prime number test
- **NP**: Graph isomorphism
- **NP-complete**: Traveling salesperson, $n \times n$ Sudoku, Boolean satisfiability problem (SAT)
- **BQP**: Integer factorization, black-box search (see Sect. 2.3)

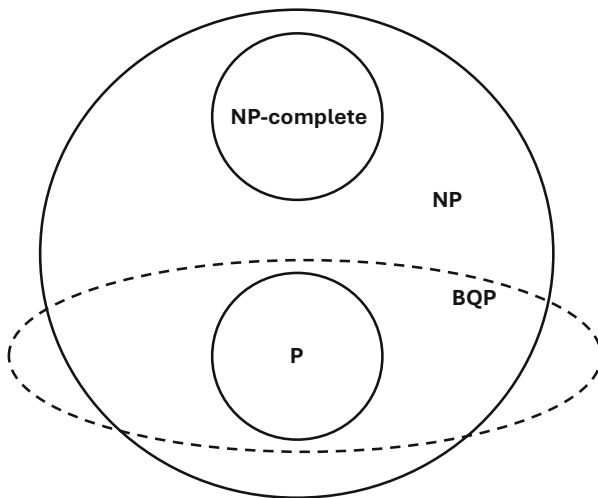


Fig. 1 Relationship of **P**, **NP**, **NP-complete**, and **BQP**. Inspired by Aaronson (2008)

The $P \stackrel{?}{=} NP$ question is one of the most fundamental unsolved problems in computer science, asking whether every problem whose solution can be quickly verified (NP) can also be quickly solved (P). If $P \stackrel{?}{=} NP$ were proven true, it would mean that many complex problems, including NP -complete ones, could be solved efficiently, revolutionizing fields such as cryptography, optimization, and beyond.

The relationship of these complexity classes is depicted in Fig. 1. It shows the niche of computational problems for which quantum computers look promising and that quantum computers will not revolutionize all computing.

2.5 Architectures of Quantum Computers

Quantum computing architectures vary significantly depending on their intended applications and underlying principles. *D-Wave Systems* has pioneered the development of **quantum annealers**, which are specialized quantum computers (Tasseff et al., 2024). Quantum annealers are not fully universal quantum computers but are today already highly effective for specific types of problems, particularly in fields like logistics and machine learning. Also, it has been questioned whether quantum annealers were actually “proper” quantum computers (Shin et al., 2014).

On the other hand, **universal quantum computers**, such as those being developed by IBM, aim to perform a broader range of computations by implementing general-purpose quantum gates (Acasiete et al., 2020). These systems are based on the circuit model of quantum computation, allowing them to run any quantum algorithm, including those that provide exponential speedups over classical algorithms. While currently still in active research development, universal quantum computers have the potential to address a wide array of complex problems across different domains, from cryptography to drug discovery, in the future.

While to date quantum annealers can have thousands of qubits and universal quantum computers have only dozens of qubits, the qubits in these two systems are not directly comparable. In addition, there are many other vendors with different approaches. A detailed comparison of those algorithms is beyond the scope of this chapter.

3 Challenges

Quantum computing holds immense potential. However, there are also major challenges that must be overcome to realize its full potential on large-scale, real-world problems. One of the primary hurdles is **deriving new algorithms**. Quantum computing operates at a fundamentally different level of abstraction compared to today’s classical computing, requiring a new way of thinking about problem solving. Early traditional computing required an understanding of binary logic and how to connect relays. This has changed over the last decades by the introduction of increasingly more abstract programming languages which are used by most

of today's software developers. The low level of abstraction in today's quantum algorithms makes the development process complex and intricate, as it demands deep understanding of quantum mechanics and often lacks the intuitive tools and methodologies available in classical computing.

Another critical challenge is **decoherence**, the loss of quantum coherence in qubits. Decoherence occurs due to interactions between qubits and their environment, leading to errors in computation. Maintaining quantum coherence for a sufficient duration to perform complex calculations requires extremely controlled environments and sophisticated error correction techniques, which are still under active research and development. Both decoherence and measurement add uncertainty to quantum computations. As a consequence, quantum algorithms are run many times on the same input in order to generate a distribution of outputs, helping to pick the most likely outcome.

Additionally, **debugging quantum programs** presents a unique challenge due to the nature of quantum measurement (Di Matteo, 2024). In quantum computing, measuring qubits collapses their quantum state, meaning that once you observe a qubit, its superposition or entanglement is lost and it can no longer participate in the computation. This makes traditional debugging techniques, which rely on inspecting the internal state of a program at various stages, impractical in quantum computing. In order to overcome this quantum-mechanical limitation, simulations on traditional computers are used (Metwalli & Van Meter, 2022). However, simulations themselves are severely limited and only work for small quantum systems.

4 Opportunities and Recent Developments

Quantum computing presents a multitude of opportunities for innovation and problem solving across various domains. The evolving landscape of quantum computing has garnered significant media attention, highlighting both breakthroughs and debates around its future.

There is a need for new and cheaper architectures that aim to improve quantum coherence times and reduce decoherence. Improved error correction techniques and innovative quantum chip designs may also help to pave the way for more stable quantum systems, enabling more reliable computations. Current works on these problems are vital as they directly impact the scalability and practicality of QC for real-world applications.

Quantum computing holds immense potential for various applications in numerous areas such as healthcare, artificial intelligence, cryptography, financial modeling, and logistics. While the potential of quantum computing is immense, some exaggerated warnings and calls for bans have emerged, particularly concerning its implications for cyber security and the potential misuse of quantum capabilities (Wadhwa & Kop, 2022). However, these concerns often lack technical in-depth expertise and overlook the nascent stage of the technology and its current and theoretical limitations. As quantum computing progresses, balanced discussions are needed to separate realistic challenges from overblown fears. Post-quantum

encryption methods have been proposed in recent years and respective standards have been released in 2024 (National Institute of Standards and Technology, 2024). IT companies have actively been working on those standards in order to transition to post-quantum encryption by the time larger quantum computers are available that could actually run Shor's algorithm on cracking real-world encryption keys.

Other than addressing the impact on traditional encryption, there is no need for quantum computing-specific regulation. Fears and demands for regulating quantum computing as a whole should be addressed by emphasizing the only niche of computational problems discussed in Sect. 2.4 for which quantum computing can actually lead to significant speedups. Despite the increased fearmongering and exaggerated warnings, regulators should stand back from regulating quantum computing horizontally as a whole similar to the European AI Act (Glauner, 2022). Such an approach would also primarily stifle innovation, reduce the competitiveness of companies and economies, and not lead to any concrete improvements.

The recent surge in interest and innovation around quantum computing is reflected in our courses at Deggendorf Institute of Technology³ (DIT):

- We teach the interdisciplinary “Quantum Computing” elective since 2021. It is open to all students at DIT. Our course provides an in-depth introduction to quantum computing in the first half of the term. In the second half of the term, students explore a specific topic related to quantum computing, either technical or related to business, on their own and give a seminar presentation on it. Our course has become very popular, and we have experienced that the number of students taking it has doubled every year. Having started with some 45 students in the first year, 90 students took it in the second year and eventually about 180 students took it in the third year. While we are very happy that our course has become the most successful elective at DIT within a short amount of time, we are facing the issue of adequately assessing the seminar presentations in a feasible amount of time. We have therefore capped the number of students to 100 as of 2024.
- Since 2020, we also teach a short introduction to quantum computing in the last week of our “Algorithms and Data Structures” course. Most of those—very important—foundations taught in such a course are some 50 years old. However, we chose to discuss it at the end of the course in order to provide an overview on how quantum computing has slowly started to change the field of algorithms and data structures and what consequences this comes with on computational complexity. As the field of quantum computing will evolve in the coming decades, we can already now prepare today's students for being able to understand and contribute to the quantum computing future.
- We extend that introduction in our “Big Data” course since 2023 and discuss how quantum computers could be used in the future in the fields of big data and machine learning in order to efficiently process large amounts of data.

³ See our lecture recordings at www.glauner.info/teaching.

5 Applications in Healthcare

Quantum computing is poised to revolutionize healthcare by addressing some of the industry's most complex and computationally intensive challenges. The unique capabilities of quantum computers, particularly their ability to process vast amounts of data and solve certain complex problems substantially, or even exponentially, faster than certain classical computers, open up several promising applications in healthcare.

One of the most promising applications of quantum computing in healthcare is in drug discovery. Quantum computers look promising to simulate molecular interactions at an atomic level. Compared to classical methods, this would allow researchers to identify potential drug candidates more quickly and accurately. For instance, quantum algorithms such as the Quantum Approximate Optimization Algorithm (QAOA) and Variational Quantum Eigensolver (VQE) could be used to simulate the behavior of complex molecules, reducing the time and cost associated with drug development. Recent studies have indicated the potential of quantum computing to accelerate drug discovery by efficiently exploring vast chemical spaces that are computationally infeasible for classical computers (Bauer et al., 2020; Cao et al., 2019).

Quantum computing could also significantly impact genomics and personalized medicine by enabling faster and more accurate analysis of genetic data. Quantum algorithms are being developed to solve optimization problems related to genome sequencing, which could lead to faster identification of genetic mutations linked to diseases and the development of personalized treatment plans. Research suggests that quantum machine learning techniques could enhance the analysis of large genomic datasets, providing new insights into disease mechanisms and patient-specific therapeutic approaches (Kösoglu-Kind et al., 2023).

Healthcare systems are complex, involving multiple stakeholders, resources, and constraints. Quantum computing offers powerful optimization capabilities that could improve various aspects of healthcare operations, from optimizing hospital resource allocation and patient scheduling to streamlining supply chains for pharmaceuticals and medical equipment. Quantum-inspired optimization methods have been explored to improve decision-making processes in healthcare logistics, enhancing operational efficiency and reducing costs (The PSC, 2023).

Quantum computing has the potential to revolutionize clinical trial design by optimizing patient recruitment, stratification, and data analysis, significantly reducing the time and cost required to bring new treatments to market. Quantum algorithms can analyze vast datasets more efficiently than certain classical methods, identifying suitable candidates and predicting patient responses with greater accuracy. This could accelerate the development of new therapies and enhance personalized medicine approaches (Doga et al., 2024).

6 Conclusions and Outlook

Quantum computing holds the potential to significantly improve the complexity of certain computational problems, offering unprecedented speed and efficiency. However, a meaningful discussion of this potential requires a deep understanding of quantum mechanics, mathematics, and algorithm design, as these foundations underpin the technology's capabilities. Nonetheless, significant challenges remain, including maintaining quantum coherence, developing effective error correction techniques and creating new algorithms that leverage quantum principles. Additionally, the field faces obstacles in translating theoretical advancements into practical, scalable quantum computing solutions that can reliably address real-world problems.

The future of quantum computing in healthcare is highly promising, though the significant challenges mentioned before remain. As quantum computing technology matures, we can expect more sophisticated applications in healthcare, such as better real-time patient monitoring and diagnosis, predictive modeling of disease outbreaks, and quantum-enhanced AI for drug discovery and personalized treatment. Collaborative efforts between academia, industry, and healthcare providers will be crucial to harnessing the full potential of quantum computing in healthcare.

Use of Generative AI Tools

ChatGPT has assisted the author in writing this chapter, in particular drafting some of the structure and turning various shorthand notes into sentences.

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Transforming Healthcare with AI: Practical Insights into Leveraging Large Language Models

Linn Bieske

Abstract

The chapter, *Transforming Healthcare with AI: Practical Insights into Leveraging Large Language Models*, explores the transformative potential of Large Language Models (LLMs) in the healthcare industry. It provides a comprehensive overview of the capabilities of LLMs, describes practical applications, and outlines the remaining challenges for their effective adoption. Overall, LLMs could play a critical role in enhancing patient care, streamlining administrative tasks, and accelerating medical research. This chapter equips readers with actionable knowledge on how to leverage LLMs responsibly and effectively. A step-by-step playbook offers guidance for developing AI assistants tailored to specific healthcare workflows. Additionally, the chapter addresses the importance of ethical adoption and the setup of a robust infrastructure to maximize AI's benefits.

1 Introduction: Contextualizing the Chapter Within the Book

The rapid advancement of artificial intelligence (AI) is also reshaping the healthcare industry in profound ways, with Large Language Models (LLMs) emerging as a particularly transformative force (Topol, 2019; Brown et al., 2020). As these

Note: The grammar and language of this chapter was improved with ChatGPT (OpenAI, 2024).

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models become increasingly sophisticated, their potential to revolutionize various aspects of healthcare—ranging from workflow automation to enhancement of the drug discovery process—cannot be overstated (Topol, 2019; Brown et al., 2020). However, with this potential comes a set of challenges and misconceptions that need to be carefully examined (Reddy et al., 2019).

This chapter, *Debunking Large Language Models—Practical Considerations for the Healthcare Industry*, aims to provide a comprehensive overview of LLMs, shedding light on their capabilities, the companies driving their development, and the practicalities of integrating these models into healthcare settings. Positioned within the broader context of this book, the chapter serves as a bridge between the technical foundations of AI and its real-world applications in healthcare.

1.1 Connecting to Previous Chapters

The preceding chapters have explored the transformative impact of cutting-edge IT on personalized medicine, as well as the role of business process automation in reducing the workload of medical staff. These discussions have highlighted the importance of leveraging advanced technologies to enhance patient care and streamline healthcare operations. LLMs, with their ability to process vast amounts of textual data and generate human-like responses, are a natural extension of these themes. They offer new possibilities for personalizing patient interactions, improving diagnostic accuracy, and automating routine tasks.

1.2 Setting the Stage for Subsequent Chapters

Looking ahead, the book will delve into the broader transformation of the healthcare sector, examining how digitalization and technology are driving change beyond mere operational improvements. This chapter serves as a precursor to those discussions by addressing the specific role of LLMs in this transformation. By understanding both the opportunities and limitations of these models, healthcare professionals and decision-makers can better navigate the complexities of AI adoption and ensure that these technologies are implemented in ways that truly benefit patients and providers alike.

1.3 Chapter Objectives

This chapter is designed to equip readers with a foundational understanding of LLMs, demystifying their capabilities and addressing common misconceptions. It will explore the key players in LLM research and development, discuss data privacy and infrastructure considerations, and highlight potential application areas within the healthcare context. Finally, it will offer practical tips for developing

customized AI assistants, ensuring that readers can translate theoretical knowledge into actionable insights.

As we embark on this exploration of LLMs, it is important to approach these technologies with both optimism and caution. While LLMs offer tremendous potential, their successful integration into healthcare requires careful planning, ethical consideration, and a clear understanding of their strengths and limitations. This chapter aims to provide the knowledge and tools necessary to harness the power of LLMs responsibly and effectively within the ever-evolving landscape of healthcare.

2 Understanding Large Language Models

Large Language Models (LLMs) are a cutting-edge type of artificial intelligence (AI) designed to understand and generate human language. These models have become essential tools in AI, capable of performing a wide range of tasks that involve processing and creating text in a way that closely mimics human communication (Brown et al., 2020).

One of the most notable LLMs, OpenAI's GPT-3, exemplifies the immense scale and capability of these models. GPT-3 is built with 175 billion parameters, which are essentially the fine-tuned components that allow the model to recognize and replicate complex patterns in language. The vast number of parameters equips LLMs with the ability to capture the nuances of human language, resulting in more sophisticated text generation and understanding (Brown et al., 2020).

LLMs are typically trained on massive datasets that include a variety of publicly available text, images, code, and other forms of data. This extensive training allows them to become proficient in several key tasks, including (Brown et al., 2020; Minaee et al., 2024):

- *Text classification*: Sorting text into categories or identifying sentiment (Minaee et al., 2024).
- *Text translation*: Converting text from one language to another while maintaining meaning and context (Minaee et al., 2024).
- *Conversations*: Engaging in natural language dialogues, often indistinguishable from human conversation (Minaee et al., 2024).
- *Reasoning about documents*: Analyzing and extracting relevant information from text, making it easier to navigate complex documents (Minaee et al., 2024).
- *Organization and curation of knowledge*: Sorting and presenting information in a structured way, enhancing access to important insights (Minaee et al., 2024).
- *Ideation and text generation*: Creating original content, such as articles, stories, or technical documents, based on prompts (Minaee et al., 2024).
- *Information retrieval*: Efficiently locating and retrieving specific information from large datasets or documents, improving research and data analysis processes (Minaee et al., 2024).

A significant development in the evolution of LLMs is the emergence of *multimodal models*, which extend the capabilities of traditional LLMs beyond text. Multimodal models are designed to process and generate multiple types of data, including text, images, audio, and video. This capability allows them to perform tasks such as generating descriptive captions for images, creating visual representations of text, and even analyzing multimedia content in a unified way (Minaee et al., 2024; Meskó, 2023).

In summary, Large Language Models are powerful AI tools that have revolutionized the way we interact with and process language. Their ability to handle a variety of tasks with high accuracy and their evolution into multimodal models underscores their significance in advancing technology across various industries, including healthcare, education, and beyond (Brown et al., 2020; Minaee et al., 2024).

3 Relevance of Large Language Models to the Healthcare Industry

Large Language Models (LLMs) are increasingly critical in healthcare due to their ability to process and generate human-like text efficiently. Their relevance spans several key areas:

1. *Enhancing Patient Care*: LLMs can personalize treatment plans by analyzing vast amounts of patient data, medical literature, and real-time information. They improve patient communication through AI-driven chatbots, offering tailored health information and advice (Topol, 2019; Thirunavukarasu et al., 2023).
2. *Streamlining Administrative Tasks*: LLMs automate time-consuming administrative processes, such as clinical documentation, appointment scheduling, and billing, reducing the workload on healthcare staff and minimizing errors (Topol, 2019; Gebreab et al., n.d.).
3. *Supporting Clinical Decision-Making*: LLMs provide real-time access to the latest research and guidelines, aiding clinicians in making evidence-based decisions. They can offer diagnostic suggestions and treatment options based on comprehensive data analysis (Topol, 2019; Hacking, 2024).
4. *Accelerating Medical Research and Drug Discovery*: LLMs analyze large datasets and generate insights that can speed up the research process, from clinical trial design to hypothesis generation, leading to quicker drug development (Topol, 2019; Thirunavukarasu et al., 2023).
5. *Improving Information Retrieval*: LLMs help healthcare professionals quickly locate relevant data from extensive medical databases, ensuring they have the latest information for decision-making and research (Gebreab et al., n.d.; Hacking, 2024).

Overall, LLMs are transforming healthcare by enhancing care delivery, improving operational efficiency, supporting research, and enabling better patient outcomes through their advanced text-processing capabilities (Gebreab et al., [n.d.](#); Hacking, 2024; Topol, 2019).

4 Key Players in LLM and Multimodal Model Development

Several leading companies are at the forefront of research and development in Large Language Models (LLMs) and multimodal models. These organizations have pioneered advancements that significantly expand the capabilities and applications of these technologies:

- *OpenAI*: Known for developing the Generative Pre-trained Transformer (GPT) series, including GPT-3 and GPT-4, OpenAI has been a trailblazer in the field of LLMs. These models are renowned for their ability to generate human-like text and perform complex tasks across various domains. OpenAI's work has set the standard for what LLMs can achieve, particularly in natural language understanding and generation (Minaee et al., 2024).
- *Google*: Through its AI research division, Google has developed powerful models like BERT (Bidirectional Encoder Representations from Transformers) and LaMDA (Language Model for Dialogue Applications). Google's research has focused on improving language understanding, enabling more accurate and context-aware responses. Google is also heavily invested in multimodal models that can process text, images, and other data types, enhancing the versatility of AI systems (Minaee et al., 2024).
- *Meta (formerly Facebook)*: Meta has been actively developing models like OPT (Open Pre-trained Transformer) and has made significant contributions to multimodal AI with models like CLIP (Contrastive Language–Image Pre-training). These models are designed to understand and generate content across multiple formats, including text, images, and video, making them highly relevant for diverse applications in the healthcare industry (Minaee et al., 2024).
- *Hugging Face*: Hugging Face is a key player in the democratization of AI, particularly in the area of LLMs. They offer an extensive library of pre-trained models through the Hugging Face Transformers library, which is widely used by researchers and developers for building and fine-tuning LLMs. Hugging Face has fostered a strong community around open-source AI tools, making it easier for healthcare organizations to experiment with and deploy LLMs tailored to their specific needs (Wolf et al., [n.d.](#)).
- *Anthropic*: Anthropic is a newer but influential player in AI, focusing on creating LLMs with a strong emphasis on safety and alignment. Their work aims to ensure that AI systems, including LLMs, behave in ways that are beneficial and aligned with human values. This focus is particularly important in healthcare, where the implications of AI decisions can directly impact patient outcomes (Anthropic, 2024).

5 Data Privacy and Infrastructure Considerations

The integration of Large Language Models (LLMs) and other AI technologies into healthcare brings immense potential to improve patient care and operational efficiency. However, it also introduces significant challenges, particularly regarding data privacy and infrastructure. Protecting patient data, ensuring regulatory compliance, and maintaining the security of sensitive information are critical concerns that healthcare organizations must address when adopting these technologies (Price & Cohen, 2019; Murdoch, 2021).

5.1 Importance of Protecting Data and Patient Privacy

Healthcare data is among the most sensitive types of information. It includes personal identifiers, medical histories, treatment plans, and other private details that, if compromised, could lead to severe consequences for patients, including identity theft, discrimination, or misuse of medical information. As such, safeguarding this data is not only a legal obligation but also an ethical one (Price & Cohen, 2019; Goodman & Flaxman, 2017).

The privacy of patient data is governed by strict regulations, such as the Health Insurance Portability and Accountability Act (HIPAA) in the United States and the General Data Protection Regulation (GDPR) in Europe (Goodman & Flaxman, 2017; Rule, 2022). These regulations mandate that healthcare providers take robust measures to protect patient information, including when using third-party services like AI models. Failure to comply can result in substantial fines and legal actions, as well as damage to the organization's reputation (Goodman & Flaxman, 2017).

5.2 Risks of Data Leakage and AI Training

One of the significant risks when engaging with AI providers is the potential for data leakage. If not properly managed, patient data could inadvertently become part of the AI's training data, leading to its integration into the model's knowledge base. This can happen if the terms of service allow the AI company to use customer data for ongoing training and model improvement (Ayyamperumal & Ge, 2024; Janryd & Johansson, 2024).

If patient data becomes part of an AI model's training set, there are several risks:

1. *External Access to Sensitive Information:* Once integrated into the AI model, the information could potentially be retrieved by other users outside the healthcare organization. This could occur if the AI generates responses that inadvertently reveal specific details about patient cases (Ayyamperumal & Ge, 2024; Janryd & Johansson, 2024).

2. *Loss of Data Control*: The healthcare organization may lose control over how the data is used, making it difficult to ensure that it is being handled in compliance with privacy regulations (Murdoch, 2021; Mittelstadt, 2019).

Data protection in healthcare can be guaranteed, but it requires a significant infrastructure investment (Ransbotham et al., 2017). Organizations need to build robust, secure environments to safeguard patient data while leveraging AI technologies (Ransbotham et al., 2017). Notably, as AI models evolve, they are becoming smaller and more efficient, which opens the possibility of hosting them locally on-premises rather than relying solely on cloud services. This shift can further enhance data security by keeping sensitive information within the organization's own infrastructure (Irugalbandara et al., n.d.).

6 Potential Applications Areas in the Healthcare Context

Generative AI (GenAI) and Large Language Models (LLMs) are revolutionizing the healthcare sector by bringing enhanced efficiency, accuracy, and personalization to various tasks. One significant area where GenAI is making a difference is in protocol development. By analyzing vast amounts of existing research, guidelines, and historical trial data, GenAI can generate initial drafts of clinical trial protocols, identifying gaps, suggesting improvements, and ensuring compliance with regulatory standards. This capability streamlines the protocol creation process, saving time and improving quality (Maleki, 2024).

Another area where GenAI excels is site engagement. It automates routine communication with clinical trial sites, generating tailored updates and responding to queries in real-time. This reduces the administrative burden on trial coordinators and ensures that sites receive timely and relevant information, which is crucial for the smooth operation of clinical trials (ZiHang et al., n.d.; Ethape et al., 2023).

In data analysis, GenAI's ability to process and analyze large, complex datasets from clinical trials and electronic health records (EHRs) is invaluable. It can identify patterns, trends, and correlations that might not be immediately apparent, enabling more accurate and insightful conclusions that support better decision-making in healthcare (Lee et al., 2020; Alsentzer et al., 2019).

GenAI also transforms report writing by automating the generation of clinical study reports, research papers, and regulatory submissions. It synthesizes and structures data into clear, coherent documents, speeding up the report-writing process and ensuring consistency and adherence to required formats. This capability is particularly beneficial in a field where precise and timely reporting is critical (Topol, 2019; Gebreab et al., n.d.).

Finally, in patient engagement, GenAI-driven chatbots and virtual assistants offer personalized, real-time responses to patient inquiries, provide reminders for medication or appointments, and deliver tailored health information. This enhances patient satisfaction and adherence to treatment plans, ultimately leading to better health outcomes. By processing large volumes of information and generating personalized

content, GenAI significantly improves the speed, quality, and effectiveness of healthcare processes (Topol, 2019; Gebreab et al., n.d.; He et al., 2020).

7 Practitioner Playbook: How to Develop Customized AI Assistants

This chapter is developed based on the author's research and experience with generative AI systems. The intention is to provide a playbook for practitioners to guide the development of customized AI assistants.

Developing customized AI assistants tailored to the unique needs of healthcare practitioners requires a strategic approach that begins with identifying the right workflows, collecting the necessary data, and ensuring that the AI is designed to meet specific objectives. This playbook provides a step-by-step guide to help healthcare organizations create effective AI assistants.

7.1 Identify Workflows That Should Be AI Assisted

The first step in developing a customized AI assistant is to identify the specific workflows that could benefit from AI assistance. Start by mapping out the entire workflow, clearly defining the start and end points. This process involves analyzing current practices to determine where AI can provide the most value, whether by automating routine tasks, enhancing decision-making, or improving communication.

Key considerations include:

- *Workflow Mapping*: Break down the workflow into individual tasks, identifying which ones could be streamlined or improved through AI.
- *Start and End Points*: Clearly define the entry and exit points of the workflow, ensuring that the AI's role is well-defined and integrated into the broader process.
- *Efficiency Gains*: Determine how AI can make the workflow more efficient, either by speeding up processes, reducing errors, or improving accuracy.

7.2 Collect the Required Data

Once the relevant workflows have been identified, the next step is to collect the data necessary to train and instruct the AI assistant. This data collection should span several key categories to ensure that the AI is well-informed and capable of performing its intended functions.

- *Context Knowledge Documents*: Gather domain-specific knowledge, such as research articles, clinical guidelines, and case studies, that can make the AI assistant more specialized in a particular area, such as a specific disease domain.

- *Process Descriptions and Standards*: Collect detailed process descriptions and standards that will inform the AI's logic. This information will help structure how the AI should be instructed and prompted to perform specific tasks. For example, providing the AI with standard operating procedures (SOPs) will guide its decision-making and response patterns.
- *Input Data*: Define and provide examples of the expected input data the AI will handle. This might include patient records, laboratory results, or other structured data inputs. Alternatively, define templates that the AI can use to understand the format and structure of incoming data.
- *Output Data*: Establish the desired output format, which could be structured templates like Word documents or PowerPoint presentations. This ensures that the AI outputs organized and accessible information, ready for immediate use by healthcare practitioners.

7.3 Difference Between Instructions and Prompting

Instructions and *prompting* are both methods used to guide the behavior of a GPT model, but they serve slightly different purposes and are applied in different contexts. Here's a breakdown of the differences:

7.3.1 Instructions

Purpose Instructions are detailed, often step-by-step guidelines provided to the model (or users of the model) to ensure that the output meets specific requirements. Instructions aim to set clear expectations and provide a framework for how the model should behave or what it should produce.

Application Instructions are typically used when setting up a customized GPT model for a particular task or series of tasks. They provide the foundational rules and boundaries within which the model operates. This might include defining the tone, format, scope, and content that the model should adhere to when generating responses.

Example:

- "Always start by summarizing the patient's medical history before providing treatment options."
- "Use formal language appropriate for a medical research paper."
- "Focus on the key findings of the study without including any speculative or unverified information."

Characteristics:

- Instructions are generally more detailed and comprehensive.
- They serve as the "rules of engagement" for the model.

- Instructions often cover multiple aspects of the task, such as content, structure, tone, and format.
- They are foundational and often provided during the initial setup or configuration of the model.

7.3.2 Prompting

Purpose Prompting involves giving the model a specific, often one-time input that directly triggers a response. A prompt is a query or a request that guides the model to generate a particular output. Unlike instructions, prompts are usually shorter and more focused on a single interaction or task.

Application Prompts are used in real-time interactions with the model to elicit a specific response. They are often tailored to the immediate needs of the user and can vary widely depending on what information or action is required from the model at that moment.

Example:

- “Summarize the key results of the latest clinical trial on Drug X.”
- “List the inclusion criteria for the Phase II study.”
- “Explain the mechanism of action for this medication in simple terms.”

Characteristics:

- Prompts are typically brief and task-specific.
- They are used on a per-interaction basis to guide the model’s immediate output.
- Prompts can be dynamic, changing with each interaction based on the user’s needs.
- They rely on the model’s existing training and instructions to generate the desired output.

7.4 Developing of Instructions

7.4.1 Develop Clear and Specific Instructions

- *Identify as a Persona:* When crafting instructions, consider identifying the model as a specific persona or role. For example, instruct the model to “act as a healthcare provider” or “respond as a medical researcher.” This helps the model align its responses with the expectations and tone appropriate to that role.
- *Contextualize Instructions:* Provide context for the task at hand. For example, if the model is to generate patient reports, briefly describe the patient’s condition or the report’s purpose to guide the model’s focus.
- *Specify Formatting Requirements:* If specific formatting is important (e.g., bullet points, headings, or sections), include these details in the instructions. For instance, you might say, “Summarize the findings in bullet points under the heading ‘Key Takeaways.’”

- *Prioritize Information:* If certain information is more critical than others, instruct the model to emphasize or prioritize that content. For example, “Focus on summarizing the most recent studies first.”

7.4.2 Iterate and Refine

- *Use a Feedback Loop:* After testing the model with initial instructions, create a feedback loop where end-users or stakeholders provide input on the model’s outputs. This feedback can guide adjustments and refinements to improve accuracy and usefulness.
- *Introduce Gradual Complexity:* Start with simple instructions and gradually introduce more complex tasks as the model’s performance improves. This approach allows you to refine the instructions incrementally and ensure that the model handles each step effectively before moving on to more challenging tasks.
- *Simulate Real-World Scenarios:* Test the model in scenarios that closely mimic its intended use in practice. For instance, simulate a patient consultation or a research meeting to evaluate how well the model performs in a realistic context.

7.4.3 Ensure Clarity and Simplicity

- *Use Layered Instructions:* For more complex tasks, provide instructions in layers. Start with a high-level overview of the task, then break it down into more detailed steps. This helps the model understand the task’s overall structure before diving into specifics.
- *Avoid Ambiguity with Examples:* If there’s a potential for ambiguity, provide multiple examples to illustrate different scenarios. For instance, show examples of both acceptable and unacceptable outputs to clearly define boundaries.
- *Establish a Consistent Tone:* Ensure that the language and tone used in the instructions match the desired output style. If the model is meant to be formal and professional, the instructions should reflect that tone to reinforce consistency in the generated responses.
- *Use Positive Reinforcement:* Phrase instructions positively, focusing on what the model should do rather than what it shouldn’t. For example, say, “Highlight key symptoms and treatment options” rather than “Don’t include irrelevant details.”

By incorporating these additional tips, you can further refine the instructions for your customized GPT model, ensuring that it delivers accurate, relevant, and contextually appropriate outputs aligned with your specific needs.

7.5 How to Develop a Good Prompt for Clinical Trial Protocol Writing

Creating an effective prompt for a GPT model to assist in clinical trial protocol writing involves providing clear, specific, and contextually relevant instructions. Here’s how to craft such a prompt, along with an example tailored to clinical trial protocol writing.

7.5.1 Be Clear and Specific

- *Define the Objective:* Clearly state what section of the clinical trial protocol you want the GPT model to draft or refine. For example, you might want the model to create the “Study Design” section or to summarize the “Inclusion and Exclusion Criteria.”
- *Include Relevant Context:* Provide the model with necessary background information about the trial, such as the therapeutic area, phase of the trial, and key objectives. For instance, “This trial is a Phase II study evaluating the efficacy and safety of Drug X in patients with moderate to severe asthma.”
- *Avoid Ambiguity:* Ensure that the prompt leaves no room for multiple interpretations. If you need a detailed description, specify this in the prompt. For example, “Describe the randomization process in detail, including the method used and how it ensures unbiased treatment assignment.”

7.5.2 Structure the Prompt Appropriately

- *Use Step-by-Step Instructions:* Break down the tasks into steps if the section is complex. For example, “First, outline the primary and secondary objectives of the study. Then, describe the study design, including the type of study, duration, and primary endpoints.”
- *Set the Tone and Style:* Specify that the writing should adhere to formal, scientific language appropriate for a clinical trial protocol. For instance, “Write the Study Design section in a formal, precise manner suitable for regulatory submission.”
- *Incorporate Examples:* If possible, include an example of a well-written section to guide the model. For example, “Use the following format for the Study Design section: ‘This is a randomized, double-blind, placebo-controlled, multicenter Phase II study designed to evaluate...’.”

7.5.3 Tailor the Prompt to the Audience

- *Identify the Audience:* The clinical trial protocol is typically reviewed by regulatory bodies, ethics committees, and clinical investigators. Guide the model to write with this audience in mind. For example, “Write the protocol section with the assumption that the audience is familiar with clinical trial terminology but needs clear and unambiguous instructions.”
- *Set the Role or Persona:* Instruct the model to take on the role of a clinical research coordinator or medical writer drafting the protocol. For example, “As a clinical research coordinator, draft the Study Design section of the protocol, ensuring it is comprehensive and aligns with ICH GCP guidelines.”

7.5.4 Limit the Scope

- *Focus the Response:* Direct the model to concentrate on a specific part of the protocol. For example, “In this prompt, focus solely on describing the randomization process and blinding methodology. Exclude any details related to statistical analysis or patient follow-up.”

- *Exclude Irrelevant Information:* Make it clear what should not be included. For example, “Do not include information about the statistical analysis plan in this section.”

7.5.5 Iterate and Refine

- *Test and Adjust:* After generating the initial draft, review it for accuracy, completeness, and clarity. If necessary, refine the prompt to address any issues. For example, “If the randomization process is not clearly explained, add more detail about the method used and how patient allocation will be managed.”
- *Seek Feedback:* If the protocol is part of a collaborative effort, gather feedback from colleagues or other stakeholders. Use their input to further refine the prompt. For instance, “Based on feedback, emphasize the importance of the blinding process in maintaining study integrity.”

7.5.6 Use Conditional Statements

- *Guide the Model’s Logic:* Use conditional statements to help the model adapt its response based on specific criteria. For example, “If the study includes multiple arms, describe the allocation ratio and blinding for each arm separately.”

7.5.7 Example of a Good Prompt for Clinical Trial Protocol Writing

Objective Draft the Study Design section for a Phase II clinical trial protocol.

Prompt “As a clinical research coordinator, draft the Study Design section for a Phase II trial evaluating the efficacy and safety of Drug X in patients with moderate to severe asthma. The study is a randomized, double-blind, placebo-controlled, multicenter trial. Include details on the randomization process, blinding methodology, study arms, duration, and primary endpoints. Ensure that the writing is formal and adheres to ICH GCP guidelines. Focus only on the study design, excluding any information related to statistical analysis or patient follow-up.”

In this example, the prompt is clear, specific, and tailored to the task. It provides the model with the necessary context, defines the scope of the response, and sets the tone for the writing, ensuring that the output is relevant and useful for developing a clinical trial protocol.

7.6 Available Resources and Inspiration

ChatGPT provides an expansive ecosystem akin to an app store, where users can share and access customized GPTs tailored to specific tasks. This ecosystem includes a wide array of specialized ChatGPTs that have been developed to address various needs, making it a valuable resource for exploration. For instance, a search query such as “clinical trial protocol” yields multiple options designed to assist in the development or review of protocol drafts (see Fig. 1).

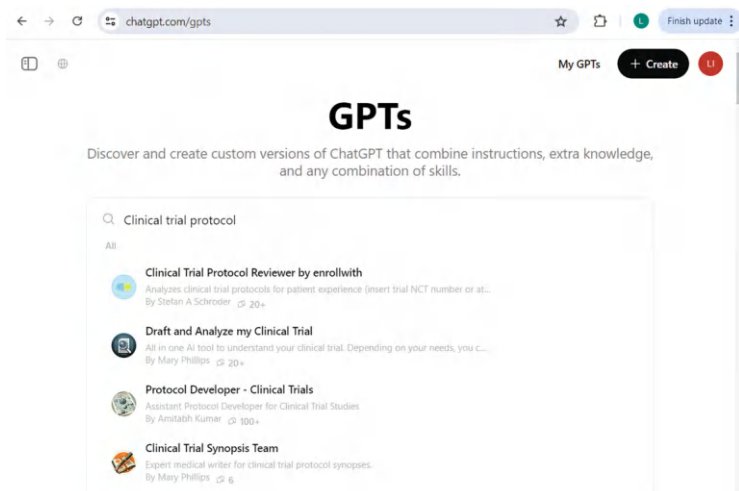


Fig. 1 Customized ChatGPTs publicly available for the search term “clinical trial protocol”

However, it is essential for healthcare organizations to exercise caution when utilizing these publicly available tools. Direct adoption of these GPTs without proper data protection measures could pose significant risks. Nevertheless, these customized GPTs can serve as valuable references, offering templates and highlighting potential use cases that can be adapted and implemented in a secure and compliant manner.

For example, the customized GPT titled “Protocol Developer—Clinical Trials” allows users to generate a protocol synopsis by simply entering a prompt such as “give me an example protocol synopsis” (see Fig. 2). The model then produces a draft protocol outline directly within the chat interface (see Fig. 3). Users can further refine this synopsis by providing additional prompts, enabling iterative development of the protocol. The resulting document can be copied into a Word file, or, with newer versions of ChatGPT, the user can instruct the model to create and directly download a Word document, thereby streamlining the process and enhancing efficiency.

This ecosystem offers significant potential for healthcare professionals seeking to enhance their workflows, providing both inspiration and practical tools for developing customized solutions.

7.7 Building Your Own Customized ChatGPT

This section provides a comprehensive guide for creating a customized AI assistant, using the fictitious example of a weight loss drug to ensure confidentiality. The focus here is on equipping medical experts with the knowledge needed to instruct

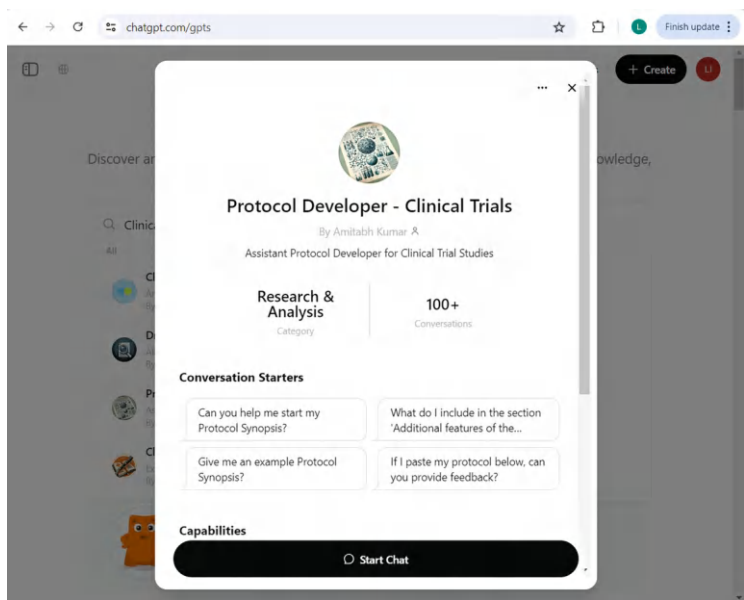


Fig. 2 Publicly available customized ChatGPT titled “Protocol Developer—Clinical Trails”

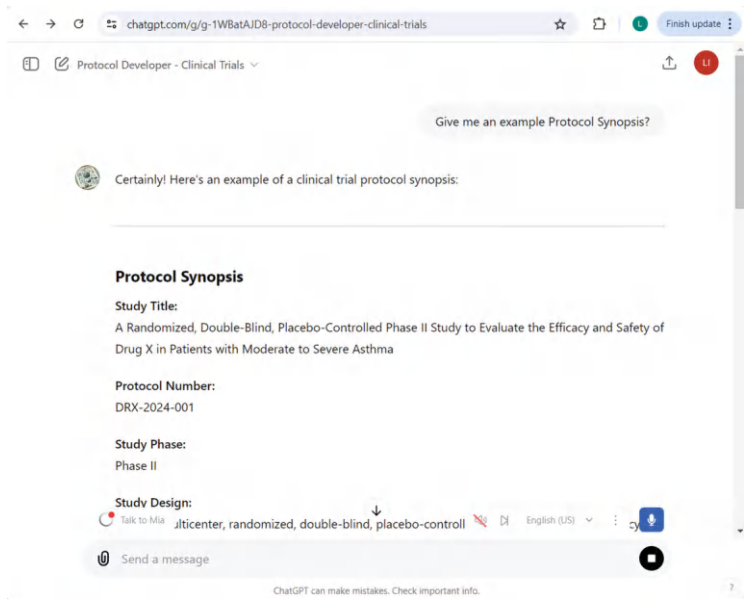


Fig. 3 Example of a protocol synopsis generated by the customized ChatGPT titled “Protocol Developer—Clinical Trials”

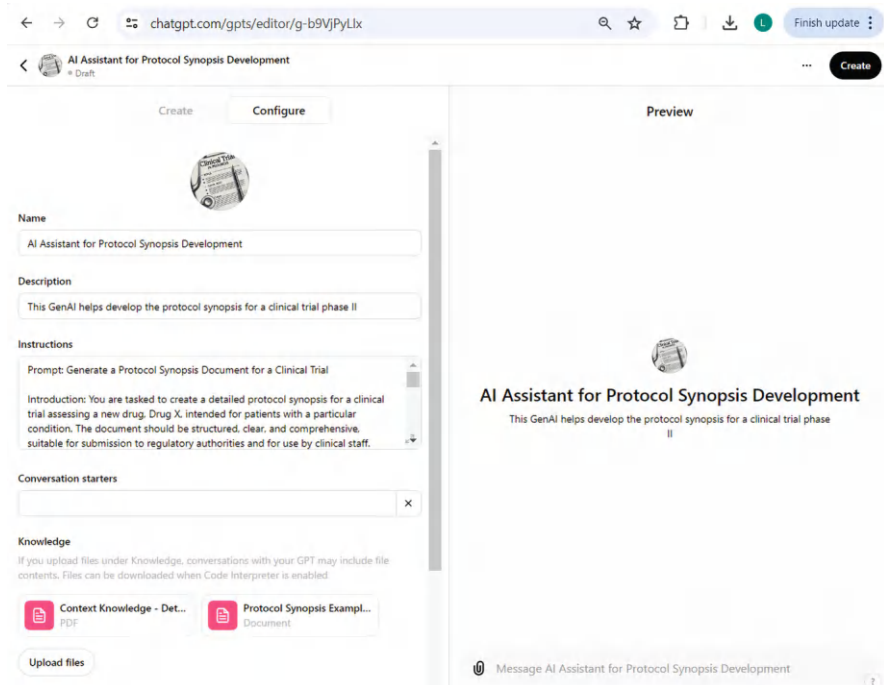


Fig. 4 Configuration interface for a customized ChatGPT. The left side shows the definition of instructions and the upload of context knowledge and output templates, making the GPT domain-specific and task-specific. The right side displays the available chat interface

ChatGPT to retrieve and organize information, rather than delving into the chemical and biological specifics of the example.

Once you have clearly defined your workflow, gathered the necessary data, and grasped the principles of instruction and prompt writing, you will be well-prepared to develop your own customized AI assistant. Subscribing to the ChatGPT Plus service grants access to a configuration interface (see Fig. 4), where you can customize various aspects of your AI assistant. This includes naming your assistant, providing a description, writing instructions, creating conversation starters, and uploading relevant knowledge documents.

The instructions you provide are crucial, as they guide the logic that your customized GPT will follow. It is essential to refine these instructions iteratively until the AI behaves as desired. Figure 5 offers a detailed view of the developed instructions. Notably, generative AI can assist in this process. For example, by asking a different ChatGPT instance to help develop instructions based on the desired output format, you can accelerate the process and ensure clarity.

In this example, two types of knowledge documents are uploaded: general context knowledge and specific information related to the targeted indication or drug, such as the fictitious weight loss drug “Silomaxatin.” After configuring

Prompt: Generate a Protocol Synopsis Document for a Clinical Trial

Introduction: You are tasked to create a detailed protocol synopsis for a clinical trial assessing a new drug, Drug X, intended for patients with a particular condition. The document should be structured, clear, and comprehensive, suitable for submission to regulatory authorities and for use by clinical staff.

Document Specifications:

1. **Format:** Professional, well-organized, and easy to navigate.
2. **Language:** Formal, precise, and devoid of ambiguity.
3. **Target Audience:** Clinical researchers, regulatory bodies, and potential trial sites.

Content Requirements:**1. Study Title:**

- Include a concise title that reflects the design and purpose of the study.
- Example: "A Randomized, Double-Blind, Placebo-Controlled Phase II Study to Evaluate the Efficacy and Safety of Drug X in Patients with Moderate to Severe Asthma."

2. Protocol Number:

- Provide a unique identifier for the study.
- Example: "DRX-2024-001"

3. Study Phase:

- Specify the phase of the clinical trial.
- Example: "Phase II"

4. Study Design:

- Describe the type of study, highlighting its main characteristics (multicenter, randomized, double-blind, placebo-controlled).
- Explain briefly the purpose of the study design.

Fig. 5 Screenshot of instructions for customizing ChatGPT to develop a protocol synopsis outline

these elements, you simply click the “Create” button in the top right corner to generate your personalized AI assistant, tailored specifically to protocol synopsis development. This AI agent is customized to the context you provided and operates according to the instructions you defined.

Next, you can prompt your AI assistant to generate a protocol synopsis. You can then refine the output by providing additional prompts in the chat window until the generated response meets your expectations. Finally, you can request the AI to create a Word document that you can download (see Fig. 6). Alternative output formats, such as PowerPoint presentations, are also possible, and formatting style guides can be uploaded as knowledge documents to ensure consistency.

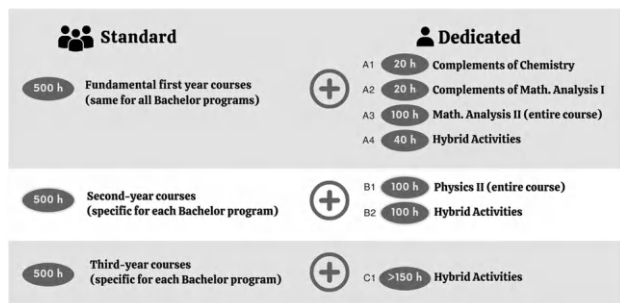


Fig. 6 Screenshot of the customized AI assistant. ChatGPT enables the direct download of a Word document with the developed synopsis outline, integrating smoothly into business workflows

By following these steps, you can create a highly specialized AI assistant tailored to your specific needs, streamlining the process of protocol development and other complex tasks.

8 Outlook: The Future of Customized AI Assistants

The landscape of artificial intelligence, particularly in the realm of generative models like ChatGPT, is evolving at an unprecedented pace. Several key developments are poised to reshape how AI is utilized across various domains, including healthcare.

What Comes Next?

One significant trend is the movement toward *multimodal and multi-domain models*. These models will integrate text, images, audio, and other data types, allowing them to operate across diverse fields and applications. However, to transform these powerful yet generic models into tools that deliver specific, actionable insights, they will still require rich and contextually relevant information. Customization will remain crucial for refining these models for specialized tasks.

The pace of *development in AI* is astonishing, with new features and capabilities being released weekly. This rapid innovation means that the tools available today will continue to evolve, offering even greater functionality and flexibility. Staying informed about these advancements will be critical for organizations that want to leverage the full potential of generative AI.

To truly harness the power of these evolving AI models, a significant *upskilling of the workforce* will be necessary. As AI becomes more integrated into everyday tasks, professionals across all sectors will need to develop new skills, particularly in how to effectively instruct and interact with AI systems. Training programs and continuous education will be key to ensuring that the workforce can fully exploit these advanced tools.

However, the *healthcare industry faces the challenge* of implementing the necessary infrastructure to support these innovations while ensuring data protection and regulatory compliance. The sensitive nature of healthcare data demands robust security measures and strict adherence to frameworks like HIPAA and GDPR. Establishing and maintaining this infrastructure will require significant investment and careful planning to meet the high standards required for patient data protection.

Moreover, as AI continues to mature, organizations must *carefully scope their use cases* to ensure a positive return on investment (ROI). While the potential applications of AI are vast, not all may lead to meaningful improvements or cost savings. Strategic planning and careful analysis are required to identify the most beneficial use cases where AI can significantly enhance efficiency, accuracy, or innovation.

Finally, AI models will become *smaller and less data and compute hungry*, making them more ubiquitous. These advancements will lower the barriers to entry, allowing more organizations, including those with limited resources, to deploy customized AI solutions. As these models become more accessible and efficient, their presence will be felt in an even wider array of applications, driving further innovation and integration into everyday processes.

In conclusion, the future of AI is both exciting and challenging. The ongoing developments in multimodal and multi-domain capabilities, coupled with the rapid pace of innovation, will offer unprecedented opportunities. However, to fully capitalize on these advancements, organizations must invest in workforce training, carefully select their AI use cases, and stay agile in adapting to new technologies. Additionally, the healthcare industry will need to overcome significant challenges in building the infrastructure required to protect patient data and comply with regulatory standards. As AI models become more refined and accessible, they will undoubtedly become integral tools in shaping the future of industries worldwide.

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Staff Retention and Development in German Hospitals—Particularly in Early Rehabilitation (Neurological, Neurosurgical and Interdisciplinary)

Pantea Pape

Abstract

The COVID-19 pandemic underscored the critical role of hospital staff, particularly in specialized fields like Neurological Early Rehabilitation (NER). Despite its indispensability, the sector faces significant challenges, including workforce shortages, high stress levels, and the increasing demands of an aging population. This article examines strategies to enhance staff retention and development in German hospitals, focusing on NER. Recommendations include advanced training programs tailored for NER staff, resilience training, coaching, and supervision to mitigate stress-related burnout. Employer branding, innovative work models such as the 4-day workweek, and corporate childcare solutions are proposed to improve work-life balance and attract talent. By implementing these measures, hospitals can foster a sustainable workforce, enhance interdisciplinary collaboration, and ensure high-quality patient care in NER.

1 Introduction

The COVID-19 pandemic has highlighted how relevant the health system, and hospitals in particular, are to society as a whole. The importance of staff becomes all the more apparent. The stability of the health system and thus also of hospitals stands and falls with their staff. Especially during the pandemic, the significance of hospital staff gained attention and high recognition, for example in thank-you texts

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in social networks or highlights in other media.¹ The same applies to the area of neurological early rehabilitation.

The Federal Working Group for Rehabilitation (*Bundesarbeitsgemeinschaft für Rehabilitation/BAR*) has developed a phase model that distinguishes between phases A to F (Table 1, see Appendix).²

Neurological early rehabilitation (NER) phase B is usually a medical-care-therapeutic complex treatment in an acute hospital. Funding is thus subject to the Fifth German Social Code (SGB V). The general legal basis for rehabilitation is enshrined in SGB IX (SGB IX § 1: “People with disabilities or people threatened by disabilities receive benefits [...] to promote their self-determination and their full, effective and equal participation in life in society, to avoid disadvantages or to counteract them”). Phase B patients usually have the following characteristics:

“Unconscious or qualitatively or quantitatively severely unconscious patients (including those with a so-called apallic syndrome) with severe brain damage as a result of craniocerebral trauma, cerebral circulatory disorders, cerebral haemorrhage, oxygen deficiency (particularly with condition after resuscitation), inflammation, tumors, poisoning, etc. [as well as] patients with other severe neurological disorders (e.g. locked-in syndrome, Guillain-Barré syndrome, high paraplegia) who still require intensive care.”³

Due to prescribed hygiene measures in about every fourth phase B patient, the colonization with a methicillin-resistant *Staphylococcus aureus* (MRSA) or a multi-resistant gram-negative germ (MRGN) is cost-intensive.⁴

Therefore, this patient clientele presents all disciplines involved in the early rehabilitation process with emotionally and rationally difficult challenges.

This article is intended to offer recommendations for action to optimize working conditions and to further develop and retain staff in hospitals.

2 Current Status

Neurological diseases are the most frequent causes of permanent damage and thus of functional disorders relevant to everyday life.⁵ If we consider the part of participation, a persisting functional disorder (e.g., mobility disorder, speech disorder, swallowing disorder, or neurocognitive disorders) can lead, for example, to longer periods of incapacity to work or even to retirement or to early admission to care facilities as a result of a necessary need for care. The consequences of this are high economic costs.⁶ In Germany, the most populous country in Western Europe,

¹ Cf. Amelung et al. (2020), p. IX.

² Cf. Nunnemann

³ BAR (1995).

⁴ Cf. Rollnik et al. (2014).

⁵ Cf. Nunnemann (2021), p. 35.

⁶ Cf. *ibid.*

there were more than 49.5 million people with neurological diseases in 2017. This corresponds to 59.6% of the population.⁷

About two thirds of all stroke patients have walking problems, at least at the beginning.⁸ The German hospital landscape has so far been structured in such a way that it consists of many small hospitals with many beds and has a correspondingly high staff requirement.⁹ Particularly in NER, a defined staffing ratio for one nurse per five patients is prescribed in accordance with the Nursing Staff Lower Limits Ordinance (*Pflegepersonaluntergrenzen-Verordnung/PpUGV*), which is also invoiced separately via the nursing budget. This requires specialized facilities.¹⁰ The content-related and structural specifications for NER are defined in the system of Diagnosis Related Groups (DRG) via OPS 8-552 (Operation and Procedure Code 8-552: “Neurological-neurosurgical early rehabilitation”) and can be found in Table 2 (see Appendix).¹¹

The presence of activating-therapeutic care by specially trained nursing staff in the field of NER as well as different therapy approaches, such as physiotherapy, physical therapy, occupational therapy, neuropsychology, and speech therapy, are required in different combinations of at least 300 min daily on average of the treatment duration of this measure. This aspect is an approach to be rethought and solved in the current situation with a known shortage of specialists. The design of the contextual factors in the hospital with severely affected patients and partly little flexible working time models poses great challenges for employers.

NER has become an indispensable part of the hospital landscape, even though there is currently no proof of its effectiveness in the sense of evidence-based medicine.¹² Experience to date, including our own, shows that through intensive interdisciplinary and multi-professional therapy, approximately one third of patients can be transferred to further phase C rehabilitation.¹³ Many neurologically initially severely affected patients can be transferred to a further rehabilitation phase, mostly phase C, of the follow-up rehabilitation after a treatment period of between 14 and 28 days. In most cases, however, it is only possible to transfer these patients to follow-up rehabilitation after completion of the acute medical hospital treatment.¹⁴ However, rehabilitation phase C is underfinanced compared to phase B, so that a noticeable reduction in urgently needed phase C beds can be heard throughout Germany. As a result, the length of stay in phase B of the hospitals increases, combined with an increased hospitalization rate. In order to avoid this, patients with

⁷ Cf. *ibid.*

⁸ Cf. Shaughnessy et al. (2005).

⁹ Cf. OECD (2022).

¹⁰ Cf. DIMDI, OPS version 2020, chap. 8. „Nicht operative therapeutische Maßnahmen“ (*non-operative measures*).

¹¹ Cf. *ibid.*

¹² Cf. Pohl and Bertram (2016), pp. 1043–1050.

¹³ Cf. Pohl et al. (2016).

¹⁴ Cf. Nunnemann (2021).

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
ärztlicher Dienst	143	139	136	136	137	136	134	132	130	128	127	125
Pflege-dienst	54	56	56	58	58	59	59	59	59	59	60	60

Fig. 1 Development of the person load figure in the entire hospital system over the years (Eichhorst & Linckh, 2017, p. 21)

rehabilitation potential are discharged into long-term care, which in turn means an increase in care costs.¹⁵

Particularly where interpersonal interactions are involved, there is a high demand of those involved for their own professional activity with the aim of achieving the best possible therapy results. Nursing therapy in NER has a special role to play here.¹⁶ This in turn requires working conditions in which nursing staff can fulfill these high demands without restrictions. However, it is often observed that cost savings are difficult to reconcile with the creation of satisfactory working conditions and that there is a corresponding lack of effective solutions. It is therefore all the more crucial to deal in depth with this problem, which has become more topical in recent years. Increasing case numbers and a persistent or increased shortage of staff with unchanged processes and structures have almost inevitably resulted in a high workload and a high level of stress on the part of the staff, which ultimately has a negative impact on patient care.¹⁷

The so-called person load figure—the number of cases to be cared for on average per full-time staff member in the year under review—is given as an indicator of the work intensity and the associated burden on health care and nursing staff as well as doctors. As can be seen in Figure 1, the workload for nursing staff in general has increased noticeably in the German hospital system—and the trend is upwards (Fig. 1).¹⁸

The qualifications that nursing staff must have are not specified in the Operation and Procedure code (OPS) 8-552 for neurological-neurosurgical early rehabilitation. Nevertheless, it can be the subject of structural audits by the Medical Service of the Health Insurance Funds (*Medizinischer Dienst der Krankenversicherungen/MDK*).¹⁹

¹⁵ Cf. Ohlerth (2023).

¹⁶ Cf. Wallesch and Lautenschläger (2017), pp. 422 f.

¹⁷ Cf. Dilcher et al. (2013), p. 4.

¹⁸ Cf. Eichhorst and Linckh (2017), pp. 20 f.

¹⁹ Cf. Hellmann (2021), p. 11.

3 Recommendations for Actions

3.1 Staff Development in NER

3.1.1 Further Training of Nursing Staff

The activating care of patients with complex diseases requires sufficient qualification of the nursing staff. Similarly, therapists must be specially trained.²⁰ The regular adaptation of therapeutic nursing knowledge must be continuously adapted to the latest scientific findings, which is what advanced training and further education are for. In view of the complex and highly demanding nursing work in NER, there has already been a specialist further training course for health care and nursing staff for NER for some time, in the context of which key medical and therapeutic aspects of the patient clientele are learnt.²¹

Further training as a nurse for neurological-neurosurgical early rehabilitation—Curriculum activating-therapeutic nursing care (“Weiterbildung Gesundheits- und Krankenpfleger*in für neurologisch-neurochirurgische Frührehabilitation—Curriculum aktivierend-therapeutische Pflege”)

OPS 8-552 explicitly specifies activating-therapeutic care by specially trained nursing staff in the field of NER as one of the minimum features. While in geriatric early rehabilitation a nurse of the geriatric team has to prove a structured curricular geriatric-specific additional qualification of at least 180 h as well as at least 6 months of experience in a geriatric facility, in NER the type and extent of training are not specified by the OPS 8-552, although they may be subject to structural audits by the MDK.²² However, the German Society for Neurorehabilitation (*Deutsche Gesellschaft für Neurorehabilitation/DGNR*) offers an additional qualification for activating-therapeutic care in NER with a scope of 219 h in this regard. This is intended to meet the demands for a standardized level of further training for activating-therapeutic care in NER that meets the requirements specific to intermediate care and rehabilitation. At the same time, the aim of the further training measure is to teach and test the theoretical basics and practical skills uniformly throughout Germany.²³

Further training as a health care and nursing assistant for intensive care in neurological-neurosurgical early rehabilitation (“Weiterbildung zum/zur Gesundheits- und Krankenpfleger*in für die Intensivpflege in der neurologisch-neurochirurgischen Frührehabilitation”)

In addition, the working group “PDL network of neurological clinics,” in cooperation with nursing service managers of other NER facilities managed by members of

²⁰ Cf. Bertram and Brandt (2007), p. 1171.

²¹ Cf. Nunnemann (2021), p. 37.

²² Cf. Wallesch and Lautenschläger (2017), p. 423.

²³ DGNR (2011), pp. 1 f.

the DGNR and with the advice of the nursing commission of the DGNR, has drafted the concept of further training to become a “health care and nursing specialist for intensive care in neurological-neurosurgical early rehabilitation.” In view of the demographic change and the associated ageing population in Germany, intensive care in the field of neurological early rehabilitation faces the particular challenge of compensating for the shortage of trained nursing staff so that a high level of quality can continue to be guaranteed with regard to the care of patients in NER.²⁴

Further training as a nursing expert for neurological early rehabilitation (“Weiterbildung zur Pflegeexpertin bzw. zum Pflegeexperten für neurologische Frührehabilitation”)

As a further training measure, the advanced training to become a nursing expert for neurological early rehabilitation proves to be very useful. Based on the patients concerned and their caregivers, it should contribute to their beneficial care. Within the framework of the further training, the participants acquire the competences for determining the rehabilitative needs of the patients as well as for the joint development of concrete support concepts at the beginning of the nursing measures. For this purpose, the participants learn a number of different support concepts so that they can succeed in designing individual support measures on a professional basis. Further components of the further training are basic competences and knowledge about nursing diagnostic measures, basics of professional law as well as nursing science findings. A special feature is the further training of the participants in the counselling and training of patients, their caregivers, other interested professionals, or individuals. In short, the further training to become a nursing expert for neurological early rehabilitation is intended to provide the health care and nursing staff with the necessary competences and soft skills to carry out reflective, life-world-oriented, process-accompanying, interdisciplinary therapy and resource-utilizing nursing care as well as counselling. Moreover, the participants are taught how to deal pedagogically with the affected persons and their relatives in their special situations. Since the qualification measure is a vocationally integrative further training, the participants must already be working in NER so that they can transfer the acquired knowledge and competences into their everyday working life. It consists of six modules and concludes with the further training certificate “Nursing expert for neurological early rehabilitation (DGGP/Deutsche Gesellschaft für Gesundheits- und Pflegewissenschaft).”²⁵

3.1.2 Staff Development Against the Backdrop of Demographic Change

Meanwhile, the competitiveness and business viability of hospitals and clinics is significantly influenced by the appropriate headcount, the optimal age structure of employees and the interplay of these. The consequences of demographic change

²⁴ DGNR (2022), p. 1.

²⁵ DGGP (2023).

already mean that there is a shortage of sufficiently qualified workers in the labor market, such as nurses with the necessary qualifications and competences in the field of NER. Similarly, it may occasionally be the case that vacancies are filled with candidates who fulfill the necessary professional requirements but do not have the sufficient soft skills, i.e. methodological, personal, or social competences. This in turn can result in personnel working in NER leaving after a short period of time or not even applying for the respective vacancies due to the sometimes stressful high psycho-physical demands of the patient clientele described above.²⁶

In addition, the work-life balance is playing an increasingly important role, particularly for the younger workforce, as they—and this is no longer only true for female employees—want to balance their work with their personal interests and their family. Nevertheless, especially in the medical profession and in hospitals, mostly female employees form the majority of the workforce. For employees in the middle and older age groups, moreover, the care of their relatives, who are often elderly and thus in need of care, is playing an ever greater role, so that they are increasingly attaching importance to reconciling their work with the possibility of providing sufficient care for their loved ones and, if necessary, to retiring from working life earlier. In view of the existing shortage of skilled workers, it is becoming all the more important to design the working conditions in the field of NER for staff in such a way that middle-aged and older employees in particular remain able to work in the early rehabilitation field in the first place for as long as possible, instead of giving up their profession prematurely due to work-related mental illnesses or physical illnesses due to wear.²⁷

According to some scientific studies,²⁸ it is wrongly assumed that there is a considerable reduction in performance, reduced work productivity, increasing absenteeism, low adaptability and mobility, a decreasing willingness for further training, a lack of resourcefulness, and decreasing self-confidence coupled with an increased level of insecurity among older staff. A change of thinking on the part of hospital management is necessary here, since nurses are not less capable with increasing age, but rather their performance shifts to other areas. Their repertoire of experience is of great value in this respect, so that they are better able to handle complex issues, use their know-how about in-patient processes, assess their own abilities, make more objective decisions, successfully cope with uncertain situations, act prudently in problem situations, compensate for weaknesses and use informal relationships. Often the challenge is not performance per se, but its impairment as a result of many years of wear and tear on the nursing staff. At this point, hospital management is called upon to offer coping strategies, such as regular coping and coaching strategies, which counteract psychological strains, such as stress, contribute to the regulation of emotions, and at the same time strengthen the resilience of the employees.²⁹

²⁶ Cf. Schönberg (2013), pp. 183 f.

²⁷ Cf. *ibid.*, p. 184.

²⁸ Cf. e.g., Bergmann (2001) or Martin et al. (2008).

²⁹ Cf. Schönberg (2013), p. 185.

3.1.3 Development of Coping Strategies and Resilience Training

Frequent reasons for sick leave in Germany are mental illnesses.³⁰ These in turn are often stress-related.³¹ Absenteeism is not only a disadvantage for hospitals, but also contributes significantly to a reduction in employee motivation, which results in impaired employee performance. In order to keep nurses mentally and physically fit, it is important to integrate stress prevention into occupational health management.³² For managers in NER, it is crucial to identify the so-called stressors, i.e. triggers of stress. Often these are too high work demands, too long working hours, and difficulties in cooperation among the nurses themselves, with their superiors or with the doctors. Overall, the longer and more intense stress is experienced, the more serious and negative the health consequences are for the person concerned. The extent to which stress affects employees depends in turn on the individual employee, in particular on his or her strategies for coping with stress, and on his or her resilience, i.e. resistance to stressful situations³³ such as stress.³⁴ According to one perspective, successful coping results in increased resilience.³⁵ Against this background, it is helpful to offer NER nurses resilience and stress management training as part of a workplace health management program, so that they can learn how to better cope with stressors or stressful situations at work, be equipped with necessary resources and strengthen their resilience to stress. The individual working hours of the employees should be taken into account.³⁶ To ensure that the offers are actually taken up, they should be mandatory for every employee.³⁷ On the part of the employees themselves, a certain degree of personal responsibility is required in order to repeatedly reflect on their personal coping strategies. Asking employees to help shape the support services related to coping strategies and resilience building has a positive effect here.³⁸

3.1.4 Coaching

Coaching is to be understood as a process in the course of which those being coached become aware of their inner knowledge regarding their own personality structures and patterns of action, so that they can further develop or modify them. The purpose of coaching is always to help people help themselves.³⁹ The self-awareness and self-reflection of the client is actively promoted by the coach so that previously ignored or unrecognized aspects are increasingly realized by the coached individual,

³⁰ Cf. Techniker Krankenkasse (2018), p. 67.

³¹ Cf. Rau and Buyken (2015), pp. 121 ff.

³² Cf. Gunkel et al. (2014), p. 258.

³³ Cf. Henninger (2016), p. 158.

³⁴ Cf. Klingenberg & Süß (2020), p. 19.

³⁵ Cf. Rice and Liu (2016), p. 329.

³⁶ Cf. Klingenberg (2022), p. 197.

³⁷ Cf. Klingenberg and Süß (2020), p. 22.

³⁸ Cf. Klingenberg (2022), p. 193.

³⁹ Cf. Schnödewind (2017), p. 53.

which contributes to the reduction of operational blindness and in turn results in the creation of new patterns of action.⁴⁰ Coaching should help the nurse to cope with different concerns by supporting them in developing their own approaches to solutions. The coach helps to identify the causes of the problem. In this way, they help to identify and solve the processes that cause the problem. Ideally, the nurse learns to solve their problems on their own, to develop their attitudes and behavior and to realize effective results.⁴¹ It is important to emphasize that the coach provides feedback without giving instructions or advice.⁴²

The often hectic workday of nurses in NER leaves little time and space for expressing and sharing needs, concerns and innovative suggestions. Even if the patients' well-being is of primary importance, the well-being of the employees in NER must not be forgotten. Coaching opens up a space for employees in NER to address their issues. Here they can voice the challenges, grievances, and potential for improvement in their daily lives. At the same time, they can reveal what moves them, delights them, and what alternative possibilities could be considered to improve their activities, cooperation, and work processes in NER. This is where a particular potential can be located that can be identified and harnessed through the use of coaching. This not only enriches the person being coached, but also all co-workers, the patients, the NER management, and, ultimately, society as a whole.⁴³

The coaching of NER employees is accompanied by a number of benefits. It contributes to the improvement of the daily work and increases the productive cooperation in NER, where the high degree of interdisciplinarity requires an effective cooperation of nurses, therapists, and doctors. By offering the coached individuals the opportunity to deal with topics of their professional everyday life in more detail, they gain the chance to get to the bottom of matters and at the same time their own personality in order to develop it further. It also makes it easier for them to identify helpful approaches to solving their perceived problems, to expand their repertoire of possible actions, and thus to experience more joy and less stress when working in NER. Thus, coaching offers hospitals and clinics with NER departments an effective tool for increasing employee retention as well as staff development. In this way, the employer in turn expresses their appreciation toward the employees of NER. Finally, coaching acts as a special driving force for the optimization of working conditions.⁴⁴

3.1.5 Supervision and Peer Counselling

A high level of absenteeism and the increasing number of employees in the health sector, including NER, with psychological complaints and illnesses, such as burnout, depression, and exhaustion, cannot be overlooked. In addition to coaching,

⁴⁰ Cf. Rauen (2021), p. 3.

⁴¹ Cf. Schnödewind (2017), p. 54.

⁴² Cf. Kocks et al. (2012), p. 19.

⁴³ Cf. medirocket (n.d.).

⁴⁴ Cf. medirocket (n.d.).

which has already been discussed, supervision can be considered as an effective remedy for the prevention of stressors and work absences.⁴⁵

According to Schreyögg, supervision can be characterized by five basic criteria, which will be related to NER workers in the following. From a content perspective, it is a matter of optimizing the work practice of NER employees with the aim of supporting them through social action. In doing so, it is important to take into account personal patterns of action as well as contextual patterns. This is realized through three possible counselling tasks, cognitive-oriented professional counselling, organizational counselling, or psychotherapy-like counselling. The examination of the different topics is always in a concrete context, which provides the corresponding framework. For example, the number of supervised employees participating may vary. The thematic discussion including its context-related counselling tasks in connection with matters in the field of NER is realized in defined supervisory relationships. Finally, the supervisor as a professional actor must manage the individual supervisory situation according to a concept.⁴⁶

In addition to supervision, there is also collegial counselling, which is to be distinguished from the former. Instead of the fixed role relationship between a supervisor and the supervisee(s), the roles rotate in the case of peer counselling within the framework of counselling sessions.⁴⁷ Supervision also requires an independent trained supervisor. Peer counselling is based on the idea that the know-how, skills, and methodological competences of one's own colleagues can be used for counselling purposes. Occasionally, peer counselling can replace supervision, as practical experience has shown. Within the framework of peer counselling, NER employees are thus advised by their own colleagues. In this way, the competences of individual employees are demanded and promoted, and the entire team is further developed. However, concrete case discussions, as they are often found in nursing, are to be distinguished from peer counselling. In order to realize peer counselling, sufficient self-organization is an urgent prerequisite (cf. Sect. 3.3.1). The fruits of the success of a more collegial consultation are in turn a stronger cohesion of the NER team.⁴⁸

In practice, supervision can be found in different institutionalized contexts. For example, a supervisor may supervise one or more employees who report to him/her. At the same time, it can be a special in-house or freelance or part-time supervisor with expertise in the field of NER who supervises one or more employees.⁴⁹ Specifically, team, leadership, individual, and group supervision can be considered.⁵⁰

The occasions for supervision are even more diverse. Within the framework of team supervision, questions about the work in the team, reflection on one's own

⁴⁵ Cf. Praxisforum Friedrichshafen (2019), p. 1.

⁴⁶ Cf. Schreyögg (2004), pp. 23 f.

⁴⁷ Cf. Akhurst and Kelly (2006), p. 4.

⁴⁸ Cf. Kocks et al. (2012), p. 5.

⁴⁹ Cf. Schreyögg (2004), p. 30.

⁵⁰ Cf. Schwarz (2009), p. 217.

actions, and the structural conditions can be dealt with. Here, human resource development can take place by raising awareness of stressful situations and subsequently strengthening the resources of employees, as well as by identifying room for maneuver and alternative solutions for the organization of work. Potential topics for leadership supervision include leadership style, professionalism, and role design, in particular staff development, work-life balance, and time management, while individual supervision can address person-related stresses such as excessive stress, a feeling of powerlessness, and burnout as well as the (self-perceived) individual position in the team. In group supervision, conflicts that often arise in nursing from unclear responsibilities can be clarified. In addition, approaches to solutions for effective work in the team can be developed and experiences can be exchanged.⁵¹

3.2 Employer Branding: Increasing the Appeal of the Hospital as an Employer

The fact that the term “employer branding” is used in connection with hospitals in the field of NER may sound surprising at first glance, since it is primarily a business term that may mainly refer to the field of marketing. But the employer brand goes far beyond the corporate brand and personnel marketing. It is fundamentally different from aspects such as branding and marketing in general, rather it represents a process of identity and organizational development. Companies that practice good employer branding benefit in many ways (see Fig. 2).

A good fit of applicants promotes team spirit, e.g. on a ward, as well as identification with the goals and values of the company. As a consequence, the willingness of employees to perform increases and the productivity of the organization grows. In practice, these effects have already been demonstrated in studies.⁵² At the same time, vacancies can be filled more quickly and sick leave reduced. In addition, different areas can communicate more efficiently with each other, which is particularly important in NER with its high degree of interdisciplinary collaboration. This also results in a stronger retention of top performers. Good employer branding of NER therefore has a positive effect on the business figures of a hospital and thus requires the increased attention of the respective management.⁵³

In practice, employer branding is promoted through HR policy and communication measures. It serves to retain as well as attract nursing staff.⁵⁴ Simply put, effective employer branding causes nurses to want to stay on the team and new employees to want to join.⁵⁵ NER must thus become a desirable employer

⁵¹ Cf. *ibid.*

⁵² Cf., e.g., TowersPerrin (2003) or Fulmer et al. (2003).

⁵³ Cf. Kriegler (2017), pp. 179 ff.

⁵⁴ Cf. Biernoth (2016), p. 2.

⁵⁵ Cf. Esslinger et al. (2019), p. 110.

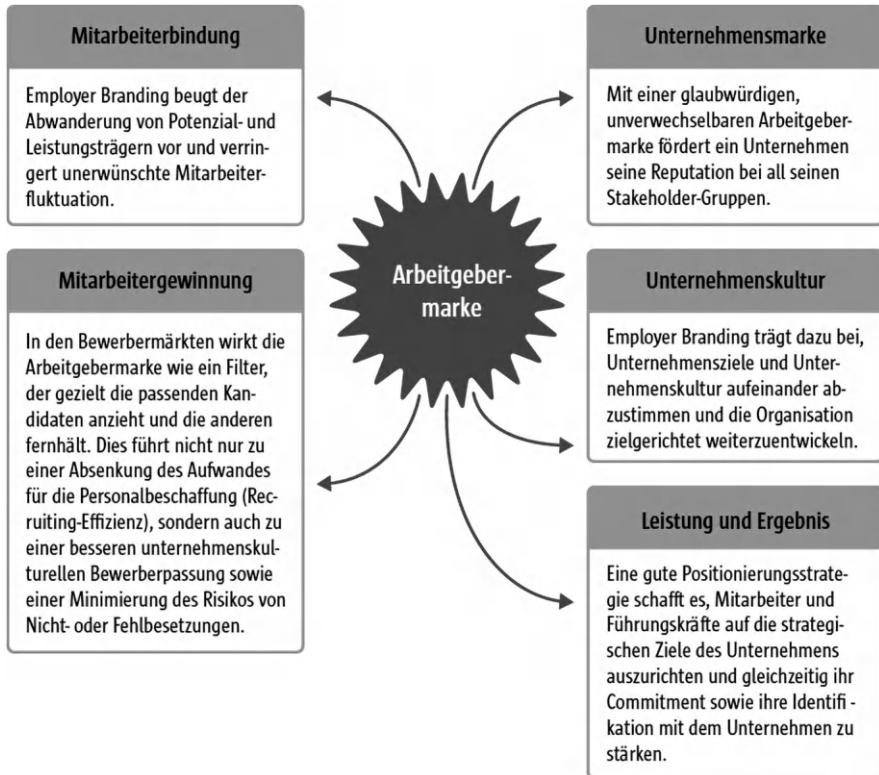


Fig. 2 Multiple positive effects of an effective employer brand (Kriegler, 2017, p. 182)

as part of the hospital.⁵⁶ In this regard, employer branding works both internally (staff retention) and externally (staff recruitment).⁵⁷ The nursing staff must clearly experience how their employer positions itself. This depends on the management of the employees and, in particular, on the way in which they communicate with them.⁵⁸ An important tool at this point is the employee appraisal. At the same time, all employees must always be shown appreciation by managers and the employer.⁵⁹ If necessary, managers must be trained in the areas of employee motivation and awareness of employee needs. Managers have a special role to play here, as their leadership style, the way they deal with their employees and their day-to-day

⁵⁶ Cf. Andratschke et al. (2009), p. 12.

⁵⁷ Cf. Biernoth (2016), p. 1.

⁵⁸ Cf. Stotz and Wedel-Klein (2013), p. 9.

⁵⁹ Cf. Bartscher et al. (2012), p. 366.

behavior have a significant influence on the working atmosphere due to their role model function for the employees.⁶⁰

In employee appraisals and employee surveys, it is possible to clarify exactly what employees want and what level of satisfaction they have.⁶¹ In this context, it is important to listen to the nursing staff, to accept critical feedback as well as suggestions, and to offer them a certain amount of freedom to work independently.⁶² Employee loyalty is inevitably highly relevant in the context of employer branding. In the field of NER, where employees are exposed to considerable physical and psychological challenges, a pleasant working environment is an essential cornerstone of staff retention. Examples of measures include the use of ergonomic aids, such as transfer aids and lifters to support physically difficult activities, sufficient equipment with NER-typical therapy items, digital tools to save time, structured team meetings or handovers before the start of a new shift, free beverages and fruit, regular team events, such as Christmas dinners and summer parties, clean and sufficiently large break rooms, and sufficient parking spaces for all employees.⁶³ But higher salaries, which nurses would like to see according to a qualitative study,⁶⁴ can also increase the attractiveness of the employer and thus employee loyalty. Equally important are internal incentives, such as career and further training opportunities, as well as possibilities with regard to work-life balance and more flexible working time models.⁶⁵ The last two points in particular will be examined in more detail in connection with New Work in the further course.

3.3 Concepts in the Context of New Work in the Area of Nursing Care

3.3.1 Self-Organization of a Care Team

In the context of new approaches to work in connection with New Work and agility, one should think in particular of a new model of work organization and work methods: the self-organization of care teams. Although this is initially associated with activities in the IT sector, impressive examples in the field of nursing have made it clear that self-organization of nursing teams can also represent a future type of collaboration in the nursing context. Accordingly, hospitals and care facilities are increasingly showing an openness to such new forms of management and cooperation.⁶⁶

⁶⁰ Cf. Klingenberg (2022), pp. 195 f.

⁶¹ Cf. Ni (2022a).

⁶² Cf. Ni (2022b).

⁶³ Cf. Ni (2022b).

⁶⁴ Cf. Scherm and Süß (2016), pp. 142 f.

⁶⁵ Cf. Bartscher et al. (2012), p. 366.

⁶⁶ Cf. Blaudszun-Lahm and Kubek (2020), p. 31.

In technical terms, self-organization is “the spontaneous emergence of new, seemingly stable structures and behaviors in systems.”⁶⁷ A system (care team) that organizes itself changes its basic structure by means of its experiences and its environment. The participants acting together (nurses, therapists, and doctors) act according to concrete rules and create their own order. In doing so, they do not need to have a vision of complete development. Experience has shown that processes of self-organization are associated with significantly more effectiveness, productivity, sustainability, and benefits for all participants than would be possible through a controlled influence on the participants from the outside.⁶⁸ In simpler terms, self-organization can be seen as the way in which individual and joint services are provided to a station when a task to be accomplished is grasped as a common problem. The aforementioned shortage of skilled workers, which is particularly prevalent in the nursing sector due to demographic change, already necessitates such an innovative model of work organization.⁶⁹

In principle, it can be assumed that a system which continues to run unchanged, i.e. by using previous methods and with increasingly fewer nursing staff, will reach its limits at some point.⁷⁰ At the same time, beyond demographic change and its consequences for the current and increasing need for skilled workers, the needs of Generation Y and Z must be considered, who enter working life at a comparatively advanced age and display greater autonomy and self-determination than their preceding generations. Accordingly, they no longer simply accept instructions without reflection.⁷¹ In this respect, it has already been proven repeatedly that greater participation of nursing staff benefits employee motivation. With regard to duty scheduling, it has also been shown that insufficient planning of work and leisure time results in increasing health complaints and growing employee dissatisfaction with regard to working hours.⁷² In contrast, the perceived overstrain on the part of the workforce decreases with increasing predictability of their working hours.⁷³ The more the nursing staff feel secure in planning their working hours and a certain degree of involvement in the design of the duty roster, the better they perceive their working hours and the better the work processes and cooperation on the ward function.⁷⁴

3.3.2 Four-Day Week in NER

The idea of continuous professional activity 4 days a week in a hospital, particularly in NER with severely affected patients, is absolutely new and so far surreal.

⁶⁷ Gloger and Rösner (2022), p. 23.

⁶⁸ Cf. *ibid.*

⁶⁹ Cf. Blaudszun-Lahm and Kubek (2020), p. 33.

⁷⁰ Cf. Gloger and Rösner (2022), p. 10.

⁷¹ Cf. Blaudszun-Lahm and Kubek (2020), p. 37.

⁷² Cf. *ibid.*, p. 34.

⁷³ Cf. Engel et al. (2014), p. 86.

⁷⁴ Cf. Blaudszun-Lahm and Kubek (2020), p. 34.

Nevertheless, Bielefeld Hospital has taken the plunge and intends to initiate a pilot project in the summer of 2023 on an internal medicine ward with 30 beds. Health care workers will benefit from this by working four shifts per week instead of five, being guaranteed every other weekend off, and being assured of the reliability of their rosters. This accomplishes exactly what is lacking in the nursing field: Sufficient incentives. However, there is no reduction in working hours, so it is more a restructuring of working hours. In the course of this, a work shift is extended to 9.5 h, so that early and late shifts would have far more time to hand over at 2.5 h. At the same time, more nursing staff can take care of patients, which is a very great advantage, particularly in the area of NER, which is associated with high mental and physical stress. In addition, this may provide an incentive for part-time staff to work as full-time employees.⁷⁵ Overall, this could strengthen employee motivation and consequently increase the efficiency of the hospital.

Although this model gives nursing staff more days off, it is accompanied by longer working hours in the context of the above-mentioned pilot project. Not to be underestimated is the shortening of work routes and the associated reduction in environmental emissions.⁷⁶

In a large-scale trial in England, the four-day working week model has already been tested as a pilot project in 60 companies, including healthcare facilities. Despite the 4-day working week and 80% working time, full pay continued to be paid. The results were promising: the sickness rate fell by 65% and the employee fluctuation rate, including the desire to leave, was reduced by 57%. In addition, 71% of the workforce suffered less burnout. The majority of the companies that participated in the project intend to continue the model. At the same time, employee satisfaction increased noticeably.⁷⁷ Due to the precarious financial situation of the German healthcare system, the Bielefeld model mentioned above, accompanied by extended working hours spread over 4 days, seems to be more realistic. In addition, parents with children or employees with longer commuting times may perceive the working days associated with longer working hours as a complication. However, in view of the advantages in favor of a work-life balance based on 3 days off per week, it seems too hasty to immediately turn one's back on the model. It is crucial to set the right course for this. For example, in NER, which is characterized by a necessary high degree of cooperation between various forces, it is important to ensure the continuous flow of information. Digital solutions could help here. In addition, it may be necessary to comply with working time regulations at weekends,⁷⁸ whereby an extension of working time to a maximum of 10 h is permitted under the German Working Hours Act (*Arbeitszeitgesetz*), provided that the average working time does not exceed 8 h per working day over a period of 6 months or 24 weeks.⁷⁹ A 4-day

⁷⁵ Cf. *Ärzteblatt* (2022).

⁷⁶ Cf. *ibid.*

⁷⁷ Cf. *ibid.*

⁷⁸ Cf. *Groß* (2023).

⁷⁹ Cf. § 3 *Arbeitszeitgesetz* (*Working Hours Act*).

workweek would at the same time enhance the appeal of the hospital as an employer and thus benefit both the retention of existing nursing staff and the recruitment of new ones. For parents with children, in-company childcare is another option, which will be examined in more detail below, together with its alternative design models and advantages.

3.3.3 Corporate Childcare in the Hospital

If hospitals set up new childcare places for the children of their employees as part of a full-day care program, they will receive a state subsidy of €400 per month for up to 2 years. If the childcare places are half-day or part-time, the subsidy is reduced accordingly. The state offers this option as part of its “Success Factor Family” (*Erfolgsfaktor Familie*) support program.⁸⁰

Increasingly, companies are becoming aware of the importance of company childcare as an elementary component of a family-friendly corporate culture. In this way, they are making a significant contribution to the work-life balance, i.e. the compatibility of professional and private life, which in turn strengthens employee motivation. For example, childcare in the immediate vicinity of the workplace offers employees greater flexibility. This applies all the more to parents who want to work more after returning from parental leave. In general, corporate childcare gives them more freedom to act and shape their own lives. This, in turn, contributes significantly to employee retention, secures existing nursing staff and at the same time attracts young healthcare and nursing staff as well as therapists with young children. In short, the advantages of setting up childcare are increased motivation of the nursing staff, lower absenteeism, easier recruitment of nursing staff, and an increase in the attractiveness of the hospital as an employer.⁸¹

In this context, a hospital is not limited to the typical option—setting up a corporate childcare center. As the following explanations will make clear, the German legislator offers hospitals a range of options within the framework of the corporate childcare model, from which hospitals as employers can also benefit significantly in financial terms.

Financial Support/Childcare Subsidy (Kinderbetreuungszuschuss)

Around half of parents would like their employer to provide them with a financial contribution to help with childcare costs. However, just over a tenth of companies do this. This allowance is even tax- and social security-free for companies for children of non-school age who are cared for in a daycare center or by a childminder (§ 3 No. 33 EStG⁸²). Thus, on the one hand, employees save taxes and social security contributions and employers save the corresponding social security contribution

⁸⁰ Cf. BMFSFJ (2020), pp. 42 f.

⁸¹ Cf. BMFSFJ (n.d.).

⁸² EStG is short for „Einkommenssteuergesetz“ (*German Income Tax Act*).

shares. The employer pays the childcare allowance to the employee for the purpose of covering the costs of childcare and accommodation for children who are not of school age with childminders or in daycare facilities, in addition to the employee's salary.

Establishing a Corporate Childcare

The establishment of a company daycare center allows parents to have their children close to the workplace and thus not only a certain degree of security, but also time savings due to shorter travel times. In addition, employers thereby make a contribution to the already shortage of daycare places. Since the childcare would be under the control of the hospital, the hospital would determine the opening hours and all other details. Cooperation with local youth welfare offices and parents' associations might be considered. However, it would be necessary to apply for a daycare center operating permit in good time. It is much less complicated for employers to set up a company daycare or large daycare center. At the same time, it is possible to commission daycare providers or book daycare places in existing facilities. Here, too, the hospital as an employer benefits from tax exemption on all expenses incurred.

Commissioning of Emergency and Off-Peak Care

If the child's caregiver falls ill, the child is off school early, or a parent has to go on an unforeseeable business trip, it is a good idea to hire an emergency daycare provider. It is advisable to set up several child-friendly rooms where the children in need of acute care can stay, play, and be cared for by the emergency daycare mother or caregiver. In addition, the establishment of parent-child offices is conceivable. The hospital can also deduct these short-term compulsory work-related expenses for each employee up to an amount of €600 per year for tax purposes (cf. § 3 No. 34a EStG).

Holiday Care

In addition to school hours, the weeks off from school pose a challenge for working parents, as students have more than twice as many vacations as their parents and vacation times may not always overlap. In addition, daycare centers themselves are sometimes closed during the vacations. Hospitals can help out by working with youth welfare offices, youth, family and neighborhood associations, and churches to offer vacation programs, or by hiring private companies to do so. As an employer, the hospital in turn benefits from a tax perspective, as the costs incurred are considered deductible operating expenses.

Consulting and Mediation

It is not always mandatory to set up a corporate childcare service or to hire third parties for this purpose. Instead, employees can be advised in their search for childcare options or referred to private or public family service providers, who in

turn refer childminders, au pairs and the like to the parents. These expenses are again tax-free for the employer (§ 3 No. 34a EStG).

4 Conclusion

NER phase B usually corresponds to a medical-care-therapeutic complex treatment in an acute hospital. In this area, it is important that professionals from different disciplines work together in the best possible way in order to provide patients with the most effective rehabilitation possible.

At the same time, this area is accompanied by considerable physical and psychological stress for the employees in NER. For example, the person load figure of nurses in hospitals has clearly increased over the past two decades. This has resulted in a significant shortage of skilled workers and the risk of growing turnover of nurses and other workers in NER. In the wake of the COVID-19 pandemic, this situation has been exacerbated to a significant degree. At the same time, to meet these challenges, the NER sector and hospitals have various tools at their disposal to strengthen the retention and development of their employees.

For staff development, further training courses for the special field of NER come into consideration in particular. In this regard, the further training of nurses for neurological-neurosurgical early rehabilitation—curriculum of activating-therapeutic care (*Weiterbildung Gesundheits- und Krankenpfleger*in für neurologisch-neurochirurgische Frührehabilitation—Curriculum aktivierend-therapeutische Pflege*) should be mentioned first. This additional qualification for activating-therapeutic nursing in NER with a scope of 219 h is an offer of the DGNR. The aim is to standardize the content requirements of NER as far as possible and to teach both uniform theoretical principles and helpful or necessary practical skills. Furthermore, further training as a health care nurse for intensive care in neurological-neurosurgical early rehabilitation (*Weiterbildung zum/zur Gesundheits- und Krankenpfleger*in für die Intensivpflege in der neurologisch-neurochirurgischen Frührehabilitation*) is recommended. Against the backdrop of demographic change and the increasing aging population in Germany, intensive care nursing in NER faces the challenging task of balancing the shortage of sufficiently trained nursing staff in order to continue to offer a high level of quality with regard to patient care in NER in the future. Finally, further training as a nursing expert for neurological early rehabilitation (*Weiterbildung zur Pflegeexpertin bzw. zum Pflegeexperten für neurologische Frührehabilitation*) enables the employees in NER to acquire competences for identifying rehabilitative needs of the patients as well as for the joint development of concrete support concepts at the beginning of the nursing measures. In short, the further training to become a nursing expert for neurological early rehabilitation should provide the employees of NER with the necessary competencies and soft skills for the implementation of a reflective, lifeworld-oriented, process-accompanying, interdisciplinary therapy and resource-utilizing care as well as consultation.

At the same time, in view of the demographic shift, it is important to take advantage of the competencies of older employees, such as their expertise, instead of labeling them as less capable and less motivated co-workers. In this way, existing employees can be deployed in NER according to their strengths and thus more efficiently, which in turn strengthens their loyalty to the employer.

Moreover, in areas such as NER, in which nurses and therapists are exposed to considerable stress situations on a daily basis, it is particularly important that they have coping strategies at their disposal so that they can cope with everyday stress situations in the best possible way in order to prevent consequences, such as burnout and depression. Apart from that, they should be offered mandatory resilience training to strengthen their resilience in the face of challenging situations.

In addition, coaching of employees in NER should be considered. This not only enables employees to reflect on patterns of thought and action, but also to get rid of issues that are bothering them and to find solutions on their own. In doing so, they can express how the work processes and cooperation between nurses, therapists, and doctors can be optimized in NER, where there is a high degree of interdisciplinarity. This is where there is particular potential that can be identified and harnessed through the use of coaching. This not only enriches the person being coached, but also all colleagues, the patients, the NER management, and, ultimately, society as a whole.

In addition, supervision should be mentioned as an effective recommendation for action, which intends to improve the work practice of NER employees for the purpose of supporting them. More specifically, team, leadership, individual, and group supervision can be considered. The supervisor is an expert from outside the company. Alternatively, or as a supplement, peer consultation can be considered, in which colleagues advise their co-workers in order to impart their own skills, methods, and know-how for the field of NER to the latter.

Furthermore, hospitals with NER departments should engage in more intensive employer branding. Now more than ever, hospitals are companies that need to increase their appeal as employers in a highly competitive market for specialists. By enabling not only additional employees to be recruited but existing employees to be retained more strongly, it serves as a special means of employee recruitment and retention.

In addition, the COVID-19 pandemic has set in motion compelling thought processes with regard to new-work approaches accompanied by an increased work-life balance that can no longer be overlooked. The self-organization of care teams was considered here. In this context, employees should be granted greater participation in the design of work processes, which can also increase their motivation. Reliable duty rosters also contribute to an increase in job satisfaction. At the same time, the model of the 4-day week is currently under discussion and is being tested at the Bielefeld Clinic. The results remain to be seen. What is certain is that this would entail somewhat longer working hours for NER employees, but in return they would have 3 days off. This concept would be very interesting for employees with longer commuting times or children, but also for others who would like to have longer periods of rest. NER could thereby increase its appeal and strengthen

the loyalty of its employees. In parallel, because of the always high proportion of female employees in hospitals and NER, corporate childcare should be set up to offer parents more flexibility and at the same time contribute significantly to the compatibility of their professional and private lives. As alternatives, hospitals can make use of comparable models of corporate childcare, all of which are tax deductible and therefore profitable for employers from a financial point of view.

Appendix

Table 1 Phase model of neurological rehabilitation—BAR

Phase	Charakteristika
A	Akutbehandlung im Krankenhaus
B	Frührehabilitation (Akutphase II) mit noch schwer betroffenen Patienten, die teilweise noch intensivmedizinische Behandlungsmaßnahmen sowie eine Beatmung benötigen
C	Frühmobilisation; Patienten sind noch in hohem Maß auf eine medizinische und pflegerische Versorgung angewiesen
D	Selbstständigkeit in den Aktivitäten des alltäglichen Lebens besteht weitgehend
E	medizinisch-berufliche Rehabilitation
F	funktionserhaltende Dauerpflege in spezialisierten Langzeiteinrichtungen

Table 2 Minimum characteristics according to OPS 8-552 “neurological-neurosurgical early rehabilitation”

Bereich	Merkmale
Ärztliche Leitung	Frühreha-Team unter Leitung eines Facharztes für Neurologie, Neurochirurgie, Physikalische und rehabilitative Medizin oder Kinder- und Jugendmedizin mit der Zusatzbezeichnung Neuropädiatrie, der über eine mindestens 3-jährige Erfahrung in der neurologisch-neurochirurgischen Frührehabilitation verfügt. Im Frühreha-Team muss der neurologische oder neurochirurgische Sachverstand kontinuierlich eingebunden sein.
Frühreha-Assessment	Standardisiertes Frührehabilitations-Assessment zur Erfassung und Wertung der funktionellen Defizite in mindestens 5 Bereichen (Bewusstseinslage, Kommunikation, Kognition, Mobilität, Selbsthilfefähigkeit, Verhalten, Emotion) zu Beginn der Behandlung. Der Patient hat einen Frührehabilitations-Barthel-Index nach Schönle bis maximal 30 Punkte zu Beginn der Behandlung.
Teambesprechungen	Wöchentliche Teambesprechung mit wochenbezogener Dokumentation bisheriger Behandlungsergebnisse und weiterer Behandlungsziele.
Therapeutische Pflege	Aktivierend-therapeutische Pflege durch besonders geschultes Pflegepersonal auf dem Gebiet der neurologisch-neurochirurgischen Frührehabilitation.
Therapeutische Disziplinen	Vorhandensein und Einsatz von folgenden Therapiebereichen: Physiotherapie/Krankengymnastik, Physikalische Therapie, Ergotherapie, Neuropsychologie, Logopädie/faziorale Therapie und/oder therapeutische Pflege (Waschtraining, Anziehtraining, Esstraining, Kontinenztraining, Orientierungstraining, Schlucktraining, Tracheostomamanagement, isolierungspflichtige Maßnahmen u.a.) patientenbezogen in unterschiedlichen Kombinationen von mindestens 300 Minuten täglich (bei simultanem Einsatz von zwei oder mehr Mitarbeitern dürfen die Mitarbeiterminuten aufsummiert werden) im Durchschnitt der Behandlungsdauer der neurologisch-neurochirurgischen Frührehabilitation.

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Transformation in the Healthcare Sector—More Than Digitalisation and Technology

Hans-Juergen Bruhn

Abstract

When we talk about transformation, most people think of technology and digitalisation. Certainly, these topics play a special role. However, they are not the only ones. This is the subject of this book contribution. It categorises the factors influencing the healthcare system of the future and the various perspectives associated with them. Based on this, various digital services, their functionality and their benefits for stakeholders in the healthcare system are discussed. In addition to patients, these include insurers, service providers and the companies that create the technical infrastructure and specifically the solutions on offer.

1 Introduction

When we talk about transformation, most people associate it with digitalisation and technology. However, digital transformation means more than just implementing and providing technology (cf. Zukunftsinstitut, 2024a). In total, there are 12 megatrends from which the factors influencing the healthcare system of the future can be derived (Fig. 1). This article gives a rough outline of megatrends. This overview focuses on placing them in the overall context of market development. On the corporate side, it is the employees of the various disciplines in the organisation, from IT to marketing and communication, HR development, finance and customer service. In order for the interaction within the company to work, it is essential that the company management or top management is the driver of this transformation. A clear commitment from top management is required. Strategic objectives and the will to undergo far-reaching change are necessary (cf. Bearingpoint, 2020a). On the

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Einflussfaktoren auf das Gesundheitssystem der Zukunft

Verortung der zwölf Megatrends

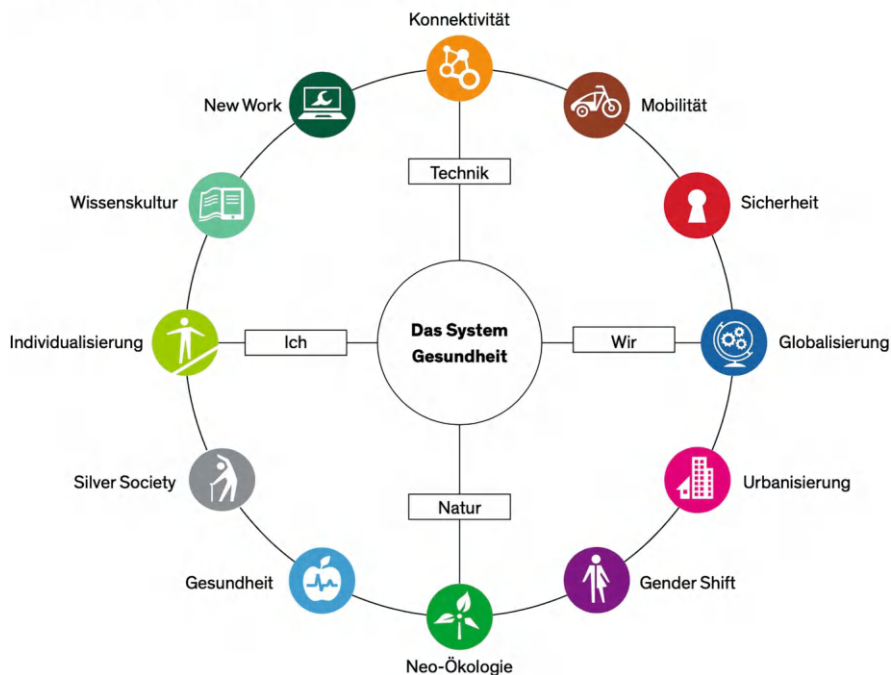


Fig. 1 Factors influencing the healthcare system of the future (Roche, 2020, Gesundheitswelt 2049, S. 17). Diagram titled “Einflussfaktoren auf das Gesundheitssystem der Zukunft” showing twelve megatrends influencing the future health system. Central circle labeled “Das System Gesundheit” connects to three main categories: “Technik,” “Ich,” and “Wir.” “Technik” links to “Konnektivität,” “Mobilität,” and “Sicherheit.” “Ich” connects to “Individualisierung,” “Wissenskultur,” “New Work,” and “Silver Society.” “Wir” links to “Globalisierung,” “Urbanisierung,” and “Gender Shift.” “Natur” connects to “Gesundheit” and “Neo- Ökologie.” Each trend is represented by an icon

other hand, there are the legislators, the providers of digital solutions and the users who, in the best case scenario, utilise the solutions.

The healthcare market has been striving to simplify and speed up processes with the help of digitalisation since 2006 at the latest. In recent years, efforts to implement this have gained momentum. From 1 January 2024 at the latest, health insurance companies are to provide insured persons with a secure, barrier-free digital identity for the healthcare system on request. From 1 January 2026, this digital identity will then be used to authenticate insured people in the healthcare system, effectively as proof of insurance. The requirements for security and interoperability will be defined by the German Telematics Society (cf. §291 (8) SGB V). Nevertheless, the healthcare sector is still 10–15 years behind other sectors in many areas. For example, around 70% of communication takes place via fax

machines and is paper based. According to Prof. Dr David Matusiewicz, the German government recently stated that 744 million sheets of paper are used every year. Therefore, the expansion of digital services in communication and documentation offers enormous efficiency gains (cf. Matusiewicz, D., 2024).

The health insurance funds offer insured people a suitable user interface that can be used to request proof of utilisation of services within the scope of statutory health insurance from the respective statutory health insurance fund for submission to a service provider. The prerequisite is a secure transmission procedure in accordance with §311 (6) to the service provider. § 291b (3) applies accordingly to the notification of the verification carried out by the service provider in accordance with sentence 1 (cf. § 291 (9) SGB V). This creates the basis for the comprehensive use of digital services.

In the following, the article looks at a selection of existing and upcoming digital offerings (Sect. 2) and describes these and their benefits for users. The key players are then described under Sect. 3 and the challenges that the transformation poses for them. The article concludes with an outlook and conclusion.

2 Digital Offers

2.1 eGK

The electronic health card (eGK) serves as proof of authorisation to use services within the framework of statutory health insurance and for billing with service providers in the healthcare market (§291a (1) SGB V). It is the first card to support the applications of the telematics infrastructure. In addition to basic data such as name, date of birth and insured person status, which are all listed in detail in §291a (2) and (3) SGB V, emergency data and medication plans can also be stored (cf. KBV, 2024). The features associated with the card have been gradually introduced since autumn 2020. Access to emergency data requires the equivalent of the eGK, the so-called health professional card (eHBA) (Federal Ministry of Health, 2024).

In order to gain access to the medication data (eMP), this must be authorised by the insured person. For this purpose, the health insurance companies provide their customers with a PIN for the eHC. The insured person decides on the use of the data and can use the PIN to authorise access at the doctor's surgery, hospital or pharmacy, or deactivate the PIN function and thus give individual players free access. The switch to e-prescriptions alone saves up to 500 million paper prescriptions per year (cf. Gematik, 2024). The electronic patient file offers features for the further expansion of digitalisation in the healthcare sector, which are discussed in the next chapter.

2.2 ePA and ePA4all

As the legal authority, the Federal Ministry of Health (BMG) describes the electronic patient file (ePA) as an opportunity for greater patient sovereignty. The functionalities of the ePA have been successively expanded since 1 January 2021. In contrast to the eHC, the EPR can be used as a smartphone application (app) and is therefore more digital than the eHC. Since January 2022, the ePA can also be used browser based, for example as a desktop version on a PC.

The basic data are those which can also be used with the eGK. In addition, more sensitive health data such as findings, diagnoses and treatment reports will also be accessible. One aim of the ePA is to provide patients with more precise information about their diagnosis and treatment. In the long term, this transparency should empower and enable them to engage in dialogue with their treating physicians on an equal footing and have a greater say in their health (Bruhn, H., 2023). Since its introduction, the use of electronic patient records has been voluntary for health insurance customers. This will change from 15 January 2025, when the new electronic patient record will become part of standard care in the German healthcare system and therefore the ePa for all or ePA4all. This means that digitalisation in

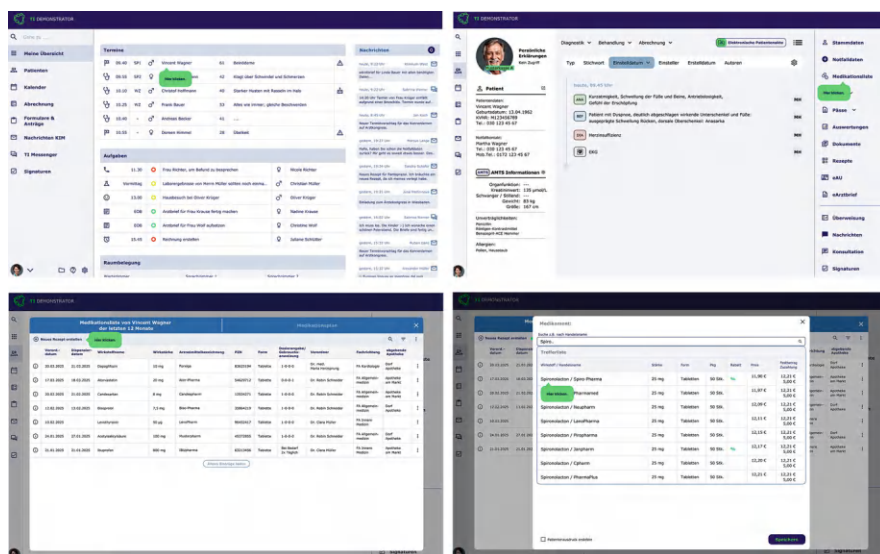


Fig. 2 Extract from an ePA as a click dummy for the medication case (Gematik GmbH, 2024a, <https://www.gematik.de/anwendungen/epa/epa-fuer-alle>, 03.08.2024. 18.00 Uhr). A split-screen interface of a medical software application. The left side displays a dashboard with sections for appointments, tasks, and messages. Appointments include names like Vincent Wagner and Christof Hoffmann, with tasks such as “Anruf für Frau Wolf aufzeichnen.” The right side shows a patient profile with personal details, medical information, and tabs for diagnostics, treatment, and billing. A highlighted button labeled “Werkzeuge” appears on both sides. The interface uses a blue and white color scheme with navigation menus on the left and right

the German healthcare system will virtually take its next step. As the ePA4all will become part of standard care, a corresponding digital file will automatically be created for everyone. A novelty. While opt-in, i.e. active consent, otherwise applies in Germany, the opt-out procedure applies here. Insured persons must actively object if they do not wish to use ePA4all (Gematik GmbH, 2024b). The advantage of ePA4all is the usability of health data. It is bundled in the ePA and can be utilised for everyday care thanks to its digital form. Access no longer has to be authorised individually by the patient. However, it is still possible to object to access. Insured persons remain in control of their data. The Patient Journey is more easily integrated into everyday life. Networking between doctors, pharmacists and nursing staff will become more individualised and simpler. There is a click dummy on the Gematik website (Fig. 2), which uses a patient's medication as an example to interactively illustrate the Patient Journey using the ePA app.

The most important thing: the data is protected in line with the times. Everything remains within the telematics infrastructure. The health insurance companies, as the so-called payers, do not have access to the stored data, even if it could be assumed, as the health insurance companies are the operators of the ePA record system.

With all digital solutions, it is important to ultimately enable those who should and want to use these features in their patient journey.

2.3 TI Messenger—TIM

What is taken for granted in the private sphere with WhatsApp, Signal or Telegram is not available in messenger form in the healthcare sector. Not yet. With the TI-Messenger, or TIM for short, fast messages in real time are also set to find their way into the German healthcare sector.

With TI-M Pro, health professionals can communicate with each other quickly. These are, in particular, healthcare professionals and cost bearers. With the TI-M ePA, the focus is on fast and simple communication between the insured and healthcare professionals as well as health insurance companies. This messenger will be available in the course of 2025 and will simplify communication. TI-M Connect will be able to be integrated into the products and platforms of certified providers. The focus here is on value-added applications such as video chat and video consultations.

For users, the TI-M ePA is likely to be the messenger that is most relevant to them. The big difference and advantage of the TI messenger is that messages are sent securely and confidentially. The telematics infrastructure has been developed for the healthcare sector and participants in the healthcare market. Unlike WhatsApp and Co., the strict German data protection guidelines apply to the TI Messenger (cf. Gematik, 2024).

For TIM to be used and accepted, users must also be able to use this feature. More on this in Sect. 24.3.

2.4 Service App

The health insurance companies also offer their policyholders service apps. Some integrate the ePA and ePA4all into their service apps, others offer them in addition. It depends on which app strategy the individual health insurance companies pursue.

Basically, the so-called self-services are offered via the service apps. These include, for example, changes of address, changes to bank details or uploading documents as proof and for the reimbursement of costs or subsidies such as professional dental cleaning.

The legislator has also specified which self-services should be offered via the service apps in any case. This is regulated by the Online Access Act (OZG). The OZG applies to administrative services provided by public bodies at the federal and state level and includes, in particular, legal entities under public law. This also includes the health insurance funds, both federal and state (cf. § 1 (1) OZG). The administrative services that are to be mapped as digital processes include applications for maternity benefit, home help, children's sickness benefit, family insurance, preventive care, short-term care, care services and combination services as well as digital bonus programmes, foreign sickness certificates, substitute treatment certificates, exemption from statutory co-payments and changes to the insured person's status and accident questionnaires.

2.5 DiGA

Digital health applications, or DiGA for short, are digital offerings that are evaluated and authorised by the Federal Institute for Drugs and Medical Devices (BfArM) (2024). In accordance with the provisions of § 139e SGB V, the BfArM examines whether the relevant requirements for authorisation have been met. The aim is to demonstrate that the digital services have a positive effect on care and thus contribute to maintaining or improving the health of patients. There are currently 64 digital services. The major advantage for users is that the costs of the DiGA are reimbursed by health insurance companies if it has been approved by the BfArM and prescribed by a doctor. The Federal Institute for Drugs and Medical Devices provides an up-to-date overview on its website.

3 Participants

3.1 User

Customers are changing their behaviour. They communicate everywhere and at all times. At the same time, expectations regarding the availability and quality of customer service are rising (cf. Bearingpoint, 2017). According to a representative end customer survey with 1004 participants, 65% of respondents have no problem spending 1–2 min on hold on the phone if their enquiry is subsequently resolved. At

Wie wichtig oder unwichtig ist es im Allgemeinen, dass die von Ihnen bevorzugten Marken auf folgende Weise handeln und kommunizieren? - Mit Authentizität

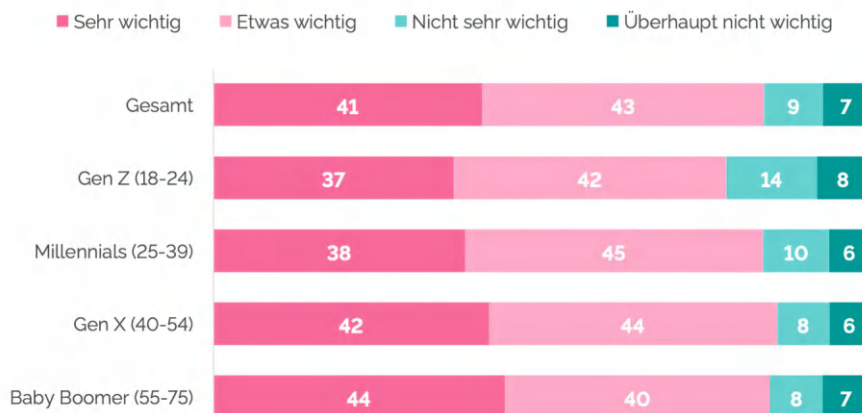


Fig. 3 YouGov Profiles (Stand: 19.07.2020), Total population ($n = 11.345$) compared to respondents between the ages of 18 and 24 ($n = 1.294$), 25 and 39 ($n = 2.989$), 40 and 54 ($n = 2.805$) and between the ages of 55 and 75 ($n = 3.941$) (YouGov, 2020, Marketing-Trends der Zukunft, S. 7). The image is a horizontal bar chart showing the importance of authenticity in brand communication across different generations. The title in German asks how important it is for preferred brands to act and communicate authentically. The categories are “Sehr wichtig” (very important), “Etwas wichtig” (somewhat important), “Nicht sehr wichtig” (not very important), and “Überhaupt nicht wichtig” (not important at all). The chart compares responses from Gen Z (18-24), Millennials (25-39), Gen X (40-54), and Baby Boomers (55-75), as well as an overall total. The majority across all groups find authenticity very or somewhat important, with Baby Boomers rating it highest in importance

52%, every second respondent expects a service time of 8 am to 8 pm from Monday to Friday to be perfectly adequate. At 50%, fast, simple and conclusive processing of concerns is more important than a wide range of contact channels (Fig. 3).

The study on the ‘10 Trends für die Zukunft der Gesundheit’ acts as a valuable guidelines that enable you to act competently and confidently in the dynamic world of healthcare. In addition to healthcare organisations, health insurance companies and healthcare associations, local authorities, politicians, training and education providers, retailers, industry, technology developers and HR are also influenced by these trends.

The majority of consumers want authentic communication. With increasing age the wish for this grows. The older people get, the more important this becomes for them. Generation X (40–54 years) in particular attaches great importance to this (Fig. 3).

Younger customers in particular appreciate self-service offers, for example to change their address or bank details. For many customers, the possibility of personal

contact with a human is still extremely important. Only 17% of respondents can imagine discussing their concerns exclusively with a robot in the future (cf. Bearingpoint, 2020b). In a 2017 survey, 23% of all respondents stated that they would only communicate digitally (cf. Bearingpoint, 2017).

Increasing digitalisation in the healthcare sector and the current and upcoming services (cf. Sect. 2) offer insured persons the opportunity to actively take control of and promote their health (cf. Zukunftsinstitut, 2024b). In the Zukunftsinstitut's publication on the world of healthcare in 2049, patient well-being takes centre stage. Essentially, this means that it is about shaping a healthcare world that thinks radically from the patient's perspective. This means that they are involved in all decisions that affect their own health. The megatrend of individualisation (op.cit) is a basic prerequisite for this change in values. For people, this means more rights on the one hand and more duties on the other. They have to take more responsibility for themselves and their health, but in return receive more participation and sovereignty (cf. Roche, 2020). The so-called patient journey (cf. Thieme, 2024) is moving to the centre of the process design.

For this to succeed, it is important to enable insured persons to understand and use digital services. This support option is regulated in §20k of the Fifth Social Security Code. It states that the health insurance fund shall provide benefits in its statutes to promote the self-determined, health-oriented use of digital or telemedical applications and procedures by the insured persons. 'The services are intended to provide the skills required for the use of digital or telemedical applications and procedures' (§20k (1) SGB V).

With this legal provision, the health insurance funds are obliged not to leave their policyholders alone with the digital offerings.

This could include providing specific further training programmes, contributing to the costs as part of cost reimbursement and, as part of their duty to provide advice (cf. §14 SGB I), supporting insured persons in setting up and using them.

This is a requirement for customer service counselling, which is a new addition to the existing counselling portfolio. In order for counselling to be successful here, employees in the company must also be empowered to meet this requirement (see Sect. 3.2).

3.2 Employees and Companies

The aim of the companies is to communicate the digital offers, as we learnt about them in Sect. 2, to the customers. On the one hand, this is done through suitable communication measures that are controlled by marketing and are broadly based. On the other hand, it is the employees in customer service who are in daily contact with customers. The digital features can be actively and specifically addressed in personal customer contact. In addition, the customer advisors are available to users as a contact for queries or product information. More and more companies are attaching great strategic importance to customer service. Outstanding service is an important lever for setting oneself apart from the competition, other health

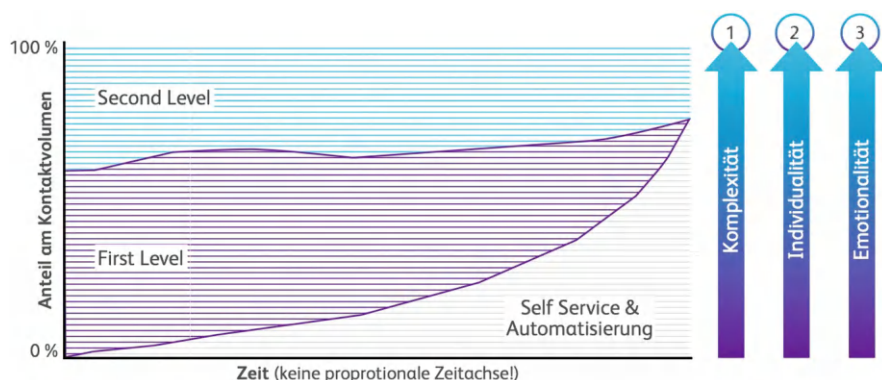


Fig. 4 Due to the increasing automation of simple and standardised service contacts, the remaining enquiries are becoming increasingly complex, individual and emotionally charged (Serviceexzellenz im persönlichen Kontakt, 2020, S. 3). A graph illustrates the distribution of contact volume over time, divided into “First Level” and “Second Level” sections. The x-axis represents time, labeled “Zeit (keine proportionale Zeitachse!)” indicating a non-proportional timeline. The y-axis shows the percentage of contact volume from 0% to 100%. The graph highlights a trend towards increased self-service and automation. On the right, three vertical arrows labeled “Komplexität,” “Individualität,” and “Emotionalität” suggest increasing complexity, individuality, and emotionality

insurance companies. Service contacts are becoming a ‘moment of truth’. The right mix of human expertise and technological support plays a decisive role in this (cf. Bearingpoint, 2020b). Younger customers in particular appreciate a mixture of self-service offerings, e.g. to enter their address or bank details change (e.g. with an app, website or chat). Nevertheless, the possibility of personal contact with a person is still extremely important to many customers. The fact that self-service offerings are used for the majority of standard enquiries and requests means that the remaining enquiries are predominantly the more complex issues (Fig. 4).

These more complex issues must be handled by the service employees. The requirement profiles therefore need to be updated both in terms of the breadth and depth of advice. Personal initiative, personal responsibility, emotional intelligence as well as a desire to learn and curiosity are coming to the fore. Companies must create the necessary framework to enable employees to fulfil the new requirements (Fig. 5).

In the study *Service Excellence in Personal Contact* (2020), Bearingpoint describes the change in customer service teams as the move from generalists to future agile and creative consultants. Fig. 5 shows what these characteristics are. These characteristics are confirmed in the study *Man & Machine in Customer Service* as part of a company survey on the future requirements for service employees.

In order for this path to be successfully travelled, employees must (also) be empowered by companies so that they can (further) develop their skills to meet the changing requirements (cf. Zukunftsinstitut, 2024b). At the same time, it also means



Fig. 5 Five characteristics or skills of customer service employees in particular will become increasingly important in personal customer contact in the future. Note: Personal contact also includes telephony (Bearingpoint, 2020b, Serviceexzellenz im persönlichen Kontakt, S. 9). A diagram illustrating key competencies for professional development, centered around an icon of a person with a gear in place of the head, symbolizing problem-solving. Surrounding the central figure are five labeled sections: “Resilienz” with skills like critical thinking and stress management; “Fachwissen” emphasizing higher qualifications and depth of knowledge; “Problemlösungskompetenz” highlighting analytical thinking and developing solutions; “Eigeninitiative” focusing on intrinsic motivation and decision-making; and “Emotionale Intelligenz” about understanding and responding to customer emotions. Each section is linked with icons representing the respective skills

a change in the recruiting process when looking for and hiring new employees for the service. According to Bearingpoint, there are five strategies for companies to respond to the changing requirements (Fig. 6).

Technical assistants are important so that advisors can concentrate fully on their advisory activities and inspire customers at the ‘moment of truth’. Their task is to provide the information required for comprehensive advice quickly and easily. These can be knowledge databases, group chats or digital platforms, for example, where service advisors can exchange information and share their experiences.

The further development or empowerment of employees and recruiting was discussed above.

Another important component is the coaching of managers, who are the first point of contact for employees as enablers. They should support and empower rather



Fig. 6 Fünf wesentliche Strategien, um auf die veränderten Anforderungen an die Kundenservice Mitarbeitenden zu reagieren (Bearingpoint, 2020b, Serviceexzellenz im persönlichen Kontakt, S. 13). Five interconnected blocks illustrate a process. Block 1: “Technische Unterstützung” with a robot icon, indicating technical support. Block 2: “Weiterentwicklung bestehender Mitarbeiter” with a presentation icon, representing employee development. Block 3: “Recruiting neuer Mitarbeiter” with a magnifying glass icon, signifying recruitment. Block 4: “Coaching der Führungskräfte” with a group and question mark icon, denoting leadership coaching. Block 5: “Schaffung organisatorischer Rahmenbedingungen” with a hierarchical icon, indicating organizational framework creation

than control and motivate. In order for this to be successful, managers must also be developed further.

Organisational competence for employees is a mandatory requirement so that advisors can respond quickly and, above all, individually to customer concerns. For example, flat hierarchies and agile methods are helpful.

This presupposes that the organisation, in particular the management and corporate culture, allows this. This is a question of attitude, which must also evolve. The emergence of every new mindset is a form of expanding awareness (Permantier, M., 2019).

In his book *HALTUNG ENTSCHEIDET* (engl. Mindset matters), Martin Permantier describes further examples of new competences with an expanded view of leadership:

- Being open to cultural change.
- Promoting value orientation and creating meaning.
- Establishing flexible working models.
- Acting in an environmentally conscious manner and developing sustainable concepts.
- Develop agile working methods.
- Establish a common understanding of leadership.
- Recognising and adequately promoting employee potential.
- Being able to utilise emotional intelligence.
- Putting together heterogeneous interdisciplinary teams.
- Recognising yourself as a manager as part of the problem.
- Recognising your own shadow.
- Dealing with different cultures and diversity.

Depending on what stage of development the organisation is at, adapting to change and the necessary further development of the framework conditions (*loc. cit.*) is easier and faster or more painful and slower.

Development takes place in leaps and bounds. Everything changes at each subsequent stage (Laloux, F., 2017, p. 18). The impulsive worldview (red), the traditional conformist worldview (amber), the modern performance-orientated worldview (orange), the postmodern pluralistic worldview (green) or the integral evolutionary worldview (petrol).

With regard to the healthcare industry and the assessment of the status quo, the majority of organisations are at the amber level. This is expressed in particular through process orientation and stable organisational structures (line or staff line organisation). As today's examples, Laloux specifically describes government agencies and public institutions as conformist. When the world changes, it is difficult for these organisations to accept this and to change and adapt (*cf.* Laloux, F., 2017, p. 23).

3.3 Provider

Gematik GmbH in Berlin is an important provider responsible for setting up and operating the telematics infrastructure (TI) (*cf.* GKV Spitzenverband, 2024). The TI is the platform for healthcare applications in Germany. The aim and task of Gematik GmbH is to expand and modernise this infrastructure and thus make it fit for the digital healthcare system of the future (Gematik, 2024).

Based on the specifications provided by Gematik, the health insurance funds make healthcare applications available to their policyholders and thus act as providers. In the development and operation of the applications listed under Sects. 2.1–2.4, the health insurance funds are supported by companies that have been awarded the contract as part of a tendering process in accordance with the award guidelines.

The digital health applications under Sect. 2.5 are created by various providers and made available to the healthcare market via the authorisation procedure of the Federal Institute for Drugs and Medical Devices.

‘The more digital we become, the more empathetic and emotional the technology needs to be. A good example of this is gamification and UX design in healthcare applications. These elements are crucial for the acceptance and use of health technology solutions by people. Emotional and empathic technologies will ultimately determine how successful digital health services will be’ (Matusiewicz, D., 2024).

4 Summary and Outlook

The functionalities of the applications will be further expanded. Processes along the patient journey will be further digitalised. The networking of the various participants in the healthcare system will continue. On the one hand, this is necessary regarding

the technical details. On the other hand, it is necessary in direct personal contact. More collaboration in the transfer of knowledge and experience is necessary. Technically, billing and cost transfer processes will be transferred to dark processing and processed and fed back by the machine in real time. Checking routines will be increasingly automated, freeing up the time required for increasingly complex advisory issues. Digital technologies and intelligent algorithms will speed up research, improve prevention and treatment decisions and make the healthcare system more efficient. Digital applications will enable insured persons to actively manage their health and discuss treatment with doctors on an equal footing. Patient empowerment is the magic word. The concrete next stages of development can already be found at Gematik GmbH and in the Online Access Act. Healthcare can be designed in such a way that it becomes more personalised, precise and preventative (cf. Traub, D., 2020). The more complex the interrelationships become due to the deliberate increase in networking, the more important the task of communication becomes in order to create transparency and establish traceability. Trust is a key factor in gaining the acceptance of patients and insured persons. Digitalisation and technology can help to improve quality in the healthcare sector. However, more is needed as part of this transformation process. Collaboration, transparency, communication and empowerment of all those involved is a mandatory prerequisite for jointly shaping the healthcare system of the future. Digital applications are only the tools needed to realise future-oriented and high-quality care.

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Hans-Juergen Bruhn has been Head of Customer Service at one of the largest company health insurance funds since 2021.



Unlocking the Potential of Automation and AI for Medical Practices

Shabnam Fahimi-Weber

Abstract

This chapter examines how medical practices can streamline administrative tasks, such as scheduling and billing, and enhance medical processes such as diagnostics and personalized care through the use of automation and AI. A case study highlights the tangible benefits of integrated solutions in reducing staff burden and improving the patient experience. Based on an assessment of Germany's current and potential adoption of automation and AI, Fahimi-Weber finds that administrative automation and AI applications offer immediate efficiency gains, while medical automation and AI tools face regulatory and ethical challenges. The chapter emphasizes the need for regulatory reform, practitioner education, and cultural change to enable wider adoption. Fahimi-Weber concludes automation and AI to be essential for the future of healthcare and the future of medical practices.

Is healthcare a handcraft? Undoubtedly, much of the core healthcare is closely linked to the personal involvement of highly trained doctors and medical staff. However, with the accelerated rise of technology, especially automation and AI, in all areas of life, we are almost forced to consider how, not if, healthcare can benefit from it too.

This question has never been more relevant. Of course, that is due to the extremely rapid pace at which these technologies are advancing. But it is also driven by the growing need for healthcare providers, such as medical practices, to operate at the highest levels of efficiency. In an environment where fees for medical services

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are stagnating in real terms and qualified staff is scarce, medical practices are almost forced to pursue initiatives for more efficiency. This is especially true for innovations that reduce the demands on medical staff, as they have the potential to alleviate both the operational and economic pressures that medical practices face today.

In fact, it is widely accepted, that digital tools should be a cornerstone of the future of medicine. A [survey](#) found that 7 out of 10 medical practitioners agree there is great potential in adopting digital technologies. Yet in many places, digitization faces an uphill battle. There is real resistance to it among medical practices—for absolutely valid reasons. Forced digitization without real benefits for those involved has caused so many negative experiences that the very idea of digitization seems to deter many owners of medical practices from implementing new tools. Moreover, the change that is necessary requires physicians to rethink not only their professional self-perception, but also their role within their own organization toward being a force for change and modernization.

The following pages examine the value of automation and AI for medical practices and how they are already improving daily workflows. We differentiate between administrative and medical applications and also assess the obstacles to a broader adoption of automation and AI tools in medical practices.

1 Automation vs. AI in the Context of Medical Practices

Historically, business process automation (BPA), or simply automation, is not an invention of the healthcare sector. It originates in the optimization of industry processes—an area that operates in a very different way, compared to healthcare. However, the idea behind automation is just as relevant to healthcare: to create efficient processes that reduce the reliance on staff while at the same time speeding up processes without compromising the quality of the output or outcome. Engaging in automation has always been advantageous, whether in industry or in healthcare. But the current economic conditions make it even more important now—for the health of the practice itself. Perhaps the AI boom, which is now sparking a renewed interest in automation, is coming just in time to give struggling healthcare providers another chance.

Both automation and AI can make daily tasks easier. There is, however, an important difference between the two. Automation is particularly useful for tasks that are repeated very often without being very demanding each time. More complex tasks can quickly become out of reach for automation tools, as there is always a certain limit to the depth at which automation tools can operate. AI can extend this limit significantly. As a result, automation tends to provide quantitative relief, while AI provides qualitative relief. Combining both types of tools can lead to big leaps in productivity—which in turn translates into better outcomes for everyone involved in the delivery of healthcare—from practices to payors to patients.

AI is often seen as an evolution of simpler automation algorithms. However, in many cases algorithms without AI are perfectly adequate to solve a problem, so AI should not be overused as a label of excellence—and software solutions should not be categorized as containing or not containing AI. A more useful approach to categorizing available automation and AI tools is to ask what their intended use is. In general, automation and AI tools can support either administrative processes or the actual delivery of medical care. Administrative tools have lower barriers to adoption. Therefore, a wide variety of use cases can be supported by automation and AI. Medical automation and AI tools are much more scrutinized and often serve very specific niche use cases for different medical fields. As a result, their availability is much more limited. In the following chapters we will take a closer look at both widely available and adopted administrative tools and emerging but limited medical automation and AI tools.

2 Automation and AI for Administrative Purposes in Medical Practices

Medical practices have long been burdened by labor-intensive administrative processes. Patient scheduling, billing and workflow management are not only some of the most common, but also some of the most tedious daily tasks for medical staff. As such, these areas are poised to benefit from automation and AI in much the same way as they have outside of healthcare, where automation and AI are already proving to be increasingly powerful. By streamlining their operations, medical practices can not only reduce administrative burdens and decrease human errors, but also free up staff resources to focus on delivering high-quality patient care. Patients, in turn, benefit from smoother processes, more accessible services and better communication with healthcare providers. Therefore, an emphasis on a more technology-enabled practice management could actually pave the way for a future where patient care is more efficient, accurate, and patient-centered.

2.1 Automated Appointment Scheduling and Patient Management

Traditionally, scheduling and patient data management have been handled manually, often resulting in inefficiencies, missed appointments, or communication lapses. With the rise of digital platforms, these processes are being streamlined, creating a more patient-friendly experience while significantly reducing the administrative burden on healthcare providers by immediately reducing the number of calls that medical practices must answer and process. With many practices already using these technologies, the potential of automation in appointment scheduling and patient

management is already very visible. In general, these systems offer the following key features:

- **Online appointment booking:** Patients can independently book appointments at any time of the day through easy-to-use online interfaces.
- **Automated reminders:** SMS or email reminders ensure patients are well informed in advance. Rescheduling options reduce no-show rates.
- **Practice integration:** Scheduling systems should be linked to broader practice management tools for seamless data flow, ensuring smooth communication and workflows.

In the future, appointment scheduling may see further integration with AI-driven systems that could offer even more personalized appointment times based on historical data and patient profiles. These systems could also assist in patient triage, offering symptom-based scheduling to prioritize urgent cases—although this application would obviously involve a medical use of AI.

2.2 Automated Billing Management

The administrative demands of billing are notoriously complex, particularly in systems like Germany's, where multiple insurance providers and public health systems are involved. Healthcare professionals often spend significant time ensuring accurate billing and compliance with regulatory requirements—sometimes even shutting down medical practices for an entire day to work on documentation and billing requirements. Modern practice management systems offer automated billing features that significantly reduce these burdens. Key functions include:

- **Automatic recording:** Documentation is an oftentimes tedious task. Speech-to-text is therefore a major driver of efficiency for many doctors.
- **Automatic coding of services:** This ensures that the services provided are suitable for billing purposes.
- **Digital invoicing:** Automated systems create and transmit invoices for the statutory health insurance system or to private patients.
- **Error checks:** Billing errors or risk of recourse can be detected by AI-driven algorithms that ensure completeness and plausibility before submission.

In Germany, practice management systems must meet the stringent requirements of the Kassenärztliche Bundesvereinigung (KBV). Systems that match these certifications ensure that healthcare providers consistently comply with national regulations, reducing the risk of costly errors or audits. However, they rarely include advanced automation.

Looking ahead, AI-based documentation is likely to remain an area of new product innovation, which in turn will minimize errors and increase efficiency

throughout the billing process. We may also see more advanced financial tools that provide insight into resource allocation to help medical practices manage financial planning.

2.3 Automated Workflow and Resource Management

Automating workflow and resource management is critical to improving the operational efficiency of medical practices. When should a patient be called? What room will be available next? In how many minutes? Digitizing internal processes makes it easier to answer these questions by standardizing workflows and tracking progress in real time but workflow automation can go much further, eliminating many manual steps to reduce the likelihood of human error and ensure consistency in care delivery. These are some of the features that are already being used:

- **Automated document generation and delivery:** Documents can be generated based on specific actions and then sent to a specific address. For example, personalized medical history questionnaires can be sent in advance of a patient's first appointment.
- **Automated recalls:** Patients can be automatically contacted and reminded of their next regular appointment within a specified period of time after their last appointment.
- **Advanced inventory management:** AI-powered systems can predict demand based on historical data, allowing medical practices to optimize inventory levels, such as vaccines.

In the future, AI is expected to take a more active role in workflow management, not only organizing tasks but also suggesting process improvements based on predictive data. AI systems may soon be able to identify inefficiencies in real time and recommend changes that could further optimize workflows and resource allocation—including medical staff.

3 Automation and AI for Medical Purposes in Healthcare

A recent [survey](#) highlights that 70% of Germans believe that doctors should be assisted by AI whenever possible. This reflects growing public trust in the role of AI in healthcare. These technologies are being adopted across Germany, with pilot projects and real-world applications demonstrating their ability to improve clinical accuracy, efficiency, and patient outcomes—while at the same time reducing the time medical staff spends on these tasks.

Imaging and diagnostics	AI is making significant contributions in medical imaging and diagnostics. Both accuracy and speed are being affected. For example, AI algorithms are already being used to analyze radiology images faster and with fewer errors than traditional methods, reducing the diagnostic burden on healthcare professionals.
Clinical decision support	AI-powered clinical decision support systems assist healthcare professionals by analyzing vast amounts of data to provide evidence-based recommendations. However, the technology still faces regulatory and ethical challenges. Data privacy concerns and the need for further validation are needed before widespread use. In general, large providers such as hospitals are closer to using such tools than medical practices.
Personalized medicine	AI can facilitate personalized medicine by using patient data to tailor treatments based on genetic, environmental, and lifestyle factors. This approach holds great potential for individualized treatment plans and risk prediction. While personalized medicine is still in its infancy in Germany, advances in AI are driving risk assessment for conditions such as cardiovascular disease and cancer, promising more precise treatments in the future.
Remote patient monitoring	AI is also transforming patient monitoring. By enabling continuous, remote tracking of patient health, chronic conditions such as diabetes can be effectively monitored. AI can potentially play a big role in identifying early signs of health complications and triggering alerts for both patients and healthcare providers. Similar technologies are already reducing hospital visits and empowering patients to manage their health more proactively, although there is still room for improvement regarding the amount of data analyzed and its AI-based interpretation.

As these technologies continue to advance, they promise to reshape healthcare. In Germany, however, due to high regulatory hurdles, automation and AI are currently not as widely used for medical purposes as they are for administrative purposes. This, of course, means that there is great potential to improve accuracy, efficiency, and patient outcomes while maintaining or decreasing workload for highly skilled personnel.

4

Case Study: How Dubidoc’s Smart Solutions Automate Administrative Workflows

As demonstrated in the preceding paragraphs, there is significant potential for the enhancement of various administrative workflows. Dubidoc, a German provider of automation software for medical practices, addresses these challenges by offering comprehensive solutions. The goal of the software is to transform the entire patient journey, except for the actual medical treatment, into a seamless process. This chapter examines Dubidoc’s approach to improving workflows through smart online appointment booking and self-check-in solutions and assesses their impact on patient management, staff efficiency, and overall practice operations.

4.1 Dubidoc's Online Booking System: Automating Patient Intake

The traditional method of appointment booking in medical practices has been a manual and inefficient process. Patients call the practice on the landline, a staff member answers, manually checks the availability of time slots, negotiates times with the patient, and finally enters the appointment into the practice management system. If time allows, medical staff should also make reminder calls, which adds to the workload. This process is time-consuming and resource-intensive, as it diverts staff with medical training from more valuable interactions with patients, particularly in assisting with actual healthcare delivery. Additionally, busy phone lines, human errors, and a limited ability to efficiently manage time slots can lead to stress and dissatisfaction for both patients and staff.

Dubidoc's automated online appointment booking system eliminates these inefficiencies. Patients can access the booking platform 24/7 via the practice's website, view real-time availability based on the actual schedule, and select their preferred appointment slot—which can vary in length according to the selected type of appointment. Once the patient selects an appointment, the system automatically confirms the booking and adds it to the practice management software. Then it triggers a series of automated reminders via SMS or email leading up to the appointment. This reduces the likelihood of missed appointments, or “no-shows,” which are otherwise a very common source of frustration and lost revenue.

This self-service solution also offers advanced algorithms that optimize the distribution of appointments. They consider a variety of factors, including the type of visit, the availability and specialization of practitioners, the number of similar appointments, and the urgency of the consultation. As a result, the software is able to recommend suitable slots with remarkable accuracy, thereby further streamlining practice operations.

By automating the scheduling process and adding novel algorithms, Dubidoc helps medical practices not only to reduce phone calls, allowing administrative staff to focus on in-person patient care and other complex tasks, but also in aligning the schedule with the medical practice's own preferences and priorities.

The benefits of this automated system are significant:

- *24/7 availability* for patients to schedule their appointments, offering greater flexibility and convenience.
- *Reduced workload* for receptionists, as phone calls are minimized.
- *Optimization of schedules*, thanks to AI-driven algorithms that ensure optimal use of time and resources.
- *Fewer no-shows* due to automatic reminders.

4.2 Dubidoc's Self-Check-in: Streamlining Patient Admission

The conventional patient check-in process is another area that presents an opportunity for improvement. Typically, when patients arrive at a practice, they are required to wait in line to speak with a member of staff. The next step in the process requires patients to complete or update paperwork regarding insurance and personal details or medical information. This process is time-consuming and creates a risk for bottlenecks, particularly during peak hours. Furthermore, staff is usually tasked with simultaneously handling check-ins and other patient-facing responsibilities, which can result in longer waiting times and increased stress and unhappiness for patients.

Dubidoc's self-check-in stations provide a digital alternative that dramatically speeds up the patient admission process. Upon arrival, patients can quickly check in by entering their personal information and verifying or updating their insurance details through the interface. Any necessary forms, such as consent forms, can also be completed digitally. The system automatically updates the patient's record in real time. This way, medical practices have the most up-to-date information available when the patient is ready for their consultation. Furthermore, patients receive clear instructions on where to go next, making the process more intuitive and less stressful—with minimal need for staff assistance. The self-check-in stations also offer multi-language support, which makes the check-in process much smoother for a wider range of patients. With its numerous advantages, this solution reduces the administrative burden on staff, allowing them to focus on more complex tasks or provide personalized assistance to patients.

The main benefits include:

- *Reduced waiting times* as multiple patients can check in simultaneously, which eliminates long queues.
- *Accuracy* due to direct input by patients that minimizes errors related to manual data entry by staff.
- *Real-time updates* for patient records, providing medical practices with reliable information.
- *Improved accessibility* for a diverse patient population through multi-language support.

4.3 Automation Across the Patient Journey

The true power of Dubidoc's system lies in its ability to integrate these tools into a cohesive digital ecosystem that enhances the entire patient journey, from the moment an appointment is scheduled to the final steps of follow-up care. By connecting its online appointment booking platform to the practice's self-check-in stations and patient management system, Dubidoc creates a seamless flow of information. Dubidoc's platform also supports video consultations, allowing patients to meet with providers remotely, as well as live waiting time updates and

other innovations. In the future, Dubidoc aims to develop advanced algorithms that can automatically manage the distribution of appointments based on real-time data.

The entire patient journey, except for the physical treatment itself, will be digitized, increasing efficiency, minimizing human error, and providing greater continuity of care. As a result, the patient experience is greatly improved, while medical staff is freed up for other tasks. As medical practices continue to adopt technology solutions to meet growing demands, platforms like Dubidoc will be essential in ensuring that healthcare providers can focus on what matters most: delivering quality care.

5 Barriers Toward a Broader Implementation in Germany

5.1 Technical Barriers to Automation and AI in Healthcare

Medical practices cannot be expected to manage a multitude of additional software solutions. Automation and AI must be a part of existing software. Here, the legacy software used by most of the medical practices stifles innovation by giving medical practices a false sense of simplicity. Many think, it is easiest to just have one legacy system for most workflows. In this case, the simplicity comes from having fewer tools rather than from having tools that do their job very well and interact seamlessly. As a result, many medical practices may be missing out on automation or AI opportunities, that could actually make life easier for medical staff. Of course, there are conversion costs associated with switching to another software vendor, but these may not be as high as expected. Therefore, many medical practices simply stick with their system and in doing so actually disincentivize their vendor from introducing product innovation. When the staying power is so great, it is simply too attractive not to innovate.

On the other hand, medical practitioners are not as knowledgeable regarding technology as they would need to be. This goes back to the nature of the profession, which is much more human-focused than technology-focused. This means that medical training, as extensive as it is, does adequately prepare doctors to assess the potential of automation and AI tools. It could be argued that standard medical training does not even prepare doctors to run a medical practice at all, except for the craft of medicine itself.

5.2 Ethical and Societal Barriers to Automation and AI in Healthcare

When medicine is viewed primarily as a craft, then working in this field does not necessarily involve the use of cutting-edge technology. Of course, this perception is changing. It has to but as long as this perception exists, it can stifle progress. Again, this goes back to the medical training. The way we think and talk about working in healthcare is not the way it should be. Healthcare should attract not only

the compassionate and the caring with an interest in anatomy, but also those with a great interest in technology. This is, of course, a societal issue.

On the other hand, patients want to be treated in the most promising way possible. This issue requires minimal concern, as it is evident that patients are considerably less concerned and markedly more open to the utilization of technology in healthcare. For example, a survey of 1000 patients conducted in 2024 revealed that two-thirds of patients would be generally willing to accept digital treatments (EY “Digital Health” study 2024). It is reasonable to assume that patients have the greatest interest in an efficient and effective healthcare system. It could be argued that patients are more concerned with the outcome than the method of treatment. Consequently, if automation and AI enhance the healthcare system, it is likely that patients will support these developments. Indeed, 16% of respondents of the same survey indicated a preference for digital treatments, which implies that they believe this will result in better outcomes than traditional treatments.

It should be noted, however, that there are certain limitations regarding participation. This is not a factor that is relevant for the utilization of automation or AI tools that are employed behind the scenes. It is not necessarily the case that patients must have a detailed understanding of the precise technical processes that are occurring. This remains the responsibility of medical practitioners. However, if automation or AI tools require input from patients, it is essential that they are aware of these tools and how to use them. Digital health literacy will continue to grow, but there is a real possibility that some segments of the population will have a harder time benefitting from digital health solutions than others. Based on our observations, even elderly people often see value in these and try to participate as much as possible. Nevertheless, this limitation remains a relevant consideration.

5.3 Regulatory Barriers to Automation and AI in Healthcare

One of the key challenges to the adoption of automation and AI in healthcare is the presence of regulatory barriers. It is not the intention of this brief analysis to provide a comprehensive legal assessment of the situation. However, it is clear that the handling of medical data, or even just personalized data sets, requires the utmost level of care. This means that medical practices are not free to test and experiment with technology in the same way as other businesses. Medical practices are, for instance, obliged to use whitelisted software for a range of vital tools for functions such as billing, the administration of patient data, or video calls.

But strict regulation not only places a hard limit on what is possible and what is not. It also acts as a deterrent for medical practitioners from exploring the potential of advanced software tools because of the significant legal risks involved. In particular, when medical practices are unsure whether a tool can be used, the prospect of potentially violating data protection regulation discourages many practitioners from implementing a tool. There is always a risk of non-compliance with data privacy regulations, such as the General Data Protection Regulation (GDPR). Medical practitioners may not be able to fully understand all relevant

legislation and may therefore act more cautious than absolutely necessary. This, however, leads to medical practices being unable to fully exploit the potential of technological advances.

6 Future Perspectives for Automation and AI in Medical Practices

The German healthcare system is facing challenging times. Demand for healthcare services is growing, while medical staff is in short supply. To make matters worse, the overall cost-benefit ratio of the healthcare system is lagging. This imbalance suggests that simply throwing more money at the problem will not produce the desired improvements. Instead, automation and AI offer a smarter alternative that can streamline workflows, improve patient care, and reduce the burden on healthcare staff. Medical practices play a key role in this context.

6.1 The Path Forward for Medical Practices

For medical practices, automation and AI should no longer be considered a luxury, but a necessary step to remain competitive and efficient. Key areas such as scheduling, billing, and workflow management offer opportunities for significant improvement with relatively low barriers to entry. By starting with these administrative tasks, practices can achieve sustainable gains that benefit both staff and patients—particularly by speeding up processes and reducing demands on medical staff. In the longer term, more advanced AI applications, such as predictive analytics and clinical decision support, will further enhance care delivery and resource management.

While the benefits are clear, progress in Germany has been surprisingly slow. Resistance to digital transformation remains prevalent in many medical practices, driven by skepticism and fear of disruption, compliance concerns, and a lack of familiarity with new technologies. However, given the high potential for improved outcomes, practices need to overcome these hesitations. Education and support are crucial in this regard. Medical staff need not only technical training but also an understanding of how these tools can improve their workflow and the overall performance of the practice, including financial aspects.

To encourage wider adoption, the regulatory framework in Germany needs to evolve to support innovation. Currently, the regulatory burden discourages practices from considering AI and automation. Policymakers should aim to streamline regulations in a way that balances patient privacy with the need for technological advancement. Clear guidelines and certifications can give medical practices confidence in adopting new tools without fear of violating regulations. After all, medical professionals should be free to spend the majority of their time doing what matters most: providing quality patient care.



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Human–Computer Interaction: Paths to Understanding Trust in Artificial Intelligence

Stefanie Steinhauser

Abstract

Healthcare is being transformed by artificial intelligence (AI), enhancing efficiency, accuracy, and personalization. AI's capabilities, including analyzing large datasets for diagnosis and predictive analytics, have the potential to reshape healthcare delivery. However, the successful integration of AI depends heavily on the trust placed in these systems by healthcare professionals and patients. Trust in AI systems in the context of human–computer interaction (HCI) involves the belief in its performance, data handling, and unbiased information, necessitating transparent and user-friendly AI design. This chapter explores the critical role of human–machine trust (HMT) within healthcare, examining how it can be built and maintained. By addressing human and machine-related factors as well as regulatory and ethical considerations, AI's potential can be fully realized to improve healthcare outcomes.

1 Introduction

The healthcare sector is undergoing a profound transformation, driven by the integration of artificial intelligence (AI) and the increase of human–computer interaction (HCI). These developments are reshaping the way healthcare is delivered, making it more efficient, accurate, and personalized. From streamlining administrative tasks to supporting complex diagnostic processes and enabling remote patient monitoring, AI is becoming an indispensable tool in modern healthcare. However,

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the successful implementation and acceptance of AI in healthcare heavily depend on the trust that humans place in these intelligent systems.

AI's capabilities in healthcare are vast. It can analyze large datasets from patient records, imaging procedures, and electronic medical devices to uncover patterns and insights that might elude human practitioners. For example, AI algorithms can assist in diagnosing diseases with high accuracy by interpreting medical images and predicting patient outcomes based on historical data.

HCI describes the engagement of healthcare professionals and patients with AI systems. Effective HCI design ensures that AI tools are user-friendly, transparent, and reliable, which is essential for fostering trust. Trust in AI is multifaceted; it involves the belief that AI systems will perform as expected, handle data responsibly, and provide accurate, unbiased information. This trust is not easily granted; it must be earned through consistent performance, clear communication, and demonstrable benefits.

Trust in AI within the healthcare context is particularly critical. Healthcare professionals need to trust that AI systems can aid them without compromising patient safety or autonomy. For patients, trust in AI involves confidence that their personal health data is secure and that AI-driven recommendations are in their best interest. Establishing this trust requires addressing ethical concerns, such as data privacy, algorithmic transparency, and the potential for biases in AI systems.

The dual impact of AI and HCI on healthcare can be seen in various applications. AI-powered virtual health assistants provide round-the-clock support, answer medical queries, and remind patients to take medications, thereby enhancing patient engagement and self-care. Robotic surgery systems, guided by AI, offer unprecedented precision, reducing the risk of complications and speeding up recovery times. These advancements underscore the importance of trust, as patients and healthcare providers must rely on these systems to function accurately and safely.

This chapter is structured as follows. First, AI and its applications in healthcare are illustrated. Thereafter, human–computer interaction and the concept of trust are introduced. Subsequently, factors influencing trust in the context of HCI in healthcare, dynamics of trust, and measures to build trust are discussed.

2 Artificial Intelligence

AI has become one of the biggest technological trends in recent years. The US market researcher Gartner describes it as one of the most disruptive technologies with growing potential, thanks in part to open source innovations (Gartner, 2019, 2023). Interest in the capabilities of AI is omnipresent, and new publications on the topic are released on a daily basis.

AI can be divided into “weak” and “strong” concepts. Weak AI is often used in commercial areas and utilizes human-like abilities (e.g., Cimatti et al., 2003; Hengstler et al., 2016). Through visual perception or the recognition of correlations,

specific problems can be solved in concrete applications. This AI can learn from its own mistakes and achieve increasingly better results. Its outcomes in individual aspects of human intelligence, such as visual perception, are evaluated more accurately and faster than humans could. Therefore, it serves to support humans by providing precise data. All existing AI approaches to date can be classified as weak AI. AI-supported systems used today are heavily dependent on human input and the availability of data. The “strong” concept of AI goes beyond the capabilities of “weak” AI. It not only masters individual skills used for specific tasks but also possesses an intelligence similar to human intelligence. However, this level of AI has not yet been realized, and the AI systems currently in use primarily support human activities rather than replace human intelligence.

The almost universal applicability of AI makes it interesting for numerous areas of our lives. In principle, the use of AI is conceivable wherever the collection of large amounts of data is possible and their evaluation is useful.

2.1 AI in Healthcare

Health data, obtained from patient records, imaging procedures, or electronic records of medical devices, form the basis for AI-based applications and hold immense potential for improved diagnosis and treatment. However, this potential often remains untapped, as only a fraction of the data collected is currently processed and used for further applications. Only when all health data is available in digital form can the benefits of AI solutions be fully exploited.

One important measure to unlock this potential is the introduction of electronic health records (EHRs). While these records are already standard in many countries, such as the USA, Estonia, or Scandinavian countries, other countries such as Germany have some catching up to do in terms of digitization in the healthcare sector (e.g., Steinhäuser & Raptis, 2023). An EHR can be described as a database where doctors can make individual entries for each patient. These entries can be viewed, changed, or deleted by the patient at any time. The aim is to achieve cross-case and cross-institutional cooperation, more time for actual care, and transparency for the patient.

The goals of using AI in the healthcare sector can be defined, among others, as relieving the burden on nursing staff, supporting doctors in making diagnoses, and helping to prevent errors. The use of AI in the medical environment can be divided into two areas: virtual systems and physical applications. Virtual systems take the form of mathematical algorithms, which are programmed by humans and trained on the basis of large amounts of data using deep learning. Physical applications, on the other hand, consist of robots or medical devices that can be fed with AI-based programs.

2.1.1 Existing and Potential Future Areas of Application

The areas of application for AI in healthcare are very diverse and range from performing simple administrative tasks to highly complex robot-assisted surgery

(e.g., Guo et al., 2020; Schwalbe & Wahl, 2020; Rajpurkar et al., 2022). Here are some key areas where AI is making significant impacts:

- *Administrative efficiency*: AI can streamline administrative processes by automating routine tasks such as scheduling, billing, and maintaining medical records. This reduces the administrative burden on healthcare providers and allows them to focus more on patient care.
- *Diagnosis and treatment*: AI algorithms can analyze vast amounts of medical data to support doctors in diagnosing diseases more accurately and quickly. For instance, AI can assist in interpreting medical imaging, identifying patterns that may not be visible to the human eye, and suggesting potential diagnoses.
- *Predictive analytics*: By analyzing historical patient data, AI can predict disease outbreaks, patient admissions, and the likelihood of certain diseases. This predictive capability enables proactive healthcare measures, improving patient outcomes.
- *Personalized medicine*: AI can help tailor treatments to individual patients based on their genetic information, lifestyle, and other factors. This personalized approach enhances the effectiveness of treatments and minimizes side effects.
- *Drug discovery and development*: AI accelerates the drug discovery process by analyzing biological data to identify potential drug candidates, predicting their efficacy, and optimizing clinical trial processes. This can significantly reduce the time and cost involved in bringing new drugs to market.
- *Robotic surgery*: AI-powered robots can assist surgeons in performing precise and minimally invasive surgeries. These robots can enhance the surgeon's capabilities, reduce the risk of complications, and speed up patient recovery times.
- *Virtual health assistants*: AI-driven virtual health assistants can provide patients with medical advice, answer health-related questions, and remind them to take medications. This enhances patient engagement and supports self-care.
- *Remote monitoring*: AI can be integrated with wearable devices to continuously monitor patients' vital signs and health conditions. This data can be analyzed in real time to detect any anomalies and alert healthcare providers, enabling timely interventions.
- *Mental health support*: AI applications can offer mental health support through chatbots and virtual therapy sessions. These tools can provide immediate assistance, reducing the stigma associated with seeking help and improving access to mental health care.

AI's transformative potential in healthcare is vast, but it requires a solid foundation of digitized health data and robust infrastructure. The continued development and integration of AI technologies promise to improve the healthcare sector, enhancing patient care, improving outcomes, and creating a more efficient healthcare system.

3 Human–Computer Interaction

HCI is an interdisciplinary field focused on the design and use of computer technologies, emphasizing the interaction between humans and computers (e.g., Gerlach & Kuo, 1991; Carroll, 2020; Diederich et al., 2022). HCI involves understanding how people use technology and creating interfaces that enhance user experience, making systems more efficient, intuitive, and accessible. Drawing from computer science, psychology, cognitive science, and design, HCI aims to improve usability and satisfaction, ensuring technology is effective and user-friendly, thus making technology more intuitive for a wide range of users. This field addresses challenges like designing for diverse user needs, developing adaptive interfaces, and fostering interaction with technology, particularly with the rise of AI and its integration into daily life.

The interaction between humans and computers can be examined through the lens of socio-technical systems. A socio-technical system relies on the interplay of three critical components: the human user aiming to achieve a specific goal, the task that needs to be performed to reach that goal, and the technology (including software, hardware, and data) employed to complete the task (Goodhue & Thompson, 1995; Heinrich et al., 2011).

Furthermore, the advent of advanced technologies such as AI, virtual reality (VR), and the Internet of Things (IoT) has broadened the scope of HCI. These technologies provide new opportunities for enhancing user experience and developing more sophisticated socio-technical systems. AI-driven interfaces, for example, can adapt to individual user preferences and behaviors, offering a more personalized interaction experience. VR can create immersive environments that enhance learning, training, and entertainment, while IoT devices enable seamless interactions across various smart devices, enhancing convenience and efficiency.

The evolution of HCI continues to be driven by the need to understand and improve the ways humans interact with technology, ensuring that these interactions are efficient, effective, and enjoyable. The interdisciplinary nature of the field remains a fundamental aspect of its development, fostering ongoing collaboration and innovation across diverse academic and practical domains. This continuous integration of multidisciplinary perspectives and emerging technologies underscores the dynamic and evolving nature of HCI.

4 Trust

The concept of trust is abstract and complex, with various analyses and definitions across different fields. Numerous researchers have defined and analyzed trust. Despite varying definitions, there is consensus that trust is fundamental to relationships involving transactions or exchanges. Mayer et al. (1995) proposed a model of trust that includes the characteristics of the trustor, the trustee, and the role of risk, defining trust as the willingness to accept vulnerability due to potential risks

from another party's actions. Trust is understood as "the willingness of a party to be vulnerable to the actions of another party based on the expectation that the other will perform a particular action important to the trustor, irrespective of the ability to monitor or control that other part" (Mayer et al., 1995, p. 712). It can be used for "a relationship with another identifiable party who is perceived to act and react with volition toward the trustor" (Mayer et al., 1995, p. 712). This definition is still used in research today (Hoff & Bashir, 2015; Hengstler et al., 2016; de Visser et al., 2019). Trust can therefore be seen as a psychological state between two parties, taking into account expectations and promises. Trust also means being willing to take a certain risk by giving up things that are currently available in order to receive expected rewards (Rempel et al., 1985; Rousseau et al., 1998). If trust is based on the trustworthiness of another, it is justified, otherwise not (McLeod & Ryman, 2020). Trust is crucial in several contexts: Within interpersonal relationships, within and between organizations, between different disciplines, during change processes, or as a causal role (trust as a cause, outcome, and moderator) (Rempel et al., 1985; Rousseau et al., 1998). It influences decisions about others' behavior in various settings, and involves risking possible harm from the other party's behavior (Cottrell et al., 2007). Trust can also be important in the context of machines (i.e., technologies) (e.g., Hoff & Bashir, 2015). The latter is examined in more detail in this chapter.

5 Trust in AI in the Context of HCI: Human–Machine Trust

Human–machine trust (HMT) refers to the relationship established between a human and an intelligent machine based on mutual trust (e.g., Lin et al., 2024). As advanced technologies continually evolve, AI-driven machines and other innovations are increasingly integrated into daily life (e.g., cell phones, hospitals, and homes). Consequently, HCI and HMT have become prominent research topics. As a result, the focus shifted from interpersonal trust among humans to trust in human–machine interactions.

While HMT differs from interpersonal trust, it plays a significant role in HCI. Muir (1994) extended the model of trust from Rempel et al. (1985) to human–machine relationships, creating a framework for studying automated trust (Schilke et al., 2021). Trust in human–machine cooperation arises during the interaction between humans and machines (i.e., technologies such as AI systems). A widely accepted concept of HMT was introduced by Lee and See (2004), defining trust from an attitudinal perspective. In healthcare scenarios, trust involves an individual (e.g., a patient) believing that an agent (e.g., an AI chatbot) can help achieve a goal (e.g., disease detection) in uncertain or vulnerable situations. Siau and Wang (2018) consider trust in HCI as human trust in AI systems or AI developers. Moreover, trust in human–machine cooperation can be viewed as a dynamic process (Hoffman, 2017). Mis-calibration of trust, such as misuse, disuse, and abuse of autonomous machines, can have negative consequences (Lee & See, 2004; Parasuraman & Manzey, 2010; Parasuraman & Riley, 1997). Trust influences human dependence

on machines in HCI. Trust in HMT is often generated through instantaneous human judgment of machines, relying on various factors for building and sustaining trust (Rheu et al., 2021). In this context, trust is influenced by factors that fall into three categories: human, machine (technology), and environment.

6 Factors Influencing Trust in AI in Healthcare

HMT in healthcare is shaped by system-level, human, and machine-related factors. Figure 1 depicts an overview over factors influencing trust of humans in machines (i.e., AI technologies).

6.1 System-Level Factors of HMT

The healthcare environment plays a crucial role in shaping the trust dynamics between humans and AI systems. Healthcare is a sensitive and complex sector. Hence, it is highly regulated (e.g., Steinhauser et al., 2020; Steinhauser, 2021), and the innovation system in which AI technologies are being used plays a vital role (e.g., Steinhauser & Borst, 2024). Several factors significantly influence HMT:

- *Laws and regulation:* The legal framework for data protection and patient privacy is foundational to building trust in AI systems. Regulations such as the General Data Protection Regulation (GDPR) in Europe ensure that patient data is handled

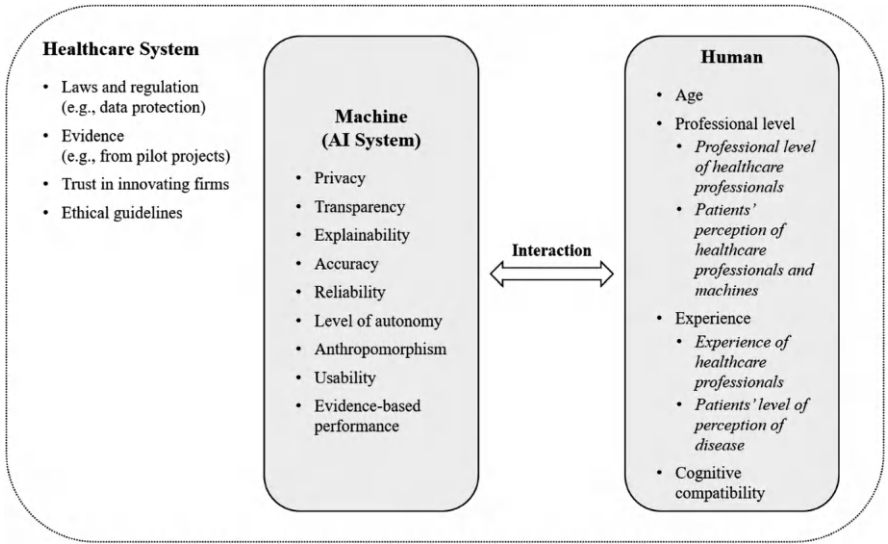


Fig. 1 Factors influencing Human–Machine Trust

with strict confidentiality and security measures. Compliance with such laws reassures patients and healthcare providers that their sensitive information is protected from misuse and breaches.

- *Empirical evidence* from pilot projects and clinical trials is essential for demonstrating the efficacy and reliability of AI systems in real-world healthcare settings. Successful pilot projects provide proof-of-concept and validate the practical benefits of AI, encouraging broader adoption. Published results and case studies from these projects help build credibility and trust among stakeholders.
- *Trust in innovating firms*: The reputation and track record of firms developing AI technologies significantly impact trust levels. Companies known for their ethical practices, transparency, and consistent delivery of high-quality products are more likely to gain trust from healthcare providers and patients. Collaborations with reputable healthcare institutions and adherence to industry standards further enhance trust in these innovating firms.
- *Ethical guidelines*: Adherence to ethical guidelines ensures that AI systems are developed and deployed responsibly. Ethical considerations include fairness, accountability, transparency, and the avoidance of bias in AI algorithms. Clear ethical guidelines help address concerns about the potential negative impacts of AI on patient care and promote the development of trustworthy AI applications in healthcare.

6.2 Machine-Related Factors of HMT

Several machine-related factors significantly influence HMT in healthcare (e.g., Hengstler et al., 2016; Lin et al., 2024):

- *Privacy* stands out as a critical aspect; ensuring data protection and user privacy through advanced technologies such as the blockchain can greatly enhance trust.
- *Transparency* is another vital factor. By converting opaque black-box models into transparent white-box models, trust can be substantially improved. This transparency allows users to understand and see through the processes of the machine, making its actions more predictable and acceptable.
- *Explainability* is closely related to transparency and involves making machine learning models more interpretable. When users can understand the reasoning behind a machine's decisions, their trust in its actions increases.
- *Accuracy* and *reliability* are foundational to trust as well. Machines that consistently deliver high performance and reliable outcomes build greater trust among users.
- The *level of autonomy* also plays a significant role; while autonomy can enhance efficiency, it must be balanced carefully, as too much automation can reduce human trust due to perceived loss of control.
- *Anthropomorphism*, or the attribution of human-like characteristics to machines, has a nuanced effect. Moderate levels of anthropomorphism can initially increase

trust by making machines seem more relatable. However, if machines become too human-like, it can lead to discomfort and reduced trust.

- The *usability* of AI-based devices is also important. If an AI-based technology is easy to use, it is more likely to be trusted.
- For technologies which are cognitive systems that build hypotheses based on evidence, the ability to show accurate, *evidence-based performance* enhances trust in the system.

6.3 Human Factors of HMT

Human factors are equally crucial in shaping HMT in healthcare (e.g., Hengstler et al., 2016; Lin et al., 2024):

- *Age* is a significant determinant; older adults and children tend to show higher levels of trust in intelligent machines compared to younger adults. This variation can be attributed to differing levels of familiarity and comfort with technology across age groups.
- The *professional level and experience* of healthcare professionals also affect their trust in machines. Higher professional levels are associated with increased trust in machines' capabilities but may also come with a reduced willingness to rely on them. This can be due to a confidence in their expertise and a critical perspective on machine capabilities.
- *Experience with diseases* enhances trust in machines among healthcare professionals. Those with more experience dealing with specific medical conditions are likely to have a better understanding of how machines can assist in diagnosis and treatment, thus trusting them more.
- The *cognitive compatibility* of AI-based systems with users' needs is another critical factor. If an AI-based system is easy to understand, and aligns well with users' cognitive processes, it is more likely to be trusted.

These system-level, machine-related, and human factors must be carefully considered to foster better cooperation and trust between humans and machines in healthcare settings. Understanding these dynamics helps in designing systems that are more acceptable and trustworthy to users, ultimately improving the effectiveness of human-machine collaboration in healthcare.

7 Dynamics of Trust in AI in the Context of HCI

Trust in the context of HCI is not a fixed construct but rather evolves over time (especially since AI systems are able to learn and improve) and may also require repair to persist. De Visser et al. (2018) propose a cycle of trust repair. This cycle of trust begins with an action by the trustee (i.e., AI system) that has either a beneficial or detrimental impact. Trust is negatively affected by detrimental

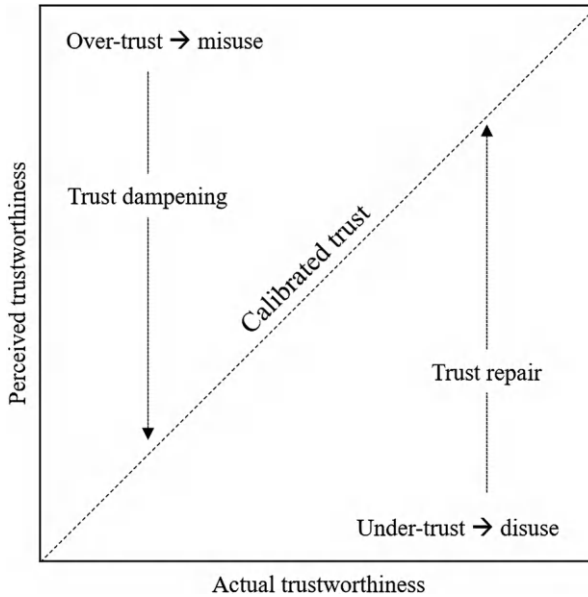


Fig. 2 Dynamics of Trust (based on de Visser et al., 2019)

actions such as mistakes or inefficiencies. Conversely, beneficial actions, such as presenting opportunities or demonstrating correct working practices, enhance credibility, goodwill, and forgiveness of mistakes. In the second phase, the relationship between humans and autonomous machines is regulated through corrective actions in response to detrimental events or dampening actions in response to beneficial events, applied either immediately or retrospectively to maintain balance. The final phase, the net victim impact, considers the cumulative effects of previous phases and the individual differences in humans' capacity for repair. In this context, trust can be understood as a determinant of future use, consent, approval, and feelings of vulnerability. If the relationship is compromised by an action in the first phase, it can lead to discomfort, restlessness, mistrust, or concern. Once trust is repaired, it can result in relaxation, well-being, or compliance with AI systems. The model facilitates balanced relationships, promoting more resilient and productive interactions through trust calibration (see Fig. 2).

8 Measures to Build Trust in AI

To build and sustain trust in AI within healthcare, several measures can be employed:

- *Transparency and explainability*: Clearly explaining how AI systems work, their decision-making processes, and their limitations can help users understand and trust these technologies. Furthermore, developing Explainable AI (XAI) applications, which include an explanation model to communicate the internal decisions, behaviors, and actions to the interacting humans, can improve users' trust in AI systems (e.g., Yang, 2022).
- *Data protection and security*: First, the implementation of and adherence to regulations such as the GDPR ensure the confidentiality and security of sensitive healthcare data. Second, data protection can be facilitated through advanced technologies such as the blockchain technology (e.g., Yaqoob et al., 2022; Steinhäuser et al., 2024). Both measures can greatly enhance trust.
- *Performance consistency*: Ensuring that AI systems are reliable and consistently perform well across diverse clinical scenarios is critical. Regular updates and validation against clinical standards are necessary.
- *User training*: Educating healthcare professionals and patients on how to effectively use AI systems and interpret their outputs can reduce mistrust and enhance user confidence.
- *Human oversight*: Maintaining a human-in-the-loop approach where AI supports but does not replace human decision-making can reassure users and mitigate fears of complete automation.

9 Conclusion

This chapter underscores the relevance of trust in AI in the context of HCI. AI systems can foster advancements in medical diagnostics, treatment personalization, and patient care efficiency. Central to their integration is human–machine trust, which is pivotal for the widespread acceptance and effective use of AI technologies in healthcare. Factors influencing this trust include system-level factors (i.e., laws and regulation, empirical evidence, trust in innovating firms, and ethical guidelines), machine-related factors (i.e., privacy, transparency, explainability, accuracy, reliability, level of autonomy, anthropomorphism, usability, and evidence-based performance), and human factors (i.e., age, professional level and experience, experience with diseases, and cognitive compatibility). Addressing these factors can ensure that AI technologies are trusted and effectively utilized, ultimately leading to improved patient outcomes and enhanced medical practices.

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Renal Denervation: A New Chapter in Curing Drug Resistance in Hypertension

Mark Dankhoff

Abstract

Dankhoff describes a further method helping to cure drug resistant hypertension. In this relatively new catheter-based procedure, nerve fibers of the involuntary nervous system (sympathetic nervous system) in the renal arteries are deactivated using radio waves. This procedure is particularly beneficial for patients who are already receiving three or more antihypertensive drugs and who still do not experience satisfactory blood pressure normalization. Various studies and analyses show a positive effect of the procedure on lowering blood pressure.

1 Basics

1.1 What Is Hypertension?

Hypertension (HTN), or high blood pressure (BP), is a chronic medical condition in which BP in the arteries is persistently elevated above defined values. The latest European Society of Hypertension guidelines define HTN as office systolic BP (SBP) values ≥ 140 mmHg and/or diastolic BP (DBP) values ≥ 90 mmHg.

1.2 How Many People Have Hypertension?

Hypertension is a growing problem that affects 1/3 of the global adult population. In Europe, more than 150 million people have HTN, and its prevalence is predicted to rise. In Europe, at least 50% of patients treated remain uncontrolled with up to 30%

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of hypertension remaining untreated. About 5% of overall hypertensive patients are estimated to have resistant hypertension.

1.3 What Is Resistant Hypertension?

Resistant hypertension is the uncontrolled hypertension (confirmed by out-of-office BP measurements), despite treatment with ≥ 3 anti-HTN medications (typically including a diuretic) at maximally tolerated doses.

2 Treatment Options for Hypertension

Hypertension treatment options include lifestyle changes (e.g., regular exercise, dietary changes, weight reduction, etc.), antihypertensive medications (e.g., ACE inhibitors, calcium channel blockers, diuretics, etc.), and device-based treatments such as renal denervation (RDN).

3 Consequences of Untreated or Treatment-Resistant High Blood Pressure

High blood pressure is one of the strongest risk factors for cardiovascular diseases. Significantly elevated blood pressure over a longer period of time can lead to organ damage such as weak heart pumping (heart failure), heart attack, stroke, or impaired kidney function. These diseases alone account for over 40% of deaths in Germany.

It is therefore important to lower the blood pressure of those affected to an acceptable range. This happens primarily with the help of medications that affect blood pressure, the so-called antihypertensives.

However, monotherapy, i.e., the administration of a single active ingredient to lower blood pressure, is often not sufficient to achieve normotensive values. In these cases, two, three, or sometimes even four preparations are used at the same time so that therapeutic success can be achieved.

Nevertheless, many of those affected are resistant to therapy with insufficient blood pressure reduction.

For patients in whom a sufficient reduction in blood pressure cannot be achieved despite taking several medications or who have a high risk of heart attack or stroke, for diabetics and also after a heart attack or stroke that has already been suffered, treatment with renal denervation is in question.

4 Proceedings

The procedure works on the kidneys, or rather on the arteries through which blood flows to the kidneys. Fibers of the involuntary nervous system (sympathetic nervous system) end here. The central nervous system controls blood pressure via this

connection. The stronger the nerve activity, the higher the pressure in the veins. If the nerves are switched off, blood pressure can drop. The fact that the kidneys function well even without these nerves is shown in kidney transplants, because the donor kidneys also work without these nerves.

Patients who cannot achieve a sufficient reduction in blood pressure despite taking their medication are therefore eligible for the renal denervation procedure, taking into account the requirements (see below).

Under local anesthesia, a catheter is inserted through the femoral artery in the groin area artery and pushed through the abdominal aorta into the renal artery (see image). There heat energy is briefly released using radio frequency waves to destroy the nerves that run around the artery. This is also referred to as the so-called ablation of the renal nerves.

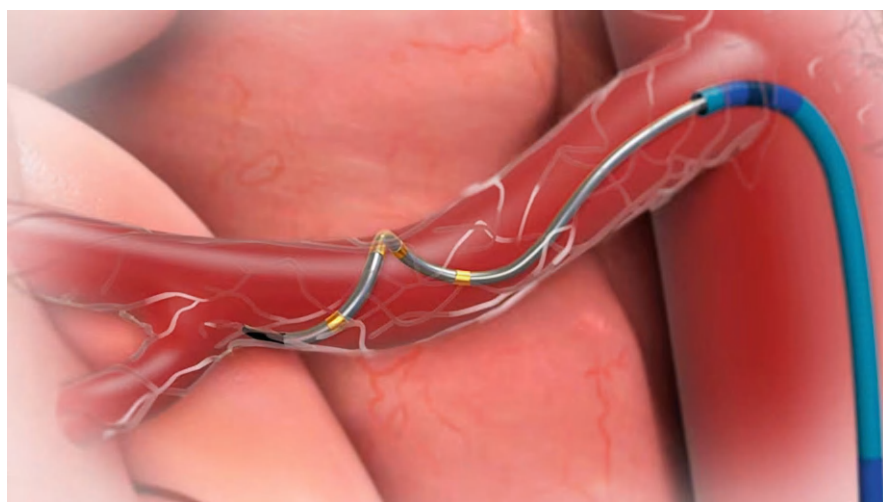


Image provided by: Medtronic

This process is usually repeated 5–6 times and carried out in the same way on the renal artery on the opposite side. In total, the procedure takes approximately 40–60 min.

The entire procedure is performed in a catheter laboratory as part of a short-term inpatient hospital stay.

5 Requirements

Requirements for treatment using renal denervation are:

- Blood pressure far above the target range despite taking at least three different antihypertensive drugs (systolic value over 160 mmHg or over 150 mmHg if diabetes mellitus is present).
- Confirmed therapy-resistant high blood pressure in the 24-h measurement.
- Sufficiently good kidney function.
- Appropriate renal artery diameters.
- Exclusion of relevant renal artery narrowings.
- Exclusion of a curable cause of high blood pressure such as pheochromocytoma (tumor of the adrenal medulla), Conn syndrome (tumor of the adrenal cortex), renal artery stenosis, or sleep apnea.

These examinations can be carried out by practicing specialists (angiologists, nephrologists, and cardiologists) or in angiology outpatient clinics.

6 Possible Side Effects

The procedure has few complications, although side effects are of course still possible.

Common side effects (temporary and non-serious):

- Nausea and vomiting.
- Problems with using painkillers or sedatives during or after the procedure.
- Pain and bruising (hematoma) at the catheter insertion site in the groin area.

Uncommon side effects (usually manageable):

- Injuries to the kidney, which can still be treated during the procedure.
- Cardiac arrhythmias.
- Vascular injuries requiring surgical intervention.
- Embolism (formation and detachment of a blood clot).

Follow-up observations over a period of 3 years have revealed no long-term side effects on the renal vessels.

7 Forecast

It may take days and weeks, sometimes even months, for the full effect of the treatment to occur.

This procedure makes it possible to reduce the systolic blood pressure by up to 20 mmHg and the diastolic blood pressure by up to 6 mmHg while continuing current drug therapy (see Sect. 7.1).

Studies show that renal denervation works well for about 70% of people with high blood pressure who have been treated so far, but not for 30%. Why this is the case has not yet been fully clarified—there may be another cause of high blood pressure in these cases or the nerve was not properly hit during the sclerotherapy.

7.1 Current Study Situation

The pre-specified analysis of the SPYRAL HTN-ON MED study shows, for example, that renal denervation can be an effective additional therapy for people with high blood pressure for whom drug therapy with antihypertensives does not achieve sufficient reduction. In this study, the effect and safety of the procedure were evaluated over a total of 36 months. In addition to antihypertensive medication, renal denervation resulted in a statistically significant, sustained reduction in blood pressure.

The randomized, single-blind study, which was controlled by a placebo intervention, included participants from 25 centers in the USA, Germany, Japan, UK, Australia, Austria, and Greece. The patients had therapy-resistant hypertension in which the systolic values were between 140 and 170 mmHg in the 24-h measurement despite taking up to three antihypertensives.

80 of the 467 patients met the inclusion criteria. They underwent renal angiography to rule out secondary hypertension and were randomized equally into two groups, with one group being treated with renal denervation ($n = 38$) and the control group with a sham procedure ($n = 42$). The primary endpoint was the difference in mean 24-h systolic blood pressure between the two groups after 6 months. The result of the primary endpoint was published in 2018. As a proof of concept study, it demonstrated the success of the procedure and showed a decrease in mean 24-h systolic blood pressure in the denervation group by 9.3 mmHg and by 1.6 mmHg in the control group ($p = 0.0041$). The mean 24-h diastolic blood pressure fell by 6.0 mmHg in the intervention group and by 1.9 mmHg in the control group ($p = 0.018$). At that time, however, it was not clear whether the observed reduction would persist in the long term or not.

In 2022, the long-term results were presented and published at the American College of Cardiology Congress. The changes in 24-h systolic and diastolic blood pressure showed a permanent reduction or even a further increase up to the 36th month. After 36 months, the mean systolic blood pressure in the denervation group ($n = 30$) had fallen by 18.7 ± 12.4 mmHg—compared to 8.6 ± 14.6 mmHg in the control group ($n = 32$); the difference of -10 mmHg was significant ($p = 0.0039$). The mean diastolic blood pressure was also significantly lower (-5.9 mmHg; $p = 0.0055$). No short- or long-term safety concerns were associated with renal denervation in the study. In the practice measurement, blood pressure also fell more in the intervention group than in the control group (-20.9 mmHg vs. -12.5 mmHg).

Compared with the sham procedure, renal denervation resulted in a statistically significant, sustained reduction in blood pressure over the entire follow-up period

of 36 months, even with lower adherence to the basic antihypertensive medication. An interesting side aspect was that 25 of the 27 patients (93%) in the control group took their medication as prescribed after 36 months, while in the intervention group this figure was only 24/31 (77%). This difference is clear and could mean that if the medication intake in the intervention group remained the same, renal denervation as an “add-on” therapy might have been even more successful. Therapy adherence therefore remains a major challenge in the treatment of high blood pressure.

8 Implementing Centers

Renal denervation should generally take place in a certified RDN center. For this purpose, the German Hypertension League (Deutsche Hochdruckliga e.V.), the German Society for Cardiology—Heart and Circulation Research (Deutsche Gesellschaft für Kardiologie – Herz- und Kreislau fforschung e.V.), and the German Society for Nephrology (Deutsche Gesellschaft für Nephrologie e.V.) have created specific certification guidelines. The certification of a center ensures that renal denervation is carried out there in accordance with the current medical knowledge and the recommendations of the experts.

There are currently specialized and certified RDN centers throughout Germany that have particularly extensive experience with this technology.

Information about these centers is provided by:

Deutsche Hochdruckliga e.V.:

- <https://rdz.dgk.org/zertifizierte-rdzs/>

Medtronic GmbH:

- <https://www.medtronic.com/de-de/patienten/produkte-therapien/bluthochdruck-behandeln/klinikfinder.html>

9 Assumption of Costs

To date, renal denervation is not part of the standard care provided by statutory health insurance companies in Germany. However, many experts in high blood pressure see the urgent need to expand treatment options and are committed to certifying additional qualified centers (see above).

Since the health insurance companies are still dealing with the so-called individual case decisions, those affected should contact their treating doctor, who can support them with regard to the reimbursement of costs by the insurance provider if RDN therapy is necessary.

10 Summary

With renal denervation, practitioners have an additional treatment option with few complications and side effects when it comes to sufficiently reducing therapy-resistant high blood pressure and getting the affected patients out of the high-risk area.

Future investigations and studies, especially when it comes to long-term effects, will show that renal denervation will play an important role in the long-term treatment and curing drug resistant hypertension.

The RDN is an example of how there are other treatment options besides medication to cure a disease. The future of therapy options must therefore not be limited to medication or invasive surgery alone.

The important way of thinking out of the box ultimately made the development and use of RDN possible. May many more of these developments follow in the interest of medicine and patients.



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Strategic Challenges in Hospital Management: A German and European Perspective for the Future

Guido Lerzynski

Abstract

Hospital management faces a multitude of challenges that must be addressed both nationally and at the European level. The coming decade will be marked by profound changes in demographics, technology, finance, and regulation. To successfully navigate these changes, strategic planning is essential. This chapter highlights the key strategic challenges that hospital management in Germany and Europe must address and provides insights into possible solutions.

1 Introduction

Hospital management involves the leadership and administration of hospitals and healthcare facilities with the goal of ensuring optimal patient care while operating efficiently. It encompasses a wide range of tasks, including personnel management, financial planning, quality management, and the implementation of new technologies. In recent years, hospital management has become increasingly professionalized, with a focus on strategic planning and sustainable development.

Strategic planning is crucial in healthcare as it allows for the setting of long-term goals and efficient use of resources. Given demographic changes, technological advancements, and increasing financial challenges, it is essential for hospitals to act proactively and develop flexible strategies. Well-thought-out strategic planning helps minimize risks, seize opportunities, and improve the quality of patient care. According to a study by Porter and Lee (2013), the implementation of value-based healthcare strategies is key to improving efficiency and quality in healthcare.

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2 Current Situation and Trends

2.1 Demographic Change

Demographic change represents one of the biggest challenges for hospital management. In many European countries, including Germany, the proportion of older people in the population is steadily increasing. This rise leads to higher demand for healthcare services, particularly in chronic and age-related diseases. According to a study by the Federal Institute for Population Research (2021), the number of people over 65 in Germany will increase by about 22% by 2030. This development requires an adjustment of care structures and a stronger focus on geriatric and preventive medicine.

To meet the demands of an aging population, hospitals must adjust their care structures. This includes expanding departments and specialized clinics for geriatric medicine. Geriatric patients often have complex medical needs that require close collaboration between various disciplines. Interdisciplinary teams, consisting of doctors, nurses, physiotherapists, and social workers, are crucial to ensuring holistic and effective care (Löckenhoff & Carstensen, 2004).

Additionally, integrating preventive measures into medical care is of great importance. Preventive medicine can help delay or prevent the onset of chronic diseases and improve the quality of life for older individuals. Programs promoting a healthy lifestyle, regular health check-ups, and vaccinations are examples of preventive measures that should be integrated into everyday care (Fried et al., 2001).

Close collaboration with other healthcare providers, such as general practitioners, nursing homes, and outpatient services, is essential to ensure continuous and comprehensive care for older patients. Integrated care models that facilitate seamless transitions of patients between different levels of care can help improve care efficiency and patient satisfaction (Kodner & Spreeuwenberg, 2002).

Finally, promoting research and innovation in geriatric medicine and age-related diseases is of great importance. Research can provide new insights into the prevention, diagnosis, and treatment of age-related diseases and contribute to the development of new therapeutic approaches. Hospitals should therefore closely collaborate with research institutes and universities to foster knowledge exchange and develop innovative solutions (Beard et al., 2016).

2.2 Digitalization and Technological Progress

The advent of digitalization and rapid technological advancements are fundamentally transforming the healthcare landscape, presenting hospitals with both significant opportunities and formidable challenges. Modern technologies such as Artificial Intelligence (AI), Big Data, and telemedicine are at the forefront of this revolution, promising to enhance the efficiency of patient diagnosis and treatment, optimize operational workflows, and ultimately improve patient outcomes. How-

Table 1 Opportunities and challenges for hospitals in the field of digitalization

Opportunities	Challenges
Enhanced Diagnostic Accuracy and Treatment	Significant Financial Investments
Predictive Analytics and Big Data	IT Infrastructure Overhaul
Telemedicine and Remote Monitoring	Data Protection and Security
Operational Efficiency and Cost Reduction	Ethical and Legal Considerations

ever, the successful implementation of these technologies necessitates substantial investments and a comprehensive overhaul of existing IT infrastructure (Table 1).

There are vast opportunities for hospitals in the field of digitalization:

Enhanced Diagnostic Accuracy and Treatment: AI algorithms, particularly those leveraging machine learning, have demonstrated remarkable potential in improving diagnostic accuracy. For instance, AI can analyze medical images with a precision that often surpasses human capabilities, identifying anomalies and patterns that might be missed by radiologists. A study published in The Lancet Digital Health (2021) revealed that AI systems could match or even exceed the diagnostic performance of healthcare professionals in certain medical imaging tasks.

Predictive Analytics and Big Data: Big Data analytics enables hospitals to harness vast amounts of patient data to uncover trends, predict disease outbreaks, and personalize treatment plans. Predictive analytics can identify patients at high risk of complications, allowing for proactive interventions. For example, the implementation of predictive analytics in intensive care units (ICUs) has been shown to reduce mortality rates by anticipating patient deterioration and enabling timely medical responses.

Telemedicine and Remote Monitoring: Telemedicine has gained significant traction, especially in the wake of the COVID-19 pandemic. It allows patients to consult healthcare providers remotely, reducing the need for physical visits and minimizing the risk of infection. Remote monitoring technologies, such as wearable devices, enable continuous tracking of patient health metrics, facilitating early detection of potential health issues and reducing hospital readmission rates.

Operational Efficiency and Cost Reduction: Digital technologies streamline hospital operations, reducing administrative burdens and improving resource allocation. Electronic Health Records (EHRs) facilitate seamless information sharing among healthcare providers, enhancing coordination and reducing redundant tests. According to a Deloitte study (2022), hospitals that invest in digital technologies can significantly lower operational costs while improving the quality of care.

Even if the opportunities look promising, the challenges cannot be denied:

Significant Financial Investments: Implementing advanced technologies requires substantial financial investments. Hospitals must allocate funds not only for the

acquisition of new systems but also for the training of staff and the maintenance of these technologies. Smaller hospitals, in particular, may struggle to secure the necessary capital, potentially widening the gap between well-funded and under-resourced healthcare facilities.

IT Infrastructure Overhaul: The integration of modern technologies necessitates an extensive upgrade of existing IT infrastructure. Legacy systems must be replaced or integrated with new solutions, which can be a complex and time-consuming process. Moreover, ensuring interoperability between different systems is crucial to avoid data silos and facilitate seamless information flow.

Data Protection and Security: With the increased digitization of patient data comes heightened concerns about data protection and security. Cybersecurity threats, such as ransomware attacks, pose significant risks to healthcare institutions. Ensuring robust data protection measures is essential to maintain patient trust and comply with regulatory requirements such as the General Data Protection Regulation (GDPR).

Ethical and Legal Considerations: The use of AI and Big Data in healthcare raises ethical and legal questions, particularly concerning patient consent and data privacy. Hospitals must navigate these complexities to ensure that technology adoption aligns with ethical standards and legal frameworks.

Digitalization and technological progress offer transformative potential for healthcare, enabling more accurate diagnoses, personalized treatments, and enhanced operational efficiency. However, the journey toward a fully digitalized healthcare system is fraught with challenges, including significant financial investments, IT infrastructure overhauls, and stringent data protection requirements. Hospital management must strategically navigate these challenges to harness the full potential of modern technologies, ultimately improving patient care and operational sustainability.

By carefully balancing the opportunities and challenges, hospitals can leverage digitalization to create a more efficient, effective, and patient-centric healthcare system. The insights provided by studies such as Deloitte's (2022) underscore the long-term benefits of investing in digital technologies, highlighting the importance of strategic planning and robust implementation frameworks in achieving sustainable healthcare transformation.

2.3 Financial Framework and Regulation

The financial framework conditions in healthcare, coupled with stringent regulatory requirements, present central challenges for hospital management. These issues become even more pronounced when considering the broader context of digitalization and its impact on healthcare systems.

The financial framework conditions in healthcare are a central challenge for hospital management. Hospitals across many European countries face significant cost pressures due to limited public funds and rising expenses. This financial strain

necessitates the development of innovative financing models and the implementation of cost-cutting and efficiency-boosting measures to remain economically viable.

In Germany, for example, the Institute for Health and Social Research (IGES) found that funding gaps in hospitals are increasing, leading to a greater need for efficient budgeting strategies. The study highlighted that the financial sustainability of hospitals is increasingly threatened by rising operational costs, including labor, medical supplies, and technological investments. To address these challenges, hospitals are exploring various approaches such as public-private partnerships (PPPs), which can provide additional funding and expertise, helping to bridge financial gaps (European Observatory on Health Systems and Policies, 2017).

Additionally, shifting from volume-based to value-based care models can incentivize hospitals to focus on patient outcomes and cost efficiency, potentially leading to better resource allocation (Porter & Lee, 2013). Implementing lean management principles can streamline hospital operations, reduce waste, and improve overall efficiency (Womack & Jones, 2003). Diversifying revenue sources, such as through specialized services or medical tourism, can also provide additional financial stability (Connell, 2006).

These financial strategies are essential to support the broader goals of digitalization in healthcare, such as enhancing diagnostic accuracy, predictive analytics, telemedicine, and operational efficiency. Without a robust financial framework, the implementation of advanced digital technologies would be challenging.

2.4 Regulatory Requirements and Healthcare Reforms

Regulatory requirements and healthcare reforms significantly impact hospital management. In Germany and other European countries, reforms are regularly carried out to improve the quality and efficiency of healthcare. These reforms often include new legal requirements that hospitals must meet, necessitating adaptive strategies to remain compliant and financially stable.

For instance, the introduction of the Hospital Future Act (KHZG) in Germany in 2020 brought about extensive changes in the areas of digitalization and IT security. The KHZG aims to modernize hospital infrastructure, enhance digital capabilities, and ensure robust IT security measures. According to a study by the German Hospital Institute (2022), hospitals that proactively adapt to new regulatory requirements are better able to ensure the quality of care and minimize financial risks. Other key reform projects in Germany, such as the Hospital Transparency Act (KHTG) and the Hospital Care Improvement Act (KHVVG), aim to promote the quality of care and allocate financial resources in a targeted manner. As a result, existing care structures will be scrutinized in order to ensure that the population can be cared for in the face of existing challenges.

Key aspects of regulatory adaptation include investing in digital health technologies, such as electronic health records (EHRs) and telemedicine, which can improve patient care and operational efficiency. The KHZG provides funding for

such initiatives, encouraging hospitals to modernize their digital infrastructure (Deloitte, 2022). Ensuring compliance with stringent IT security standards protects patient data and mitigates the risk of cyberattacks. Hospitals must invest in advanced cybersecurity measures to safeguard sensitive information (The Lancet Digital Health, 2021). Implementing comprehensive quality assurance programs helps hospitals meet regulatory standards and improve patient outcomes. Continuous monitoring and evaluation of care processes are essential for maintaining high-quality services. Ongoing staff training and development programs ensure that healthcare professionals are well-versed in new regulatory requirements and best practices. This enhances the overall competency of the workforce and supports compliance efforts (WHO, 2015).

These regulatory frameworks are crucial for the successful integration of digital technologies in healthcare. For example, enhanced diagnostic accuracy through AI algorithms and the use of predictive analytics rely heavily on secure and compliant IT systems. Telemedicine and remote monitoring require robust data protection measures to maintain patient trust and comply with legal standards.

Navigating the financial framework and regulatory landscape in healthcare is a complex but crucial aspect of hospital management. By adopting innovative financing models, embracing digital transformation, and ensuring compliance with regulatory standards, hospitals can enhance their financial sustainability and continue to provide high-quality care. The proactive adaptation to these evolving challenges will be key to the future success of healthcare institutions.

2.5 Shortage of Skilled Employees

The shortage of skilled workers in healthcare is one of the most pressing challenges for hospital management. According to a study by the German Council of Economic Experts for Health Care (2022), the demand for qualified medical personnel will continue to rise in the coming years, while the supply stagnates or even declines. This requires innovative approaches in personnel management to improve both recruitment and retention of professionals.

To address the shortage of skilled workers, hospitals must rethink their recruitment strategies and become more attractive to potential employees. This can be achieved through targeted marketing measures, partnerships with educational institutions, and the creation of attractive working conditions. A study by the Bertelsmann Stiftung (2023) shows that flexible working time models, training opportunities, and a good work-life balance are crucial factors for retaining professionals.

Continuous education and qualification of personnel are also of great importance. Hospitals must invest more in training programs and professional development to ensure that their staff are up to date with the latest medical science and technology. According to a report by the Robert Koch Institute (2023), regular training not only contributes to the quality of patient care but also increases employee satisfaction and motivation.

In addition to these strategies, leveraging digital tools and technologies can play a crucial role in addressing the shortage of skilled workers. The German Hospital Institute (2022) highlights the impact of the Hospital Future Act on the digitalization of healthcare, which aims to improve efficiency and reduce administrative burdens on medical staff. By incorporating telemedicine, electronic health records, and other digital solutions, hospitals can streamline operations and allow healthcare professionals to focus more on patient care.

Furthermore, international recruitment can be an effective strategy to mitigate the local shortage of skilled workers. The European Commission (2023a) emphasizes the importance of cross-border healthcare cooperation and the mutual recognition of qualifications within the EU. By creating a more inclusive and diverse workforce, hospitals can tap into a broader pool of talent and enhance their capacity to provide high-quality care.

Another critical aspect is the improvement of working conditions to prevent burnout and turnover among healthcare professionals. According to the International Labour Organization (2023), promoting diversity and inclusion in the workplace can lead to better job satisfaction and retention rates. Hospitals should foster a supportive and inclusive work environment where all employees feel valued and respected.

Lastly, hospitals should actively engage in policy advocacy to address systemic issues contributing to the shortage of skilled workers. The King's Fund (2021) outlines several challenges facing the NHS, including funding constraints and regulatory barriers. By collaborating with policymakers and industry stakeholders, hospitals can help shape policies that support workforce development and sustainable healthcare systems.

3 Hospitals of the Future

The landscape of healthcare in Europe is poised for significant transformation in the future, driven by technological advancements, demographic shifts, and evolving healthcare policies. By 2040, hospitals in Europe are expected to be highly digitalized environments, leveraging advanced technologies to improve patient outcomes and operational efficiency. The European Commission (2023b) has emphasized the importance of digital health initiatives, such as the European Health Data Space, which aims to facilitate secure access to health data across member states. According to a report by the European Hospital and Healthcare Federation (2022), the integration of AI and machine learning will enable personalized medicine, allowing for tailored treatment plans based on individual genetic profiles and health histories (Table 2).

Patient-Centric Care: The future of hospital care in Europe will be increasingly patient centric, with a focus on improving the patient experience and outcomes. Hospitals will adopt a holistic approach to healthcare, addressing not only physical ailments but also mental and social well-being. The King's Fund (2021)

Table 2 Key strategic focuses for hospitals in the future

Patient-Centric Care
Sustainability
Workforce Dynamics
Policy and Regulation

outlines the shift toward integrated care systems, where hospitals collaborate with primary care providers, social services, and community organizations to deliver comprehensive care. Patient empowerment through digital tools, such as mobile health apps and wearable devices, will enable individuals to take an active role in managing their health.

Sustainability: This will be a cornerstone of hospital structures in Europe by 2040. The European Green Deal (2019) sets ambitious targets for reducing carbon emissions and promoting environmental sustainability across all sectors, including healthcare. Hospitals will adopt green building practices, utilizing renewable energy sources, and implementing energy-efficient technologies. A study by Health Care Without Harm Europe (2020) highlights the potential for hospitals to reduce their environmental footprint through sustainable procurement, waste management, and water conservation. Additionally, the circular economy model will be integrated into hospital operations, promoting the reuse and recycling of medical supplies and equipment.

Workforce Dynamics: The healthcare workforce in 2040 will be characterized by greater diversity, flexibility, and specialization. The International Labour Organization (2023) predicts that the demand for healthcare professionals will continue to grow, necessitating innovative workforce planning and development strategies. Hospitals will employ a mix of full-time, part-time, and gig economy workers to address fluctuating patient needs. Continuous professional development will be essential, with hospitals investing in training programs to keep staff updated on the latest medical advancements and technologies. Moreover, the European Union’s emphasis on cross-border healthcare cooperation will facilitate the mobility of healthcare workers, allowing for the sharing of expertise and best practices.

Policy and Regulation: Evolving policies and regulations will shape the hospital structures of the future. The European Union’s focus on harmonizing healthcare standards across member states will ensure consistent quality of care and patient safety. The European Health Union initiative aims to strengthen health systems, improve crisis preparedness, and enhance the resilience of healthcare services. Hospitals will need to comply with stringent data protection regulations, such as the General Data Protection Regulation (GDPR), to safeguard patient information in an increasingly digitalized environment.

4 Financial Sustainability and Cost Efficiency

In the face of financial constraints, hospitals must diversify their funding sources to ensure long-term sustainability. Public-private partnerships (PPPs) offer a viable solution by leveraging private sector investment and expertise to enhance healthcare infrastructure and services. According to the World Health Organization (WHO) (2023), PPPs can provide much-needed capital for hospital expansion, modernization, and technological upgrades. Additionally, hospitals can seek grants from government bodies, non-profit organizations, and international agencies to fund specific projects and initiatives.

Efficient use of existing resources is paramount for financial sustainability. Hospitals must implement robust cost management systems to monitor and control expenditures. This involves conducting regular financial audits, identifying areas of waste, and reallocating resources to high-priority areas. The Health Management Institute (2023) highlights the importance of adopting lean management principles to streamline operations, reduce waste, and enhance value. By minimizing unnecessary expenses and optimizing resource allocation, hospitals can achieve significant cost savings.

Process optimization is a key element of sustainable hospital management. Hospitals must continuously evaluate and improve their processes to enhance efficiency and reduce costs. Lean management principles, which focus on eliminating waste and improving workflow, can be applied to various hospital operations. For example, optimizing patient flow and reducing waiting times can improve patient satisfaction and reduce operational costs. The Health Management Institute (2023) reports that hospitals implementing lean management practices have achieved substantial cost reductions and improved care quality.

Innovative technologies play a crucial role in enhancing efficiency and reducing costs in hospitals. Digital health solutions, such as electronic health records (EHRs), telemedicine, and AI-driven diagnostics, can streamline operations and improve patient care. The European Commission (2023b) emphasizes the potential of digital health initiatives to transform healthcare delivery and achieve cost efficiencies. For instance, telemedicine can reduce the need for in-person consultations, lowering costs and increasing access to care. Sustainable financing models are essential for securing the long-term viability of hospitals. The WHO (2023) advocates for the development of financing models that ensure stable and adequate funding for healthcare services. This includes exploring innovative payment mechanisms, such as value-based care models, where hospitals are reimbursed based on patient outcomes rather than the volume of services provided. Value-based care incentivizes hospitals to deliver high-quality, cost-effective care, ultimately improving financial sustainability.

The efficiency of the healthcare workforce is another critical factor in achieving cost efficiency. Hospitals must invest in continuous education and professional development to ensure that staff are equipped with the latest skills and knowledge. The Robert Koch Institute (2023) underscores the importance of regular training

programs in enhancing workforce efficiency and patient care quality. Additionally, hospitals can employ workforce management tools to optimize staff scheduling, reduce overtime costs, and improve productivity. Supportive policies and regulations are vital for the financial sustainability of hospitals. Governments and regulatory bodies must create an enabling environment that facilitates innovative funding mechanisms and cost-saving initiatives. The European Health Union initiative aims to strengthen health systems and enhance their resilience through policy reforms and financial support. By fostering collaboration between public and private sectors and promoting best practices, policymakers can help hospitals achieve long-term financial sustainability.

Financial sustainability and cost efficiency are indispensable for the long-term success of hospitals. By exploring new funding opportunities, utilizing resources efficiently, optimizing processes, adopting innovative technologies, and enhancing workforce efficiency, hospitals can navigate financial challenges and remain economically viable. Supportive policies and sustainable financing models are also crucial in ensuring the stability and resilience of healthcare systems. Through these multifaceted strategies, hospitals can continue to deliver high-quality care while maintaining financial health.

5 Differences in Hospital Management and Hospital Organization in Germany and Europe

Hospital management and organization vary significantly across Europe due to differences in healthcare systems, cultural contexts, and economic conditions. It is a complex field that encompasses various aspects such as administration, finance, human resources, quality control, and technological integration. The effectiveness of hospital management directly impacts patient care, efficiency, and overall healthcare outcomes. Understanding the differences in hospital management and organization across Europe can provide valuable insights for policymakers, administrators, and healthcare professionals and can help to overcome challenges in the future (Table 3).

Germany's Dual Healthcare System

Germany's healthcare system is characterized by its dual structure, comprising both statutory health insurance (SHI) and private health insurance (PHI). This dual system allows for broad coverage and access to healthcare services but presents challenges in terms of cost control and efficiency. The healthcare system is decentralized, with significant autonomy granted to regional health authorities and individual hospitals. The Federal Ministry of Health sets national policies, while regional governments manage local healthcare delivery. Hospitals in Germany are categorized into public, private non-profit, and private for-profit institutions.

The financing of hospitals in Germany is a mix of public funding, SHI contributions, and private payments. SHI covers approximately 90% of the population, while the remaining 10% are covered by PHI. Hospitals receive funding based

Table 3 Types of European Healthcare Systems

Beveridge Model	A healthcare system where the government funds and provides healthcare services through taxation, ensuring that they are free at the point of use for all residents. This model emphasizes universal coverage, preventive care, and cost control by centralizing healthcare management and regulation. While it promotes equity and cost efficiency, it can face challenges such as longer waiting times and bureaucratic inefficiencies.
Bismarck Model	A healthcare system characterized by compulsory health insurance funded jointly by employers and employees through payroll deductions, ensuring universal coverage. Healthcare providers are typically private, and the system is heavily regulated by the government to control costs and maintain quality. This model promotes efficiency and access but can be complex due to the involvement of multiple insurance funds and regulatory bodies.
Mixed Model	The Mixed Model of healthcare combines elements from both public and private sectors, offering a blend of government-funded services and private health insurance options. This model aims to provide universal coverage while allowing individuals the choice to purchase additional private insurance for faster access or enhanced services. It seeks to balance equity and efficiency but can lead to disparities in care quality and access depending on one's financial means.

on Diagnosis-Related Groups (DRGs), which categorize hospital cases into groups with similar resource usage.

A significant challenge for German hospitals is managing the financial pressures arising from an aging population, technological advancements, and rising healthcare costs. According to the German Council of Economic Experts for Health Care (2020), healthcare expenditures could rise to about 12% of the gross domestic product by 2030.

Germany has made significant strides in integrating technology into healthcare. The introduction of the electronic health record (eGA) and the use of telemedicine are notable initiatives. However, the implementation of these technologies requires substantial investments and adaptation of existing IT infrastructure.

The United Kingdom’s National Health Service (NHS)

The NHS exemplifies the Beveridge model, predominantly funded through taxes and providing free healthcare for all citizens. It operates as a centralized system, with services delivered by government-funded organizations. The Department of Health and Social Care sets overall policy and allocates funding, while NHS England oversees service delivery. Hospitals in the UK are primarily public and managed by NHS trusts, responsible for administration and financial management. The centralized nature of the NHS allows for uniform standards of care but can lead to bureaucratic inefficiencies.

The NHS is funded through general taxation, ensuring broad access but presenting challenges in managing rising costs and demand. According to the King’s Fund (2021), long waiting times and staff shortages are central challenges facing the NHS.

Recent reforms aim to enhance efficiency and patient satisfaction. Initiatives such as online appointment bookings and telemedicine services have been introduced to improve service delivery. The NHS has proactively adopted digital health solutions, including electronic health records, telemedicine, and mobile health apps, enhancing patient care and operational efficiency, while data security and patient privacy remain critical concerns.

France's Social Insurance-Based System

France's healthcare system is based on the Bismarck model, funded through mandatory social insurance contributions. It provides comprehensive coverage and high-quality care. Being decentralized, regional health agencies oversee the delivery of healthcare services. Hospitals in France are categorized into public, private non-profit, and private for-profit institutions.

Public hospitals, funded primarily through social insurance contributions, form the core of the French healthcare system. Private non-profit hospitals, often affiliated with religious organizations, and private for-profit hospitals add to the diversity of healthcare providers.

The financing of hospitals in France relies on social insurance contributions from employees and employers. Patients initially pay for services and then receive reimbursement from their insurance. This reimbursement system ensures comprehensive coverage but can lead to administrative complexities.

According to the OECD report "Health at a Glance" (2020), healthcare expenditures in France have risen sharply, leading to challenges in financing. Reforms aim to increase efficiency and improve access to healthcare services, particularly in rural areas.

France has been at the forefront of adopting digital health technologies. The use of electronic health records, telemedicine, and health information systems has enhanced patient care and operational efficiency. However, ensuring data security and interoperability remains a challenge.

Sweden's Decentralized Healthcare System

Sweden uses a national healthcare system funded through taxes. Healthcare is decentralized, with responsibility lying with regional health authorities. Sweden's healthcare system is managed by 21 regional health authorities, each responsible for the delivery of healthcare services within their region. Hospitals in Sweden are primarily public, with a few private providers.

The decentralized nature of Sweden's healthcare system allows for tailored healthcare services based on regional needs. However, it can lead to variations in care quality and access between regions. It is funded through taxes, making services free at the point of use. This model ensures broad access to healthcare but presents challenges in managing rising costs and demand.

According to the European Observatory on Health Systems and Policies (2020), there are significant challenges in Sweden regarding waiting times and access to specialists. Reforms aim to increase efficiency and reduce waiting times.

Sweden is a leader in digital health innovation. The use of electronic health records, telemedicine, and health information systems has significantly improved patient care and operational efficiency. However, data protection and security remain ongoing challenges.

The Dutch Social Insurance-Based System

The Netherlands has a social insurance-based system funded through mandatory health insurance. Every citizen must take out health insurance, with premiums being income-dependent. It is characterized by its high efficiency and quality of care. Hospitals in the Netherlands are categorized into public, private non-profit, and private for-profit institutions.

Public hospitals are funded primarily through social insurance contributions, and form the core of the Dutch healthcare system. The financing of hospitals in the Netherlands relies on mandatory health insurance contributions. Patients pay premiums based on their income, ensuring comprehensive coverage and access to healthcare services.

According to the OECD report “Health at a Glance” (2020), healthcare expenditures in the Netherlands have risen sharply, leading to challenges in financing. Reforms aim to increase efficiency and ensure access to healthcare services for all population groups.

The Netherlands is also a leader in the adoption of digital health technologies. The widespread use of electronic health records, telemedicine, and health information systems has significantly improved patient care and operational efficiency. However, the country continues to face challenges related to data security and protection.

Italy’s Mixed Healthcare System

Italy has a mixed system that combines elements of the Beveridge and Bismarck models. Financing is through taxes and social insurance contributions. Regionally organized, the system is leading to significant differences in care quality between regions. Hospitals in Italy are categorized into public, private non-profit, and private for-profit institutions.

Public hospitals are funded primarily through taxes and social insurance contributions, whereas private non-profit hospitals and private for-profit hospitals add to the diversity of healthcare providers. The financing of hospitals in Italy relies on a combination of taxes and social insurance contributions. This mixed model ensures comprehensive coverage but presents challenges in managing rising costs and regional disparities in care quality.

According to the European Observatory on Health Systems and Policies (2020), there are significant regional differences in healthcare provision in Italy. Reforms aim to increase efficiency and improve care quality across the country.

Italy has made notable progress in integrating digital health technologies. The implementation of electronic health records, telemedicine, and health information systems has improved patient care and operational efficiency. Despite these advancements, challenges persist in ensuring data security and system interoperability.

5.1 Structural and Financial Differences in Healthcare Systems

The structure of healthcare systems in Europe is diverse and reflects different historical and cultural developments. While Germany has a dual system with a strong role for self-governance, other European countries vary from state-funded systems to mixed systems. These differences impact the organization and administration of healthcare services as well as the autonomy of actors in the healthcare system.

The financing of healthcare systems is a central aspect that influences the sustainability and efficiency of healthcare provision. Germany's dual system, which combines SHI and PHI, contrasts with the tax-funded NHS in the UK and the social insurance-based systems in France and the Netherlands. These financial structures impact how hospitals manage their budgets, invest in technology, and deliver patient care.

In Germany, the DRG system incentivizes efficiency but can also lead to financial pressure on hospitals to minimize costs. In contrast, the NHS's tax-based funding ensures universal coverage but struggles with budget constraints and long waiting times. France's reimbursement model offers comprehensive coverage but involves complex administrative processes. The Netherlands' income-dependent premiums balance equity and efficiency, though rising costs remain a challenge.

5.2 Technological Integration and Innovation Across Europe

Germany has actively integrated technology into its healthcare system, with electronic health records (eGA) and telemedicine enhancing patient care and operational efficiency. However, standardizing IT systems across regions and ensuring data security remain challenges. The Federal Ministry of Health has initiated projects to improve digital health infrastructure, but implementation varies by state.

The NHS in the United Kingdom has embraced digital health solutions such as electronic health records, telemedicine, and mobile health apps, which have improved patient care and streamlined operations. Nonetheless, data security and patient privacy are critical concerns. The NHS Long Term Plan emphasizes digital transformation to enhance service delivery and patient outcomes.

France has made notable progress in adopting digital health technologies. The use of electronic health records, telemedicine, and health information systems has improved patient care and operational efficiency. However, data security and interoperability remain challenges. The French government's "Ma Santé 2022" strategy aims to enhance healthcare delivery through technology.

Sweden is a pioneer in digital health innovation. The adoption of electronic health records, telemedicine, and health information systems has significantly improved patient care and operational efficiency. Yet, data security and interoperability continue to be issues. The Swedish government has invested heavily in digital health infrastructure to create a seamless and integrated healthcare system.

The Netherlands leads in adopting digital health technologies, with electronic health records, telemedicine, and health information systems enhancing patient care and operational efficiency. However, data security and interoperability remain challenges. The Dutch government's "eHealth Action Plan" aims to improve healthcare delivery through technology.

Italy has made significant strides in digital health technology adoption. The use of electronic health records, telemedicine, and health information systems has enhanced patient care and operational efficiency. However, data security and interoperability remain challenges. The Italian government's "Piano Nazionale della Sanità Digitale" aims to enhance healthcare delivery through technology.

6 Recommendations for Hospital Management Models in Europe

Investing in digital health technologies can improve patient care, operational efficiency, and cost-effectiveness. Governments and healthcare providers should prioritize the implementation of electronic health records, telemedicine, and health information systems. Ensuring data security and interoperability is crucial for the success of these initiatives.

Healthcare systems must balance the need for comprehensive coverage with financial sustainability. Governments should consider reforms to improve efficiency and control costs, such as optimizing the DRG system in Germany or addressing budget constraints in the NHS. Implementing value-based healthcare models can incentivize quality care and cost control.

Decentralized healthcare systems, such as those in Germany and Italy, must address regional disparities in care quality and access. Governments should implement policies to ensure equitable healthcare delivery across regions. This may involve reallocating resources, standardizing care protocols, and enhancing regional healthcare infrastructure.

Healthcare systems across Europe face challenges related to staff shortages and workload pressures. Governments and healthcare providers should invest in workforce planning, training, and retention strategies. Enhancing working conditions and providing opportunities for professional development can improve staff satisfaction and retention.

Effective personnel management is crucial to combat the shortage of skilled workers and increase employee motivation and satisfaction. Innovative approaches in personnel management can help attract and retain qualified staff.

Flexible working time models can improve employees' work-life balance, thereby increasing their satisfaction and motivation. According to a study by the Hans Böckler Foundation (2023), flexible working hours are an important factor in making healthcare jobs more attractive. Hospitals should therefore increasingly adopt part-time models, flextime, and home office options. Promoting diversity and inclusion in the workplace can also contribute to increasing employee satisfaction. Hospitals should take measures to create a diverse and inclusive work environment.

A study by the International Labour Organization (2023) shows that diverse teams are more innovative and productive and have higher employee retention.

European countries can benefit from increased collaboration and knowledge sharing in hospital management and organization. Governments and healthcare providers should participate in international forums, research initiatives, and best practice exchanges. Learning from successful models in other countries can inform policy and practice improvements.

7 Conclusion

Hospital management in Germany and Europe faces significant challenges due to demographic shifts, technological advancements, financial constraints, and regulatory changes. Strategic planning is essential to navigate these complexities and ensure optimal patient care and operational efficiency.

Demographic changes, particularly an aging population, require hospitals to focus on geriatric and preventive medicine, integrating interdisciplinary teams and fostering research in age-related diseases. Technological advancements, including AI and telemedicine, offer opportunities to enhance diagnostics and treatment but demand substantial investments and robust IT infrastructure.

Financial sustainability is a core challenge, with rising costs and limited public funds necessitating innovative financing models like public-private partnerships and value-based care. Regulatory frameworks, such as Germany's Hospital Future Act, are crucial for modernizing infrastructure and enhancing digital capabilities.

The shortage of skilled healthcare workers requires innovative recruitment and retention strategies, including flexible working models, continuous education, and international recruitment. Creating an inclusive and diverse work environment can improve job satisfaction and retention.

Future hospitals in Europe are expected to be highly digitalized, patient-centric, and sustainable. Advanced technologies will enable personalized medicine and improve patient outcomes, while green practices will reduce environmental footprints. Workforce dynamics will evolve, necessitating innovative planning and continuous professional development.

By enhancing digital health integration, promoting financial sustainability, addressing regional disparities, improving workforce management, and fostering collaboration, European hospitals can navigate these challenges and continue to deliver high-quality care. Strategic planning and robust implementation frameworks will be key to achieving sustainable healthcare transformation.

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Digital and AI Applications from Pre-visit to Post-visit Services in Outpatient Care

Jacqueline Detert and Markus Detert

Abstract

Society is undergoing change worldwide, which is largely due to digitalization. The challenge in the transformation process is not only the large amounts of data (Internet of Things), but it will be important to record, interpret and then use them correctly. Digital networking connects the real world from the idea to implementation and optimization in medicine (self-measurement of the ego), especially the improvement of diseases or the maintenance of health. The focus is not only on the detection and treatment of diseases but also on individual health management. The age-old idea of “the right patient at the right time to the right doctor” can be implemented with the help of digital and AI-based assistance systems. AI-powered assistance has been added to two common traditional processes of specialist patient admission. With the help of the “shortest route strategy” in everyday medical care, it is shown how transformation can change everyday patient care.

By the end of the twentieth century, digital networking had already penetrated almost all levels of society. The first functional computer was developed as early as 1941. First, there is internal networking in offices and companies, enabling private networking via the Internet, cable networks, and satellites. With the COVID-19 pandemic, the home office is now part of everyday working life for many.

Digitalization is a trend and a global phenomenon reshaping societies, economies, and industries worldwide.

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Realize that digitalization is not just about technology, economy, and ecology but also how it influences social and interpersonal interaction. Communication has shifted to social networks and forums, supported by podcasts and videos on various topics.

The challenge in the transformation process is not only the large amounts of data (Internet of Things), but it will also be important to correctly record, interpret, and then use it. Society is experiencing a paradigm shift across industries and professional groups. Watches, smartphones, and even cars collect digital health data through analysis and targeted recommendations for action to project maximum safety to people. Digital networking connects the real world from the idea to implementation and optimization in medicine (self-measurement of the self) (Meißner, 2016; Schumacher, 2016), “Nothing seems unmeasurable” (Andelfinger & Hänisch, 2016). Digitalization, which focuses on improving illness and maintaining health (prevention), promises a brighter, healthier future. The focus is not only on detecting and treating illnesses but also on individual health management. With the help of apps and other technological developments, there seem to be no limits to measurement anymore. Due to the continuous and ever-accelerating technological development of apps, boundaries in the interpretation of data are also being increasingly crossed (Santinelli, 2013). With the help of the “digital twin,” prediction scenarios can be developed in healthcare so that health and the course of illness can be “planned” with a high probability of being true (Iqbal et al., n.d.) (Fig. 1).

In everyday medical care, obtaining complete information, findings, or examination results about the patient as the treating doctor is challenging. In Germany, the patient often acts as a messenger with folders full of paper documents. The problem of the required information that is available and specifically requested is shown in Fig. 2. There are knowledge gaps, particularly when information is initially presented, which can have a positive impact on the shortage of skilled workers and the availability of appointments through a targeted anamnesis and an obligation to provide examinations that have already been carried out in conjunction with AI-based systems.

There are daily reports in the national and international media about a shortage of skilled workers in all sectors, including healthcare. People in Germany are

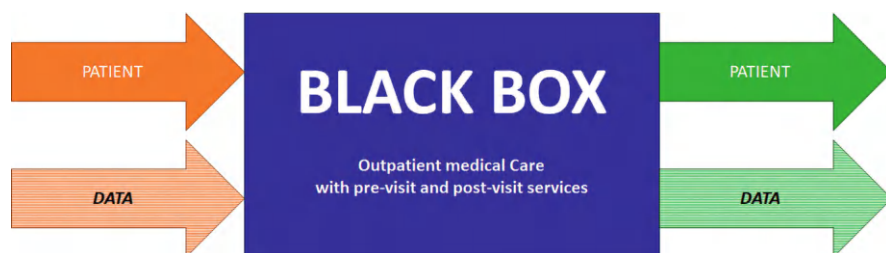


Fig. 1 Black Box: simple, efficient input for the maximum best excellence output in everyday medical supply

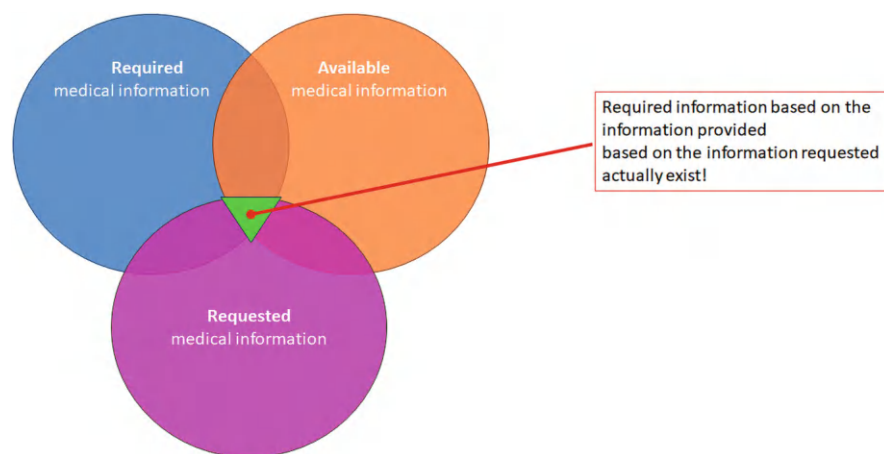


Fig. 2 Challenge of data

getting older and older, which means the number of skilled workers required in the healthcare industry and medical care is continually increasing. In addition, older citizens often remain in rural care, while younger citizens move to big cities (Bertelsmann Stiftung, 2024). The example of internal rheumatology shows the dilemma in Germany. Around 600 internal rheumatologists currently provide outpatient care for 1.8 million rheumatoid patients in Germany. There is already a need for 1500 more rheumatologists who can care for these patients. These are missing and are not in prospect in the next few years (Muth et al., n.d.). The only chance is to break down traditional supply processes and think out of the box. The opportunity to create efficient, modern care has never been better.

1 Strategy of the Shortest Route in Everyday Medical Care

If you follow the approach to the strategy of the shortest route that is typical in process technology (Helmberg, 2020), you can implement the age-old idea of “getting the right patient to the right doctor at the right time” in a targeted manner through the consistent use of modern information technologies and the planned use of AI-based assistance systems.

In our example, we have added the category of AI-powered assistance to the two usual traditional processes for specialist patient admission. Today, it is still often the case that patients come to their first appointment with a specialist doctor without any findings or previous diagnostics. The result is that no treatment decisions can be made at this point, and valuable time is lost until a confirmed diagnosis and therapy initiation are made. Treatment decisions are only made on the second or third follow-up appointment. Due to the usual 12-week billing structure in Germany, it takes 12–24 weeks or more for patients to wait for their therapy. Until then,

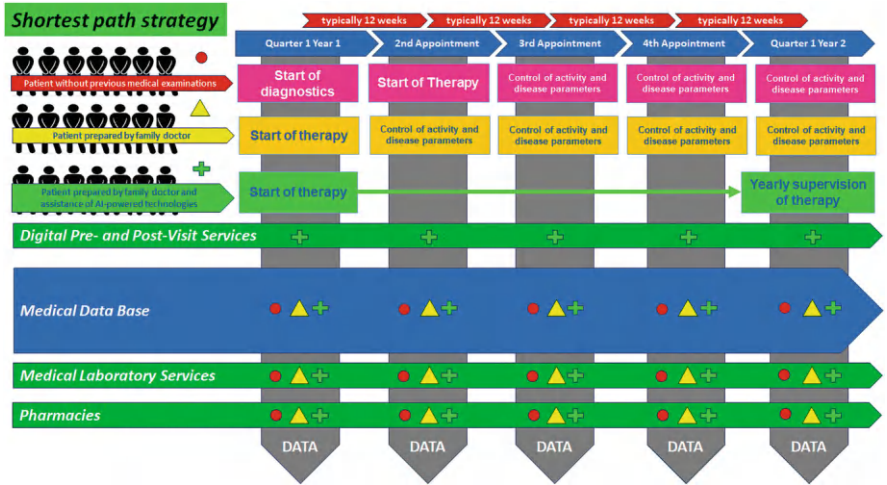


Fig. 3 Strategy of the shortest route in everyday rheumatology medical care

the patient is treated symptomatically as needed. Early detection is, therefore, delayed by ineffective structures. After the start of therapy, the disease and activity parameters are monitored quarterly by national and international guidelines.

If the family doctor, who is often referred to as a primary doctor in other countries, has already completed part of the diagnostics and preliminary examinations, the specialist disciplines, which are often referred to as secondary doctors in other countries, can then make a therapy-relevant decision at the first appointment. After the initiation of therapy, the disease and activity parameters are monitored regularly every 12 weeks (Fig. 3).

The dilemma, however, is that the appointments for monitoring disease and activity parameters tie up resources (PROMs, Patient’s Reported Outcome Measures) that are not available for processing new patients. However, today’s digital options and AI-supported methods are available to take consultation hours with pre- and post-visit services for patients and refer doctors to a new level. When determining laboratory parameters, AI-based systems can provide information about which other parameters still need to be determined or which other examinations need to be carried out to rule out a disease or narrow it down more specifically by adding further details.

In internal rheumatology, more than 400 different forms and subtypes of diseases affect the eyes, the brain, the digestive tract, the cardiovascular system, the urinary tract, muscles and tendons and joints, the skin, and all possible combinations thereof.

Despite good preparation, an initial appointment with an internal rheumatologist is not a 5-min appointment like when you have a cold. The AI of the young company of “medicalvalues” (medicalvalues GmbH, [n.d.](#)) has already developed a tool that provides appropriate support in laboratory parameters. Furthermore, the patients

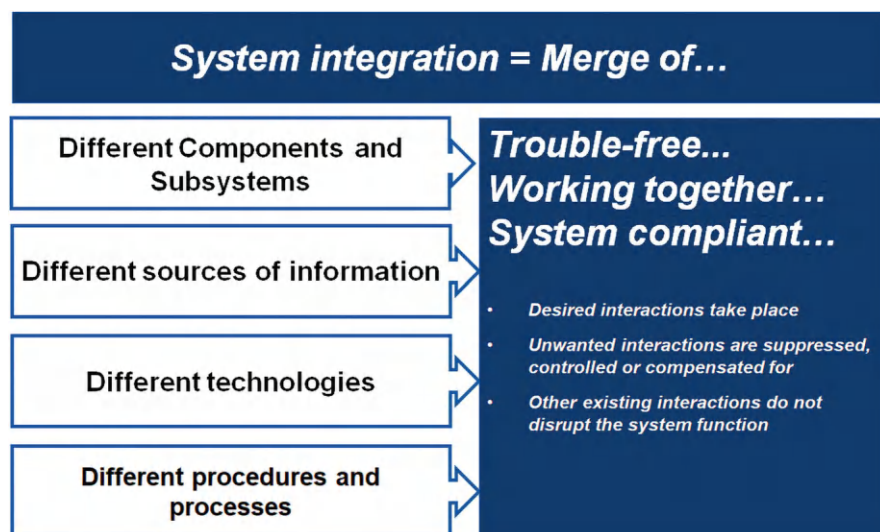


Fig. 4 Challenge of system integration

prepared in this way receive access to tools that support the anamnesis and the collection of disease and activity parameters before the first visit to the doctor's office and consultation hours, as well as the digital delivery of preliminary findings via data protection-compliant delivery channels. In recent years, tools in Germany such as IDANA (Idana AG, [n.d.](#)), Rhedat (BDRh-Service GmbH, [n.d.](#)), and online calendars for data and appointment exchange have proven themselves thousands of times. If the patient is doing well after the initiation of therapy, secondary doctors can return the patient to the close care of the primary doctor and take over annual or semi-annual supervision. If questions arise, digital consultations can be resolved in interdisciplinary discussions. The activity and illness parameters collected (from appointment to appointment) are still completely and automatically available to the secondary doctors. Depending on the available technologies, this data can be shared with multiple primary and secondary physicians in a data-protect-compliant manner. Examples include the Rhecord (RheCORD Healthcare GmbH & Co. KG, [n.d.](#)) and MIDAIA systems (Midaia GmbH, [n.d.](#)).

However, a key challenge is ensuring that the different components, systems, and processes work together seamlessly and without errors. Colleagues working in the outpatient and inpatient areas know numerous examples from their everyday work of how things often don't work (Fig. 4).

2 Personalized and Individualized Medicine

You can already hear and read success reports every day about how science is approaching P4 medicine (Hood, [n.d.](#); Sagner et al., [n.d.](#)).

- Predictive: Early detection of potential diseases.
- Preventive: Targeted prevention of the disease based on its prediction.
- Personalized: The individual is viewed as a unit of diagnosis and treatment.
- Participatory: Each individual is responsible for optimizing their health.

This concept inspires digital patient care developments and processes across all industries. Salutogenic treatment motivation aims at maintaining health and early detection of the transition from well-being to illness to enable early intervention and, thus, disease prevention (Hood, [n.d.](#); Sagner et al., [n.d.](#); Detert & Detert, 2023). It is gradually replacing the disease-oriented treatment tradition. This change is supported by increased patient sovereignty, which aims at transparency and timely information and communication. In support of this, the idea of prevention and longevity is moving into the focus of society's perception, not only to save care costs in the medium and long term but also to pursue the dream of healthy aging free of serious illnesses that minimize the quality of life (quality life). The basis is the increasing understanding of the molecular interaction levels and specialized test procedures (including sequencing of the human genome, epigenetics, multi-omics, and biomarkers), which are now also available in the online shop. The framework is provided by innovative imaging procedures, tests and analyses, big data, and omics, which are now AI-supported, leading to personalized and participatory care. Underlying technologies are experiencing impressive dynamics in their development, which form the basis for computing, data storage, and AI applications. Patients can access this data via their smartphone or similar. Access your device and have it evaluated and explained in understandable language via AI. The traditional doctor's office-hospital care system is changing. In addition to a digital care process, it now receives trans-sectoral networking based on diverse data streams and is the basis for future research and development (Fig. 5).

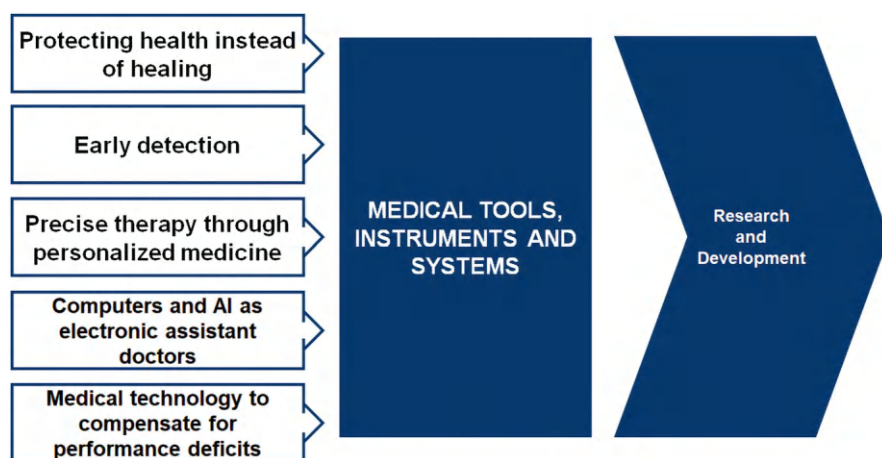


Fig. 5 4P and the world of research and development

3 Mindset in Transformation

Today, transformation in medicine is primarily associated with the digitalization of processes and work steps. Digital transformation primarily impacts the world of work. However, such a transformation can only be successful if an appropriate mindset (digital mindset) and a change in the corporate/clinic/practice culture have been developed. The focus is primarily on people whose wishes and requirements should be focused on. In addition to trust and customer loyalty, this view is particularly important because medical care often involves behavior-based changes (e.g., preventive measures and the development of digital skills). Since a transformation begins primarily by changing business processes, the focus is primarily on the people in the processes (doctors, employees, other service providers, and health insurance companies) (Schendzielorz et al., [n.d.](#); Kolasa, 2023). A failed transformation is usually due to an incorrect digital mindset (curiosity and acceptance of new technologies or supply processes) (Belliger & Krieger, 2023). Above all, it is about questioning traditional approaches in care processes, out-of-the-box thinking, overcoming the “we have always done it this way” and hierarchies in the decision-making processes.

4 Digital Transformation in Outpatient Practice (Outpatient Before Inpatient)

4.1 Process Thinking and Digital Transformation in Outpatient Practice (Outpatient Before Inpatient)

1. *Process Analysis*

The basis of a transformation is the visualization of all core processes and interface processes in progress. The patient’s care process traditionally begins with an appointment made in practice by the patient himself or the primary care provider or when a patient presents unannounced in an “acute” manner. Due to numerous interfaces and communication points, this process is still unsatisfactory for patients, practice teams, and their doctors. After the initial assessment, an anamnesis, diagnosis, communication of results, and, if necessary, therapy initiation or similar are carried out. Particularly in rural care areas with increasingly scarce care resources, such a process can take days to months, depending on the diagnostics to be carried out until a treatment specific to the patient can be initiated.

The aim of a transformation is the “strategy of the shortest route,” i.e., when health deviations occur, patients want a very timely assessment, cause, and, if necessary, a personalized and individualized package of measures.

First, structural quality must be developed to achieve a process quality that enables the “shortest route.”

2. *Structural Quality*

The digital networking of all partners involved in the treatment (internal and external to the practice) and the patient has been implemented in many countries for years but has been neglected in Germany. For this purpose, a so-called telematics infrastructure was developed in Germany with various services for electronic prescriptions, data-secure exchange platforms for reports and findings (KIM, communication in medicine service), electronic medication plans, electronic patient records (EPA), and messengers (Debatin & Dirks, [n.d.](#); Leyck, [2021](#)). Patients can now be scheduled using online appointment calendars or PVS (practice management software) calendar systems and telephone AI or messengers. Such systems focus on patients who can manage their appointments/contacts. It is a clear advantage over the classic appointment and notepads in everyday treatment with good reproducibility via appointment management. The spatial world can now be moved outside the facility (e.g., home office) while protecting data. Employees don't need to be present for such appointments and telephone structures. In addition to the high level of medical care quality (specialist standard), this includes the development of digital competence among doctors, employees, and patients. In addition to providing information, this is one of the complex structural improvement measures that involves training, repeated training in dealing with digital tools and software, and sub-processes that are now digitally mapped. Ideally, check-in into the practice should be carried out from any patient's device so that the usual registration procedure in Germany with the electronic health insurance card reading and verification becomes consistently available digitally. The structural quality also includes interfaces to pharmacies, hospitals, nursing homes, therapists, medical supplies, state offices, pension insurers, and health insurance companies to ensure smooth, fast, and secure communication and data exchange.

3. *Process Quality*

The “strategy of the shortest route” is often associated with the term “control of the patient,” which only partially describes such a strategy. The description “The right patient, to the right doctor, at the right time with prompt treatment as the goal” is more apt. This is precisely where the greatest potential lies for medical practices to increase efficiency without reducing the quality of care. This requires breaking up the traditional patient path. A new patient path could look like this to open the bottleneck in the supply chain, especially in specialist medical care, to provide every patient who needs such special care.

- (a) Digital screening based on medical history, symptoms, medication/treatment history.
- (b) Digital and AI-driven initial diagnostic process.
- (c) Digital information process.
- (d) Appointment and care for the right patient with the right patient.
- (e) Digitally supported care process outside of the practice.

(a) *Digital Screening Based on Medical History, Symptoms, and Medication/Treatment History*

When complaints occur, many people are unsure about their relevance. With the introduction of media information research, they relatively quickly come to technical terms, diagnoses, and treatment suggestions, which, if left undirected, often escalate uncertainty and even fear. Chatbots such as ADA Health are trying to assist through a structured collection of symptoms and anamnestic data to develop a diagnosis suggestion (Gräf et al., [n.d.](#); Knitza et al., [n.d.](#)). A doctor's visit is often unnecessary or can be planned at your leisure. Individual specialist areas also try to help patients classify these symptoms to select the right patients for the respective specialist area. However, appointments are not assigned immediately. However, the proportion of patients who receive an unnecessary appointment in the specialist care chain and should be taken care of by the family doctor himself or another specialist is still very high. Some countries (including Denmark) increasingly use a preparatory and selective preliminary diagnostic process (e.g., ultrasound robot "Arthur") (Frederiksen et al., [n.d.](#)).

(b) *Digital and AI-Driven Initial Diagnostic Process*

A digital diagnostic first process that can be easily included via AI and robotics with little personal effort (Chandwar & Prasanna, [n.d.](#)). In addition to laboratory AI, which can provide appropriate laboratory values based on the symptoms, ultrasound robots can now be used to carry out appropriate diagnostics for joint pain (medicalvalues GmbH, [n.d.](#); Frederiksen et al., [n.d.](#)). However, digital AI-supported module systems for collecting vital data, photos of skin symptoms, etc., can also supplement such screenings (Chandwar & Prasanna, [n.d.](#)). The so-called diagnostic hubs centralize preliminary and further diagnostics during treatment, where patients experience respective diagnostic procedures in one appointment. Findings can then be communicated and assessed promptly to doctors providing further treatment so that more targeted appointments can be made. Given the demographic development with the increasing aging of the population, such diagnostic hubs can be driven to patients in rural care. The so-called HeartCheck project showed how a high-performance cardio-MRI (magnet resonance imaging) gives all citizens easy access to early detection of heart failure. Specialists could not only remotely influence the execution of the MRI itself but also immediately assess and advise on critical findings and initiate further measures (Kelle et al., [n.d.](#)).

(c) *Information Management*

Information and communication management with patients is crucial in this preliminary digital care phase so patients can be informed immediately about the results and any further necessary measures. In addition to online advice, a wide range of digital options are available. This way, findings, and results can be translated understandably for the patient via AI (Chandwar & Prasanna, [n.d.](#)). In addition, explanatory videos and messenger-supported information can be conveyed, and the virtual world can be used via VR (virtual reality) glasses (Dreesmann et al., [n.d.](#)). Any conversations can be recorded and conveyed

to patients in patient-friendly language as a document for them to read. In addition, various preventative measures can be included here, and digital health applications (DiGA) can be pointed out and explained (Schmidt et al., [n.d.](#)). In the diagnostic facilities of the doctor's office, helpers such as robot assistants can also accompany information processes and inform patients in advance about, for example, therapies.

(d) *Appointment and Care for the Right Patient with the Right Patient*

Data from previous data collections and diagnostic procedures can be combined and analyzed in a digital cockpit. Using this data basis, patients can be specifically referred to a specialist or a family doctor, or a further wait-and-see can be a result for many patients. In such cases, patients have suggested a package of measures they can implement (e.g., flu-like infections). The main advantage of the preceding digital process is that the doctor can access several current results and promptly suggest therapy. The informative nature of such discussions can be much more targeted through the digital information process. Therefore, time and human capacities are treated carefully and enable the development of new time contingents.

(e) *Digitally Supported Care Process Outside of the Practice*

With digital options, patients undergoing initiated and ongoing therapy can be cared for almost entirely outside the practice. This allows new time resources to be developed for complex treatment situations or new patients. In addition to digital patient questionnaires to collect disease data and progression (disease activity, treatment response, PROMs), deviations can be interpreted promptly, and treatment measures can be adjusted. Online consultation hours reduce the presence time in waiting rooms and the on-site personnel costs as far as possible. Further digital tools are expected to expand the diagnostic spectrum during an online consultation, reducing doctors' concerns that findings could be overlooked. Patients can conveniently conduct laboratory checks using home monitoring systems, reducing travel and transport. In the future, patients can decide to what extent an in-person appointment is necessary. In addition, the possibilities of the digital information process already described also provide support here.

4. *Quality of Results*

The system's financing continues to be based on the illness and being ill. The aim should be to maintain a healthy society and a healthy citizen, and all measures should be geared towards this. This is not a feasible goal for all diseases, but improving the disease can still be achieved. For example, a better quality of life and freedom from pain can be achieved. As the amount of data increases, it is expected that current key performance indicator systems that provide information about this must be realigned or optimized. New key performance indicator systems may also be necessary to develop, which will allow the basis for performance-related, appropriate financing based on a reproducible and binding quality of results.

5 Summary

With the help of digital and AI-supported tools, healthcare opportunities, including prevention and improvement of diseases and quality of life, are greater than ever. To use this efficiently, it is necessary to rethink and structure care processes and the patient's path. Day-to-day outpatient care includes numerous interfaces that must be taken into account. The focus on the patient should not be lost, and patients should be included in the change processes.

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Revolutionising Personalised Medicine Using Cutting-Edge IT

Guido Kemper

Abstract

This chapter outlines a much-needed overview of the upcoming revolution in personalised medicine through the increasingly accelerating integration of state-of-the-art IT and artificial intelligence (AI) in particular. Through a comprehensive description of the possibilities of personalised medicine, he draws attention to the important social role that this development will play.

Kemper not only examines the areas in which the use of new IT/AI applications promises ground-breaking progress in personalised medicine, but also describes specific examples of the use of IT/AI in personalised medicine, some of which are already a reality.

“Revolutionising personalised medicine using cutting edge IT” concludes with a consideration of the ethical challenges posed in particular by the use of AI.

1 Introduction

For years, a trend towards personalised medicine has been discernible, which has accelerated significantly with the emergence and integration of cutting-edge IT and, in particular, artificial intelligence (AI), helping personalised medicine to achieve a veritable revolution.

In principle, the term personalised medicine can be used to subsume all approaches that promise individualised treatment and aim to cure patients according to their illness and individual characteristics.

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This innovative approach contrasts sharply with the generalised approach that patients with the same diagnosis also receive the same treatment.

How a disease develops or progresses depends, among other things, on the genetic predisposition of the individual and on environmental influences. Medicine is becoming increasingly knowledge based and can therefore fundamentally enable more targeted treatment with greater decision-making certainty, targeted treatment steps, fewer costly sources of error and more efficient use of resources. Individualised medicine aims to capture all of these factors as far as possible and use the constantly growing knowledge base to derive the path to customised therapies.

For this type of precision medicine, however, it is necessary to identify and collect a large number of individual criteria that can be used to better predict diseases and the effects of therapies. The implementation of this strategy therefore requires extensive data collection and advanced analyses that can only be realised using modern IT and artificial intelligence (AI).

The aim and challenge of healthcare research has always been to achieve the highest possible level of therapeutic efficacy for every patient—while at the same time minimising side effects.

With advances in knowledge about the causes and development of many diseases, new methods such as genome analysis and the rapid acceleration in the development of cutting-edge IT and artificial intelligence (AI) in particular, this now seems within reach. We are on the way to personalised medicine.

This chapter describes how IT, and artificial intelligence (AI) in particular, is already transforming personalised medicine today, overcoming the greatest challenges and enabling future developments.

2 Fundamentals of Personalised Medicine

In personalised medicine, particular attention is paid to the different requirements and needs of individual patients and different patient groups. For example, women with breast cancer only receive the active substance Herceptin if their tumours have a specific genetic characteristic (Slamon et al., 2001). Tumours without this characteristic do not respond to Herceptin, meaning that the treatment is not only ineffective but can also cause unnecessary side effects.

In the future, individualised medicine should be able to select the optimal therapeutic procedure for each person before treatment begins. In this way, it will be possible to determine in advance whether a patient or a specific patient group tolerates a drug well and whether the drug will actually be effective for the respective individual disposition and disease type. In addition to the medical history and clinical data, demographic data, genetic information, psychosocial factors, immunological status, lifestyle and environmental factors, for example, can also be included as a basis for applications in personalised medicine (Aebersold & Mann, 2003; Alipanahi et al., 2015).

Personalised medicine in the broader sense therefore includes not only pharmacogenetic approaches, such as the stratification of patients based on biomarkers,

but also individual prosthesis and implant therapies (unique specimens), patient model-based therapies in the operating theatre and the care of patients in their home environment with the help of assistance systems (telemonitoring). The aim is to achieve prevention, diagnosis, prognosis and therapy that is better tailored to the individual or to specific patient subgroups.

A fundamental prerequisite for personalised medicine is an understanding of the underlying disease mechanisms and the identification of molecular switch points that influence the development of a disease. Disease and therapy-relevant genes, proteins and other molecules are used for a specific diagnosis and customised therapy. The targeted use of these therapies can make them more effective and lead to better results for patients. In order to successfully translate research findings into medical products, procedures and general care, it is crucial to carefully evaluate the effectiveness and benefits of the new approaches.

The current trend towards personalised medicine is already permeating many disease patterns (Ashley, 2016; Burky, 2022) such as tumour therapies or genetic diseases like cystic fibrosis, which are increasingly being treated in a personalised manner based on the patient's individual genetic variants. Personalised therapies are also increasingly being used for neurological diseases such as ALS, Parkinson's (Chen & Asch, 2017) and Alzheimer's (Collins & Varmus, 2015).

3 The Role of IT in Personalised Medicine

Personalised medicine promises revolutionary advances in the treatment of individual patients, particularly in complex clinical pictures. Despite its potential, it faces obstacles solely due to the flood of knowledge, which on the one hand makes individualised approaches possible, but on the other hand is becoming increasingly difficult to keep track of:

Medical knowledge currently doubles approximately every 73 days (Aebersold & Mann, 2003; Alipanahi et al., 2015). Over 1 million medical publications are published every year (Ashley, 2016), making it almost impossible for individual doctors to keep track of everything. Today, a CT scan typically provides between 2000 and 3000 images. The number of images produced by an average MRI scan can vary, but is often between 100 and 1000 images per examination, depending on the body region examined and the specific protocol (Burky, 2022).

In addition, there is often a lack of accessibility and usability of patient data as well as a lack of time- and cost-efficient methodology for drug selection in patient-specific treatment cases. These components are essential to determine the best possible treatment options for the individual.

The structuring and focused provision of the multitude of data from clinical treatment and other patient-specific data represents a major challenge here and is considered a necessary prerequisite for personalised treatments.

New concepts for data storage and data management are required to ensure that ever more complex results are available with increasingly large amounts of data and under growing time pressure. These include storage in the cloud, documentation

in electronic patient records, the development and expansion of infrastructure for biobanks and the use of artificial intelligence and machine learning for efficient data analysis and management.

In this context, modern IT technologies act as central building blocks for tapping into the constantly growing medical knowledge base in order to enable knowledge-based healthcare: access to analyses of similar cases, structured analyses of treatment successes, context-sensitive decision support systems and guidelines.

The IT-relevant subject areas in personalised medicine can be roughly divided into two categories.

3.1 Data Integration and Management

Personalised medicine requires the processing and analysis of huge amounts of heterogeneous and unstructured data, including genetic information (whole exome sequencing, transcriptomics, etc.), medical images, laboratory results and patient records.

Innovative data storage solutions such as a data lakehouse now make it possible to store, manage and integrate these heterogeneous data sources. The data is stored in a high-performance, document-oriented manner and can be used for complex analyses and overview dashboards.

This further development of established big data data storage solutions (data lakes) is a milestone in modern data processing and shows how usable information can be obtained from data in the future: Scalability combined with transaction security and the speed of a streaming platform for a wide range of analyses (Fig. 1).

Cloud computing technologies enable the efficient processing of huge amounts of data and ensure that data is available anytime and anywhere.

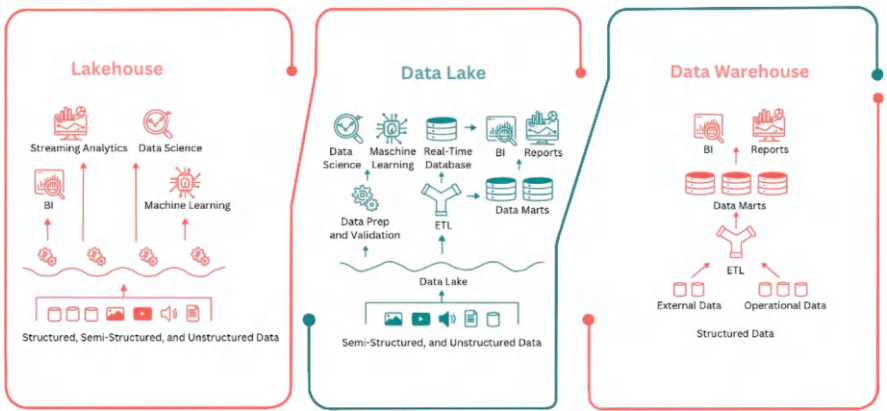


Fig. 1 The evolution towards the Data Lakehouse architecture

3.2 Data Analysis and Interpretation

Artificial intelligence (AI) and machine-learning technologies can recognise hypothesis-free patterns in large data sets without relying on predetermined assumptions and help to predict disease risks, diagnose and select the optimal therapy.

Bioinformatics is becoming increasingly important as a discipline in its own right in this context and uses IT tools to analyse biological and clinical data in order to gain new insights into diseases and treatment methods.

Due to their high relevance and extremely dynamic development, these two subject areas (AI and bioinformatics) are analysed in detail in the following two chapters.

4 The Role of Bioinformatics in Personalised Medicine

Bioinformatics is an interdisciplinary field that combines the methods of computer science, mathematics, statistics and biology to analyse and interpret biological data. The main aim of bioinformatics is to understand and model biological processes and systems through the application of computer-aided techniques.

In this respect, bioinformatics uses IT for data analysis and interpretation in order to gain meaningful insights from large and complex biological data sets and therefore plays a central role in personalised medicine. In the field of personalised medicine, this includes, for example,

4.1 Genome Sequencing and Analysis

Bioinformatics tools are used to process the huge amounts of data from genome sequencing. This enables the identification of genetic variants that are associated with certain diseases or disease risks. For example, BRCA1 and BRCA2 mutations have been linked to an increased risk of breast and ovarian cancer based on the analysis of genome data (Aebersold & Mann, 2003).

4.2 Proteomics and Protein Interaction Networks

Bioinformatics is used to analyse proteomics data and create protein interaction networks. This helps to understand the function of proteins and their role in biological processes and diseases. The analysis of protein interaction networks can, for example, identify potential target structures for new customised drugs (Alipanahi et al., 2015).

4.3 Metagenomics

Bioinformatics methods are used to analyse the genetic composition of microbial communities living in different environments or organisms. This can help to understand the role of the microbiome in health and disease. In this context, the human gut microbiome and its influence on individual metabolic diseases has already been analysed in order to make individual diagnoses and prognoses based on gut microbiome samples (Ashley, 2016).

4.4 Structural Bioinformatics

This sub-discipline uses computer-aided techniques to predict the three-dimensional structure of proteins and other biomolecules. This is crucial for understanding the function of molecules and developing new personalised medicines. The technique is used, for example, to predict the structure of protein-ligand complexes in order to identify new compounds (Burky, 2022).

5 The Use of Artificial Intelligence in Personalised Medicine

In addition to bioinformatics as an overarching methodology, AI as a technology plays a central role in personalised medicine. AI is set to revolutionise personalised medicine by providing the ability to analyse and interpret large and complex amounts of data, develop predictive models and create personalised treatment plans.

AI as a generic term that encompasses the important analytical methods of machine learning (ML) and deep learning (DL). In addition to these methods, there are also a large number of methods based on mathematical logic processes or search and optimisation processes that are also classified as AI.

Machine learning (ML) refers to a collection of mathematical methods for recognising patterns. These methods recognise patterns in the sense of rules, for example by breaking down data sets into hierarchical structures (decision trees)—geared towards the best possible entropy. In an alternative method, vectors are used to determine similarities between data sets and patterns are derived from them, either trained (e.g. k-nearest-neighbour) or untrained (e.g. k-means).

Deep learning (DL) is a discipline of machine learning using artificial neural networks (AN). While the ideas for decision trees, k-nearest-neighbours or k-means were developed from a certain mathematical logic, there is a model from nature for artificial neural networks: biological neural networks.

Hierarchically, this can be categorised as follows (Fig. 2):

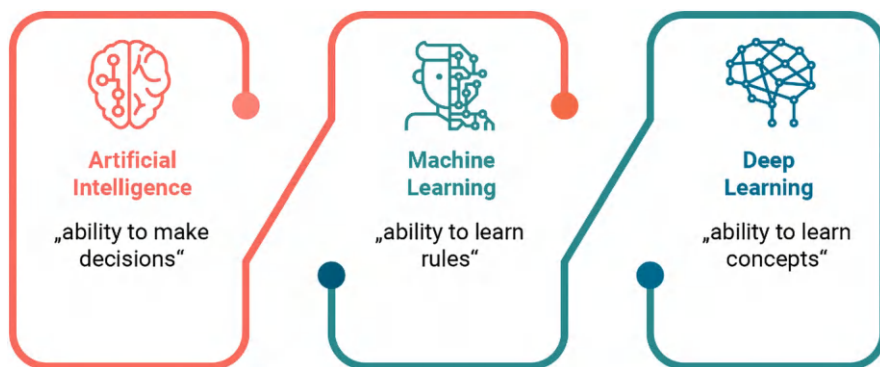


Fig. 2 Hierarchies of AI

5.1 Current Forms of Neural Networks

Convolutional neural networks (CNNs) are a specialised form of neural networks that are primarily used for the classification of image data. They are essentially classic neural networks, but have a convolutional and a pooling layer upstream. The convolution layer reads sections of the data input (e.g. photo sectors) several times in succession, while the pooling layer reduces the section data (in the case of photos: pixels) to essential features. This is done by summarising neighbouring pixel values in a smaller area. This is followed by the actual neural network.

Furthermore, recurrent neural networks (RNN) are of great importance as they have a temporal memory and take into account the history of a signal. This is particularly important for applications in the field of language or for time series analyses, where references to previous input values play a major role.

Long Short-Term Memory (LSTM) as an extension of conventional RNN is a technique that has made a significant contribution to improving the development of artificial intelligence [0]. In complex deep neural networks, the principle of error minimisation no longer works optimally in some cases due to mathematical limitations. In contrast to conventional recurrent neural networks, LSTM enables a kind of memory of previous experiences: “A short-term memory that lasts a long time”.

Particularly disruptive and promising areas of application for AI include:

5.2 Diagnostics

AI algorithms can analyse medical images (such as X-rays, MRIs and CT scans) to detect diseases early and make more accurate diagnoses (Aebersold & Mann, 2003). This is particularly useful in radiology and pathology. By analysing medical images, AI can provide an automated diagnosis that increases the accuracy and efficiency of diagnosis (Alipanahi et al., 2015). CNNs are primarily used as the underlying

technology for this. This technology is particularly well suited to analysing image data and has achieved great success in medical image processing.

In genomics, RNNs are also used to analyse DNA and RNA sequences and identify genetic variants associated with certain diseases (Ashley, 2016).

In principle, AI algorithms are able to help doctors diagnose complex cases by suggesting relevant data and possible diagnoses. This has been shown to improve accuracy and reduce error rates (Burky, 2022).

AI can recognise complex patterns in the data that are difficult for human analysts to identify (Chen & Asch, 2017). This is particularly useful in identifying disease markers and predicting disease risk. For example, AI systems can recognise unusual patterns or outliers in the data that indicate rare genetic variants or atypical disease progression (Collins & Varmus, 2015).

5.3 Personalised Prognoses and Therapies

Personalised medicine requires the analysis of huge amounts of genetic, clinical, imaging and behavioural data. Big data technologies, AI algorithms, in particular machine learning and deep learning, are able to process this data efficiently and extract valuable information from it, especially for prognoses (Kosorok & Laber, 2019).

However, the central challenge in making predictions is that the database is usually made up of completely different types of data (genomics, proteomics, clinical data, psychosocial factors, immunological status, lifestyle and environmental factors, etc.). Due to the heterogeneity of the data types, a comprehensive analysis of this so-called multimodal data is very complex. AI technologies such as deep learning are increasingly being used to address this problem (Kourou et al., 2015). Deep learning frameworks such as TensorFlow and PyTorch are now able to provide individual models that can process data from different modalities.

Furthermore, ensemble methods have become established in which several models are combined in order to process different data types and improve the accuracy of predictions. This can be achieved by combining models that have been trained on different types of data.

A patient's risk of developing certain diseases can be predicted using AI based on genetic and clinical data (Gasser, 2009). For example, machine learning models can predict the risk of cardiovascular disease or cancer. AI is also used for disease progression analysis to model the progression of chronic diseases such as diabetes or cardiovascular disease by analysing long-term patterns and trends in patient data. LSTMs are often used for this purpose, as they are known for their ability to learn and store long-term dependencies in sequences (Lazaridis & Athreya, 2020).

AI can also predict how a patient will respond to certain treatments based on historical data and individual characteristics (Goecks et al., 2020). This enables the customisation of therapies to the individual needs of the patient.

Personalised treatment recommendations are also already possible through AI by analysing large amounts of literature, clinical trials and patient data (Jameson &

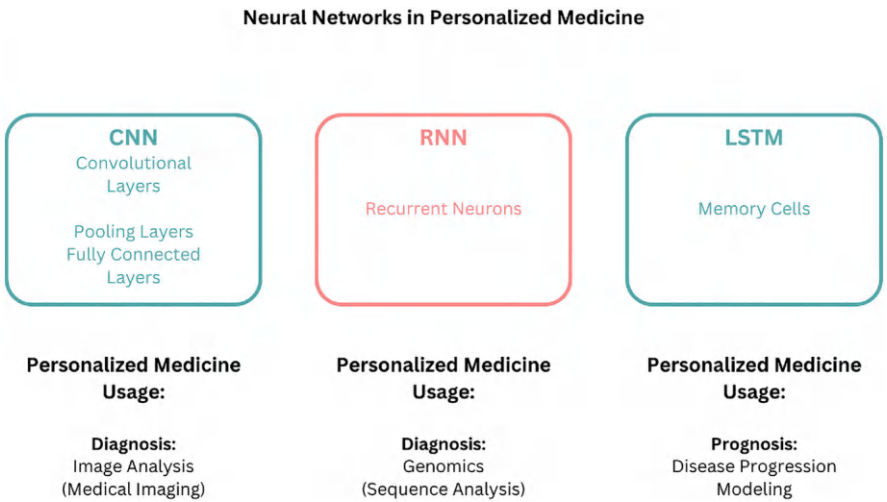


Fig. 3 Neuronal networks in personalised medicine

Longo, 2015). This helps doctors to choose the most effective and safest treatment options for each individual patient (Fig. 3).

6

Application Examples of AI in Personalised Medicine

6.1

Prognostic Models for Cancer

Artificial intelligence (AI) is playing an increasingly important role in the diagnosis and treatment of cancer, as it is able to recognise patterns and correlations in data without having to rely on predetermined assumptions. Therefore, innovative AI models could be used to develop prognostic models without prior hypotheses.

Cancer remains a significant public health challenge and is the second leading cause of death worldwide (Aebersold & Mann, 2003; Alipanahi et al., 2015). Current standardised therapeutic approaches are often inadequate, as cancers respond differently to drugs in different individuals. Personalised medicine therefore strives for tailored therapies that are adapted to the specific characteristics of each type of cancer (Ashley, 2016). A major difficulty here is the selection of the optimal therapy for individual patients, as the relevant data is often available in different formats and systems.

Innovative data storage solutions such as a data lakehouse can help to integrate this information and extract decision-relevant data. The integration of patient data can make it easier to identify patient subgroups and link them to clinical metadata. Based on these subgroups and existing patient histories, AI can be used to create predictive models that lead to better treatment strategies and thus have the potential to predict the effectiveness of cancer therapies for individual patients.

Although comprehensive solutions are not yet available, there are already increasing approaches to data integration and the development of initial prognostic models, for example based on histological data (Chen & Asch, 2017).

6.2 Integration of Machine Learning in the Estimation of the Average Treatment Effect Such as CATE (Conditional Average Treatment Effect)

The Conditional Average Treatment Effect (CATE) is a concept from causality research and statistics that focuses on measuring the average treatment effect in certain subgroups of a population. The CATE therefore indicates how a certain treatment or intervention (e.g. a drug) works in a certain subgroup (e.g. defined by age, gender or genetic characteristics).

In contrast to the average treatment effect (ATE), which measures the average effect of a treatment across the entire population, the CATE allows a differentiated view by taking into account the heterogeneity of the treatment effects in different subgroups.

The integration of machine learning to determine CATE now makes it possible to develop personalised models that can predict how different individuals will respond to certain treatments. In contrast to traditional methods, ML-based CATE estimation examines individual differences in patient response to treatments. By analysing a wide range of patient data, such as age, medical history and previous treatment outcomes, these algorithms can predict the potential benefits or risks of a treatment for each person. In other words, this technology uses ML to predict how effective a medical treatment will be for an individual based on their unique characteristics.

For example, if a new cancer drug is being developed and tested, instead of just looking at the average effect of the drug on all patients, the CATE can be analysed for different subgroups, e.g. for patients with a specific genetic mutation. Machine learning models can then be used to predict which patients are most likely to benefit from the drug based on their individual genetic profiles and other characteristics. In this way, the development of a personalised cancer drug is possible.

Current examples of this include studies on the effectiveness of psychotherapy. Psychotherapy has proven to be effective on average, although patients respond very differently to treatment. Machine learning has been used here to understand which characteristics are associated with the heterogeneity of treatment effects (Collins & Varmus, 2015). This can be instrumental in tailoring therapy to the individual patient.

On the other hand, ML was used to obtain a more accurate prediction of the individual survival benefit of adjuvant therapy for patients with early invasive breast cancer. Machine learning technologies can enable accurate prediction of patient outcomes under different treatment options through data-driven modelling of complex interactions between risk factors. Here, an automated and interpretable machine learning algorithm was used to develop a breast cancer prognostic and treatment benefit prediction model (Gasser, 2009). The model showed significantly

improved accuracy in both internal and external validation compared to the main prognostic tool currently used in the clinic.

The performance of this ML method in predicting treatment effects for individuals is promising for improving clinical decision-making. Research shows that ML can predict a patient's response to treatment more accurately than conventional methods (Goecks et al., 2020).

7 Challenges and Opportunities

7.1 Opportunities

The development of IT and AI in particular has accelerated so rapidly in the last 5 years that it is almost impossible to predict what possibilities will be available in another 5 years.

What is already clear, however, is that the leaps in development and knowledge in knowledge-based medicine and IT are mutually reinforcing. Personalised medicine is benefiting disproportionately from this, as the synergistic combination of both disciplines means that many things that were only theoretically conceivable for a long time are now becoming feasible.

Modern medicine has always claimed to want to look at people holistically and offer medicine that is individually tailored to the patient and at the same time optimises the relationship between effect and side effect.

The convergence of knowledge-based medicine and IT is a great opportunity to gain momentum on this path. Bioinformatics has already demonstrated the added value that can be created through the interaction of the disciplines of biology and IT.

7.2 The Database Challenge

Despite all the promising opportunities and, in some cases, already usable solutions for data analysis for personalised prognoses, therapies or diagnostics, the establishment of a high-quality, comprehensive and multimodal database remains a central challenge.

The enormous amounts of data from demographic, genomic, proteomic and clinical data sources must not only be stored, but also efficiently processed and integrated in order to gain meaningful medical insights (Aebersold & Mann, 2003). Privacy and data security are also critical aspects, as medical data is particularly sensitive and must be protected from unauthorised access (Alipanahi et al., 2015). In addition, standards and interoperability between different IT systems and platforms must be improved to ensure seamless exchange and meaningful integration of data (Ashley, 2016).

Establishing a database, for example, has a significant influence on the quality of the forecasts and recommendations derived by AI and usually accounts for a large part of an AI project. Before the actual development of the AI, a database must be

made available that fulfils the requirements for processing in the AI. This can lead to a variety of challenges.

If, for example, only small amounts of data (“little data”) are available, as is the case with rare diseases, this requires special training and testing approaches in order to develop trustworthy AI models. Distributed and particularly sensitive data often cannot simply be used to develop AI models, but requires decentralised methods for secure data processing such as federated learning. The availability and quality of data pose a major challenge, particularly in the case of rare diseases, due to the scarcity of data.

Another challenge is that often only a very small part of the available data is “labelled”: for a large part of the data, there is no “label” that describes what the respective data set is about, as this description process is very time-consuming. However, the detailed annotation of the data is usually essential for training the AI, which means that a large proportion of the data remains unused when using the supervised learning methods that dominate the deep learning field. New, very sophisticated methods, such as contrastive learning, use the method of self-supervised learning to integrate unlabelled data into the learning process (Burky, 2022; Chen & Asch, 2017).

7.3 The Trustworthy AI Challenge

A trustworthy AI is less error-prone, as explainable and comprehensible as possible, so that society can trust it. This is particularly essential in safety-critical contexts such as medicine.

Current developments such as the “EU AI Act”, the European Union’s AI regulation (Collins & Varmus, 2015), demonstrate the increasing importance of creating an ethical and regulatory framework for AI systems that society can trust.

However, the validation and standardisation of these AI models poses a considerable challenge, as the models must be based on extensive and diverse training data in order to be reliable.

Explaining and understanding the results of AI systems, the so-called black box problem (Gasser, 2009), is also a significant obstacle. This can affect the trust of healthcare professionals and patients in these technologies. The “black box problem” describes the fact that, in contrast to conventional systems, the information contained in a neural network is not localised at specific memory locations (addresses), but is distributed as patterns across the entire network structure. Information and thus ultimately memory content is diffusely distributed in the network and encoded in the strength of a large number of connections—similar to the human brain.

This learning principle therefore appears to be both a curse and a blessing, as the resulting enormous learning ability and successes come at the price of a serious disadvantage: the user has no way of understanding how the AI arrives at the solution to a problem. The decision path remains hidden in the black box. However, decisions made by algorithms that cannot be explained or understood

can raise serious social and ethical questions, depending on the area of application, particularly in medicine.

The explainability and comprehensibility of AI is still a current field of research under the keyword Explainable AI (Goecks et al., 2020; Jameson & Longo, 2015). The aim is to offer solutions that make the basis for decision-making, for example in diagnostics, understandable and verifiable for users.

8 Summary

Medicine that sees the whole person, is individually tailored to them, maximises effects and minimises side effects has always been regarded as both an ethical aspiration and a challenge for health research.

The progressive integration of IT and, in particular, artificial intelligence (AI) in many medical fields shows how this vision has already become reality in some areas: personalised medicine is already possible in many applications in the field of diagnosis and personalised prognoses & therapies and is increasingly being used.

Through the use of innovative data storage solutions and advanced data analysis using AI, customised treatment approaches are already being developed, for example in the field of solid tumours, which significantly improve the efficiency and effectiveness of medical interventions.

AI algorithms are successfully used in medical imaging, in predicting person-specific treatment effects in breast cancer and in analysing DNA and RNA sequences in genomics to identify individual genetic variants associated with specific diseases.

However, considerable technological, ethical and economic challenges still need to be overcome in order to exploit the full potential of personalised medicine.

Nevertheless, it can be concluded that cutting-edge IT technologies and artificial intelligence (AI) are about to revolutionise personalised medicine. The transformation of personalised medicine into a new discipline deeply interwoven with these technologies has already begun and is accelerating synergistically with advances in medicine and IT.

With continued research, investment and training, personalised medicine can become a standard in healthcare that meets the individual needs of each patient and the ethical demands of healthcare research.

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Open Innovation Platforms as a Sustainable Future Concept for Innovations in the Healthcare Sector (Follow-Up Study)

Julia Plugmann and Philipp Plugmann

Abstract

The research question of the previous study (Study No. 1) was motivated by open innovation platforms in other industries—such as the previously well-known American company LOCAL MOTORS from the automotive industry—where technological products were built with an effective marketing approach that appealed to creative and innovative individuals. While in “Study No. 1” we focused on the “willingness of academics to participate and collaborate in an open innovation platform to develop new innovative medical technology products with individuals, groups, communities and companies,” this follow-up study (Study No. 2) focuses on the “willingness of academics to participate in an open innovation platform in healthcare outside their qualifications and work experience,” which also leads to the need for these academics to build self-taught competence. This should activate creativity among the participating academics and promote new individual and group-based approaches to innovation management. In Study No. 2, we only surveyed those who had responded in Study No. 1 the willingness to co-develop medical technology products within an open innovation platform.

Academic discipline (six categories) was the most important predictor of whether participation in an open innovation platform was likely outside of one’s own qualifications and professional experience. Academics from medicine and biology, as well as physics and chemistry, were significantly more willing to participate compared to philosophers. Language barriers, duration of the projects, acceptance of a project manager or motivating factors, such as money or fun,

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did not say anything about the prediction of possible participation. Overall, the development of an open innovation platform as a sustainable future concept for innovations in the healthcare sector offers an opportunity and should be promoted in order to offer academics interested in innovation another option for participating in innovation processes.

1 Introduction

The development of an open innovation platform as a sustainable future concept for innovation in the healthcare sector can have a local and global approach (Chesbrough et al., 2014). Through knowledge transfer (Bacon et al., 2019), inter-organizational relationships (Radziwon & Bogers, 2019), research opportunities (West & Bogers, 2017), impact on entrepreneurship (Nambisan et al., 2018), as well as companies and communities networking together (Gupta et al., 2017), there is enormous potential for open innovation platforms in healthcare.

The research question of the previous study (Study No. 1) was motivated by open innovation platforms in other industries—such as the previously well-known US company LOCAL MOTORS from the automotive industry—where technological products were built with an effective marketing approach that appealed to creative and innovative individuals (https://www.youtube.com/watch?v=azCRuwTE_n0).

The research question was how willing academics are to participate in such a platform that develops medical technology products. By medical technology products, we mean future medical technology that is able to solve serious health crises in the future, such as cancer or trauma injuries in a new way, by combining various current and future technologies supported by artificial intelligence (AI)—similar to the “Med-Bay” from the movie *Elysium* (<https://www.youtube.com/watch?v=XwaljThPDh0>) as an example.

While the research in “Study No. 1” focused on “The willingness of academics to participate, collaborate and co-create on an open innovation platform for the development of medical technology with individuals, groups, communities and companies,” in Study No. 2, in terms of a “follow-up study,” we focused on: “The willingness of academics to participate in an open innovation platform in healthcare outside their qualifications and professional experience.”

In the following section, I will present the previous study “Study No. 1,” which was the starting point for “Study No. 2,” so that readers can better follow our thoughts on this research process.

2 Open Innovation Platforms: Study No. 1

2.1 Theoretical Background Study No. 1

In *Study No. 1*, we analyzed the willingness of academics to participate, collaborate, and co-create on an open innovation platform for the development of medical technology with individuals, groups, communities, and companies.

The potential of radical innovation through “open innovation” (Kennedy et al., 2017), the advantages of external knowledge search and its implementation capability (Flor et al., 2018), as well as components of heterogeneous intellectual capital (Agostini & Nosella, 2017) have a significant impact and bear benefits to companies and the global economy (Vanhaverbeke et al., 2018).

There is still untapped potential that is dependent on the participation of academics. Barriers to innovation (Smith & Sandberg, 2018), failed implementations (Von Briel & Recker, 2017), and companies with established social and cultural patterns are just some of the challenges that open innovation platforms must meet in order to be successful. The best way seemed to be to ask academics directly about their willingness.

2.2 Research Design Study No. 1

This study was based on three books that we published at Springer International with several co-editors: “Innovative Technologies for Market Leadership” (Glauner & Plugmann, 2020), “Creating Innovation Spaces” (Nestle et al., 2021) and “Digitalization in Healthcare” (Glauner et al., 2021). In total, over 60 co-authors contributed exciting chapters, but we wondered about their willingness to participate in an open innovation platform that develops new and radical medical technology and related products.

Initial discussions with these co-authors, via phone or physically, did not reveal any clear motivation or willingness to do so. We therefore decided to ask academics from different disciplines about their willingness to participate and to identify key factors that would increase their willingness.

Research question. We expected that the research results would have a major impact on the industry and could help to promote such open innovation platforms to jointly develop radically innovative medical technology. For such projects, we believed at the time, we would need not only the willingness of academics to participate but also highly motivated individuals who could persevere and continue over a long period of time despite failures, obstacles, and conflicts.

The questions were as follows:

1. Would you be interested in participating?
2. Would you invest your time and take part for a year?
3. Would you invest your time and participate for more than a year?
4. Would the language be an obstacle if it was not German or English?
5. Could you accept a project manager?
6. Is money a motivating factor for you in this context?
7. Is fun a motivating factor for you in this context?

Primary Data. We conducted the interviews over a period of 2 years (February 2019 to February 2021), by phone or video call, in North Rhine-Westphalia, Ger-

many. For our study, we interviewed 306 academics in Cologne, Bonn, Leverkusen, and Dusseldorf, from six different disciplines. These disciplines were:

1. Engineering and bioengineering (50) = EngBio
2. Computer science (52) = CompS
3. Medicine and biology (51) = MedBio
4. Physics and chemistry (50) = PhysCh
5. Design (53) = D
6. Philosophy (50) = Phil

The inclusion criteria were that the academics surveyed had worked in their field for at least 3 years after graduation, at a university, in a company, or part-time in both areas. Age was not an exclusion criterion. The academics were randomly selected from the social platforms LinkedIn and XING and contacted via professional email. If they agreed to participate in the survey, they were contacted by phone or video call. In the first round, we contacted 941 academics by e-mail and received 213 responses. After the second round 4 weeks later, there were finally 306 who took part in the survey.

Before using the questionnaire as a quantitative research tool, we conducted a preliminary exploratory study as a qualitative research method in order to identify clusters or key factors that we wanted to consider for the questionnaire design.

For this exploratory preliminary research, we organized seven interviews with experienced academics. They all had more than 15 years of professional experience in the industry, in scientific and industry-related projects, to develop new technologies and implement the results in innovative products and services.

We asked 42 academics for interviews by e-mail, from small and medium-sized technology companies or universities in the German state of North Rhine-Westphalia. Twenty-six responded and seven accepted to take part in the interview.

These academics came from our personal network and in each case had been in contact for at least 5 years. Each interview lasted about 30 min, and we basically talked about experiences and key factors that could increase the willingness of academics to participate in an open innovation platform to co-develop innovative medical technology.

Data analysis. The interviews (step 1) were followed by an evaluation of the main statements, and we coded these in order to later consolidate and identify patterns and clusters that could be relevant for a higher willingness to participate from the perspective of academics. The questionnaire (step 2), which was then finalized based on the findings of the exploratory preliminary investigations, was used for the survey. The factors identified from the seven preliminary interviews were: time, money, social, and cultural conditions.

The academics' responses to the standardized questionnaire were then evaluated using the statistical software IBM SPSS 28.0. The possible answers in the questionnaire were coded dichotomously with "yes" and "no." The items were therefore nominally scaled. Absolute and relative frequencies of "yes" answers were given as N (%) both for each discipline individually and averaged across

groups. To determine differences between the groups, cross-tabulations with χ^2 -tests were calculated. First, differences between all groups were tested. In case of significance, post-hoc tests with pairwise comparisons between groups were performed, including a Bonferroni correction for multiple comparisons.

Those p-values that lost their significance after Bonferroni correction were marked with * and can be interpreted as a trend toward significance. The p-value and the effect size (Cramer's V for 6×2 cross-tabulations and phi for 2×2 cross-tabulations) were given for each test, with 0.1 corresponding to a small effect, 0.3 to a medium effect, and 0.5 to a strong effect.

2.2.1 Platform for an Open Innovation Ecosystem for the Development of Medical Technology Products

This future platform will be available to scientists to cooperate, interact, and jointly develop new medical technology products. These products could contribute to solving individual health crises, e.g. cancer or traumatic injuries, in a very short time, with high quality, a high degree of safety, and at affordable prices.

This requires both interdisciplinary approaches and scientists from all disciplines with different levels of experience and without age discrimination. The scientists contribute their work and time to these projects on a voluntary basis, making sure that no conflicts arise with the universities or companies they work for. The individual scientists are open to innovation and make their free time, knowledge, and commitment available for a common goal—the development of a new radical medical technology product.

2.3 Results Study No. 1

The following results show how many of all *academics* surveyed ($n = 306$) answered “yes” to the following seven questions:

1. *Would you be interested in participating?* 85.0% ($n = 260$)
2. *Would you invest your time and take part for a year?* 46.4% ($n = 142$)
3. *Would you invest your time and participate for more than a year?* 19.9% ($n = 61$)
4. *Would the language be an obstacle if it was not German or English?* 62.4% ($n = 191$)
5. *Could you accept a project manager?* 69.6% ($n = 213$)
6. *Is money a motivating factor for you in this context?* 18.6% ($n = 57$)
7. *Is fun a motivating factor for you in this context?* 75.5% ($n = 231$)

Our results show that 85.0% ($n = 260$) of the academics surveyed ($n = 306$) would participate in a platform for an open innovation ecosystem for the development of medical technology products. Interestingly, there was a systematic difference between disciplines ($p < 0.001$, Cramer's V = 0.462), with engineers showing a significantly lower willingness to participate (48.0%) than any other

discipline (CompS = 90.4%, $p < 0.001$, $\phi = 0.461$; MedBio: 92.2%, $p < 0.001$, $\phi = 0.483$; PhysCh: 96.0%, $p < 0.001$, $\phi = 0.535$; D = 88.7%, $p < 0.001$, $\phi = 0.439$ and Phil = 94.0%, $p < 0.001$, $\phi = 0.507$).

In general, 46.4% of all respondents were willing to participate for up to 1 year, although there were also systematic differences between the disciplines ($p = 0.004$, Cramer's $V = 0.239$): Engineers and philosophers were significantly less willing to participate than all other disciplines, with a share of 30% each (CompS = 57.7%, $p = 0.005$, $\phi = 0.297$; MedBio: 58.8%, $p = 0.004$; $\phi = 0.290$; PhysCh: 52.0%, $p = 0.025^*$, $\phi = 0.224$ and D = 49.1%, $p = 0.048^*$, $\phi = 0.195$).

With regard to the question of participation for longer than 1 year, the disciplines differed even more in their response behavior ($p = 0.003$, Cramer's $V = 0.243$): While on average, only 19.9% answered "yes" to this question, participants from physics or chemistry agreed with a proportion of 40.0%. This was significantly or almost significantly more frequent than for all other groups with the exception of engineers (EngBio = 22.0%, $p = 0.052$, $\phi = 0.195$; CompS: 15.4%, $p = 0.005$, $\phi = 0.276$; MedBio: 11.8%, $p = 0.001$, $\phi = 0.323$; D = 11.3%, $p < 0.001$, $\phi = 0.330$ and Phil = 20.0%, $p = 0.029^*$, $\phi = 0.218$).

With regard to language barriers, 62.4% of respondents stated that they had concerns if the project language was not English or German. Here, too, there were significant differences between the disciplines ($p < 0.001$, Cramer's $V = 0.367$): Participants from medicine and biology indicated the lowest level of concern at 39.2% and were thus significantly less likely to answer "yes" to the question than participants from any other academic discipline with the exception of engineering (EngBio = 42.0%, $p = 0.776$, $\phi = 0.028$; CompS: 63.5%, $p = 0.014^*$, $\phi = 0.243$; PhysCh: 80.0%, $p < 0.001$, $\phi = 0.415$; D = 62.3%, $p = 0.019^*$, $\phi = 0.230$ and Phil = 88.0%, $p < 0.001$, $\phi = 0.506$).

Acceptance of project management was high on average (69.9%), but again varied systematically between the disciplines ($p < 0.001$, Cramer's $V = 0.470$): Only 28.9% of the scientists from the field of computer science were willing to be led by a project leader. This was significantly lower than all other disciplines (EngBio = 80.0%, $p < 0.001$, $\phi = 0.513$; MedBio: 86.3%, $p < 0.001$, $\phi = 0.580$; PhysCh: 60.0%, $p = 0.002$, $\phi = 0.314$; D = 94.3%, $p < 0.001$, $\phi = 0.674$ and Phil = 68.0%, $p < 0.001$, $\phi = 0.392$).

When asked about the motivating factors for participation, the fun factor (75.5%) clearly exceeded the money factor (18.6%). This assessment was homogeneous across disciplines (fun: $p = 0.608$, Cramer's $V = 0.108$; money: $p = 0.152$, Cramer's $V = 0.162$, for details see Table 1 and Fig. 1).

2.4 Conclusions Study No. 1

The results of Study No. 1 revealed that the willingness of academics to participate in an open innovation platform for the development of innovative medical technology is high and that this willingness decreases if the project lasts longer than 1

Table 1 Descriptive statistics: absolute and relative frequencies

	Engineering and Bioengineering (N = 50)	Computational science (N = 52)	Medicine and Biology (N = 51)	Physics and Chemistry (N = 50)	Design (N = 53)	Philosophy (N = 50)	Gesamt (N = 306)	χ^2 -Test
Would you be interested in participating?	24 (48.00%)	47 (90.38%)	47 (92.16%)	48 (96.00%)	47 (88.68%)	47 (94.00%)	260 (84.97%)	p < 0.001
Would you invest your time and take part for a year?	15 (30.00%)	30 (57.69%)	30 (58.82%)	26 (52.00%)	26 (49.06%)	15 (30.00%)	142 (46.41%)	V = 0.462 p = 0.004
Would you invest your time and participate for more than a year?	11 (22.00%)	8 (15.38%)	6 (11.76%)	20 (40.00%)	6 (11.32%)	10 (20.00%)	61 (19.93%)	V = 0.239 p = 0.004
Would the language be an obstacle if it was not German or English?	21 (42.00%)	33 (63.46%)	20 (39.22%)	40 (80.00%)	33 (62.26%)	44 (88.00%)	191 (62.42%)	V = 0.243 p < 0.001
Could you accept a project manager?	40 (80.00%)	15 (28.85%)	44 (86.27%)	30 (60.00%)	50 (94.34%)	34 (68.00%)	213 (69.61%)	V = 0.367 p < 0.001

(continued)

Table 1 (continued)

	Engineering and Bioengineering (N = 50)	Computational science (N = 52)	Medicine and Biology (N = 51)	Physics and Chemistry (N = 50)	Design (N = 53)	Philosophy (N = 50)	Gesamt (N = 306)	χ^2 -Test
Is money a motivating factor for you in this context?	7 (14.00%)	10 (19.23%)	5 (9.80%)	11 (22.00%)	9 (16.98%)	15 (30.00%)	57 (18.63%)	$p = 0.152$
Is fun a motivating factor for you in this context?	41 (82.00%)	39 (75.00%)	36 (70.59%)	37 (74.00%)	43 (81.13%)	35 (70.00%)	231 (75.49%)	$V = 0.162$ $p = 0.608$

Note. Absolute (and relative) frequencies separately for each item and each discipline

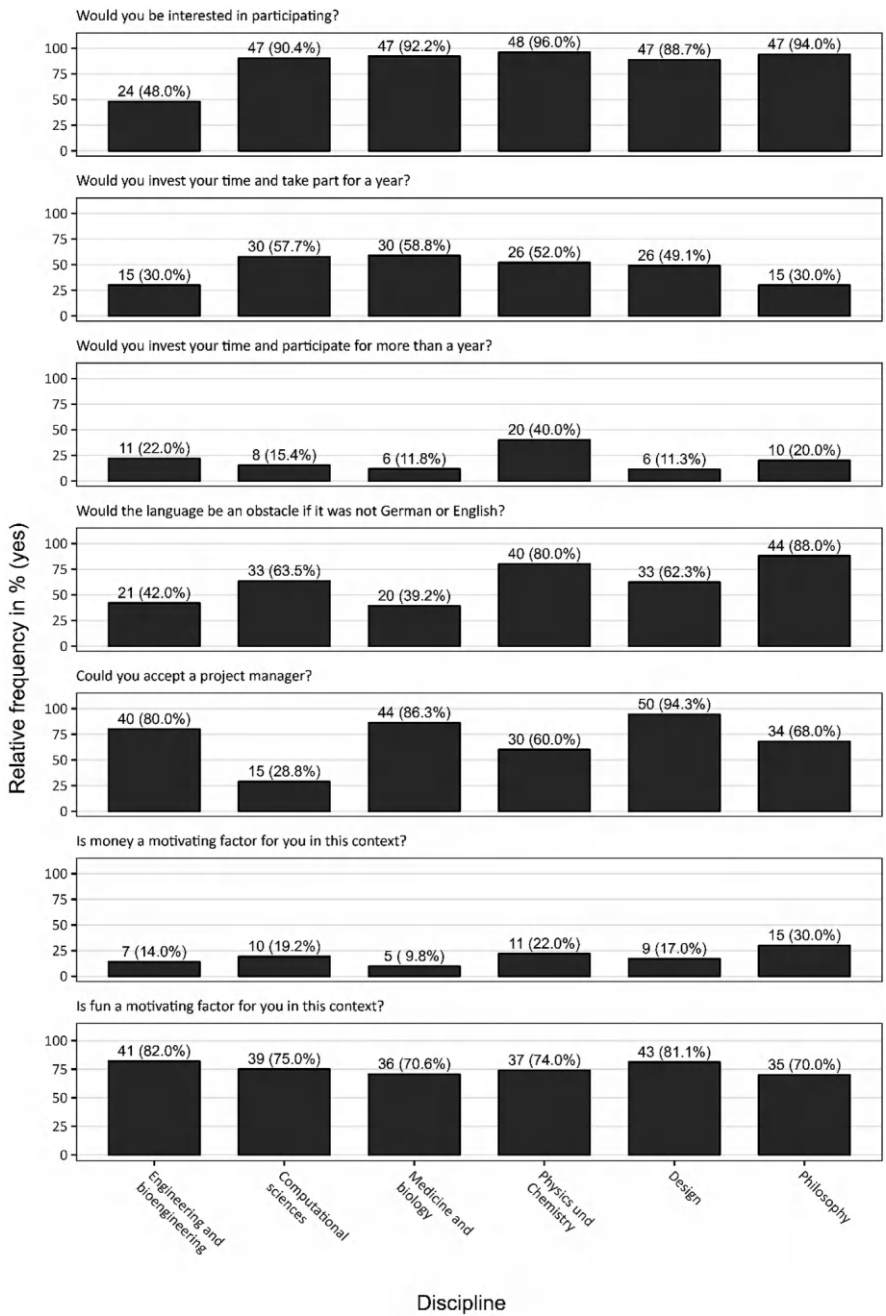


Fig. 1 Descriptive statistics: absolute and relative frequencies

year. If the project language is neither German nor English, this represents a barrier. Money is not a key factor for academics to participate, whereas fun clearly is.

This “Study No. 1” contributes to a better understanding of the relevance of factors such as the duration of a project (time), material incentives (money), and social and cultural factors (fun) on the willingness of some of the academics surveyed to participate in the open innovation process (von Hippel et al., 1999).

3 Follow-Up Study (Study No. 2)

Based on the results of Study No. 1, we were interested in the proportion of academics surveyed who showed their willingness to participate in open innovation platforms for the development of innovative medical technology ($n = 260$) and now in Study No. 2 with the research question of whether they would leave their comfort zone and choose a project outside their own qualifications and professional experience. This would mean that they should have a certain level of self-taught competence or would have to develop it first, including in the area of creativity, and should use methods such as “design thinking.”

Such a project would activate their “thinking out of the box” as well as new individual and group-based approaches to innovation management. Therefore, in Study No. 2, we only interviewed those from Study No. 1 who confirmed their willingness to participate in question 1 of the questionnaire.

3.1 Literature Research for Study No. 2

We have focused on three aspects: Design thinking, autodidactic learning skills, and creativity. The integration of design thinking in entrepreneurship education (Hölzle, 2022) and competition in digital innovation ecosystems (Hölzle et al., 2022) can help to reduce barriers in innovation processes (Mirow et al., 2007).

Students, as part of the education system, bring in their own “footprints” through their own learning styles, meaning that “Generation Z” is changing learning styles.

Developing autodidactic learning styles (self-learning) by using social networks (Turkey & Soliman, 2020) is another option. Educational equity (Matthews, 2021) and questions about the ability to choose freely are discussed, also in reference to the historical consideration of different opportunities and possibilities of access to education depending on gender, social class, and origin. Self-learning appears to be a relevant factor in innovation processes.

A dynamic definition of creativity (Walia, 2019) interacts with self-learning and the reduction of barriers in innovation processes, as numerous studies have shown.

The role of creativity in education also leads to the realization that creativity can be learned and this competence can be developed (Kaplan, 2019), and at the end of these explanations is the question of whether in the future an artificial algorithm will be able to learn and apply creativity and thus the future of creativity will also be widespread in well-programmed machines (Du Sautoy, 2019).

3.2 Methods Study No. 2

The academics' responses to the standardized questionnaire were evaluated using the statistical software IBM SPSS 28.0. The answer options in the questionnaire were "yes" and "no," and the items were therefore nominally scaled. The absolute and relative frequencies of the "yes" answers were given as N (%), both for each discipline and averaged across groups.

A logistic regression was calculated to predict the willingness to participate in a project outside of one's own qualification. Predictors were academic discipline, willingness to participate for (a) 1 year or (b) more than 1 year, language barrier as an obstacle to participation, acceptance of a project leader and money or fun as a motivating factor. Various model selection algorithms were tested, including a forced-entry stepwise-backward algorithm. The most suitable model was defined using a minimum -2LL deviance statistic in combination with a maximum explained variance (Nagelkerke's R^2). As a result, a forced-entry approach including all predictors, but without moderation effects, was determined to be the best statistical model. The odds ratio (OR) including 95% confidence interval and Wald statistic were calculated for each predictor in the model. Nagelkerke's R^2 and the omnibus test of the regression model were reported as well.

3.3 Results Study No. 2

A total of 260 participants were included in the *second study*, of which 140 (53.8%) were willing to participate in the project of an open innovation platform for healthcare and life sciences outside their comfort zone. Logistic regression revealed that only academic discipline significantly predicted willingness to participate.

Academics from the fields of medicine or biology were 4.43 times more likely to participate in a project outside their comfort zone compared to philosophers (OR = 4.43 [1.72–11.42], $p = 0.002$). Similar results were found for academics from the fields of physics and chemistry, who were 4.33 times more likely to participate compared to philosophers (4.33 [1.78–10.55], $p = 0.001$). No other subject area or predictor showed significant effects. (See Table 2 for all effects of logistic regression and descriptive statistics regarding willingness to participate for each predictor.) The regression model explained 11.9% of the variance and was significantly better than the base model ($\chi^2(5) = 24.30$, $p = 0.012$) (Fig. 2).

3.4 Conclusions from Study No. 2

Academic discipline (six categories) was the most important predictor of whether participation in an open innovation platform was likely outside of one's own qualifications and professional experience. Academics from medicine and biology,

Table 2 Results of the logistic regression

Disciplines	N (%) ready to take part	OR [95%-CI]	Wald statistic
Reference = Philosophy	17/47 (36.2%)		
Engineering and Bioengineering	8/24 (33.3%)	0.85 [0.29–2.52]	p = 0.767
Computational science	24/47 (51.1%)	1.64 [0.68–3.96]	p = 0.267
Medicine and Biology	34/47 (72.3%)	4.43 [1.72–11.42]	p = 0.002
Physics and Chemistry	34/48 (70.8%)	4.33 [1.78–10.55]	p = 0.001
Design	23/48 (48.9%)	1.73 [0.72–4.18]	p = 0.224
Take part for a year (yes)	124/260 (47.7%)	1.07 [0.63–1.82]	p = 0.806
Take part for > year (yes)	54/260 (20.8%)	0.88 [0.45–1.71]	p = 0.701
Language barrier (yes)	165/260 (63.5%)	0.86 [0.48–1.52]	p = 0.596
Acceptance project manager (yes)	177/260 (68.1%)	0.82 [0.44–1.53]	p = 0.531
Money as motivation (yes)	48/260 (18.46%)	1.10 [0.56–2.16]	p = 0.788
Fun as motivation (yes)	196/260 (75.4%)	0.91 [0.50–1.67]	p = 0.765

Note. Nagelkerke’s $R^2 = 11.9\%$, model test: $\chi^2 = 24.30$, $p = 0.012$

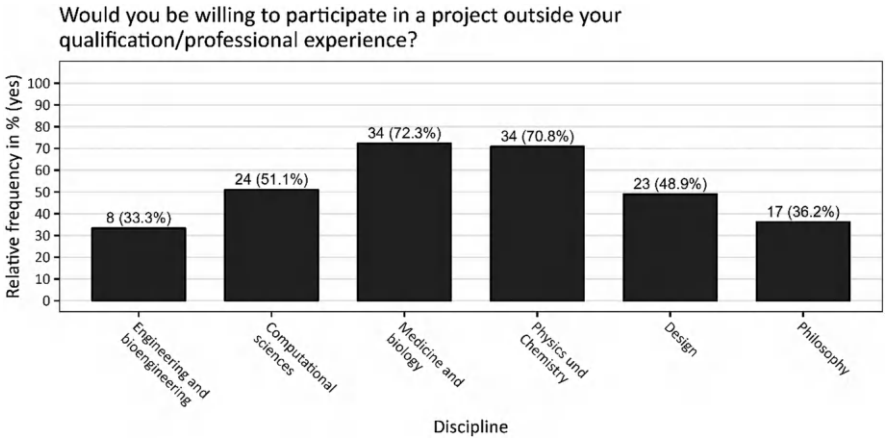


Fig. 2 Willingness to participate in a project outside their qualification/professional experience according to academic groups

as well as physics and chemistry, were significantly more likely to participate compared to philosophers.

Language barriers, duration of the projects, acceptance of a project leader or motivating factors such as money or fun did not say anything about the prediction of possible participation. Overall, the development of an open innovation platform as a sustainable future concept for innovation in the healthcare sector offers an opportunity and should be promoted in order to offer academics interested in innovation as another option for participating in innovation processes.

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Beyond the Couch: Harnessing Creativity with Smartphone Apps to Revolutionize Mental Health Care

Seda Röder

Abstract

This chapter explores the transformative potential of smartphone apps in mental health care, highlighting how they democratize access to therapy through affordability, convenience, and innovative approaches. Emphasizing the therapeutic role of creativity, it examines how apps leverage creative activities such as journaling, digital art, and AI-driven interactions to improve mental well-being, cognitive flexibility, and emotional resilience.

With examples like “Talkspace,” “Woebot,” and “Headspace,” the chapter underscores the efficacy of digital solutions in addressing mental health challenges. It also delves into the integration of wearable technology, data-driven insights, and hybrid care models, illustrating their ability to personalize and enhance user experiences.

Further, the chapter discusses the implications of digitalization for healthcare delivery, the evolution of business models, and the management skills required to navigate this innovative landscape. By merging creativity with technology, mental health apps are poised to redefine care delivery, making it more inclusive, accessible, and responsive to diverse needs worldwide.

This work positions creativity and digital innovation as pivotal forces in the future of mental health care, shaping a more holistic and equitable approach for all.

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1 Introduction

Driven largely by the advent and proliferation of smartphone technology, the landscape of mental health care is undergoing a transformative shift. Traditional paradigms, characterized by in-person therapy sessions and extended waiting times for appointments, are being disrupted by the rise of mental health apps. These digital solutions offer accessibility, affordability, and innovative ways to deliver mental health care, breaking down barriers and democratizing access to essential services.

Integral to this digital transformation is the exploration of the relationship between mental health and creativity. Creativity has long been recognized as a powerful tool for enhancing mental well-being, fostering emotional expression, and improving cognitive flexibility. Many of these smartphone apps are tapping into the therapeutic potential of creative activities. By integrating creative tasks and experiences into their platforms, they are not only introducing new therapeutic modalities but also enabling users to engage in self-exploration and personal growth. This convergence of technology and creativity marks a significant evolution in the approach to mental health care.

In this chapter, I will explore how smartphone apps are harnessing creativity to redefine mental health care, delving into the technologies that underpin these innovations, real-life examples of successful applications, and the implications for future healthcare delivery and business models. I will also examine the role of digitalization in health care, its potential to enhance patient interactions, and the new management skills required to meet the evolving needs of patients in the coming decade.

2 The Rise of Mental Health Apps

Three main reasons why mobile mental health applications are on the rise can be summarized as follows:

1. Immediate Accessibility and Convenience

Smartphone apps have made mental health care more accessible than ever before. According to a report by the American Psychological Association (APA), nearly 50% of Americans own a smartphone, most of which are equipped with Internet access and the ability to download apps. Similarly, as of 2024, approximately 75% to 80% of adults in the European Union own a smartphone, according to Counter Point Research (Counter Point, [2024](#)). This widespread smartphone ownership means that mental health support is now within easy reach for millions, helping to reduce the stigma and logistical challenges associated with seeking help.

One of the most compelling examples of this accessibility is the app “Talkspace,” which connects users with licensed therapists through text, voice, or video messages. Talkspace has transformed the traditional therapy model by allowing users to communicate with their therapists at any time, offering a level

of flexibility that conventional in-person sessions cannot match. Research has shown that this form of digital therapy can be just as effective as face-to-face sessions for treating conditions like anxiety and depression, further highlighting the potential of smartphone apps to revolutionize mental health care.

2. **Affordability**

The cost of traditional therapy can be prohibitive for many individuals, with sessions often ranging from 80 EUR to 200 EUR per session for adults. This expense can quickly add up, making it difficult for many people to afford consistent and sustained treatment. In contrast, mental health apps offer a more affordable alternative, making therapy more accessible. For instance, the app “BetterHelp” provides access to licensed therapists for a monthly fee that is typically lower than the cost of a single traditional therapy session. This fee structure allows users to communicate with their therapist via text, audio, or video at their convenience, often for less than 100 EUR per month (Hull & Mahan, 2021).

The affordability of these apps significantly lowers the barrier to entry for receiving mental health support. It democratizes access to therapy, enabling individuals from various socioeconomic backgrounds to seek help without the heavy financial burden. Moreover, by offering flexible communication methods, these apps cater to diverse needs and preferences, making it easier for individuals to find a therapeutic approach that works best for them. This increased accessibility can lead to earlier intervention and support for mental health issues, potentially preventing them from escalating into more severe conditions.

3. **Innovative Therapies**

Smartphone apps are also introducing innovative therapeutic approaches that were previously unavailable. Cognitive Behavioral Therapy (CBT), a widely recognized form of psychotherapy, has been effectively adapted into digital formats. CBT focuses on identifying and challenging negative thought patterns and behaviors, helping individuals develop healthier ways of thinking and coping. It is particularly effective for treating disorders like anxiety and depression. One notable app, “Woebot,” is an AI-driven chatbot that utilizes CBT principles to engage users in conversations aimed at reshaping their thinking patterns and promoting mental well-being. Clinical trials have demonstrated that Woebot can significantly reduce symptoms of depression and anxiety (Fitzpatrick et al., 2017).

The widespread adoption of CBT is crucial because it offers practical tools and techniques that individuals can use to manage their mental health independently. By providing these resources through accessible platforms like smartphone apps, CBT can reach a broader audience, including those who might not have access to traditional therapy due to cost, location, or stigma. The success of digital adaptations like Woebot highlights the potential of AI and technology to expand the reach of effective mental health treatments.

3 The Interplay of Mental Health and Creativity

Creativity is a vital component of human experience, playing a crucial role in mental health. In the following paragraphs, I will explore some of the areas where creative (digital) activities help individuals to improve overall mental health.

Creativity as a Therapeutic Tool

Creativity has long been recognized as a powerful therapeutic tool, as engaging in creative activities can help individuals express emotions, reduce stress, reinforce a positive self-image, and improve overall mental well-being. Below are a few application areas where mental health apps leverage these insights by integrating creative tasks into their platforms:

1. Emotional Expression and Release

Creativity allows individuals to express emotions that may be difficult to articulate through words alone. Engaging in creative activities such as painting, writing, or playing music provides a safe outlet for emotions, enabling individuals to process and release feelings in a healthy way. This can lead to emotional catharsis and relief from stress and anxiety. Studies conducted by A.O. Pennebaker and Chung found that expressive writing can help individuals make sense of their emotions and experiences, leading to improved mental health (Pennebaker & Chung, 2007). “Jour,” for example, is a journaling app that encourages users to write about their thoughts and feelings, helping them process emotions and gain insights into their mental well-being. Another example is “Calm,” an app that offers guided meditation and relaxation exercises, along with a feature called “Sleep Stories,” where users can listen to bedtime stories narrated by well-known voices. These stories are designed to spark the imagination and provide a creative escape, helping users relax and improve their sleep quality.

2. Stress Reduction

Creative activities can serve as a form of mindfulness, helping individuals focus on the present moment and reduce stress. Activities such as drawing, coloring, or crafting require concentration and can induce a state of flow, where individuals become fully immersed in the task at hand. This immersion can distract from stressors and promote relaxation. Research by Kaimal, Ray, and Muniz demonstrated that art-making can lead to significant reductions in cortisol levels, a biomarker of stress (Kaimal et al., 2016).

For instance, the app “Colorfy” allows users to engage in digital coloring, which according to users can be a meditative and stress-relieving activity. Similarly, “Flow,” an app designed for people with ADHD, incorporates creative tasks like drawing and music creation to help users focus and manage their symptoms.

3. Cognitive Flexibility and Problem-Solving

Engaging in creative activities enhances cognitive flexibility, the ability to think outside the box and adapt to new situations. This cognitive flexibility is cru-

cial for problem-solving and emotional regulation, both of which are important for mental health. Apps like “Lumosity” and “Peak” offer brain-training exercises that enhance cognitive flexibility through creative and challenging tasks.

Creative problem-solving tasks stimulate new ways of thinking and can help individuals develop resilience in the face of challenges.

Research published in the journal *Frontiers in Psychology* has shown that engaging in creative activities can improve cognitive flexibility and reduce symptoms of depression and anxiety (Tang et al., 2021). By incorporating creative tasks into their platforms, mental health apps are helping users develop these important cognitive skills.

4. Building Self-Esteem and Self-Efficacy

Creating something gives individuals a sense of accomplishment and pride, boosting self-esteem and self-efficacy. This is particularly important for individuals struggling with mental health issues, as these conditions often undermine self-worth. Engaging in creative projects allows individuals to set goals, work toward them, and see tangible results, which then reinforces a positive self-image.

5. Enhancing Social Connections

Many creative activities incorporate social aspects, providing opportunities for individuals to connect with others. Group activities like collaborative art projects, music groups, or writing workshops can build a sense of community and support. Social connections are a critical component of mental well-being, and creative activities can foster these bonds.

4 Examples of Successful Mental Health Apps

The market for mental health apps has seen significant growth in recent years, driven by increasing awareness of mental health issues and the widespread availability of smartphones. These apps offer a range of services, from mindfulness and meditation to therapy and crisis management, catering to a broad spectrum of mental health needs. The COVID-19 pandemic has accelerated the adoption of digital health solutions, including mental health apps, as people seek accessible and convenient ways to manage their well-being.

In Europe, the market is particularly vibrant, with a diverse array of apps available in multiple languages and tailored to different cultural contexts. European consumers have embraced digital health tools, partly due to the region’s strong regulatory framework that ensures data privacy and security. The European Union’s General Data Protection Regulation (GDPR) has set a high standard for app developers, promoting trust among users.

Below is a discussion of some of the most successful mental health apps from the United States and EU markets.

Headspace and Mindfulness

“Headspace” is a widely popular app that focuses on mindfulness and meditation. Founded in 2010 by Andy Puddicombe, a former Buddhist monk, Headspace has

grown to serve millions of users worldwide. The app offers guided meditation sessions, mindfulness exercises, and sleep aids. Research published in the journal *Current Psychology* has shown that using Headspace can reduce stress, improve focus, and enhance overall well-being (Lahtinen et al., 2023).

PTSD Coach and Veteran Support

Developed by the U.S. Department of Veterans Affairs, “PTSD Coach” is an app designed to help veterans manage symptoms of Post-Traumatic Stress Disorder (PTSD). The app provides users with education about PTSD, self-assessment tools, and resources for finding professional support. Studies have shown that the app is a valuable supplementary tool for veterans undergoing PTSD treatment. For instance, a study involving 45 veterans in residential treatment for PTSD reported high user satisfaction, with nearly 90% of participants finding the app moderately to extremely helpful (U.S. Department of Veterans Affairs, 2014). The features of the app, such as symptom management tools, were particularly appreciated for their accessibility and practicality in real-life situations. Furthermore, it has been shown that PTSD Coach can be an effective supplementary tool for veterans undergoing treatment for PTSD, helping to reduce symptoms and improve coping mechanisms (Miner et al., 2016).

Moodpath and Depression Screening

“Moodpath” is an app that offers users a way to track their mood and detect signs of depression. By asking users daily questions about their emotional state and physical well-being, Moodpath creates a detailed report that can be shared with healthcare providers. This app has been particularly useful in helping individuals identify patterns in their mood and seek professional help when needed. A study published in “JMIR mHealth and uHealth” found that Moodpath’s screening tool is effective in identifying symptoms of depression and encouraging users to seek further evaluation (Wachtler et al., 2018).

Meditopia and Multilingual Mindfulness

Meditopia, headquartered in Berlin and Istanbul, provides mindfulness and meditation content in 12 languages, making it one of the most inclusive apps for non-English speakers. The app offers meditation programs and quick sessions designed to reduce stress and improve sleep. Meditopia also extends its services to the workplace, offering tailored mental health solutions. Although the scholarly research is not yet to be found on the effects of the app, users report very positive experience (Calisir, 2024).

Unmind and Workplace Well-Being

Unmind, founded in the UK, focuses on enhancing mental well-being in the workplace. The platform offers a range of resources, including a mood diary, stress and sleep exercises, and educational content. It aims to support employees’ mental health by providing clinically backed tools and resources. Unmind’s services have been adopted by various organizations, helping to promote a positive mental health culture at work (Sierk et al., 2022).

5 The Role of Digitalization in Mental Health Care

The advent of digital technologies has revolutionized the landscape of mental health care, making services more accessible, efficient, and personalized. Digitalization enables a shift from traditional, in-person consultations to a more flexible and comprehensive approach. This transformation is evident in various aspects, including patient interactions, continuous monitoring, and data-driven insights. Through telemedicine platforms and mental health apps, individuals can now receive support and treatment tailored to their specific needs, regardless of their location. This shift not only broadens access to mental health services but also enhances the quality and effectiveness of care, offering a more holistic approach to mental well-being.

Enhancing Patient Interactions

Digitalization in health care is enhancing the way patients interact with mental health services. Telemedicine platforms, such as “Teladoc” and “Amwell,” enable patients to have virtual consultations with mental health professionals from the comfort of their homes. This not only makes mental health care more accessible but also reduces the time and cost associated with travel.

Furthermore, digital platforms allow for continuous monitoring and support. Apps like “Pacifica” provide users with tools to manage stress and anxiety on a daily basis, offering exercises and tracking progress over time. This continuous engagement can lead to better outcomes compared to traditional models where support is often limited to scheduled appointments.

Data-Driven Insights

The integration of data analytics into mental health apps is providing valuable insights into patient behavior and treatment efficacy. Apps such as “Ginger” use data analytics to monitor user engagement and outcomes, allowing for personalized care plans that adapt to the individual’s needs. This data-driven approach can help identify which interventions are most effective, leading to more targeted and efficient treatments.

6 Future Implications for Healthcare Delivery and Business Models

As the digital transformation of mental health care continues, the future is likely to see the emergence of hybrid models that seamlessly blend digital and in-person services. This integration promises to enhance accessibility and convenience while retaining the personal touch essential in therapeutic relationships. The potential expansion of wearable technology into mental health monitoring further enriches this landscape, offering real-time data that can inform more personalized care strategies. Alongside these technological advancements, innovative business models are also evolving. From subscription-based services to employer-sponsored wellness programs, new revenue streams are emerging, reflecting the growing recognition

of mental health's critical role in overall well-being and productivity. These developments indicate a shift toward a more holistic, integrated, and accessible approach to mental healthcare delivery.

Hybrid Models of Care

The future of mental health care is likely to involve hybrid models that combine digital and in-person services. These models can offer the best of both worlds, providing the flexibility and accessibility of digital solutions while maintaining the personal connection of face-to-face interactions. For example, a patient might use an app like "Talkspace" for regular check-ins and self-management, supplemented by occasional in-person sessions with a therapist.

Integration with Wearable Technology

Wearable technology, such as smartwatches and fitness trackers, is poised to play a significant role in the future of mental health care. Apps like "Apple Health" and "Fitbit" already track physical activity and sleep patterns, which are closely linked to mental health. Integrating these data streams with mental health apps can provide a more holistic view of a user's well-being and enable more personalized interventions.

Business Models and Revenue Streams

The rise of mental health apps is also driving innovation in healthcare business models. Subscription-based services, freemium models, and partnerships with healthcare providers and employers are all emerging as viable revenue streams. For instance, many companies are now offering mental health app subscriptions as part of their employee wellness programs, recognizing the benefits of mental well-being on overall productivity and job satisfaction.

7 Management Skills for the Future

As the healthcare industry increasingly integrates digital solutions, the skill set required for effective management is evolving. Healthcare providers and managers must now cultivate digital literacy, enabling them to navigate and utilize advanced technological tools and data analytics. This digital fluency will be crucial in harnessing the full potential of emerging technologies and ensuring they are implemented effectively. Alongside this, a strong emphasis on patient-centered care is necessary to tailor digital interventions to individual needs, enhancing the therapeutic relationship. Additionally, as digital health tools proliferate, there is a growing need for a keen awareness of ethical and privacy considerations. Protecting patient data and maintaining transparency are paramount to building trust and ensuring the responsible use of technology in health care. These evolving demands underscore the need for continuous education and training in the digital and ethical aspects of healthcare management.

Digital Literacy

As digital health solutions become more prevalent, healthcare providers and managers will need to develop digital literacy skills. This includes understanding how to use and integrate various digital tools, interpreting data analytics, and staying informed about the latest technological advancements. Training programs and continuous education will be essential to ensure that healthcare professionals can effectively leverage these tools.

Patient-Centered Care

The shift toward digital mental health care also necessitates a renewed focus on patient-centered care. This involves understanding the unique needs and preferences of each patient and using digital tools to enhance the therapeutic relationship. Empathy, communication, and adaptability will be crucial skills for healthcare providers in this new landscape.

Ethical and Privacy Considerations

With the increased use of digital health solutions comes the responsibility to address ethical and privacy concerns. Healthcare providers must ensure that patient data is protected and that digital interventions are used ethically. This includes obtaining informed consent, being transparent about how data is used, and ensuring that digital tools meet rigorous standards for safety and efficacy.

8 Conclusion

The advent of smartphone apps is revolutionizing mental health care, offering unprecedented accessibility, affordability, and innovative therapeutic approaches. As we move forward, the integration of digital solutions into traditional healthcare models will continue to evolve, driven by data-driven insights and patient-centered care.

The exploration of creativity within the context of smartphone apps and mental health has revealed significant benefits that these digital tools can provide. Creativity is not only a means of self-expression and emotional release but also a powerful catalyst for enhancing cognitive flexibility, reducing stress, and building self-esteem. These elements are crucial for maintaining mental well-being and addressing various psychological challenges.

Through apps like Headspace, which integrates creative visualization techniques, and Woebot, which uses conversational AI to promote cognitive behavioral strategies, users are given innovative and accessible ways to engage with therapeutic content. Similarly, Colorfy and Flow harness creative activities such as digital coloring and music creation, providing users with meditative experiences that alleviate stress and foster mindfulness.

The convergence of creativity and technology in mental health apps also supports the development of personalized care plans. By leveraging data analytics and user feedback, these platforms can tailor their offerings to meet the unique needs of

each individual. This personalized approach not only enhances the efficacy of the interventions but also empowers users by providing them with tools to actively manage their mental health.

As we look to the future, the role of creativity in digital mental health solutions will likely expand, driven by continuous technological advancements and deeper understandings of psychological well-being. The integration of wearable technologies and more sophisticated AI could further personalize and enhance the therapeutic experience, making mental health support more accessible and effective for a broader audience.

In conclusion, the interplay between creativity and mental health, facilitated by smartphone apps, marks a significant evolution in how we approach mental wellness. These innovations offer a promising avenue for providing holistic, accessible, and effective mental health care, ultimately improving the quality of life for many individuals around the world. By embracing these creative and technological advancements, we can redefine the landscape of mental health care, making it more inclusive and responsive to the diverse needs of all users.

The future of mental health care lies beyond the couch, in the palm of our hands, powered by technology that makes support accessible to all. By embracing these innovations, we can transform mental healthcare delivery, improving outcomes and enhancing the well-being of individuals worldwide.

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Interoperability in Hospitals: Improving Work Processes in Care and Treatment with Fast Healthcare Interoperability Resources and Clinical Data Repository

Carsten Schmid

Abstract

Although there is constant technological progress in the healthcare sector, a holistic view of the entire “patient journey” is still not possible in Germany.

This can certainly be explained, on the one hand, by the fact that many different service providers, both from the outpatient and inpatient sectors, are involved in the treatment of a patient and that each of these service providers collects and documents data and information in their systems and applications. However, even a single service provider such as a hospital often lacks an overall view of the data relating to a patient and their use case.

This can certainly limit the quality of medical treatment and nursing care, but may also have an impact on patient safety.

For this reason, it is important to focus more on the topic of interoperability and how this can continuously improve healthcare on the basis of new standards such as Health Level Seven International Fast Healthcare Interoperability Resources (HL7 FHIR) and the use of interoperability platforms (IOPs).

This chapter provides a general overview of current possibilities and the current state of development as well as ideas and thoughts on the general necessity and development of an interoperability platform as the basis for cross-departmental and cross-system data exchange and data sharing within a hospital.

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1 Introduction

What is a desirable vision for sustainably improving healthcare in Germany? When all stakeholders and participants in the healthcare process, i.e. doctors, therapists, carers and patients themselves, have access to all important and necessary healthcare data.

And if this data-based information could be shared with other stakeholders in the healthcare system quickly, flexibly, digitally and without hurdles and interface problems, regardless of the place of care.

However, the German healthcare system is still heavily characterised by manual work steps, analogue work media or outdated technical infrastructure, if one considers the still very extensive use of fax machines or paper scans.

The starting point for this situation is the inability of the various systems in use to exchange data with each other (Deutsches Ärzteblatt, 2022).

Historically, the various service providers, such as general practitioners or specialists in the outpatient sector, use practice management systems (PVS), while hospitals use hospital information systems (EHR—Electronic Health Record system) in the inpatient sector.

Communication between these systems, i.e. the exchange of data, has so far been inadequate (Lorenz, 2023).

However, even within a sector such as a hospital, it is often difficult to transfer information and data automatically and electronically between individual specialities and departments. For example, the patient data management systems (PDMS) frequently used in intensive care units (ICUs) do not communicate adequately with the EHR—hospital information systems used on the peripheral wards. Patient-relevant data, such as vital signs or medication data, must therefore often be transferred manually when a patient is transferred within the hospital and then re-entered in the relevant system. On the one hand, this costs working time, but may also represent an additional source of error and can therefore have a negative impact on patient safety and quality of care (Illustration 1).

However, the reasons and, above all, the need for improved interoperability in the German healthcare system, and in the inpatient sector in particular, can first be found in an examination of the most important challenges currently facing German hospitals:

1. Shortage of skilled staff:

A shortage of qualified staff is a major challenge and is increasingly affecting the quality of care. Digital work processes and the avoidance of unnecessary work steps can support staff and optimise the use of scarce resources.

Digitalisation can therefore contribute in various ways to compensating for the shortage of skilled staff in hospitals, at least to some extent. On the one hand, digital solutions such as telemedicine, remote monitoring, automated vital data transfer and analysis tools for prevention and prediction (e.g. delirium prevention,

Situation – Complication – Solution: „Lost in Space“

„Legacy hospital IT world“

- EHR – Hospital Information System
- PDMS – Intensive Care Unit (ICU)
- LIS – Laboratory
- Document – Archive
- Pacs – Picture Archive
- etc.

Example.: Complication

No “intersectoral” data flow between the PDMS of the intensive care unit and the EHR on peripheral wards.

A lot of manual documentation and duplicate entries.

The flow of data between the Emergency unit and peripheral wards is similar.



„New Digital Health World“

- KI / Artificial Intelligence
- 3rd party best-of-breed solutions for
 - a) Diagnostic
 - b) Care by different professional groups / service providers (medicine, nursing, therapy)

Illustration 1 No continuous data flow within IT systems in the hospital

fall detection, sepsis prediction, pressure ulcer prevention, etc.) can help to increase the efficiency of existing staff and improve patient care.

In addition, digital tools such as AI-supported diagnostic systems or robotics in surgery can also help to automate certain tasks and workflows and relieve the burden on medical staff.

Another area in which digitalisation can ultimately also help is improving the training and further education of specialists. This applies in particular to the recruitment and qualification of foreign specialists and their integration into day-to-day operations.

2. Digitalisation:

Digitalisation in the healthcare sector has not yet been implemented across the board and there are still problems with data exchange between different IT systems. The problem here lies, among other things, in the organisation and structure of the IT infrastructure within a hospital. There are systems from manufacturers that have data and systems from manufacturers that need data.

Primary system manufacturers in particular, such as the providers of HIS—hospital information systems, which offer a monolithic solution “everything from a single source”, are usually reluctant to embrace interoperability, which can have a negative impact on the digitalisation of workflows and work processes.

Subsystem manufacturers, on the other hand, are dependent on interoperability and see the new FHIR standard as a welcome solution that fits in with modern architectures.

3. Financing:

Hospitals are under pressure to work economically and at the same time ensure a high quality of care.

Existing work processes in patient treatment and care, as well as downstream work processes, e.g. in documentation through to the writing of doctor's letters, which in the past were largely implemented in a very analogue and manual manner, offer great potential for saving working time through supporting digital work tools and interoperable solutions. The primary aim here is not to save labour costs, but to work as efficiently as possible with the increasingly scarce labour resources in both the medical and nursing sectors.

4. Demographic change:

The increasing number of older patients with complex medical needs presents hospitals and the healthcare system in general with new challenges. Demographic change is not only leading to an increase in patient numbers, but is also causing an increasing shortage of medical and nursing treatment and care resources. In many industrialised nations, including Germany, an increasing number of doctors and nurses will be retiring in the coming years and will only be able to be replaced by younger employees to a limited extent.

To solve these challenges, the following topics are particularly important:

1. Human Resource Management:

The predicted shortage of staff in hospitals will mean that they will have to invest more in measures to attract new and retain existing qualified staff.

In addition to attractive remuneration models and opportunities for further training, this also includes better working conditions, which also include the technical equipment of workstations. For example, there is a difference between nursing and treatment documentation being done manually in a patient file made of paper with a pencil and pen, or semi-automated with a tablet directly at the patient's bedside/point of care. The technical equipment of a workplace can certainly be used as a positive argument in personnel marketing.

2. Digitalisation:

Many work processes and workflows in everyday clinical practice, particularly in the field of nursing care, are still very analogue in nature. Many work steps, including in documentation (from anamnesis and assessment to the derivation and presentation of care risks and the creation of care plans) are still carried out manually and therefore cost valuable time.

Investments in the digitalisation of the healthcare system, standardisation of interfaces and the promotion of interoperable IT systems to improve data exchange offer the opportunity to redesign and optimise work processes and organisational procedures on the ward and therefore also to shorten process times.

3. Quality Management:

The implementation of quality standards and controls offers the opportunity to ensure a high quality of care and guarantee patient safety. Especially when it comes to redesigning work processes and workflows in the context of digitalisation, a functioning quality management system not only helps to further optimise and model processes, but also to reduce, detect and avoid errors during

the changeover and new implementation. This continuously improves the overall quality of medical care and increases patient satisfaction in the long term.

4. Prevention and Health Promotion:

The demographic change already mentioned is leading to increasing patient numbers and a simultaneous shortage of medical and nursing staff resources, resulting in challenges and burdens in the German healthcare system, both in inpatient and outpatient care. In order to prevent or reduce these in good time, it makes sense to invest in measures to prevent illness and promote a healthy lifestyle.

5. Structural Reforms:

If it is relatively clear that there will be fewer General Practitioner (GPs), specialists and nursing staff available for inpatient and outpatient care in the future, a general review and adjustment of care structures should be considered and a reorganisation of financing models can also help to ensure and improve the efficiency and quality of care.

Targeted measures in these areas and topics will enable German hospitals to respond and adapt better to current challenges.

2 Interoperability as a Solution Approach

A key approach to meeting the challenges of the future in the healthcare sector is the consistent implementation of end-to-end interoperability.

Interoperability in healthcare refers to the ability of different systems and applications to communicate with each other and exchange data to ensure seamless and efficient patient care. The international standard FHIR (Fast Healthcare Interoperability Resources) plays an important role in promoting healthcare interoperability by providing a standardised method for the exchange of healthcare data. By using FHIR, healthcare organisations, providers and technology companies can work better together and improve the quality of patient care.

Interoperability is important in patient care today as it enables seamless communication and exchange of healthcare data between different systems and providers. As a result, patients can be treated faster and more efficiently as relevant information is easily accessible and duplication of examinations can be avoided. In addition, interoperability helps to improve the quality of care, increase patient safety and ultimately optimise health outcomes.

But what exactly is behind the FHIR standard mentioned above?

FHIR stands for “Fast Healthcare Interoperability Resources” and is an international standard for the exchange of healthcare data. FHIR was developed by Health Level Seven International (HL7) and is based on modern web technologies such as RESTful APIs.

In Germany, FHIR is already playing an important role in promoting interoperability in the healthcare sector. Many hospitals, doctors’ surgeries and other

healthcare facilities use FHIR to facilitate data exchange between different IT systems and improve networking in the healthcare sector.

The importance of FHIR in Germany is expected to increase further in the coming years. The standard is likely to be increasingly integrated into new projects for the digitalisation of the healthcare system in order to ensure better interoperability between different systems and stakeholders.

In addition, further developments in the area of FHIR could also be expected, such as the introduction of new versions of the standard or the integration of additional functionalities to meet the requirements of the constantly changing healthcare system. Overall, FHIR will therefore continue to play an important role in promoting interoperability in the German healthcare system in the future.

The FHIR IT standard is not a one-sided German issue, as FHIR will become the interoperability standard for health data throughout the EU. The future European health data space will speak a common language and that language is FHIR.

FHIR is therefore a data standard that enables the exchange of data, especially health data, not only between different applications within a hospital, but also between different organisations within a region and even across national borders.

One of the objectives behind the development was the need to be able to communicate in a standardised way across institution boundaries in future, to make data available online and to be able to use mobile devices such as tablets and smartphones.

The letter F stands for FAST, as the data standard is quick to implement. This is because it works with resources that are transferred using common Internet languages and Internet protocols such as HTTP/HTTPS or XML.

FHIR has existed as a data standard since 2014 and was first published as Draft Standard for Trial Use (DSTU) as Release 1 (v0.0.82) in February 2014.

FHIR was developed as a data standard by the international standardisation committee Health Level Seven (HL7), which develops standards, data formats and protocols. Health Level Seven was also responsible for the development of the HL7 V2 standard and drew on decades of experience with this standard when developing FHIR.

The fact that Europe is now also following this standard is obvious, as cooperation and data exchange between the member states is now also to be promoted and not just within a hospital or intersectorally within a health region of a single country.

This results in new possibilities and application examples in the joint, cross-border utilisation of health data in research, but also in the transferability of data in cross-border healthcare (Deutsches Ärzteblatt, [2023](#)).

Interoperability will therefore play an increasingly important role due to a general paradigm shift in the healthcare sector. The use of common standards such as FHIR helps with implementation, but is not the primary conceptual driver.

While in the past the main task of the healthcare system was to treat and care for sick people, we are now seeing an expansion towards health prevention and a general sensitisation to the topic of maintaining health.

This is not only due to a rethink within the system, but also to a change in attitude and a greater awareness on the part of service recipients, who are now able to

implement aspects of prevention, diagnosis and therapy on their own responsibility or in a supportive manner, partly due to technological developments.

This is clear from the growing market and the increasing number of users of wearables such as Apple Watch, Garmin or Fitbit, which provide vital signs and the first basics of health information such as heart rate, SpO2 value and stress level based on heart rate variability or sleep behaviour and sleep quality. All this data provides the user with initial awareness and supports or motivates them to look after their own health.

However, digital health applications/apps, whether free of charge or for a fee from the Apple Store or Google Play Store or as a digital health application on prescription (DIGA), as has been possible in Germany for several years, also support the user either preventively in their own health care or, as a digital application, are a general component of therapy in the event of illness.

This development naturally also leads to the continuous collection of data and information, initially within the respective application used by the consumer.

However, it is precisely this data, especially information from applications that are collected as part of a therapy prescribed and permanently monitored by a doctor, that should also be made available to downstream systems and solutions. This is becoming increasingly important for telemedicine and telemonitoring of chronically ill patients in outpatient care.

Cloud-based concepts for flexible data storage, interoperability platforms and applications that can easily share and exchange data in a structured manner based on standards such as FHIR will therefore become the foundation of the healthcare system and healthcare provision of the future.

Of course, data protection must be strictly observed here, as sensitive personalised health data is involved, but the advantages for patient-centred treatment and cross-sector care definitely outweigh the disadvantages.

Other countries such as Finland, Sweden and Denmark, where care within healthcare regions has long been implemented intersectorally via interoperable interfaces and where digitalisation in the healthcare sector is therefore significantly more advanced than in Germany at present, can be used as a model for this general development.

3 The Need for More Interoperability in Hospitals

In Germany, the term “interoperability” is regulated as follows in Section 384 of the German Social Code (SGB V):

“For the purpose of this book, the term interoperability refers to the capability of two or more information technology systems,

- (a) exchange information and use it for the correct execution of a specific function without changing the content of the data,
- (b) to communicate with each other,
- (c) to work together as intended”

It is therefore relatively clearly defined that it is primarily about data exchange and communication between different devices and systems.

Interoperability in Germany, and particularly in hospitals, has taken a major step forward since 2019. This is due to the fact that gematik, among others, has been restructured organisationally and, above all, strategically by the federal government and the Federal Ministry of Health (BGM) in order to drive forward the topic of digitalisation in the healthcare sector.

gematik (officially Gematik GmbH) was originally founded in January 2005 by the leading organisations of the German healthcare system in order to promote and coordinate the introduction, maintenance and further development of the electronic infrastructure and the infrastructure required for this in Germany in accordance with the legal mandate and to ensure the interoperability of the components involved.

The expansion of the telematics infrastructure, as well as legislative projects such as the Hospital Future Act (KHZG—Krankenhauszukunftsgesetz) from the end of 2020, were the next steps taken in the recent past to promote interoperability, i.e. the exchange of data between different solutions and systems used in patient care, in addition to the general promotion of digitalisation.

Just how important the issue of interfaces is to the legislator can also be seen from the fact that the KHZG—Hospital Future Act and the funding guidelines state that planned digitalisation projects are only eligible for funding if existing technical, syntactic and semantic standards for the interoperability of digital services are used. However, this initially only applies to projects within the Hospital Future Act.

In addition, the implementation of some of the funding elements from the KHZG has been subject to a kind of penalty if the hospitals refuse to realise these topics within a certain time frame.

In addition to this, since 30 June 2021, there has been an additional requirement (Section 373 (5) SGB V) to only use “Information technology systems in hospitals—IsiK” confirmed by gematik, which are based on interoperability requirements.

This is therefore a clear requirement that the essential, central systems within a hospital, such as the HIS—Hospital Information System or a KAS—Clinical Workplace System, must fulfil the standards required by gematik and be able to exchange data within a hospital and also across sectors with other systems on the basis of HL7 FHIR.

With IsiK, gematik is therefore going much further and setting more far-reaching specifications for interface standards.

ISiK is therefore based on the FHIR standard and has defined mandatory interface standards for all hospital information systems used in Germany since August 2023.

ISiK Level I involves the standardised exchange of patient information such as name, date of birth, insurance information and medical diagnoses. Since July 2024, Level I has been expanded to include additional interface modules for the exchange of documents, medication information, vital parameters, body measurements and special care-related information (ISiP).

With these binding standards, more and more software manufacturers can develop their solutions without the uncertainty of whether they can be integrated into existing hospital IT infrastructures in the future.

In future, hospital users will also be able to switch to a best-of-breed approach without being overly dependent on the manufacturers of the existing hospital information system and implement the IT solution that appears most suitable for specific use cases in a complementary and interoperable manner (Redmann and Babl, 2023).

This is also logical when you consider the large number of solutions in use in a hospital that use and manage data as well as medical devices that continuously collect and record data and measured values on the one hand, and the workplace organisation and work processes of medical, nursing and therapeutic staff on the other. In their day-to-day work, they are repeatedly confronted with multiple or duplicate recording of data, which costs valuable working time.

Here are two examples to illustrate the problem and situation once again:

Example 1

A patient arrives at the central emergency department (ZNA) of a hospital. There, the patient's personal details are recorded and a medical history is taken with corresponding documentation in a system used in the emergency department. In addition, various vital data is collected and documented, initial laboratory data is collected and possibly further examinations such as ECG or ultrasound are carried out and initial medication may also be administered. All further information, data and examination results collected here, as well as the medication given, are also documented in the work tool used in the emergency room.

If it is now decided that the patient initially treated as an outpatient in the central emergency department is not to be discharged home again, but is to be admitted to hospital as an inpatient, initial data and information are now available in one system, but a different system is usually in use on the peripheral ward of the hospital to which the patient is now being transferred, e.g. a HIS—hospital information system.

Very often, the two different systems described here are not interoperably networked and are not able to automatically exchange data with each other. This means that existing medical history data, vital signs data and medication data must be transferred from the first system to the system used on the ward, which is often a manual and therefore time-consuming process that ties up resources.

Example 2

A patient is being treated on a peripheral ward of a hospital. The patient file in the hospital information system (HIS) is used to document the examination results, the patient's condition from a nursing and medical perspective, as well as their vital signs and medication instructions.

If the patient now has to be transferred to the hospital's intensive care unit due to a critical change in condition, the doctors and nurses there do not use the hospital information system for treatment documentation, but a system specifically tailored

to the requirements of the department, a so-called patient data management system (PDMS).

In many hospitals, there is still no automatic exchange of data from the HIS to a PDMS, which means that existing treatment-relevant data must first be entered manually into the new system, the PDMS. This in turn is a complex and time-consuming work process for the staff in the intensive care unit.

Since the patient's care in the intensive care unit is now documented in the PDMS, including the documentation of medication orders, the problematic situation arises once again when the patient is transferred back from the intensive care unit to the peripheral ward due to an improvement in condition.

Data that is relevant for the further treatment and care of the patient is then in the PDMS of the intensive care unit and must be transferred to the HIS system, which is now used by the doctors and nurses on the peripheral ward.

Since, as described above, there is often no automatic and interoperable data exchange between these two systems (HIS and PDMS) in many hospitals, treatment-relevant data must be manually re-entered from one system to the other.

Both examples, which reflect the situation in many German hospitals, illustrate once again the positive effects that implemented interoperability can have on a hospital's day-to-day work.

For this reason, interoperability in the healthcare sector, and particularly in hospitals, has been increasingly promoted in recent years, with a focus on the exchange of data between the systems used in hospitals.

In this context, it is also worth mentioning that up to 75% of the medical devices in an intensive care unit around an intensive care bed that could be integrated into hospital information systems are currently not networked (Drägerwerk and Co. KGaA). This situation also automatically leads to incomplete records and documentation and results in a considerable amount of additional manual work to avoid documentation gaps. This in turn results in an avoidable additional stress burden for medical and nursing staff, who in surveys often cite existing and increasing administrative tasks as the cause of work-related stress.

The interoperability of medical devices can therefore also help to not only improve patient safety by reducing medical errors, but also increase efficiency in clinical and, above all, administrative processes, including the automation of process steps.

This means that it is not just about the systems already mentioned, such as a hospital information system or a patient data management system (PDMS), but the system landscape can be very diverse. In addition to the laboratory information system (LIS), Picture Archiving and Communication System (PACS) for archiving images, Radiologie Informations System (RIS) X-ray information system or an audit-proof archive for documents, an average German hospital may well have over 100 different systems and applications in use, although this is not a German phenomenon, as this variety of applications and systems can also be found in other European countries.

What is the more sensible approach for a hospital, also against the background of the examples described above?

To rely on a monolithic hospital information system or to combine various systems from different manufacturers as part of a so-called best-of-breed approach? What are the advantages and disadvantages of each approach?

There is no clear answer as to which approach makes more sense for a hospital, as this depends on various factors.

A monolithic hospital information system offers the advantage of an integrated solution in which all functions and data are combined in one system. This can improve efficiency and ease of use as all information is available in one place. On the other hand, a best-of-breed approach can allow the hospital to choose specialised systems from different vendors that are tailored to individual needs. This can lead to better functionality and performance as each system is optimised for a specific purpose. However, integration and interoperability between the different systems can be a challenge (Wehrs, 2023).

Ultimately, the decision depends on what the hospital's priorities are and what resources are available. A thorough comparison of the advantages and disadvantages of both approaches and a precise analysis of your own requirements can help you make the right decision.

In the coming years, the following developments can be expected with regard to interoperability in hospitals in Germany:

1. Standardisation of interfaces:

It is expected that there will be an increased effort to standardise interfaces between different IT systems in the healthcare sector in order to enable a smooth exchange of data.

In this context, however, it should be noted that although the FHIR standard enables new and effective ways to achieve greater interoperability, hospitals must bear in mind which other levels and standards are affected here.

A study by Deloitte entitled “Into the future with interoperability—standardised data is changing healthcare” provides a good overview, in which the medical content and requirements are also clearly presented (Chelimalla, 2024). (Illustration 2).

2. Introduction of electronic patient files:

The introduction of electronic patient records will be further promoted in order to enable better networking and exchange of patient data between different facilities.

3. Use of Health Information Exchanges (HIE):

Health Information Exchanges are expected to play a greater role in facilitating the secure exchange of health data between different stakeholders in the healthcare system.

4. Promotion of telemedicine:

Telemedicine will be further expanded to ensure better care in rural areas and improve access to medical care.

Level	Goal	Examples of standards
Technical / structural level	Development of an IT infrastructure required for the structured storage of data and the exchange of information	TCP/IP, HTTPs, RESTful API SOAP, o.Auth
Syntactic level	Development of interfaces, data structures and specifications for the structuring of messages for the transmission of data	HL7 HL7 v.2 HL7 v.3 HL7 FHIR IHE ITI DICOM, xDT, CDA
Semantic level	Develop a common understanding of data to ensure that the sender and receiver interpret the data identically	ICD LOINC, SNOMED CT OPS-301, IDMP, TNM ORPHA/Alpha-ID, OMOP CDM

Illustration 2 Levels of interoperability (Source: “Into the future with interoperability”, Deloitte, November 2021)

5. Data protection and data security:

In view of the increasing importance of data exchange in the healthcare sector, data protection and data security will also play an increasingly important role in protecting patients’ sensitive health data.

Overall, it can be assumed that interoperability in hospitals in Germany will continue to be driven forward in the coming years in order to enable better networking and collaboration in the healthcare system and thus improve the quality of care for patients. This will also be very much about removing the boundaries between data silos and separate databases for the various applications (Illustration 3).

4 Interoperability as a General Basis for Improved Healthcare Provision

Interoperable solutions and organisational forms definitely offer a wide range of added value and benefits.

As already shown, the workflows and work processes on the ward can be simplified and improved in everyday clinical practice for the doctors, nurses and

Situation – Complication – Solution

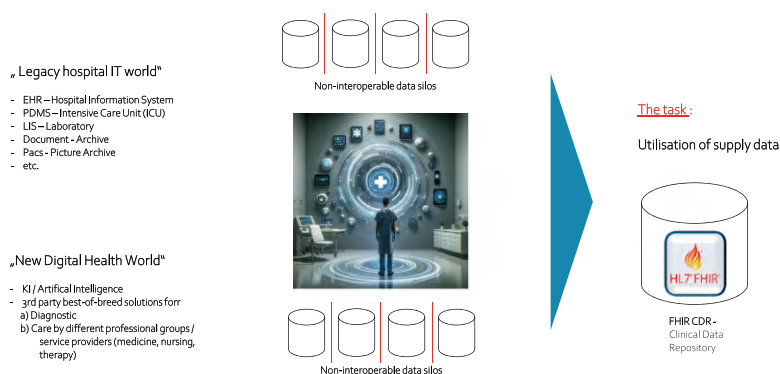


Illustration 3 Removing boundaries between data silos and databases

therapists concerned and, where it makes sense, automated work steps can also be integrated into the work procedures.

This saves time when carrying out recurring work routines, particularly with regard to the mandatory documentation of medical and nursing treatment, but the actual treatment can also be safer and better thanks to the availability of significantly more and patient-specific information.

This begins with the improved overview and available access to a patient's complete medical history. This is precisely the advantage for the patient. Patient-centred, individual and personalised treatment is facilitated and ensured by the continuous availability of data in real time.

And it is precisely here that there is no longer just a focus on a single sector, such as treatment within a hospital, but interoperability expands the possibilities for patient-orientated cross-sector care.

This is increasingly necessary and in demand for two reasons:

1. Patients are increasingly beginning to demand digital processes and digital treatment support of their own accord. This is simply due to the fact that the generation of "digital natives" will increasingly become the people who need healthcare treatment as they get older. So it's all a question of time.
2. The predicted shortage of medical and nursing staff over the next 1–2 decades will lead to bottlenecks in patient care in some regions. In order to circumvent or avoid this, new and customised forms of care are required, the implementation and quality of which can only be guaranteed through the integration of digital and, above all, interoperable solutions.

These new forms of care include, for example.

Telemedicine and Telemonitoring in the Care of Chronically Ill Patients

Chronically ill patients with conditions such as heart failure, asthma, COPD, diabetes, etc., require regular treatment and, above all, observation by specialised staff. This will potentially lead to a problem in the predicted undersupplied regions.

By integrating measuring devices (smartwatches, wearables, blood pressure monitors, pulse oximeters, scales, etc.) and many other conceivable sensors, measurement results and vital parameters can be assessed and evaluated interoperably, remotely and across locations, e.g. in a clinic or medical care centre (MVZ) by experts and specialist staff or even by AI—artificial intelligence, and subsequent treatment or advice can be provided.

Patient Portals for Appointments and Anamnesis in the Run-Up to Medical Treatments

With the Hospital Future Act (KHZG), the patient portal has become a focal point in Germany due to the second subsidy programme. The patient portal gives patients the opportunity to manage personal health data and individual health information via a secure online platform and to exchange it securely and interoperably with various service providers.

In the case of the KHZG, this initially concerns the hospital as the primary care provider, but patient portals can also be used across sectors and information can be shared.

In addition to general appointment management, relevant information for the medical history can be requested via the patient portal in advance of treatment in hospital, as well as information on medication, allergies and other risk factors.

This significantly frees up staff resources, some of whom would otherwise have to query this data several times on site, and as the data is available electronically and in a structured form from the outset, it can also be used by the next service providers in the care process.

Hospital@Home and Virtual Smart Hospitals

Thanks to interoperability and the possibility of intersectoral data availability, new care and support concepts can be designed and realised, especially with regard to follow-up care after previous inpatient hospitalisation.

While the technology and the medical expert teams providing treatment are located at a central location, the patient's nursing treatment and care takes place in their familiar surroundings at home. If necessary, the specialist experts can intervene in good time, but the entire aftercare is much more efficient with the advantage that the patients continue to be monitored with little effort. In this way, the increasingly scarce personnel resources can be optimally utilised.

Virtual hospital concepts, so-called smart hospitals, can also connect different hospital sites in an interoperable manner, in particular to share expert knowledge. Specialist medical experts in particular, who are not available at every location, can

be involved in a patient's treatment process, provided that the patient information and treatment data can be used interoperably and thus across locations.

Of course, the question of why interoperability has not yet progressed further in Germany, despite all the associated benefits for both patients and employees, must also be addressed.

For a long time, many projects to improve or achieve greater interoperability in the healthcare sector were also blocked by conflicts of interest between different stakeholders in the healthcare market.

The manufacturers and operators of monolithic hospital information systems generally have only limited interest in integrating best-of-breed solutions from other manufacturers into the IT infrastructures they dominate if they also have their own solution module in their product portfolio that can be sold to existing hospital customers as part of an "all from a single source" approach. There is therefore little interest in promoting and supporting standards and interfaces as well as open interoperability platforms that reduce their own primary system to certain basic functionalities in patient administration, patient master data management and billing.

The state of the art with modern standards such as HL7 FHIR and DICOM cannot be the reason why interoperability between different systems is not yet more advanced.

5 Organisation and Implementation with Clinical Data Repository (CDR) and Interoperability Platform

The introduction of new standards such as FHIR and the realisation of greater interoperability has a major impact on the existing organisational structure of a healthcare facility such as a hospital. In addition to the general IT infrastructure and the integration of new or supplementary software solutions, this also has a major impact on work processes and workflows, which can be redesigned and further developed.

This means that technology/infrastructure, processes and employees are directly affected.

It is important to gain the necessary transparency about the current situation from the outset in order to design the necessary target architecture. Ultimately, the aim is to merge a large number of heterogeneous, proprietary data silos into centralised repositories (CDRs—Clinical Data Repositories) used by all departments and specialist areas, in which data is stored and available in accordance with uniform standards.

A CDR (Clinical Data Repository) is a central database that stores structured clinical and medical data and information from patients. It serves as a central repository for healthcare data collected from various medical systems and applications. A CDR enables healthcare providers to access comprehensive and up-to-date patient data to improve treatment and make informed medical decisions.

The individual systems in the hospital are therefore connected to a CDR using standard interfaces—primarily via FHIR. The aim of this is to store the data that was previously separated in the data silos, some of which is still available as documents in PDF format, in a central location in a structured manner and, above all, to make it electronically analysable and usable. The data from the individual systems is stored in a standardised structure and no longer in manufacturer-specific formats and definitions.

However, the final step and the general objective must then be to set up an interoperability platform to which the clinical data repositories are connected in order to make the centrally collected data available in its various forms for the respective use cases in the hospital.

In addition to the aforementioned FHIR repository with structured data such as laboratory values, diagnoses and treatment information, this also applies to repositories for imaging with standards such as IHE XDS-I and DICOM as well as repositories for documents as standardised, digital archives with standards such as IHE XDS-I.

A single Clinical Data Repository (CDR) is therefore a database that stores clinical and medical information from patients and serves as a central storage location for healthcare data. An interoperability platform, on the other hand, is a software solution that enables different medical systems and applications to communicate with each other and exchange data. While a CDR is primarily used to store data, an interoperability platform enables seamless integration and communication between different systems to ensure a holistic view of patient treatment and care.

As already mentioned several times, the advantage of the interoperability platform is the connection of different medical systems and applications and the seamless exchange of data between them. It is a very convenient way for users to access all available patient data via the platform without having to switch back and forth between different systems. This facilitates collaboration between the various departments in the hospital, improves the efficiency of patient care and helps to make informed medical decisions. The all-round view of the data also avoids duplicate examinations and therefore improves the overall quality of treatment.

This platform can be accessed in a standardised manner via APIs (e.g. RESTful), which enables users to implement system manufacturers and their solutions very quickly and easily in a hospital's IT infrastructure if they use the corresponding APIs and standards. This massively increases the flexibility in the use of corresponding best-of-breed solutions, as not only new applications can be used but also existing ones can be exchanged quickly and easily.

However, the success of interoperability in hospitals depends only to a limited extent on the technical infrastructure and system architecture.

One added value is precisely the integration of new additional solutions and technologies that not only digitalise work processes and workflows in everyday clinical practice, but also simplify, optimise, develop and, where it makes sense, automate them. However, these possibilities also change the workplaces and structures of employees, which on the one hand definitely offers many advantages,

but on the other hand can also lead to anxiety, excessive demands and rejection on the part of employees.

It is therefore particularly important to involve them in the planning and the upcoming transformation process from the outset and to give them the space to help shape and contribute their own ideas, especially when re-modelling work processes, which massively increases acceptance of the changes.

Interoperability therefore only appears to be a purely technical issue at first glance and is usually initially located in the IT departments of a hospital. However, the possibility of a cross-departmental data flow and the consistent use of patient data and patient information provide a very good basis for the digital transformation process, also with regard to organisational changes and process optimisation. This means that, in addition to the IT department, all affected departments and their employees must be involved.

This necessary cross-departmental focus gives rise to various questions and tasks that need to be addressed and clarified within the framework of an interdisciplinary project group that should be set up, such as (Chelimalla, 2024).

- Analyse the current data flow
 - Which data is stored in which system?
 - Which departments need which data from which system?
 - How important is the data for which system?
 - Do external partners also need data and which systems are affected?
- Analysis of data usage
 - Which department uses which data for which purpose?
- Analysis of contract structures
 - What do the current contracts with existing system suppliers look like?
 - What should future contracts with system suppliers look like?

The main objective in this phase is therefore to create maximum transparency with regard to the systems and applications in use, their data flows and data utilisation as well as the existing contractual structures.

After the analysis phase, the next step is the conceptual development of the future interoperability strategy and the creation of an interoperability platform.

Separate, heterogeneous data silos must be brought together on a central data platform, for which it must be determined in advance which data standards and standards for interfaces will apply in future so that all data is stored according to uniform standards across all systems.

Once these have been defined, the reorganisation must then clarify which interfaces must be set up from which systems to the interoperability platform and for which systems the data structures must be adapted (Illustration 4).

Automation of documentation & FHIR-CDR



Illustration 4 Integration of various best-of-breed solutions via a Clinical Data Repository (CDR)

6 Conclusion

The route via legally prescribed interfaces is necessary and sensible.

In the past, there have been enough proposals for standards such as HL7, but these have been implemented rather hesitantly and restrictively by the manufacturers, no doubt also to protect their own business strategy and the “one-stop shop” business model from too much competition.

However, in order to maintain and continuously improve the quality of healthcare in the long term, especially in the inpatient sector in hospitals, there is no way around a digital transformation process and the expansion of interoperability in the face of increasing staff shortages and rising cost pressure.

Legislators must define and create the necessary framework conditions here in order to secure Germany as a sustainable and long-term healthcare centre.

Users are then required to utilise and implement these possibilities for the benefit of patients and employees in the healthcare system.

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Carsten Schmid as Head of Sales, is responsible for expanding the national and international market activities of NursIT Institute GmbH. With the mobile clinical workstation system (mKAS) careIT One, NursIT Institute GmbH provides a Fast Healthcare Interoperability Resources (FHIR)-based interoperable solution with an integrated FHIR Clinical Data Repository (CDR) and thereby enabling the digitalisation, flexibilisation, optimisation and, in some cases, automation of processes and workflows of all professional groups involved in the care process in the hospital. In addition to the intersectoral linking of the individual professional groups, a corresponding IOP strategy can also be used to develop regional care concepts in the connection between hospital–MVZ–private practice (specialist) doctor’s practice and patient. Interoperability on the basis of international standards such as FHIR is, in Carsten’s view, the central topic following the KHZG—Hospital Future Act.



Transforming the Pharmaceutical Field Force: The Future of Sales Representatives

Björn Seidel

Abstract

The integration of Artificial Intelligence (AI) is fundamentally transforming the pharmaceutical sales landscape. This article examines the impact of AI on the roles and tasks of Pharmaceutical Sales Representatives (PSRs), highlighting how AI enhances efficiency, personalization, and decision-making through data-driven approaches. AI enables optimized visit planning, automates routine tasks, and supports tailored communication strategies, allowing PSRs to focus on strategically important activities.

At the same time, challenges such as data privacy, ethical transparency, and employee acceptance are addressed. To overcome these challenges, targeted training and a seamless integration of human expertise and AI technologies are essential. External coaches and trainers specializing in the pharmaceutical industry play a pivotal role in this transformation. They provide practical training and individual support to help companies implement and leverage AI technologies effectively.

Despite technological advancements, the role of PSRs remains vital. By strategically employing AI and continuously adapting to technological developments, PSRs can enhance their efficiency while preserving the interpersonal aspect of their work. This article provides a comprehensive analysis of how AI can revolutionize pharmaceutical sales practices and outlines the competencies required to successfully navigate this transformation.

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1 Introduction

The pharmaceutical field force is undergoing a profound transformation driven by the integration of Artificial Intelligence (AI). This study examines how AI will change the specific tasks of pharmaceutical sales representatives (PSRs) and the impact on their daily work. Additionally, it explores future developments and the competencies required for this profession.

2 Application of AI in Pharmaceutical Sales

2.1 Improving Efficiency and Productivity

AI can significantly enhance the efficiency and productivity of pharmaceutical sales. AI-powered systems can analyze vast amounts of data and provide valuable insights that help PSRs better understand their target audiences and adapt their strategies accordingly (Wang & Hajli, 2017; McKinsey, 2023a). For example, AI can help determine the best times and locations for visits based on historical data and current trends (Multiplier AI, 2023a). By integrating AI into data analysis platforms, PSRs can make faster and more accurate decisions. AI models can analyze sales trends, market data, and patient information to predict future developments. These predictive analyses help deploy resources more effectively and maximize the chances of success (Davenport & Ronanki, 2023a).

A significant advantage of AI in pharmaceutical sales is its ability to personalize interactions. AI algorithms can analyze individual preferences and behavioral patterns of doctors and other healthcare providers to develop personalized recommendations and communication strategies (European Union Agency for Cybersecurity, 2023a; Bates et al., 2023a). AI can automate many routine tasks in pharmaceutical sales, allowing PSRs more time for strategically important activities. Automation tools can handle scheduling, reporting, and even generating follow-up emails (Ransbotham et al., 2023). Virtual assistants and chatbots can answer common questions from doctors and help schedule appointments or provide product information. This reduces the workload of PSRs and ensures quick and consistent communication (Pharmaceutical Technology, 2023a).

3 Challenges and Risks

3.1 Data Privacy and Security

The use of AI in pharmaceutical sales requires special attention to data privacy and security. AI systems handle large amounts of sensitive data, including patient information and confidential business data. It is crucial to protect this data and ensure that AI systems comply with data protection regulations (Floridi et al., 2023a). To minimize data privacy risks, companies must implement robust security protocols,

including encryption, access controls, and regular security audits. Additionally, PSRs should be trained on data privacy issues to ensure compliance with applicable regulations (McAfee & Brynjolfsson, [2023a](#)).

3.2 Employee Acceptance

Another challenge is the acceptance of AI among PSRs. Many employees may fear that their jobs are threatened by AI or they may struggle to adapt to new technologies (Kaplan & Haenlein, [2023a](#)).

3.3 Training and Development

To promote acceptance of AI, companies should offer comprehensive training and development programs. These programs should aim to convey the benefits of AI to employees and provide them with the necessary skills to use new technologies effectively (Pharmaceutical Technology, [2023b](#)).

3.4 Ethics and Responsibility

AI systems must be ethically justifiable and transparent. The decision-making processes of AI must be understandable to ensure that no discriminatory or unethical decisions are made (Multiplier AI, [2023b](#)).

3.5 Transparency and Accountability

Companies must ensure that their AI systems are transparent and accountable. This means that decision-making processes must be documented and verifiable to ensure that systems act fairly and responsibly (Multiplier AI, [2023b](#)).

4 Future Perspectives

4.1 Integration of AI and Human Expertise

Optimal use of AI in pharmaceutical sales requires close collaboration between human expertise and AI technologies. PSRs can be supported by AI to make more informed decisions and increase their efficiency without losing the human component (McKinsey, [2023b](#)). Collaborative approaches, where AI and human employees work together, can be particularly effective. For example, PSRs can use AI-driven recommendations to refine their sales strategies and optimize their customer interactions (McKinsey, [2023b](#)).

4.2 Continuous Development and Adaptation

AI technology is evolving rapidly. It is important for pharmaceutical sales companies to continuously invest in the training of their employees and the adaptation of their AI systems to stay competitive (European Union Agency for Cybersecurity, [2023b](#)). Companies must be willing to innovate continuously and adapt their strategies to keep pace with the latest technological developments. This requires a culture of openness and flexibility as well as investments in research and development (Bates & Saria, [2023](#)).

5 Practical Examples: How the Work of PSRs Is Changing

5.1 Visit Planning and Appointment Scheduling

A concrete example of using AI in pharmaceutical sales is visit planning. AI algorithms can analyze historical data and current trends to determine the best times and locations for visits, leading to more efficient planning and higher success rates for doctor visits (Davenport & Ronanki, [2023b](#)).

5.2 Personalized Conversations and Recommendations

AI-powered systems can help PSRs develop personalized recommendations and conversation strategies. By analyzing a doctor's preferences and past behavior, PSRs can provide tailored information and recommendations that meet the individual needs of the doctor (Kaplan & Haenlein, [2023b](#)).

5.3 Automated Follow-Up Communication

After a visit, AI-powered systems can automatically generate follow-up emails tailored to the individual conversation and preferences of the doctor. This saves time and ensures consistent and targeted communication (Goodfellow & Bengio, [2023a](#)).

5.4 Use of Chatbots for Common Inquiries

Chatbots can be used to answer frequently asked questions from doctors and provide information on products. This reduces the workload of PSRs and ensures that doctors receive the needed information quickly and efficiently (Wang & Hajli, [2023a](#)).

5.5 Remote Meetings and Virtual Engagements

The use of remote meetings and virtual engagements is a significant change in pharmaceutical sales. The COVID-19 pandemic has shown that virtual meetings are not only possible but often more efficient and convenient (McAfee & Brynjolfsson, 2023b). AI can optimize these virtual interactions by providing personalized content and presentations in real-time. For example, PSRs can use AI-driven tools during a virtual meeting to highlight the most relevant data and studies specifically tailored to the interests and needs of the doctor (European Union Agency for Cybersecurity, 2023c).

5.6 Real-Time Data and Market Insights

AI enables PSRs to leverage real-time data and market insights to support their conversations with doctors. By integrating real-time analytics, PSRs can incorporate current developments and trends into their presentations, increasing the relevance and timeliness of the information (Floridi & Cowls, 2023a). For example, a PSR can access up-to-date studies and market analyses during a conversation to substantiate the benefits of a new medication with evidence-based arguments.

5.7 Use of Augmented Reality (AR) and Virtual Reality (VR)

AI-powered AR and VR applications can be used to visually and interactively explain complex medical concepts and product mechanisms to doctors. These technologies provide an immersive learning experience and can significantly enhance the understanding and interest of doctors (Kaplan & Haenlein, 2023c). For example, a PSR could use a VR headset to present an interactive simulation of how a new drug works, leading to deeper and more sustainable knowledge transfer.

5.8 Personalized Medicine and Targeted Therapies

AI can help PSRs promote personalized medicine and targeted therapies by providing detailed patient profiles and analyses. This allows for more targeted communication with doctors who treat specific patient groups and can lead to better patient experiences and treatment outcomes (Bates et al., 2023b). For example, a PSR could present individualized therapy recommendations based on genetic profiles and specific biomarkers of patients to an oncologist (McKinsey, 2023c).

5.9 Effective Training and Support for PSRs

AI can also be used to train and continuously support PSRs. Through personalized learning programs and real-time feedback, PSRs can continuously improve their skills and knowledge, better preparing them for their visits (Multiplier AI, 2023c). AI-powered training platforms can offer simulation-based learning modules that replicate real scenarios and help representatives refine their communication and sales skills.

5.10 Compliance and Regulatory Support

AI can help ensure that all activities and interactions of PSRs comply with applicable legal and regulatory requirements. By monitoring and analyzing communication protocols, potential compliance issues can be identified and addressed early (Pharmaceutical Technology, 2023c). For example, AI can be used to ensure that all marketing materials and presentations comply with legal regulations and do not make unauthorized promises.

5.11 Individual Communication and Segmentation Models

AI can significantly enhance how PSRs interact with healthcare providers by enabling highly personalized communication strategies. By using behavioral and psychographic profiling tools like Dominance Influence Steadiness and Conscientiousness (DISC) and Herrmann Brain Dominance Instrument (HBDI), AI can help PSRs tailor their approach to each individual doctor's preferences and communication style. Advanced segmentation models can categorize doctors based on their preferences, behaviors, and needs, enabling more targeted and effective communication (European Union Agency for Cybersecurity, 2023d).

Personalized Conversation Starters

AI can generate personalized conversation starters based on the interests and past interactions of individual doctors. For instance, if a doctor has shown a particular interest in recent developments in cardiology, AI systems can suggest conversation topics focused on the latest research findings or innovative treatments in this field (Davenport & Ronanki, 2023c).

Customized Email Subject Lines

AI can optimize email marketing by creating personalized subject lines that achieve higher open rates. By analyzing previous email interactions, interests, and behaviors of a doctor, AI can generate subject lines more likely to capture the doctor's attention, such as "Discover the Latest Breakthroughs in Oncology Treatment" for an oncologist (Goodfellow et al., 2023).

Individually Tailored Event Invitations

Invitations to events like webinars, conferences, or product launches can be more effective through personalization. AI can analyze a doctor's professional interests and past event participation to create tailored invitations tailored to their interests. For example, a cardiologist might receive an invitation to a webinar on the latest advancements in heart disease treatments (Wang & Hajli, 2023b).

6 Role of Social Media in Pharmaceutical Sales

6.1 LinkedIn and Other Social Media as Contact Platforms

Social media, particularly LinkedIn, is playing an increasingly important role in pharmaceutical sales. PSRs can use LinkedIn to build and maintain professional networks, share targeted content, and directly connect with doctors and other healthcare providers (McAfee & Brynjolfsson, 2023c). These platforms allow PSRs to position themselves as experts in their field and share valuable insights and information with their target audience.

6.2 Omnichannel Approach for Effective Networking

An omnichannel approach combines various communication channels such as personal visits, emails, phone calls, and social media to ensure cohesive and consistent customer engagement. This approach allows PSRs to maximize their reach and effectively communicate with doctors by considering their preferences and behaviors (European Union Agency for Cybersecurity, 2023e).

6.3 Requirements for PSRs in Social Media

Digital Competence

PSRs must be familiar with the various social media platforms and know how to use them effectively to reach their target audience. This includes creating and sharing relevant content, networking with key individuals, and using analytics tools to measure and optimize the impact of their activities (Floridi et al., 2023b).

Building and Maintaining Networks

The ability to build and maintain networks is crucial in social media. PSRs should actively seek new contacts, maintain their existing networks, and regularly participate in conversations and discussions to increase their visibility and credibility (Kaplan & Haenlein, 2023d). LinkedIn is an excellent platform for this purpose, as it is specifically designed for professional networking and offers numerous opportunities to engage with doctors and other healthcare providers.

Content Creation and Management

PSRs must be able to create high-quality, informative, and engaging content that appeals to their target audience. This can include articles, blog posts, videos, infographics, and more. The content should be not only informative but also current and relevant to capture and retain the interest of the audience (Bates et al., [2023c](#)).

Data Privacy and Compliance

When using social media, PSRs must ensure they comply with all data privacy and compliance regulations. This includes maintaining the confidentiality of patient data and adhering to industry regulations and company policies (McKinsey, [2023d](#)). It is important for PSRs to stay informed about current regulations and best practices and ensure that their online activities are compliant.

7 Changes and Opportunities for External Trainers and Field Coaches

7.1 Importance of External Trainers and Field Coaches

The transformation in pharmaceutical sales presents significant opportunities for external trainers and field coaches. As companies increasingly adopt innovative technologies and new communication strategies, the need for specialized training and coaching grows. External experts can play a crucial role by developing customized training programs and supporting PSRs in implementing new technologies (Multiplier AI, [2023d](#)).

7.2 Training and Support in Digital Transformation

External trainers and field coaches can help PSRs develop the necessary digital competencies and effectively integrate them into their daily work. This includes training on the use of AI tools, applying data analysis, and optimizing communication through social media (Pharmaceutical Technology, [2023d](#)).

7.3 Coaching for Employee Development and Support

A key task of external trainers and field coaches is to support PSRs in adapting to new technologies through coaching. This involves reducing fears and reservations about new systems and processes. Through individualized coaching, trainers can show employees the opportunities and benefits of digital transformation and motivate them to actively participate in these changes (European Union Agency for Cybersecurity, [2023f](#)). External trainers and field coaches should develop tailored training programs that address the specific needs and challenges of individual companies and their PSRs. These programs might include training on the use of

AI, personalization of customer interactions, and effective use of social media (Davenport & Ronanki, [2023d](#)).

7.4 Continuous Education and Adaptation

The rapid technological progress requires continuous education. External trainers and field coaches can help companies ensure their PSRs are regularly trained and up-to-date. This includes adapting to new technologies, introducing new strategies, and continuously improving PSR skills (Goodfellow & Bengio, [2023b](#)).

7.5 Benefits for Companies from External Support

Companies benefit from the expertise of external trainers and field coaches as they bring an objective perspective and specialized knowledge into the organization. By working with external experts, companies can ensure their PSRs are well-prepared for the challenges of digital transformation and continuously develop their skills (Wang & Hajli, [2023c](#)).

8 Future of the PSR Role

8.1 Will the PSR Job Still Exist?

The role of PSRs will significantly change with the adoption of AI and other technologies, but it will not disappear. The human component will remain crucial, especially in areas like relationship management and complex negotiations that require empathy and interpersonal skills (McAfee & Brynjolfsson, [2023d](#)). AI will serve more as a support system, enhancing the efficiency and effectiveness of PSRs.

8.2 Required Competencies for Future PSRs

Future PSRs must develop a deep understanding of AI and other digital tools. They should be able to use data analysis tools to gain insights into market trends and customer preferences and be familiar with CRM systems and other digital platforms (European Union Agency for Cybersecurity, [2023g](#)). The ability to interpret data and develop analytical skills will become increasingly important for PSRs. They must be able to understand large data sets and derive actionable insights to improve their sales strategies (Floridi & Cowls, [2023b](#)). As personalization becomes more critical, PSRs must learn how to create and present personalized content effectively. They should be able to develop tailored conversation starters, emails, and event invitations based on the specific interests and needs of their clients (Kaplan & Haenlein, [2023e](#)).

Despite technological advancements, the ability to build strong interpersonal relationships remains essential. PSRs need to develop empathy and emotional intelligence to understand and appropriately respond to their clients' needs and concerns (Pharmaceutical Technology, 2023e). The ability to adapt to new technologies and market changes will be crucial for PSRs. They must be open to continuous learning and development to succeed in an ever-evolving environment. PSRs must be committed to continuous learning to keep pace with technological advancements. Companies should offer regular training and workshops to keep their employees up-to-date with the latest technologies and best practices. External trainers and field coaches play a crucial role in this ongoing education.

9 Summary

Artificial Intelligence has the potential to revolutionize the pharmaceutical sales force. By enhancing efficiency, personalization, and automation, AI can make the sales force more effective and customer-focused. However, challenges such as data privacy, employee acceptance, and ethical considerations must be addressed to ensure successful implementation. With the right balance between technology and human expertise, the pharmaceutical sales force can benefit from AI and continue to evolve successfully.¹

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How Tech Foster Longevity Medicine

Tatsiana Akhrymenka

Abstract

Longevity medicine is an emerging field that focuses on extending life span and improving quality of life by maintaining biological and psychological health. Ageing is a complex, multifactorial process that affects multiple systems within the human body, leading to age-related diseases and functional decline. Recent technological advances, particularly in artificial intelligence (AI), machine learning (ML), and deep learning (DL), have opened up new possibilities for understanding and intervening in the ageing process.

AI-driven tools analyse large data sets to predict ageing patterns and develop personalised treatment strategies. The shift towards precision medicine allows for more accurate biomarkers of ageing, enabling earlier intervention for age-related diseases. AI applications are also transforming drug discovery processes, clinical trials, and regenerative medicine, with the ultimate goal of extending health span—the time spent in good health.

Despite rapid technological advances, longevity medicine faces challenges, including regulatory barriers and the need for interdisciplinary collaboration.

1 Introduction: Longevity Medicine

Ageing is a gradual, time-dependent, and multifactorial process that results in biological and physical damage and loss of various functions that are influenced by or lead to age-related diseases (Zhavoronkov et al., 2019). Due to the hierarchical organisation of living systems, ageing progressively affects most regulatory mechanisms. The human organism is a multi-level, complex system composed of billions

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of independent cells that form different types of tissues that are used to assemble organs, and these organs are organised into different systems, such as the lymphatic, respiratory, digestive, urinary, or reproductive systems, to perform specific tasks. The complex interplay between environmental, mechanistic, biochemical, and genetic constraints can influence ageing. The human body is a complex network of systems that work together to keep life-sustaining processes going. Therefore, dysfunctions that affect one or a few biological processes within the cells of one or more organs or parts of a system can spread to all parts of the body. This explains why ageing cannot be fully understood or controlled by monitoring only a limited number of physiological processes and should be seen as a complex, multifactorial process (Bischof et al., 2021).

Ageing is the major risk factor for most acute and chronic diseases. The last few decades have shown that we are now on the verge of being able to intervene in the ageing process, which will probably allow us to reduce the overall mortality and morbidity of the elderly population. Although much of this progress has been at the academic level, there is now a great need to translate this knowledge into clinical practice (Bischof et al., 2021).

Longevity medicine combines all preventive healthcare practices that rely on biomarkers of ageing, such as ageing clocks, to keep the patient's biological and psychological age as close to peak performance as possible throughout life (Bischof et al., 2021). It is a fast-growing field that began to emerge at least ten years ago and has developed rapidly in the last four to five years.

The field of longevity has its roots in anti-ageing medicine, age management medicine, or in other words regenerative medicine. Anti-ageing medicine as a movement led to the founding of the American Academy of Anti-Ageing (4Am) in 1993 in the United States by osteopathic physicians Robert M. Goldman and Ronald Klatz. The field is not recognized by the established medical organizations American Board of Medical Specialties (ABMS) and the American Medical Association (AMA). Like anti-ageing medicine, in the early 2000s, age management medicine was not recognized by conventional medicine and was considered alternative medicine. The practices used by age management medicine were controversial and, because it was under-regulated, it promoted drugs and treatments that were not scientifically proven, such as growth hormones or other nutritional supplements or hormone replacement, which could have caused harmful side effects.

The anti-ageing movement, which has evolved over time, now encompasses rapidly developing scientific disciplines such as

- GeroScience—It is the study of the social, cultural, psychological, cognitive, and biological aspects of ageing. It is at the interface of basic ageing biology, chronic disease, and health; it aims to understand how ageing processes enable disease and to use this knowledge to slow the onset and progression of age-related disease and disability (American Federation for Aging Research (afar.org), 2025).
- Biogerontology—The study of biological ageing, or more specifically, the biological basis of ageing and age-related diseases at the molecular and cellular levels (Rattan, 2018).

- Precision, predictive—It refers to the grouping of patients based on their risk of disease or response to therapy, using diagnostic tests or techniques that offer personalized treatment options rather than traditional one-size-fits-all approaches (Rattan, 2018).
- Functional medicine—It is a systems biology-based approach that focuses on identifying and addressing the root causes of disease. A model of care that provides a patient-centred approach to chronic disease management and seeks answers to the root causes of disease (Rattan, 2018).

All of these disciplines are based on systems thinking and the search for the root causes of the health conditions that lead to disease and ageing. Systems medicine aims to do just that: to connect the dots; It is an interdisciplinary field of study that considers the systems of the human body as part of an integrated whole, including biochemical, physiological, and environmental interactions. Systems medicine uses large data sets to track complex biological networks, building a network of networks to better understand human biology. With large amounts of data and analysis of biological networks, more precise conclusions and predictions can be made about individual health or disease conditions based on individual genetic structure and environment (Akhrymenka, 2024).

With improvements in technology, all of the above fields of medicine have started to evolve and progress strongly. With modern advances in artificial intelligence and machine learning, biomarker research and drug development, numerous tools have been developed for early diagnosis and prevention of communicable diseases—caused by infectious agents such as bacteria, viruses, fungi, and parasites—and non-communicable diseases caused by non-infectious factors such as lifestyle, genetics, and environmental factors, which remain largely unknown to the global medical community. The reasons for this lack of awareness are due to the complete absence of structured, pedagogically designed educational resources tailored to specific audiences, primarily consisting of physicians, biotechnologists, and public health professionals. Access to appropriate longevity medicine education for practitioners is therefore essential (Zhavoronkov et al., 2019).

The development of longevity-focused practice requires bridging the gap between the knowledge of healthcare providers and knowledge of other interdisciplinary fields such as biogerontologists, artificial intelligence experts, and computer scientists. Patients in order to receive longevity-based treatments need well-trained practitioners who can address the common strong contributors to disease, unhealthy lifestyle, and ageing with a practical lens.

Innovations, in particular deep-learning and data-based artificial intelligence, allow to determine the biological age of the patient and to determine the path to achieve the best possible individual performance or ideal biological age. Since a few years, especially in 2019–2020, the interest of scientists, practitioners, technical experts, longevity experts, entrepreneurs, and investors in longevity medicine, in particular technological advances related to artificial intelligence and machine-learning based on big data advances, has increased enormously in academia and research institutions. This interest has led to collaborations that have resulted in

further innovation progress and market attention. Recent educational initiatives of educational institutions, practical courses, and collaborations allow to provide an overview of clinical applications of recent advances in ageing research, of skills required to assess the validity of ageing biomarkers and biological age testing systems, and knowledge of available longevity therapies.

Ageing appears to be the long-term result of the imbalance of different dynamic equilibria established between opposing processes, rather than the sudden occurrence of isolated molecular processes. The complexity of ageing, driven by its systemic and multifactorial nature, makes understanding its biology and mechanisms a challenge. Therefore, ageing research requires constantly evolving multidisciplinary approaches to address this complexity (Zhavoronkov et al., 2019).

The major progress was made in understanding and analysing the ageing processes since big data collection and analytics have been evolving. The most relevant ageing-related data including genomic and metagenomic, metabolic, physiological, imaging, microRNA, proteomic, antigen in combination with adapted computational approaches such as machine learning (ML), its subfield deep learning (DL) with neural networks building up the backbone of deep learning algorithms and of course AI as overarching system. The appeal of AI lies in its ability to identify relevant and recurring patterns in complex, non-linear data without needing to understand biological processes. DL and AI algorithms have been successfully developed and applied in many pharmaceutical areas within various applications such as drug discovery and design, drug repurposing, predictive biomarker discovery, clinical trial optimisation while selecting suitable patient groups for trials and predicting trial outcomes, drug side effects and safety monitoring, and many more (The Lancet Digital Health, and Journal of Medicinal Chemistry, n.d.).

AI is expected to have a major impact going forward on precision and longevity medicine, analysing and interpreting large medical data sets from patients, health-care providers and companies, particularly in the pharmaceutical sector.

2 AI and Its Subfield: Machine-Learning Advancements in Longevity Medicine

Longevity medicine cannot be separated from other medical fields, as different conditions, diseases, and factors influence the ageing process over time. AI technologies and algorithms are analysing large data sets to discover patterns related to health, ageing, and disease progression, facilitating early intervention and personalised treatment strategies. Personalised treatments in this context do not refer to treatments developed for a single individual or patient but rather treatments developed by grouping patients based on disease risk and response to treatment through diagnostic tests, leading to more effective and targeted treatments for these groups and individuals. The development of systems medicine is very closely linked to the development of AI technologies and algorithms, as it focuses on exactly the same thing: the integration of various large data sets (genomic, metabolic, transcriptomic, lifestyle and behavioural, etc.) for individuals, groups of individuals

or populations in order to classify or stratify health and disease conditions into different groups (Akhrymenka, 2024).

The link between AI, machine-learning, and deep learning: AI is the overarching system. Machine learning is a subfield of AI. Deep learning is a subset of machine learning, and neural networks are the backbone of deep-learning algorithms (IBM, 2023).

Machine learning (ML), as a branch of AI, focuses on using data and algorithms to enable AI to mimic the way humans learn, gradually improving its accuracy. While artificial intelligence encompasses the idea of a machine that can mimic human intelligence and cognitive functions associated with human intelligence, such as the ability to see, understand, and respond to spoken or written language, analyse data, make recommendations and more, machine learning does not. Machine learning aims to teach a machine how to perform a specific task and to provide accurate results by identifying patterns. It automatically enables a machine or system to learn and improve from experience. Instead of explicit programming, machine learning uses algorithms to analyse large amounts of data, learn from the insights, and then make informed decisions. ML algorithms improve in performance over time as they are trained and exposed to more data. Machine-learning models are the output, or what the program learns, from running an algorithm on training data. The more data used, the better the model becomes.

ML can make predictions about data by building a model from sample inputs. appears to be very useful in both medicine and longevity medicine, where many factors and patterns that lead to ageing are not yet fully explored.

3 Deep Learning and Other Useful Algorithms for Better Decisions

Deep learning definition: a branch of machine learning that structures algorithms in layers to create an “artificial neural network” that can learn and make intelligent decisions on its own. Deep learning models can continuously analyse data. Hierarchical learning refers to a class of ML techniques that use many layers of non-linear computational units to model complex relationships between data. Deep neural networks and artificial neural networks have more than three layers, where “depth” is the underlying complexity.

Other useful algorithms with applications in medicine and longevity medicine are Reinforcement Learning (RL) or goal-directed algorithms, Generative Adversarial Networks (GANs) or structured probabilistic models for data generation, Transfer Learning (TL) where the set of learned features of a model for one task is reused or repurposed as the starting point for a model for a second task, or Meta Learning (Arulkumaran et al., 2017; Kulkarni, 2017; Goodfellow et al., 2014; Goodfellow, 2017; Torrey & Shavlik, 2010; Zhou & Wu, 2018; Gupta et al., 2018).

4 Longevity Medicine: Applications of AI, Machine, and Deep Learning

Precision medicine relies on robust quantitative biomarkers—tools that can provide a quantitative basis for evaluating the therapeutic efficacy of clinical, lifespan-enhancing interventions. However, one of the current major problems in human ageing research is the lack of biomarkers that can be targeted and measured to track the effectiveness of anti-ageing therapeutic interventions. Standard biomarkers are developed to measure a well-defined physiological process and specific clinical procedures are based on the use of predefined biomarkers. As a result, they are not necessarily suited to measuring the effects of a systemic process such as ageing (National Library of Medicine, 2004).

Currently, biomarkers are being developed to monitor a number of physiological functions, not just one, whose disruption is known to trigger specific age-related diseases and dysfunctions. Although this strategy provides accurate results and useful information about ageing itself, the considered biomarkers are not always able to represent the health state with enough accuracy. The development of such biomarkers is a time-consuming, multi-step process that includes proof of concept, experimental validation, and analytical performance validation. AI technologies offer effective alternatives for the development of ageing biomarkers, and DL-based ageing clocks have already been used to identify quantitative biomarkers. There are a number of market players who are focusing on these developments:

BioAge Labs (<https://bioagelabs.com>) is a company that uses ML and genomic data for the development of biomarkers of ageing and drug discovery for ageing and age-related diseases. The company analyses human biological data to identify drivers of ageing. Its mission is to develop therapies that can extend lifespan and health span (BioAge Labs | Targeting metabolic aging, n.d.).

Insilico Medicine uses artificial intelligence and machine learning to focus on drug discovery and ageing research. The company is developing DL-based algorithms and deploying an integrated AI pipeline for ageing research, biomarker development and drug discovery in an end-to-end learning pipeline to identify compounds for longevity. The company's goal is to find novel solutions for ageing and age-related diseases using advances in genomics, AI, and big data analytics (Main (insilico.com), n.d.).

Atomwise is applying AI to ageing research with a drug discovery pipeline targeting age-related diseases for which there are still no effective treatments, such as Alzheimer's disease, with the aim of facilitating the development of new drugs faster, cheaper, and more effectively (Atomwise – Better medicines faster, n.d.).

AgeX Therapeutics: A biotechnology company developing regenerative medicines for age-related diseases. Their research includes applications of stem cell technology to promote healthy ageing (AgeX Therapeutics, n.d.).

In addition to AI, ML, and DL, there are a number of other technologies that are advancing longevity medicine in a number of powerful ways, including (National Library of Medicine, n.d.)

- **Genomic Research and Gene Editing:**

Advances in genomics, such as whole genome sequencing, are allowing researchers to identify genetic factors that contribute to ageing and longevity, enabling personalised health assessments, identifying genetic predispositions to disease, and enabling preventive measures tailored to individual risk factors.

Technologies such as CRISPR (clustered regularly interspaced short palindromic repeats) enable precise gene editing to modify genes associated with age-related diseases, potentially reversing or slowing the ageing process.

- **Wearable Technology:**

Wearable devices such as smartwatches and fitness trackers continuously monitor health metrics such as heart rate, sleep patterns, physical activity, and other vital signs, providing users with real-time insights to promote healthier living.

This data can help individuals make informed lifestyle choices to improve overall health and reduce risk factors associated with age-related diseases.

- **Telemedicine and Remote Monitoring:**

Telemedicine allows patients to consult with healthcare professionals from home, enabling on-going health monitoring and management without barriers to access.

Remote monitoring tools provide real-time health data, enabling early intervention in age-related health issues.

- **Digital Health Platforms:**

Virtual health platforms aggregate and analyse patient data to provide personalised health assessments and recommendations based on genetic, lifestyle, and environmental factors.

These platforms can help identify health risks early and facilitate lifestyle changes tailored to individual needs.

- **Nutrigenomics and Precision Nutrition:**

Technologies that analyse the interaction between diet and genetics are enabling personalised dietary recommendations that can optimise health and mitigate age-related diseases.

Tailored nutritional supplements can target specific pathways associated with ageing.

- **Regenerative Medicine:**

Advances in stem cell research and tissue engineering are enabling the development of therapies that can repair or replace damaged tissues and organs, thereby addressing the biological effects of ageing. Regenerative medicine technologies have the potential to rejuvenate aged tissues and extend healthy life span.

- **Bioinformatics tools synthesise and analyse biological data to identify biomarkers of ageing and track the progression of age-related diseases, helping to develop new drugs and therapies to extend health and life span.**

5 Future Outlook and Conclusion

There are probably two ways of looking at the purpose of longevity: to maximise years of life and to maximise the peak performance of the human body, thus the number of quality-adjusted life years of the population—both are certainly linked. Technological development supports the goal of increasing health span (the time spent in good health) and longevity through improved prevention, treatment, and lifestyle choices.

Using technology, longevity medicine researchers and companies are working to develop novel interventions that not only extend life span but also improve the quality of life as people age. The personal contribution and involvement of patients in their own health improvement is essential.

AI and its applications are a major technological contributor to longevity and are gradually moving from the status of an over-hyped technology with few proof-of-concept examples to a massively adopted and accepted trend in health care.

There are several regulatory issues that need to be addressed to ensure that technological advances safely support developments in medicine, including longevity. In both the United States and the EU, there are initiatives by regulatory institutions to create a safe regulatory framework and environment for innovation: some positive examples are FDA approval of the first cloud-based DNN under the category of medical devices, or EU regulations on medical software enabling prediction and prognosis. At the same time, potential barriers to innovation development, such as GDPR (General Data Protection Regulation), need to be carefully assessed. As AI development is highly dependent on data availability, regulation should take into account that collaboration between health care and AI-based companies is necessary to create an efficient pipeline for secure data collection while limiting abusive practices.

In overall, the population specificity of the many different ageing biomarkers demonstrates the need for international collaborations and consortia focused on data economics, generation, exchange, and validation, as well as meta-analysis, clinical trials, and educational programmes (Zhavoronkov et al., 2019).

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Legal Implications of Transformation in Health Care

Kyrill Makoski

Abstract

All changes in the provision of health care can only succeed if the legal regulations are adapted accordingly. Often, it is necessary to change the framework or/and the manner of financing to successfully implement transformation. This is especially true in Germany, where legal responsibility, financing, and provision are divided among many actors.

1 Divided Competences

1.1 Who Can Do What

Healthcare systems are shaped by the powers of the actors. Changes are easier if there are less actors involved. Systems where only one actor can set the regulations is responsible for financing and also the biggest provider of healthcare services are easier to modernize than systems where different actors are regulating parts of the healthcare system, other actors are paying for services and services are provided by another set of actors.

In a unified system, the regulator (normally the state) can set the standards and determine which obligations must be fulfilled. By setting the payment preferences, choices of service providers and patients alike can be influenced. Finally, healthcare providers react to changes in regulation and payment systems.

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For example, in the United Kingdom, the national government regulates health care, finances health services via the National Health System (NHS) and is also the main provider of medical services.

1.2 Situation in Germany

The Federal Republic of Germany has a ramified system of health care backed up by appropriate social services. Although health care is basically the individual's own responsibility, it is also the concern of society as a whole. All people, regardless of their financial or social situation, should have the same chance to maintain or restore their health. Health care in Germany is a decentralized, pluralist, and self-governing system.

Constitutional powers are split. The *Grundgesetz* (GG)¹ allows the federal government to regulate social security (Art. 74 para. 1 no. 12 GG) and the principles of hospital remuneration (Art. 74 para. 1 no. 19a GG). Also, the federal government enacts the provisions for medical education. The *Länder* have the power to regulate the exercise of the medical profession, and they are responsible for the provision of hospital services, i.e. they are planning which hospitals are necessary for the welfare of the people.

The German healthcare system is dominated by two great divides, one on the payers' side between public health funds and private health insurance and one on the providers' side between outpatient and inpatient services.

1.2.1 The Payers' Side: (Public) Health Funds and (Private) Health Insurance

Nearly everyone in the Federal Republic of Germany has health insurance, whether as compulsory or voluntary members of the statutory health insurance scheme or through private insurance.

89% are members of public health funds (*Krankenkasse*), 10% have private health insurance, 0.8% have some other form of protection (e.g. soldiers, civil servants), and 0.2% have no health insurance.

Public Health Funds

Under the statutory scheme, insurance is compulsory for all employees up to a certain income level. Voluntary insurance is possible under certain circumstances. The statutory system also covers pensioners, the unemployed, trainees, and students, subject to certain conditions. Family members without a job or another health insurance are also covered automatically free of charge (which is a real bonus for families). Currently, there are 95 health funds (down from over 2000 twenty years ago). All funds are represented by the *Spitzenverband Bund der Krankenkassen* (Federal Association of Health Funds).

¹ https://www.gesetze-im-internet.de/englisch_gg/index.html (26.2.2025).

Employees can choose their health funds. To prevent an accumulation of (expensive) sick patients in the public health insurance fund, an elaborate scheme has been created to mitigate risks, whereby funds with many young insured transfer money to those with many old beneficiaries.

The health insurance fund pays the cost of medical and dental treatment, drugs and medicines, etc., as well as hospitalization and preventive health care. All insured persons have a free choice of panel doctors and dentists as well as hospitals. Details are often decided by the Federal Joint Committee [*Gemeinsamer Bundesausschuss*],² consisting of representatives of health funds, physicians, hospitals, and patients. While outpatient procedures must be approved, hospitals are free to use all methods not expressly prohibited.

Private Health Insurance

Self-employed and those earning more than 73,800 € per year can choose to opt out of the public scheme and purchase health insurance. Private insurance exists in many forms, from full-coverage to basic coverage with a co-pay. The insurance company may only terminate the insurance contract if the insured is at fault (e.g. fraud). But the insurance companies can raise the rates—which often forces the insured to change the terms of their contract.

Special Situation: Civil Servants

Traditionally, civil servants enjoy a special privilege. The state pays half or more of their health costs by a subsidiary system, called *Beihilfe*. Civil servants are required to obtain private health insurance for the other half of their health costs.

1.2.2 The Provision of Healthcare Services

Outpatient Services

In 2023, there were about 428,000 doctors active in Germany³ as well as 73,000 dentists.⁴ Fewer than half of the nation's doctors are in private practice. The others work in hospitals or administration or are engaged in research. Doctors working in hospitals are usually employees of the hospital. Only few doctors in private practice have the privilege of admitting patients to the hospital for their own procedures [*Belegärzte*].

As stated above, Germans are either insured through a health insurance fund or a private health insurance. There exist two distinct systems of reimbursement for each sector.

Patients of private health insurance are billed by their physicians and reimbursed by their insurer. Doctors' fees are regulated by the federal government in a fee schedule [*Gebührenordnung für Ärzte—GOÄ*].⁵ Patients have a free choice of

² <https://www.g-ba.de/english/> (26.2.2025).

³ <https://www.bundesaeztekammer.de/baek/ueber-uns/aerztestatistik/2023> (26.2.2025).

⁴ <https://www.bzaek.de/ueber-uns/daten-und-zahlen/mitgliederstatistik.html> (26.2.2025).

⁵ https://www.gesetze-im-internet.de/go__1982/BJNR015220982.html (26.2.2025).

physicians and generally, no prior approval is required. This scheme also applies for public servants, whose healthcare costs are borne partly or completely by the state.

The vast majority of people are insured by a health insurance fund. These funds do not reimburse the patients or pay the doctors directly. Rather, another complex scheme has been constructed: In order to be eligible to treat patients insured by health insurance funds, a physician has to be a member of the Association of Statutory Health Insurance Physicians [*Kassenärztliche Vereinigung—KV*]. These organizations, though set up by the state, are governed by the physicians themselves. They control the number of doctors in their district (usually covering one *Land*) and try to ensure that there are sufficient specialists to treat the population by limiting the number of doctors in most specialities in counties and cities; new doctors can usually only be admitted as successors to existing doctors. The KV also organizes an emergency service. As public entities they have to adhere to the limitations of administrative and constitutional law. On the federal level, the National Association of Statutory Health Insurance Physicians [*Kassenärztliche Bundesvereinigung—KBV*]⁶ represents the interests of the physicians, e.g. during legislative proceedings and on negotiations about the fee schedules.

The KV also negotiates with the health insurance funds, receives money from them, and distributes it among the physicians. At the end of each quarter, the physicians document the number of procedures and treatments they have done and send this list to the KV. There, a point value according to a federal regulation [*Einheitlicher Bewertungsmaßstab—EBM*] is noted for each procedure and all points are totalled. Subsequently, the available amount of money is divided by the number of points and thus the value of each point is fixed. Originally, each point was intended to represent about 6 cents. Due to an increase in the number of procedures and the decrease in contributions, the point value has decreased in recent years.

The patient pays his contribution to his health fund which negotiates the total payment with the *Kassenärztliche Vereinigung*. The physician records his services and bills it to the KV at the end of the quarter (i.e. only four times per year). The KV takes all bills of the physicians and divides the total payment accordingly. This means that the physician does not know during the treatment, how much the treatment is. On the other hand, he does not need to deal with a large number of bills and receives his money quarterly (with monthly advances). The payments of the KV are usually sufficient to cover the operating costs of the practice.

Since 2004, outpatient services may also be delivered by ambulatory healthcare centres [*Medizinisches Versorgungszentrum—MVZ*]. An MVZ must have a medical director who is working in the centre. Also, if a MVZ provides services in one of the specialities with limitations on doctors (e.g. surgery, internal medicine, gynaecology, and anaesthetics), it needs the necessary number of licences (e.g. by “buying” the practices of established physicians). Until now, about 4600 MVZs have been established, about 45% by hospitals, 45% by physicians, and the rest by others.

⁶ https://www.kbv.de/html/about_us.php (26.2.2025).

Hospitals may provide outpatient services only in few circumstances, e.g. if there are not enough specialized physicians, before or after an inpatient treatment period or as ambulatory surgeries. For certain illnesses requiring either specialized knowledge or a combination of various specialities, hospitals may be allowed to provide outpatient services (*Ambulante spezialfachärztliche Versorgung*, § 116b SGB V). Also, there are special provisions allowing hospitals to provide outpatient services to psychiatric or geriatric patient. University hospitals can also treat outpatient hospitals in the context of medical education. Recently, there have been further options for hospitals to treat patients without having to admit them completely, e.g. the inpatient-by-day treatment (*Tagesstationäre Behandlung*, § 115e SGB V).

In-patient Services

Currently, there are 1893 hospitals in Germany (29% public hospitals, 31% hospitals maintained by independent non-profit organizations, mainly religious charities, and 40% private hospitals) with a total of approximately 4,480,000 beds.

In 2022, about 161,000 beds were also available in 1089 preventive care or rehabilitation centres. For-profit organizations run mostly specialized hospitals or rehabilitation facilities, though there has been an effort to convert some non-profit hospitals into for-profit institutions.

University hospitals play a special role because they serve as general hospitals, care also for complicated cases, and are involved in research.

The market share of private hospital operators has risen steadily, while the share of public hospitals has decreased—in the number of hospitals as well as the number of beds. Non-profit hospitals have managed to hold their ground, but are also feeling financial stress—and their numbers are currently dwindling due to a lack of funds.

Hospitals are financed in two ways: Payments by health insurers usually covers the operating costs of the institution. The states provide grants to cover investments and substantial expenditures.

In 2003, Germany introduced a new payment system based on Diagnosis-Related Groups (DRG). Until then, each hospital negotiated its budget with the health funds; the budget was divided by the expected number of hospital days of all patients, and each patient was billed a standard amount per day. The new system is based on a scheme of diagnoses and procedures which are then grouped into cases (*Fallpauschale*). Each case has a certain value attributed. This value is multiplied with the base rate (*Basisfallwert*) giving the cost of the hospital stay. Modifications are possible for shorter or longer stays. Since 2020, the costs of care personnel are negotiated separately and paid for in full by the health funds (*Pflegeentgelt*).

Patients treated in a hospital have to pay only a small co-pay directly to the hospital. The hospital sends the main bill to the health fund and receives the money. Objections are dealt with bilaterally between the health fund and the hospital, without involving the patient.

All hospitals receiving public funds (and connected institutions) are required to bill their patients the same amount regardless of their status, i.e. a private health insurance pays the same amount as does a public health fund. All patients may

choose supplementary services, e.g. single-room accommodation, or treatment by the head physician. Most private insurance contracts cover these extras, and many members of public health funds have a supplementary private insurance contract to cover them. The Association of Private Health Insurance Companies (*Verband der Privaten Krankenversicherung*)⁷ has the right to control the fees demanded for supplementary non-medical services and can even take a hospital to court.

2 Confronting Sectors: In-Patient Versus out-Patient

Medical advances make it possible to perform more and more procedures in an outpatient setting, i.e. without the necessity to admit the patient into a hospital. Basically, this should lead to more operating capacities in the outpatient sector and a reduction of hospital capacities.

As shown above, ambulatory services are often limited by law. If demand grows, these limits have to be raised or shifted. At the same time, hospital capacities cannot be reduced in the same manner because there is a need for spare capacities, e.g. in case of emergency. This includes operating theatres and —more importantly— personnel.

The solution to this problem seems easy: Allowing hospitals to provide more outpatient services. However, this may lead to unfair competition: While hospitals can use their spare capacities for such interventions, i.e. they have only low additional costs, a “normal” outpatient provider has to finance all costs by these services.

Also, there are different providers for inpatient and outpatient services, so a shift of resources is not easy—because such a shift is connected to losing past privileges and possibilities and also requires many people to adapt their career plans. Usually, physicians choose after finishing their medical education whether they want to stay in a hospital or whether they want to go into private practice. It is therefore imperative to convince the personnel to follow these changes.

Finally, a complete shift from inpatient to outpatient services is not feasible since this would lead to a severe shortage in emergency capacities.

3 Who Is Paying for What

Often, healthcare services are paid differently to different providers. E.g. hospitals often receive state financing to pay for buildings and major investments, so that the service fees need only to cover variable costs and personnel expenses.

In contrast, physicians need to cover all costs by the fees. This means that there is no level playing field since these fees need to be higher.

⁷ <https://www.pkv.de/> (26.2.2025).

Also, there is a special problem in the German healthcare system: Health funds pay a lump sum to the KV for all outpatient services, i.e. the health fund does not really care how many services have to be paid. In contrast, hospital bills are paid as they come—and even though there are some budgetary provisions, it still is a system of pay-for-service.

Also, health funds have different departments and different budgets for inpatient and outpatient expenses. This may seem like a trivial bureaucratic problem, but in practice, there is no incentive within the organization to shift services from the (more expensive) inpatient sector to the (cheaper) outpatient sector. Every part of health funds cares primarily for the expenses of their sector, and even though small changes may lead to a reduction in total costs, the expenses of one sector may rise, so that this part is against the change.

For example, a more expensive medication may lead to a reduction in hospital stays or doctor's visits and thus to less costs overall. But currently, administrative practice and jurisprudence take a narrower approach. Since a health fund may only provide services that are "economical" (*wirtschaftlich*) according to Sect. 12 para. 1 SGB V, and the scale for this decision focuses solely on the service in question, i.e. if the medication is too expensive, it is not covered, even though there may be savings in other sectors.

This problem grows when different actors are responsible for paying for the services, i.e. savings in one part may be connected to higher costs in another part—and those higher costs have to be paid by someone else.

Similar problems arise in regard to costs due to climate change. The adaption requires major investments—and may, at least in the short term, lead to higher costs. A clear political commitment is necessary to allow this adaption.⁸

4 Rights and Interests of the Parties: Practical Limits

Basically, all providers have the interest of providing the largest scope of services possible at the highest remuneration.

Each provider wants to expand his reach—and by definition, this can only happen to the detriment of other providers if the market does not grow in general.

The patient wants to receive the best services possible, and also have at least some choice regarding his providers.

Finally, the payers want to spend as less as possible. This means that they want to shift services to those providers that demand the lowest fees.

Since each party is focused on its own interest, it is always problematic to "optimize" the system, so that the best services are provided at the lowest cost.

Also, there are legal limits. It is not easy to make personnel switch their employers. As in many other sectors, the demographic development means that the

⁸ See Katzenmeier/Berweiler, Nachhaltigkeit im Gesundheitswesen, ZRP 2024, 120.

lack of qualified personnel is felt by all providers—and the gap will grow.⁹ But recent events have also shown that people cannot be “transferred” automatically. If a hospital closes, this does not mean that all employees are employed by neighbouring hospitals, some choose to go to the outpatient sector, others leave the healthcare sector completely.

All the providers have invested in their businesses, and these investments are protected by law, e.g. by the protection of occupational freedom (Art. 12 GG) or of property (Art. 14 GG). It is not easy to limit prior business activities. And later limits are only allowed if required by a superior public interest.

Finally, legal changes are hampered if the competences are distributed amongst several institutions, e.g. in Germany amongst the federal government and the states. This is most obvious in the hospital sector, where states are responsible for the organization and the federal government for the financing. Any major changes—such as those contemplated in 2024—can only be implemented in cooperation between states and the federal level.¹⁰

Similarly, all changes to emergency services require the inclusion of the federal government (which determines what the health funds will pay), the states (which regulate emergency services), and the local level (where emergency services are operated), as well as the local KV (which is responsible for outpatient services outside of normal office hours). This means that the current structure is not well connected or designed. The federal government plans to redesign this sector,¹¹ but the coordination with the states seems to be suboptimal.¹²

5 Data Use: Balancing the Interests of Patients and Providers

In an ideal world, all healthcare providers would have total knowledge of the medical data of the patient. And in case of an emergency, most patients would appreciate such data sharing.

But apart from an emergency, most patients are wary of sharing too much information, or at least they want to control who can see what. Accordingly, even health funds have only limited access to the data of the patients.¹³

⁹ See *Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen und in der Pflege*, Fachkräfte im Gesundheitswesen – Nachhaltiger Einsatz einer knappen Ressource, BT-Drs. 20/11880.

¹⁰ See *Wollenschläger*, Krankenhausreform und Grundgesetz, Tübingen 2024.

¹¹ See <https://www.bundesgesundheitsministerium.de/service/gesetze-und-verordnungen/detail/notfallreform.html> (26.2.2025).

¹² See *Pitz*, Die Reform der Notfallversorgung 2.0, SGb 2023, 717; *Müssig*, Herausforderungen bei der Gestaltung der Notfallversorgung und des Rettungsdienstes, GuP 2024, 77.

¹³ See *Bieresborn*, Datenschutzrechtliche Herausforderungen im deutschen Sozialrecht, NZA-Beilage 2023, 33.

5.1 Electronic Patient Records in Germany

Traditionally, this control existed through the fact that paper records were rarely changed—and the patient could determine which addressee should receive a medical statement.

With the introduction of electronic medical records, it has become easier to exchange information. Even though the patient often has the right to limit access to certain records, most patients will simply grant full access to all treating physicians—by default.

In Germany, the electronic patient record (*Elektronische Patientenakte—ePA*) was introduced in 2021 on a volunteer basis, i.e. the patient could choose to use it and demand that healthcare providers upload information into the database.¹⁴ Beginning 2025, such a record is provided to all members of health funds if they do not object.¹⁵ The aim is to build up a complete medical record of all patients. Data protection laws require that the participation of patients is voluntary, i.e. no-one is forced to have his records included in the central registry.¹⁶ This requirement conflicts with the aim of completeness.

Centralized medical records can have great benefits for medical research. Therefore, the government wants to allow easier access to the trove of information found there.¹⁷ This project is hotly debated, especially with regard to data protection.¹⁸

5.2 Centralized Patients Record and Research

Complete medical electronic records have several advantages: All physicians have access to all medical data, especially in emergency situation; less time is needed for documentation; medication errors can be avoided; electronic records of prescriptions and transfers allow an easier overview. Medical research would also profit from a general database, including AI analysis of existing records to predict medical risks.

¹⁴ See *Eichenhofer*, Die elektronische Patientenakte—aus sozial-, datenschutz- und verfassungsrechtlicher Sicht, NVwZ 2021, 1090.

¹⁵ See Gesetz zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz – DigiG), BGBl. 2024 I Nr. 101 dated March 25, 2024; see *Bretthauer*, Das Digital-Gesetz—Zentrale Neuerungen zur Beschleunigung der Digitalisierung des Gesundheitswesens, NVwZ 2024, 1047.

¹⁶ See *Bundesverfassungsgericht*, decision dated January 4, 2021–1 BvR 619/20 –, ECLI:DE:BVerfG:2021:rk20210104.1bvr061920.

¹⁷ Gesetz zur verbesserten Nutzung von Gesundheitsdaten (GDNG), BGBl. 2024 I Nr. 102 dated March 25, 2024.

¹⁸ See *Moreno*, Der Entwurf eines Gesundheitsdatennutzungsgesetzes (GDNG) – Kontroverse um die erweiterte Verantwortungsebene der Gesetzlichen Kranken- und Pflegeversicherung, GuP 2023, 189; *Gassner*, Sekundärnutzung von Gesundheitsdaten für die kommerzielle Medizinproduktforschung, MPR 2024, 95.

On the other hand, the following arguments have been brought against a centralized database: Physicians want to follow their own style of documentation; patients want to keep the list of providers to themselves, e.g. they may not want all physicians to know that they sought psychiatric help; a data breach may have much bigger consequences than in the past since it concerns all health data; a centralized database is easier to attack than separate records with different providers; errors made by one provider are perpetuated and widely disseminated; access to the centralized database may be slower than local records; if a patient does not permit all providers to include their data in the centralized database, the records are not complete, and therefore not necessarily reliable; knowledge of prior data may lead to treatment bias, i.e. a physician is led to suspect a certain condition if other physicians have done the same; sometimes, repeated examinations may be more helpful than harmful.

Many countries operate centralized health records for all their citizens, by default (e.g. Denmark). Coupled with a more relaxed approach to data protection, this system means that the individual providers keep only a limited documentation. At the same time, cooperation is easier since prior health information is readily available.

A centralized system offers many advantages to medical research. This has been recognized by the European Union. Commission and Council have agreed on the draft of a directive for the “European Health Data Space.”¹⁹ This proposal shall make it easier to exchange patient data across borders and, at the same time, protect patients’ interests.²⁰

6 Health Apps and AI

In recent years, many health apps have entered the market. Such apps may be financed by the health funds as “*Digitale Gesundheitsanwendungen (DiGA)*” (Sect. 33a SGB V). They must fulfil certain requirements regarding quality, data protection, and medical concept.²¹ If all these requirements are met, the app is included in a central registry²² and may be prescribed by a physician to a patient. The access hurdles have been lowered in recent years to help competition.²³

¹⁹ See https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en (26.2.2025); COM(2022)197final.

²⁰ Buchholtz/Schmalhorst/Brauneck, Der Gesetzgeber im Spannungsfeld zwischen Patientensouveränität und Forschungsinteressen - eine Bewertung der neuesten Gesetzgebungsaktivitäten auf EU-Ebene und nationaler Ebene, MedR 2024, 471.

²¹ See Münkler, Health-Apps im gesundheitsrechtlichen Regulierungsgefüge, NZS 2021, 41; Seeliger, Qualitätskriterien für Gesundheits-Apps—Eine Analyse der bisherigen Rechtslage, GuP 2022, 91.

²² https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/DiGA-und-DiPA/DiGA/_node.html (26.2.2025).

²³ See Klass/Fuderer, DiGAs nach dem Digital-Gesetz—Zeitenwende für das System digitaler Gesundheitsanwendungen, MPR 2024, 48.

Health apps are medical products in the sense of the Medical Device Regulation (MDR),²⁴ mostly in risk classes I or IIa.²⁵ Such apps must be certified by a licensing authority before they can be marketed to the public.

Another challenge is posed by artificial intelligence in the healthcare sector. These programmes can also be classified as medical devices and require certification.²⁶ This legal regime is applicable in addition to general rules on AI.²⁷

All these technical changes in recent years are not that easy to implement with the current legal framework.²⁸

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²⁵ v. Czettitz/Strelow, “Beam me up, Scotty” – die Klassifizierung von Medical Apps als Medizinprodukte, *PharmR* 2017, 433.

²⁶ See Handorn/Juknat, KI und Haftung bei Medizinprodukten, *MPR* 2022, 77.

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Empowering Patients and Healthcare Professionals: MedTech Meets Digital Learning

Michael R. Kinville

Abstract

This chapter explores the intersection of medical technology (MedTech) and digital learning, focusing on how these fields empower healthcare professionals (HCPs) and patients. As MedTech devices become increasingly complex, the need for effective device training grows. Systems theory is used to highlight how knowledge transfer bridges the gap between these technologies and their users. The discussion covers digital training for HCPs, with an emphasis on the rise of online enablement education. Interviews with specialty surgeons reveal a strong demand for case-based, on-demand training that fits seamlessly into their workflows. In addition, the chapter examines patient education, addressing the need for accessible, patient-centric content. Studies underscore the value of adaptive instructional design tailored to individual needs. Patient- and HCP-focused instructional design offers significant opportunities to enhance the adoption and effective use of MedTech devices. By leveraging evolving digital tools, MedTech companies can improve both professional training and patient engagement, ultimately leading to better health outcomes.

1 Introduction

Medical Technology (MedTech) as a field has seen impressive growth since at least 2010, when a total of 3859 MedTech patents were granted in Europe, compared with 9088 granted in 2023. What is more, compared to other fields, MedTech had the second-most European patent applications among fields as of 2023 (MedTech

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Europe, 2024). As the technology behind these innovations becomes more complex, there arises a need to ensure that this technology can be understood and utilized to its full extent, both by patients and healthcare professionals (HCPs).

Advancements in the field of digital learning have proceeded in such a way that the creation and delivery of effective content has become much less complicated, thanks in large part to what can be called multi-cloud solutions which can be seamlessly integrated via common interfaces (with xAPI being the most common) to bring together effective content creation and its delivery (Mauth, 2018). In other words, transferring knowledge about specific technology has never been easier, whether this knowledge is intended to be conveyed within a company or from a company to its customers or partners.

The promise of technology to transfer vital knowledge is most optimistically exemplified by the development of the learning app Daariz, which aims to counter one of the world's most intractable challenges, namely the inability to read and write. Just 2 years after its launch in 2021, the app had achieved over 400,000 downloads across the Horn of Africa. The learning materials were written with the target group in mind, and the material was delivered in a form that led to easy digestion during "spare time" (Monetta, 2023). All this is to say that both MedTech and digital education have the potential to solve problems. But what is the connection?

In continental sociology, Niklas Luhmann of systems theory fame still plays an outsize role in attempts to understand complex societies. His notion that "the system is the difference between the system and its environment" (Luhmann, 2006) seems tautological, but it can help to contextualize emergent challenges in the broad field of MedTech, including ensuring that technology does not become too complex for those who rely on it.

If a MedTech device is viewed as a system, then it becomes clearer what Luhmann was talking about, as a device only functions in relation to its user or wearer (in other words, its environment). How can HCPs and device developers ensure that the system and its environment interact sufficiently well for the system to have a positive impact on patients' healthcare outcomes? Knowledge transfer, specific to the basic functionality of a device and its intended effects, seems to be the answer.

But what kind of education is necessary? As the technological sophistication of products increases, there is a natural inclination to offer sufficiently sophisticated user manuals and educational programs or to assume that patients are technologically savvy enough to understand how to best use the product they are utilizing or wearing. This assumption especially holds true for healthcare professionals—most hold advanced degrees, the thinking goes, so they should be able to figure out how to use these devices. What if the key to making major progress in care outcomes does not have much to do with the technical capability of the device but more so with the technical capability of the user?

The following will first focus on emerging trends in patient education, with a specific look toward how asynchronous e-learning can help them to optimally follow their potentially life-saving treatment or monitoring regimens. Then, the gaze will

shift to the level of HCP education, more specifically to training that does not fit in the purview of “continuing medical education” but is rather what can be referred to as “engagement education.” The final part will include a brief discussion of how industry can adapt to the changing technological landscape in order to enable more optimal health outcomes.

2 Digital Training for Healthcare Professionals

Digital training for HCPs is not a new concept, as online course offerings for formal continuing education have obtained since at least the turn of the century. This section will begin with a brief overview of the marketplace for Continuing Medical Education (CME) courses before discussing enablement education initiatives and results from conversations with specialty surgeons about their preferences for voluntary e-learning courses.

2.1 The Growing Market for CME Courses

The marketplace for online CME courses has expanded in recent years. According to Research and Markets’ 2024 report, the global market for CME courses is projected to expand from \$9.3 billion in 2023 to \$15.3 billion by 2032, growth which the report attributes to new infections and diseases that require the transfer of new knowledge and the shifting preference toward flexible online education options (Research and Markets, 2023).

This growth in the market for CME courses is reflected in recent studies analyzing why demand for online medical education is growing. Flexibility, accessibility, and cost-effectiveness are identified as three key drivers behind this growth (Vaona et al., 2018; Abuhassna & Alnawajha, 2023), features which can lead to higher learner satisfaction.

2.2 Enablement Education

The following discussion of digital training for HCPs will focus not on CME courses, the market for which can be measured more reliably as HCPs or their supporting institutions generally pay for the courses, but rather on non-obligatory digital training. In parallel to the growing market for online-based CME courses, manufacturers are investing in what can be called enablement education, as evidenced by Medtronic’s 2020 acquisition of UK-based Digital Technologies, a company staffed with former Hollywood animators, to create “enhanced training experiences” for surgeons around the world (Medtronic, 2024).

The impetus behind an investment like this in enablement education is related to the trope that “a tool is only as good as its user,” meaning here that innovations in MedTech need to be accompanied by clear and actionable explanations of their

use. The point is equally valid for material innovations (e.g., polymers that help the cardiologist perform an angioplasty) and for data-based innovations (e.g., a new algorithm that helps the hematologist diagnose blood-borne diseases more reliably).

In a busy training landscape filled with compulsory (CME) trainings, it can be difficult for voluntary enablement education measures to stand out. Key features of CME courses, however, can help to inform what features of digital training might work for voluntary, MedTech enablement approaches. One recent study drew attention to the alignment of “task demands” in an e-learning module and the digital infrastructure of HCP participants in sub-Saharan Africa, concluding that HCPs’ participation in the module bolstered measures to provide more support for HIV/AIDs and tuberculosis patients (Ajenifuja & Adeliyi, 2022). Another study focused on the effectiveness of e-learning for professional development of surgeons and proceduralists and concluded that there is a correlation between e-learning and higher levels of satisfaction, knowledge gains and “procedural competencies” (including improvements in diagnostic accuracy) among the study cohort (Williams et al., 2023).

2.3 Instructional Design for Specialty Surgeons

This is all to say that e-learning can be a highly effective means to train HCPs. Some original research was required, however, to gauge the level of interest in and openness to e-learning among specialty surgeons at six public hospitals throughout Germany. In the course of 2 months, 15 specialty surgeons of varying ages and levels of seniority were interviewed to ascertain their level of knowledge about the devices they employed and their openness to on-demand learning modules that might help inform their intervention plans in line with different material technologies on offer.

This particular group of specialists reported that there was a lack of digital training material about the subject, and a unanimous opinion emerged that digital training offers would be warmly received, with a few important caveats. The first was that digital training activities should focus on medical scenarios that are common to the field, meaning less of a focus on theory and more of a case-based approach to employing the devices. In other words, case studies and scenarios that are as close to reality as possible are key. With that, interview partners also responded that the sole selection of “success” stories would be of little use to them; instead, procedures that did not go as well should be featured so that they HCPs could also reflect on how the process of selecting a given device can lead to alternative outcomes.

The second main finding was that a digital training offer could help unburden more senior HCPs from having to transmit basic knowledge about material devices and their essential properties to junior surgeons, as this essential information is given relatively short shrift during their medical training as specialty surgeons. Conveying material device properties in a digital, case-based format could empower junior surgeons to learn on their own while freeing up precious time for senior surgeons.

Third, the responses from the HCPs regarding learning formats were largely expected. Learning material should be available on-demand, consumable via a smartphone and learning units should be short, freely navigable and searchable, intelligently indexed, and should use interactive formats as opposed to blocks of text. This important caveat, that any learning activities should not waste the surgeons' time but should rather add value for their work, was reported repeatedly.

Information like this can help MedTech educators, product trainers, and even marketers conceptualize digital training offerings that add value to those who put their products to use to the benefit of patients. Face-to-face product trainings should not necessarily be replaced by impersonal digital educational products, but the economics of product trainings and re-trainings do not always add up. The age-old practice of polishing doorknobs at hospitals to get a few moments of attention from a surgeon can be largely replaced, however, by offering them valuable, case-based training materials that are innovative, easy to access, and at least somewhat immersive. With e-learning, MedTech companies have a new venue for communication with their HCP customers, one with a built-in value proposition, namely, the transfer of specialty knowledge to the operating room.

This transfer of knowledge need not include Hollywood animators and immense production costs, although these certainly would not diminish the value of an e-learning module. Instead, resources can be invested in recruiting HCPs to share case studies which might be relevant for others in their fields.

Referring again to a medical device as a system, the aim of any device training should be to first understand the environment in which a system is intended to function, whether it be implanted in a patient or put to use by a surgeon in the operating theater. Once an understanding of the environment has been reached—through observation, interviews, focus groups, etc.—the goal is to shrink the gap between intended use and the everyday contexts in which it is used. E-learning, assuming it is conceived of and implemented smartly, can ensure that a given MedTech device is used in such a way that it leads to positive outcomes.

3 Educating Patients via E-Learning

There is a paucity of available data about the efficacy of patient education programs related specifically to MedTech devices. There is optimism that training programs can be effective in helping patients to manage their therapy, but it seems the fundamental problem is related to how device manufacturers communicate with patients.

3.1 Challenges in Patient Education

In a systematic review of patient education materials published by orthopedic implant manufacturers, for example, the authors found that the majority of education materials for patients was written at too complex a level to be understood by the

average patient (Yi et al., 2017). Addressing patients in a language that they can easily understand is the first step toward enabling them to successfully manage their treatment and devices, a central component of what other studies refer to as patient-centric instructional design.

A lot can be gleaned and then transferred from other patient-centric education endeavors. One study, for example, analyzed e-learning programs aimed at helping patients with rheumatoid arthritis effectively manage their treatment. It concludes that patient-centric instructional design is vital to ensuring more optimal adherence to treatment plans and ultimately better health outcomes (Knudsen et al., 2022). Part and parcel of patient-centric instructional design is educational content that is tailored to the individual needs, (digital) literacy levels, and cultural contexts of the patients, with an emphasis on easily reconfiguring and recalibrating content. While instructional design can help solve a lot of problems, it only touches on *what* content is consumed and not enough on *how* content is consumed.

A similar analysis was conducted to understand how e-learning can augment asthma treatment regimens. The key takeaways from the study suggest that those patients who receive targeted education are more likely to adhere to treatment plans and experience fewer asthma-related complications. In short, e-learning programs have led to better self-management of the disease among patients (Kher et al., 2019). According to the authors, e-learning content and systems are most effective when they offer tailored curricula based on the patients' respective life contexts. The technical challenge of designing a system which is capable of reacting to the life situations of individual patients needs to be met.

Other studies lead to similar conclusions, namely, that e-learning content should be patient-centric, engaging, and should add value in terms of adherence to treatment regimens. The ultimate measuring stick when it comes to e-learning content and the system in which it is embedded is the comparison of access to content and the successful completion of content. As the focus here is on voluntary participation in e-learning programs, completion percentage among a large sample can give us some insight into how engaging the content is. Internal data suggests that courses with a completion rate above 50 percent (course completions divided by enrollments) for a completely voluntary digital training can be considered a success. This rate is complicated by external factors that a digital educator can hope to mitigate but not completely overcome.

3.2 Patient-Centric Instructional Design

The influence of these external factors, however, can be diminished through a patient-centric approach to the construction of a digital learning environment, meaning seamless systems combined with compelling, adaptive learning content. Appealing to patients' desires to improve their treatment outcomes is obviously very important, but this appeal represents a big-picture learning goal that might not speak to the day-to-day challenges associated with managing a given disease. Thankfully, emergent trends in educational technology, with regard both to the

creation of interactive content and its delivery, offer tremendous opportunities for digital patient education to stand out even in an attention-demanding information ecosystem.

This requires, however, that MedTech companies mobilize resources—medical stakeholders, marketing stakeholders, trainers, and U/X designers—to leverage emergent technologies for the creation of learning environments that are easy to access, with content that is easy to digest, didactically impactful, compliant with regulatory requirements including data privacy, adaptive to the needs of the patient, up to date with regard to information and consumable from anywhere with any kind of digital device. This might have seemed like a Sisyphean task even just 5 years ago but is much more manageable today.

The patient-centric approach to onboarding and training also allows many MedTech organizations to more easily deliver on their mission statements, a feature that has increased in importance as more and more MedTech companies have become mission- or purpose-driven, usually having something to do with delivering life-saving or life-improving technology to more people. Companies which have such a “corporate purpose” enjoy greater employee engagement and motivation, both of which offer them key competitive advantages (van Tuin et al., 2020). In more commercial terms, the state of technology even allows e-learning content to make a significant contribution to reducing churn and growing a customer base.

Linking these ideas back up with Luhmann’s notion of systems, effective patient-centric digital education can help to shrink the difference between the system and its environment (the therapy or device and the patient’s life context), leading to better health outcomes, provided it is done right. If available technology is leveraged in combination with adaptive instructional design, patients can employ their medical devices and therapeutic regimens in more effective ways, positioning organizations to better serve their missions, which among other things can help organizations remain competitive.

To be sure, producing and delivering e-learning content that is adaptive to the patients’ needs, conveyed in clear language that they can understand, and delivered in a format of their choosing (i.e., smartphone, tablet, and desktop) is achievable. All of this can even be integrated into a MedTech company’s customer relationship management (CRM) software, allowing patient education to be integrated into other customer retention and marketing activities. This was the case prior to the emergence of generative artificial intelligence and is becoming even easier, a point which will be explored in the next section.

4 Discussion

The aforementioned points work to underscore the idea that patient- and HCP-centric instructional design can help to solve problems related to adoption and optimal use in the MedTech field, thus allowing companies to effectively bridge the gap between the MedTech system and the environment. Progress in educational

technology can allow MedTech companies to scale up their delivery of digital product training.

At least for the initial steps, patient- and HCP-centric instructional design cannot be aided much by e-learning technologies; rather, effective instructional design can unfold in iterations alongside the development of a product itself. Data and insights from the usability testing of a product can flow into the conception of digital product training and its design, allowing instructional designers to focus on how the product is used by HCPs or patients in their environments and then taking this knowledge and creating e-learning activities that can nudge customers in the direction of optimal use. This simply requires a slight process adjustment.

Once the instructional concept has been worked out, highly interactive e-learning activities can be created with increasing efficiency thanks to the emergence of generative AI tools, some of which have already been integrated into industry standard e-learning authoring programs. This is not to say that instructional designers need simply to upload their concepts, write a prompt or two, and a high-quality e-learning will be produced. Interventions by sentient professionals are still necessary. The idea here is rather that efficiency gains can be achieved with the use of generative AI tools by creating raw designs and interactions. The same can be said for the emergence of neural machine translation tools which can make localization processes significantly more efficient and less resource intensive. AI-driven adaptive learning, whereby digital learning content adjusts itself automatically to the knowledge level of the learner, is still in its nascent development phase but could greatly benefit enablement education by offering bespoke digital learning experiences to every customer.

When it comes to the delivery of patient- and HCP-centric e-learning content, multi-cloud integrations give MedTech companies the chance to digitally educate their customers at any step of the customer journey. E-learning activities can be produced in an authoring tool, hosted on a learning management system (LMS) and played via an inline frame (iframe) embedded on a company's homepage. Once customers complete a course, they can receive an email with a personalized certificate of completion from the company's CRM system, which in turn can receive and track data about a customer's learning progress from the LMS, actionable information which salespeople and marketeers can use. Workflows like these do not require large investments in new systems; after all, most MedTech companies likely employ these tools already. Medical, training, marketing, and IT stakeholders simply need to work together to make the connections.

5 Conclusion

This is all to say that investing in effective enablement education for patients and HCPs does not require the procurement of expensive systems. Instead, maximum impact can be reached by investing in new processes which include instructional design steps starting at the latest with the usability testing phase and by leveraging interfaces to link pre-existing programs together to create an engaging learning experience for patients and HCPs.

Enabling patients and HCPs to use their MedTech devices in such a way as to maximize the benefits of their treatment plans positions MedTech companies to deliver on their technologies' promises. Patient- and HCP-centric instructional design allows a better understanding of the environments in which MedTech devices are used. This understanding of how systems work, coupled with the ability to create seamless learning experiences thanks to emergent interoperability features in educational technology, enables companies to realize their missions, namely, better treatment and health outcomes for patients.

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AI in Remote Patient Monitoring

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Abstract

The rapid evolution of Artificial Intelligence (AI) has significantly transformed health care, particularly in the domain of Remote Patient Monitoring (RPM). This chapter explores the integration of AI in RPM, highlighting real-life applications, system architectures, and the benefits it brings to patient care and healthcare systems. Through an extensive analysis of current technologies, methodologies, and case studies, I present a detailed overview of how AI enhances monitoring accuracy, predictive analytics, and personalized treatment plans. The chapter also discusses the challenges and future directions in this field, providing a broad overview of AI's role in revolutionizing remote patient care.

1 Introduction

The healthcare industry is undergoing a paradigm shift with the emergence of AI, which has the potential to significantly transform various aspects of patient care, medical research, and healthcare administration. Among the most promising areas of this transformation is RPM, an innovative approach that leverages AI to continuously track patients' health metrics outside traditional clinical settings (Topol, 2019). RPM systems equipped with AI capabilities utilize a variety of sensors, data analytics, and machine-learning algorithms to provide real-time insights and proactive healthcare interventions, which are important for managing chronic diseases, post-surgical care, and overall patient well-being.

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The primary goal of RPM is to extend healthcare monitoring beyond hospital walls, ensuring continuous supervision and timely medical intervention. This is particularly valuable for patients with chronic conditions such as diabetes, hypertension, and heart diseases, who require ongoing monitoring and adjustments to their treatment plans.

AI-powered RPM systems gather data from wearable devices, smart home technologies, and mobile health applications, creating a complete picture of a patient's health status. These systems can track vital signs, physical activity, medication adherence, and even mental health parameters, offering a holistic approach to patient monitoring (Kvedar et al., 2014).

Furthermore, the proactive nature of AI-driven RPM systems can lead to significant cost savings for healthcare systems. By preventing hospital readmissions and emergency room visits through early detection and intervention, RPM can reduce overall healthcare costs. Studies have shown that patients monitored through AI-enabled RPM systems experience fewer complications and hospitalizations, translating into cost savings for both healthcare providers and patients (Steinhubl et al., 2015). These savings can be reinvested in further technological advancements, improving the overall quality and accessibility of healthcare services.

Another vital aspect of AI in RPM is its potential to enhance pediatric care and empowerment. By providing children with real-time feedback and insights into their health, AI-powered RPM systems encourage their parents to take an active role in managing their health. Parents and healthcare providers can track the children's progress, set health goals, and receive personalized recommendations through user-friendly mobile applications. This increased engagement can lead to better adherence to treatment plans, healthier lifestyles, and improved health outcomes (Nigar & Chowdhury, 2020).

Despite the numerous benefits, the implementation of AI in RPM comes with challenges. Ensuring data privacy and security is paramount, as the sensitive nature of health information requires robust protection against unauthorized access and cyber threats. Additionally, integrating AI systems with existing healthcare infrastructure can be complex and resource-intensive, requiring significant investments in technology and training for healthcare professionals (Rumbold & Pierscionek, 2017). Addressing these challenges is crucial for the successful adoption and scaling of AI-empowered RPM solutions. However, challenges usually are dealt with careful consideration by the practitioners, and it is always possible to take care of the scaling when collaboration takes place.

The fusion of AI technologies with RPM represents a groundbreaking milestone in healthcare progression. By seamlessly blending AI-driven analytics with continual patient data monitoring, RPM systems indicate a new era of preventive healthcare management. Offering tailor-made insights and interventions, these innovations not only refine patient outcomes and ease burdens on healthcare infrastructures but also cultivate a fresh movement of patient autonomy. As we explore the dynamic terrain of health care, the harmonious synergy between AI and RPM stands poised to unlock transformative steps in patient-centric care.

2 Components of AI-Powered RPM Systems

AI-powered RPM systems are detailed ecosystems comprising various indispensable components, each playing a significant role in enabling seamless data collection, analysis, and interaction. These components include sensors and wearable devices, data acquisition and transmission, data storage and management, AI algorithms and analytics, and user interface.

We will dive deeper to understand how the components make up AI-powered RPM systems.

2.1 Sensors and Wearable Devices

The sensors and wearable devices serve as the frontline data collectors in AI-powered RPM systems. These devices are equipped with an array of sensors capable of capturing diverse physiological data such as heart rate, blood pressure, glucose levels, temperature, oxygen saturation, respiratory rate, electrocardiogram (ECG) signals, and activity metrics in real-time (Smith et al., 2021). They are capable of monitoring vital signs and health parameters and are designed to be non-intrusive, comfortable, and easy to wear, allowing patients to carry on with their daily activities while continuously monitoring their health status. The data gathered by these sensors serve as the foundational input for subsequent analysis and interpretation within the RPM system. Table 1 describes the examples used in this context.

In recent years, there has been a proliferation of wearable devices equipped with multiple sensors capable of capturing a comprehensive set of health data. For instance, Smartwatch allows tracking, and sleep analysis, providing users with insights into their overall health and well-being. Similarly, medical-grade wearables such as continuous glucose monitors (CGMs) and wearable ECG monitors offer real-time monitoring of specific health conditions, enabling patients and healthcare providers to track and manage chronic diseases more effectively (Brown et al., 2019). These advancements in sensor technology have significantly enhanced the capabilities of AI-powered RPM systems.

Sensors and wearable devices in RPM systems are increasingly leveraging AI to enhance their functionality and capabilities. This has enabled more comprehensive monitoring of patient health metrics.

Table 1 Examples of sensors and wearable devices in remote patient monitoring

Device	Parameters monitored	Example applications
Smartwatch	Heart rate, activity, and sleep	Fitness tracking
Fitness tracker	Steps, distance, and calories	Physical activity monitoring
Continuous glucose monitor	Glucose levels	Diabetes management
Wearable ECG monitor	ECG signals	Arrhythmia detection

2.2 Data Acquisition and Transmission

Once the physiological data are captured by the sensors, they need to be securely transmitted to centralized systems for further processing and analysis. Data acquisition and transmission mechanisms facilitate this transfer of data using wireless communication technologies such as Bluetooth, Wi-Fi, and cellular networks (Jones et al., 2020). These mechanisms ensure the reliability, integrity, and confidentiality of the data during transit, safeguarding sensitive health information from unauthorized access or tampering.

2.3 Data Storage and Management

In AI-powered RPM systems, the volume of patient data generated can be substantial, necessitating robust data storage and management solutions. Cloud-based platforms offer an ideal infrastructure for storing and managing vast amounts of patient data securely and efficiently (Brown et al., 2019). These platforms provide scalability, accessibility, and reliability, enabling healthcare providers to access patient data anytime, anywhere, and from any device. Moreover, cloud-based storage solutions facilitate uninterrupted data sharing and collaboration among healthcare professionals, increasing care coordination and continuity. This requires a smooth structure. AI can ignite the process.

2.4 AI Algorithms and Analytics

At the heart of AI-powered RPM systems lay sophisticated machine-learning models and algorithms that analyze the collected data to extract meaningful insights and actionable information. These AI algorithms leverage advanced statistical techniques to identify patterns, trends, and anomalies in the data, enabling early detection of health issues and predictive analytics (Garcia et al., 2022). By continuously learning from new data and feedback, these algorithms can adapt and improve over time, enhancing the accuracy and effectiveness of the RPM system in monitoring and managing patient health. The analytics enhances the feedback loop of the system as it provides an opportunity to keep tracks.

2.5 User Interfaces

User interfaces play an essential role in facilitating interaction and communication between healthcare providers, patients, and the RPM system. Intuitive dashboards and mobile applications provide healthcare professionals with visualization tools to monitor patient health metrics, track trends, and make informed decisions (White et al., 2021). Similarly, patient-centered interfaces empower individuals to actively

engage in their own healthcare. This is done by accessing their health data, receiving personalized recommendations, and setting health goals. These user interfaces are designed to be user-friendly, accessible, and customizable, catering to the diverse needs and preferences of both healthcare providers and patients.

3 Real-Life Applications of AI in Remote Patient Monitoring

AI in RPM has been successfully applied in various healthcare scenarios, demonstrating its potential to transform patient care through continuous monitoring, early detection of health issues, and personalized interventions.

3.1 Chronic Disease Management

Chronic diseases such as diabetes, cardiovascular diseases, and hypertension require ongoing monitoring and management to prevent complications and improve patient outcomes. AI systems in RPM can monitor these conditions by analyzing real-time data from wearable devices and sensors. For instance, continuous glucose monitors (CGMs) integrated with AI algorithms can track glucose levels in diabetic patients, providing alerts for hyperglycemia or hypoglycemia and recommending adjustments in diet or medication (McGlynn & Asch, 2020). Similarly, AI-powered RPM systems can monitor heart rate and blood pressure in patients with cardiovascular diseases, predicting potential heart attacks or strokes and enabling timely interventions (Esteve et al., 2019).

3.2 Post-Surgical Monitoring

Post-surgical care is necessary for preventing complications and ensuring a smooth recovery process. AI-driven RPM systems enable continuous monitoring of patients after surgery, tracking signs, and detecting early signs of complications such as infections or internal bleeding. By analyzing data such as temperature, heart rate, and oxygen saturation, AI algorithms can identify deviations from normal recovery patterns and alert healthcare providers to intervene promptly (Kvedar et al., 2014). This continuous monitoring reduces the need for extended hospital stays, lowers healthcare costs, and enhances patient safety and satisfaction.

3.3 Elderly Care

The elderly population is particularly vulnerable to health issues that require constant monitoring and immediate response. AI-powered RPM systems play a significant role in elderly care by monitoring key signs, activity levels, and detecting emergencies.

Wearable devices equipped with AI can analyze movement patterns and identify falls, automatically notifying caregivers or emergency services (Steinhubl et al., 2015). Additionally, these systems can monitor chronic conditions prevalent in elderly individuals, such as dementia and arthritis, providing personalized care recommendations and improving their quality of life.

3.4 Mental Health Monitoring

Mental health is another aspect when it comes to AI-powered RPM systems. Mental health conditions such as depression, anxiety, and bipolar disorder can benefit significantly from continuous monitoring and early intervention. AI systems in RPM analyze behavioral data, including sleep patterns, activity levels, and social interactions, to provide insights into a patient's mental health status. By detecting changes in these patterns, AI algorithms can identify early signs of mental health issues and suggest interventions such as therapy sessions, medication adjustments, or lifestyle changes (Esteva et al., 2019). This proactive approach helps in managing mental health conditions more effectively and reduces the risk of severe episodes.

3.5 COVID-19 and Infectious Disease Tracking

The COVID-19 pandemic highlighted the essential role of AI-driven RPM systems in managing infectious diseases. These systems were used to monitor symptoms, track exposure, and manage patient care remotely, reducing the burden on healthcare facilities and minimizing the risk of virus transmission. AI algorithms analyzed data from wearable devices to detect early symptoms of COVID-19, such as fever and respiratory distress, enabling timely testing and isolation (Rumbold & Pierscionek, 2017). Additionally, AI-powered RPM systems helped in contact tracing and monitoring the health status of individuals in quarantine, contributing to better control of the pandemic.

4 Block Diagram of AI-Powered RPM Systems

A typical AI-powered RPM system block diagram includes:

1. **Sensors/Wearables:** Collect physiological and environmental data.
2. **Data Acquisition Module:** Captures and preprocesses data from sensors.
3. **Communication Network:** Transmits data to the central system using secure protocols.
4. **Data Storage:** Cloud-based databases store large volumes of patient data.
5. **AI Engine:** Processes and analyzes data using machine-learning algorithms.
6. **User Interface:** Displays insights and alerts to healthcare providers and patients.

Sensors and Wearables → Data Acquisition → Communication Network → Data Storage → AI Engine → User Interface

Fig. 1 Simplified block diagram of AI-powered RPM system

A typical AI-powered RPM system block diagram includes several key components that work together to collect, transmit, analyze, and display patient data. Below are detailed descriptions of each component:

- 1. Sensors and Wearable Devices:** Sensors and wearable devices are fundamental to RPM systems, as they are responsible for collecting both physiological and environmental data from patients. Physiological sensors, such as heart rate monitors, blood pressure cuffs, continuous glucose monitors, and ECG sensors, measure vital signs and other health parameters (Kumar et al., 2021). These devices provide continuous monitoring, ensuring that any significant changes in a patient's condition are promptly detected. Environmental sensors monitor factors like air quality, temperature, and humidity, which can have a significant impact on patient health (Lee et al., 2020). Additionally, activity trackers are wearable devices that track physical activity, sleep patterns, and other daily activities, offering a comprehensive view of a patient's lifestyle and habits (Shen et al., 2019).
- 2. Data Acquisition Module:** The data acquisition module is imperative for capturing raw data from various sensors and performing initial preprocessing tasks. This includes filtering out noise, normalizing signals, and converting data into a format suitable for analysis (Rahman et al., 2020). The integration of data from multiple sensors is also a core function of this module, ensuring synchronization and consistency, which is essential for accurate and reliable analysis (Xu et al., 2018). This preprocessing step is crucial for preparing the data for subsequent stages of analysis by the AI engine.
- 3. Data Storage:** Cloud-based databases are employed to store the large volumes of patient data generated by RPM systems securely and efficiently. These databases offer scalability to accommodate the growing data needs and redundancy to prevent data loss, ensuring data availability and reliability (Liang et al., 2020). Effective data management tools and systems are also essential for organizing, indexing, and retrieving data, facilitating easy access and analysis by healthcare providers (Cheng et al., 2019). Cloud storage solutions are integral to managing the vast amounts of data generated and ensuring that it is readily available for analysis.
- 4. AI Engine:** The AI engine is the heart of the RPM system, processing and analyzing the collected data using various machine-learning models and algorithms. These algorithms are designed to identify patterns, predict health events, and provide actionable insights based on the data (Huang et al., 2019).

5. User Interfaces: The user interface is designed to present the analyzed data and insights to both healthcare providers and patients in a user-friendly manner. Healthcare provider dashboards display comprehensive and detailed information, insights, and alerts, enabling easy monitoring of patient health and facilitating quick decision-making (Zhang et al., 2021). For patients, intuitive mobile applications provide access to their health data, personalized recommendations, and alerts. These applications also facilitate communication between patients and healthcare providers, increasing patient engagement and involvement in their own care (Lin et al., 2019).

The rapid advancements in technology and the evolving needs of the healthcare industry necessitate the continuous evolution of RPM systems. Traditional RPM systems, while effective, face limitations in scalability, data processing speed, and patient engagement. With the rise of chronic diseases, aging populations, and the demand for personalized healthcare, there is a pressing need for more robust solutions. A futuristic block diagram is essential for envisioning the next generation of AI-powered RPM systems, which will incorporate innovative components to address current limitations and meet future healthcare demands. This forward-looking approach ensures that RPM systems can offer enhanced data collection, real-time analysis, and proactive patient engagement, ultimately leading to better health outcomes and more efficient healthcare delivery.

1. Sensors/Wearables:

- **Advanced Physiological Sensors:** Future sensors will include multi-functional devices capable of monitoring a broader range of physiological parameters with higher accuracy. Innovations in nanotechnology will enable the development of ultra-sensitive and minimally invasive sensors (Gao et al., 2018).
- **Smart Textiles:** Wearable technology will evolve to include smart textiles embedded with sensors, allowing continuous monitoring of fundamental signs through everyday clothing (Stoppa & Chiolerio, 2014).
- **Implantable Devices:** Implantable sensors will offer continuous, real-time monitoring of internal physiological conditions, providing insights for managing chronic diseases (Darwish & Hassanien, 2012).

2. Data Acquisition Module:

- **Edge Computing Devices:** Incorporating edge computing in the data acquisition module will enable real-time data processing and analysis at the point of collection, reducing latency and bandwidth usage (Shi et al., 2016).
- **AI-Enabled Preprocessing:** Advanced AI algorithms will preprocess data, filtering out noise and ensuring high-quality data transmission to central systems (Ghahramani et al., 2015).

3. Communication Network:

- **5G and Beyond:** Next-generation wireless communication technologies like 5G and 6G will facilitate faster, more reliable, and secure data transmission, essential for real-time monitoring (Zhang et al., 2019).
- **Blockchain for Security:** Blockchain technology will be integrated to enhance data security and ensure tamper-proof transmission and storage of patient data (Tian, 2016).

4. Data Storage:

- **Quantum Storage Solutions:** The future of data storage will leverage quantum computing to handle vast amounts of data more efficiently and securely (Biamonte et al., 2017).
- **Interoperable Cloud Platforms:** Advanced cloud platforms will support harmonious interoperability, enabling integration and data sharing across different healthcare systems and providers (De La Torre Díez et al., 2015).

5. AI Engine:

- **Deep-Learning Models:** The use of deep-learning models will improve the accuracy of predictive analytics and pattern recognition in health data (LeCun et al., 2015).
- **Explainable AI (XAI):** XAI techniques will be implemented to ensure transparency and interpretability of AI decisions, gaining trust from healthcare providers and patients (Gunning, 2017).
- **Federated Learning:** This approach will allow AI models to be trained across decentralized data sources without exchanging data, ensuring patient privacy (Yang et al., 2019).

6. User Interface:

- **Augmented Reality (AR) Interfaces:** AR technology will provide immersive and interactive user interfaces for both patients and healthcare providers, enhancing the visualization of health data (Azuma, 1997).
- **Voice-Activated Assistants:** AI-driven voice assistants will offer hands-free interaction with the RPM system, improving accessibility for patients with disabilities (Hoy, 2018).

The futuristic block diagram presented here highlights the incorporation of state-of-the-art innovations across various components, including sensors, data acquisition, communication networks, data storage, AI engines, and user interfaces.

5 Case Studies and Evidence Materials

To illustrate the practical applications and benefits of AI-powered RPM systems, it is essential to examine real-life case studies that demonstrate their impact on patient health outcomes and healthcare efficiency. These case studies provide concrete evidence of how AI-driven RPM systems can enhance the management of chronic diseases, improve post-surgical care, support elderly individuals, and more. By analyzing these instances, we can gain valuable insights into the operational effectiveness and transformative potential of AI in RPM.

Case Study 1: Diabetes Management

A comprehensive study involving AI-driven RPM for diabetes management showcased significant improvements in patient health outcomes. The system employed continuous glucose-monitoring sensors paired with a robust AI engine to analyze the data and provide real-time feedback. Participants received personalized dietary recommendations, medication reminders, and alerts for abnormal glucose levels. Recent studies have shown that artificial intelligence can play a significant role in improving diabetes management, potentially leading to better blood sugar control among patients (Mehta & Pandit, 2018). The real-time monitoring and tailored interventions significantly improved patient adherence to treatment protocols and overall management of diabetes.

Case Study 2: Post-Surgical Monitoring

Another pivotal study implemented an AI-based RPM system for monitoring patients' post-cardiac surgery. The system continuously tracked signs such as heart rate, blood pressure, and oxygen saturation, in addition to monitoring physical activity levels. Connected health technologies, such as telemedicine and telehealth, can facilitate early detection of potential complications and allow for timely intervention by healthcare providers. This approach has the potential to reduce hospital readmissions and improve overall patient care (Kvedar et al., 2014). This proactive approach not only improved patient outcomes but also alleviated the burden on healthcare facilities by reducing the need for emergency readmissions.

Case Study 3: Elderly Care Monitoring

A study focusing on elderly care utilized AI-powered RPM systems to monitor key signs, detect falls, and track medication adherence among elderly patients living independently. The system incorporated wearable sensors and an AI-driven alert system that notified caregivers and healthcare providers of any potential health issues or emergencies. The implementation of connected health technologies has shown promise in reducing emergency room visits and improving the overall quality of life for elderly patients (Kvedar et al., 2014). The continuous monitoring and timely alerts ensured that the elderly received prompt medical attention when needed, thereby preventing minor health issues from escalating into severe problems.

The case studies presented here underscore the significant impact of AI-powered RPM systems across various healthcare scenarios. From chronic disease management and post-surgical care to elderly monitoring, these systems have demonstrated their ability to improve patient outcomes, reduce hospital readmissions, and improve overall healthcare efficiency. The evidence from these real-life applications highlights the transformative potential of AI in RPM, paving the way for broader adoption and further advancements in healthcare technology. By addressing current challenges and continuing to innovate, AI-driven RPM systems can revolutionize patient care and contribute to a more proactive, personalized, and efficient healthcare system.

6 Challenges and Limitations

While the integration of AI in RPM systems offers numerous advantages, several challenges and limitations must be addressed to realize its full potential.

1. **Technical Challenges:** Ensuring data privacy and security remains a critical concern, as RPM systems handle sensitive health information that must be protected from breaches and unauthorized access (Rumbold & Pierscione, 2017). Integrating AI systems with existing healthcare infrastructure poses another significant challenge, as it requires cohesive data interoperability and compatibility with various healthcare IT systems. Furthermore, managing the vast amounts of data generated by these systems necessitates robust data management solutions to ensure accuracy and reliability.
2. **Ethical and Legal Considerations:** The use of AI in health care brings about ethical and legal considerations that must be carefully addressed. Patient consent for data collection and usage is mandatory, and there must be clear guidelines on data ownership and the ethical use of AI in clinical decision-making (Steinhubl et al., 2015). Additionally, transparency in AI algorithms is essential to ensure that healthcare providers and patients can trust the decisions and recommendations made by these systems.
3. **Economic and Accessibility Issues:** The high costs associated with implementing AI technologies in RPM systems can be a barrier to widespread adoption, particularly for smaller healthcare providers and under-resourced regions (McGlynn & Asch, 2020). Ensuring equitable access to these advanced healthcare solutions for all patients, regardless of socioeconomic status, is necessary to avoid exacerbating existing healthcare disparities.

7 Future Directions and Innovations

The future of AI in RPM is poised to bring about transformative changes in healthcare delivery, driven by continuous advancements in technology and data analytics.

Integration of IoT Devices

The integration of Internet of Things (IoT) devices promises to enhance the thoroughness of patient monitoring. IoT-enabled sensors can collect a wider range of physiological and environmental data, providing a unified view of a patient's health and living conditions (Balakrishnan et al., 2021). This continuous integration of diverse data sources can substantially improve the accuracy of health assessments and interventions.

Use of Blockchain for Secure Data Management

Blockchain technology offers a robust solution for secure and transparent data management in RPM systems. By ensuring the integrity and immutability of health data, blockchain can enhance trust in the system and protect against data breaches and tampering (Angraal et al., 2017). This secure data management framework can also facilitate interoperability and data sharing across different healthcare providers and systems.

Development of Advanced Predictive Models

Ongoing advancements in AI algorithms, particularly in machine learning and deep learning, are expected to lead to the development of more sophisticated predictive models. These models can analyze complex data sets to predict health events with higher accuracy and provide more personalized and proactive healthcare interventions (Esteva et al., 2019). The continuous improvement of these models through training on diverse and extensive data sets will further enhance their predictive capabilities.

8 Conclusion

AI-powered Remote Patient Monitoring (RPM) systems represent a transformative approach to healthcare delivery, offering continuous, real-time insights into patient health and enabling proactive interventions. The case studies presented in this section have illustrated the diverse applications of AI in RPM, from managing chronic diseases like diabetes to enhancing post-surgical monitoring and improving elderly care. These applications have consistently shown improvements in patient outcomes, reduction in hospital readmissions, and enhanced quality of life.

However, despite the promising outcomes, several limitations and challenges must be addressed to fully realize the potential of AI in RPM. This is especially important as challenges are supposed to arise while innovating.

First, technical challenges such as ensuring data privacy and security remain paramount. The sensitive nature of health data requires robust measures to protect patient information from breaches and unauthorized access (Rumbold & Pierscionek, 2017). Additionally, integrating AI systems with existing healthcare infrastructure and ensuring flawless data interoperability across different platforms and providers present ongoing challenges (Cheng et al., 2019).

Ethical considerations surrounding the use of AI in health care also demand careful attention. Issues such as patient consent for data usage, transparency in AI algorithms, and addressing biases in AI decision-making processes are critical for fostering trust and acceptance among patients and healthcare providers (Esteva et al., 2019; Rumbold & Pierscionek, 2017).

Economically, the high costs associated with implementing and maintaining AI technologies in RPM systems pose barriers to adoption, particularly for smaller healthcare facilities and underserved communities (McGlynn & Asch, 2020). Addressing these economic challenges and ensuring equitable access to AI-powered healthcare solutions are essential for reducing healthcare disparities.

While this chapter provides a comprehensive overview of the current state and potential of AI in RPM, it is important to acknowledge several limitations. The case studies and evidence presented are predominantly based on select scenarios and may not fully capture the variability and complexities of healthcare settings globally. Additionally, the rapid pace of technological advancements in AI and health care means that new developments and innovations may have emerged since the publication of this chapter.

Future work in AI-powered RPM systems should focus on addressing the identified limitations and advancing the field in several key areas. First, further research is needed to develop more robust AI algorithms capable of handling diverse and dynamic health data with improved accuracy and reliability. Collaborative efforts among researchers, healthcare providers, and technology developers are essential to advance AI models and ensure their effectiveness across different patient populations and healthcare environments.

Additionally, ongoing efforts should be directed toward enhancing the interoperability of AI systems with existing healthcare IT infrastructures, promoting data standardization, and implementing secure data-sharing protocols (Chen et al., 2021; Liang et al., 2020). This interoperability will facilitate effortless integration and scalability of AI-powered RPM solutions, ultimately benefiting a broader range of patients and healthcare providers.

Moreover, future research should explore the integration of emerging technologies such as blockchain for secure data management, advanced IoT devices for comprehensive health monitoring, and the development of predictive analytics models for early disease detection and personalized treatment strategies (Angraal et al., 2017; Balakrishnan et al., 2021). These innovations hold the potential to further enhance the capabilities and impact of AI in RPM, paving the way for a more efficient, patient-centered healthcare delivery system.

In conclusion, while AI-powered RPM systems have shown tremendous promise in transforming healthcare, addressing technical, ethical, and economic challenges is crucial for their widespread adoption and long-term success. Continued research, collaboration, and innovation will drive the evolution of AI in health care, ultimately improving health outcomes and enhancing the quality of life for patients worldwide.

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Skill and Grade Mix in Nursing

Matthias Drossel 

Abstract

This chapter explores the concept of skill and grade mix in nursing, emphasizing its pivotal role in modern healthcare. It outlines the strategic allocation of nursing roles based on skills, qualifications, and experience to optimize patient outcomes, enhance job satisfaction, and improve cost-efficiency. Drawing on the “Novice to Expert” model, it highlights the importance of tailored competency development and structured workforce planning. Strategies for implementation include assessing patient care needs, defining clear roles, and fostering collaborative practices. Specialized units like Nursing Development Units (NDUs) and skills labs are discussed as innovative platforms for training and research. While challenges such as resource constraints and resistance to change are noted, the chapter emphasizes that a well-executed skill and grade mix contributes to improved care quality, adaptability, and workforce satisfaction in healthcare settings.

1 Introduction and Importance

In modern health care, the complexity and demands of patient care necessitate a strategic approach to workforce planning, particularly in nursing. Particularly in times of skills shortages in individual countries (e.g., Germany), a special look at international best practice examples is required. A critical component of this planning is the skill and grade mix, which involves the strategic allocation of nurses with varying levels of skills, qualifications, and experience across different roles and responsibilities. A look at skills development and experience levels is also

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interesting (Abt et al., 2007; Adams et al., 2000; Aiken et al., 2017; Benner, 1984). This chapter explores the concept of skill and grade mix in nursing, its importance, implementation strategies, and the challenges associated with it. Skill and grade mix can make an important contribution—especially when staff are systematically assessed and deployed according to their competencies—to (1) lower mortality, (2) improved quality of care, (3) economic efficiency, and (4) higher motivation among nursing staff (Benner, 2004, 2017; Cunningham et al., 2019; Daykin & Clarke, 2000; Dreyfus & Dreyfus, 1980; Drossel & Zipfel, 2014; Drossel et al., 2022a, 2022b; Flint & Wright, 2001; Jacob et al., 2015). The right skill and grade mix is pivotal to ensuring efficient and high-quality patient care. The enhanced Patient Outcomes because of a balanced team with diverse skills and expertise can provide comprehensive care addressing a wider range of patient needs. Cost-effective care is achieved through the efficient use of different nursing roles, optimizing costs by ensuring that tasks—such as examinations—are performed by appropriately skilled staff. Improved Job Satisfaction because of clear roles and responsibilities, matched to skills and grades, can enhance job satisfaction and prevent burnout and cool out. The Flexibility and Adaptability rises, because a well-mixed team can adapt more readily to changing patient needs and workload fluctuations.

2 Understanding Skill and Grade Mix

The skill mix in nursing refers to the combination of different categories of health-care workers, such as registered nurses (RNs), specialist nurses (e.g., Advanced Practice Nursing), licensed practical nurses (LPNs), and nursing assistants (NAs). An intra(!)professional approach is required. Each category brings specific competencies, experiences, and expertise to the patient care team. The grade mix, on the other hand, pertains to the distribution of staff across different levels of seniority and expertise within each category, often defined by their pay grades, job titles, and scopes of practice. In their “From Novice to Expert” model, Dreyfus and Dreyfus differentiate between the stages of competence acquisition: Novice, Advanced Beginner, Competent, Proficient, and Expert. Patricia Benner further investigated this model in her feasibility study in nursing professions (Abt et al., 2007; Adams et al., 2000; Aiken et al., 2017; Benner, 1984). Time and relevant experience in the respective field of activity are therefore a central determinant in the acquisition of skills (Abt et al., 2007; Adams et al., 2000; Aiken et al., 2017; Benner, 1984) (Fig. 1):

Level I: Newcomers (trainees, change to a new specialist area), no or little experience in care situations. Structure and rules are important for them, but they are unable to transfer them in special situations. They therefore tend to show limited ability to act.

Level II: Advanced beginners who have already gained some experience, some of it repetitive. They act appropriately in these situations, can draw on experience, and assess those in need of care and their needs. However, their ability to weigh up priorities in relation to the needs of the patients to be cared for is limited.

Novice-to-Expert scale (1)

Level	Stage	Characteristics	How know- ledge etc is treated	Recognition of relevance	How context is assessed	Decision- making
1	Novice	Rigid adherence to taught rules or plans Little situational perception No discretionary judgement	Without reference to context	None		
2	Advanced beginner	Guidelines for action based on attributes or aspects (aspects are global characteristics of situations recognisable only after some prior experience) Situational perception still limited All attributes and aspects are treated separately and given equal importance			Analytically	
3	Competent	Coping with crowdedness Now sees actions at least partially in terms of longer-term goals Conscious, deliberate planning Standardised and routinised procedures				Rational
4	Proficient	Sees situations holistically rather than in terms of aspects Sees what is most important in a situation Perceives deviations from the normal pattern Decision-making less laboured Uses maxims for guidance, whose meanings vary according to the situation	In context	Present		
5	Expert	No longer relies on rules, guidelines or maxims Intuitive grasp of situations based on deep tacit understanding Analytic approaches used only in novel situations or when problems occur Vision of what is possible			Holistically	Intuitive

Adapted from: Dreyfus, S E (1981) *Four models v human situational understanding: inherent limitations on the modelling of business expertise* USAF Office of Scientific Research, ref F49620-79-C-0063; Dreyfus, H L & Dreyfus, S E (1984) "Putting computers in their proper place: analysis versus intuition in the classroom," in D Sloan (ed) *The computer in education: a critical perspective* Columbia NY, Teachers' College Press.

Fig. 1 Novice to expert scale orientated at Benner (Koopmans et al., 2018)

Level III: Competent caregivers, persons who have 2 to 3 years of experience in the same or a similar field of activity and profession. They can plan actions and further goals. Priorities can be set. They can manage everyday tasks and special situations efficiently.

Level IV: Experienced caregivers, people who have 3 to 5 years of professional experience in the same or a similar field of activity and profession. They can analyze care situations, grasp them holistically, and deviate from the norm without difficulty. Priorities are set and challenges are mastered without difficulty.

Level V: Nursing experts, people who have more than 5 years of professional experience in the same or a similar field of activity and profession. They do not need any rules to guide their actions and act intuitively. They recognize the problem situation in the shortest possible time and react appropriately.

Nursing experts are generally also able to make their knowledge explicable and pass it on.

3 Strategies for Implementing Skill and Grade Mix

To achieve an optimal skill and grade mix, healthcare organizations can employ several strategies. First of all, to identify with an assessment the patient care needs and evaluate the specific needs of the patient population to determine the required skill sets and staffing levels. Conduct a thorough analysis of the current workforce, assessing the skills and qualifications of existing staff and identifying gaps. Role clarity and job descriptions are aligned with the skills and competencies of different nursing grades. Investing in continuous education and training programs to upskill nursing staff and support career progression. It also helps identify the real competencies of the staff and fosters a collaborative environment where different healthcare professionals work together seamlessly, leveraging their diverse expertise. Implementing technology solutions that support task delegation, communication, and coordination among team members are necessary. Project planning makes sense for every area in the field of nursing. In Nursing Development Units, special requirements can be worked out (Benner, 2017; Köppen et al., 2018; Kushemererwa et al., 2020; Lester, 2021). The view must be taken from the back to the front. The central focus must be on the patient's care situation and then the requirement profiles for the various people involved in the care must be drawn up (Lester, 2021).

For a functioning division of labor, rules must be drawn up in the form of requirement profiles, in particular for

- Tasks (description)
- Roles/Competence matrix
- Role clarity (delimitation)/Define responsibilities
- Definition of delegable tasks at various levels
- Cooperation with educational institutions (specific further education and training, skill- and grade-mix centers)
- Consideration of experience! Consideration of qualifications!

4 Nursing Development Units (NDUs)

NDUs are specialized areas within healthcare organizations dedicated to advancing nursing practice, education, and research. They are also known as Practice Development Units. They serve for innovative nursing practices and provide an environment where nurses can develop their skills, engage in research, and improve patient care standards. The primary goals of NDUs are to enhance nursing competencies, promote evidence-based practice, and foster a culture of continuous improvement and professional development. NDUs are designed to test and implement new nursing practices and approaches. This includes developing and refining clinical procedures, patient care protocols, and nursing interventions based on the latest research and evidence. They provide ongoing educational opportunities for nursing staff. This includes workshops, seminars, and training programs aimed at improving clinical skills, leadership abilities, and knowledge of emerging healthcare trends. Supporting nursing research initiatives, they encourage nurses to engage in research projects that contribute to the body of knowledge in nursing and health care. They facilitate the integration of research findings into everyday nursing practice to improve patient outcomes. They focus on the career development of nursing staff by offering mentorship programs, career advancement opportunities, and pathways for specialization. NDUs can help nurses achieve professional certifications and advanced degrees and bring quality improvement initiatives within healthcare organizations. In a projected environment, all cultures of healthcare practitioner can learn about the different field of action and how to collaborate. The focus is usually on: patient safety, care quality, sustainability, and operational efficiency (Meyer-Hänel & Umbescheidt, 2006).

By investing in NDUs, healthcare organizations can achieve higher standards of patient care, improve nurse satisfaction, and develop future nursing leaders.

5 Challenges and Risks

While the benefits of an optimal skill and grade mix are clear, several challenges can impede its implementation:

- **Resource Constraints:** Budget limitations can restrict the hiring and training of staff needed to achieve the desired mix.
- **Regulatory and Policy Barriers:** Variations in regulations and policies regarding scope of practice can complicate the assignment of tasks across different nursing grades.
- **Resistance to Change:** Cultural resistance within the organization can hinder the adoption of new roles and responsibilities.
- **Workload and Staffing Pressures:** High patient acuity and staffing shortages can make it difficult to maintain an ideal mix, leading to role overlap and increased stress

- De-professionalization
- Monotonization of everyday working life

There are many differences in the settings in which patients are cared for. It is therefore necessary to look closely at where nursing care takes place, to what extent and with what interfaces to other professions.

6 Skill- and Grade-Mix Center: Analyzing Competences and Skills, Developing Precisely

This chapter begins with a brief introduction to the need for modern training and personnel development concepts. It is based on two published articles (Benner, 2017; Cunningham et al., 2019). The increasing shortage of qualified nursing staff currently poses a major challenge in many countries worldwide. This is not only due to demographic changes and increasing economization, which pose major challenges for the care sector. There has been a failure to prepare for specialization—such as through advanced training for specialists—specifically in relation to the new nursing education and the analysis of competencies. This is for the quality of care and job satisfaction very important. At best, this should even be increased. Deploying nurses according to their skills is an important step toward achieving both. The relationship between professional competence and job satisfaction must be analyzed with a focus on skill and grade mix (Müller-Oberli, 2012). Drossel and Zipfel (2014) called for: “A solution to the increasing demand for care and the lack of young talent is urgently needed. The field of activity of caregivers in Germany seems unclear, and job descriptions do not differentiate the skills learned sufficiently.” However, differentiating the field of activity according to qualification can help to increase the quality of care, as activities and tasks are clearly assigned according to the skills acquired. In addition to increasing job satisfaction, this also makes the nursing profession more attractive. It is therefore particularly important to consider competencies. Nurses can acquire different levels of competence through experience and/or additional expansion of knowledge (Abt et al., 2007; Adams et al., 2000; Aiken et al., 2017; Benner, 1984; Needleman, 2017). In practice, the fact that the job profile sometimes does not match the acquired competence leads to great dissatisfaction. The following example illustrates this: A training graduate starts in intensive care. After training, this person takes on the same complex patients and nursing interventions as a specialist nurse who, in addition to “master status,” also has 10 years of experience, for example. This is tantamount to de-skilling (Needleman et al., 2020).

This example makes it clear that not only educational offers are necessary but also individualized management approaches/concepts are required. Based on the needs of those in need of care, these analyze which job description is necessary for individuals in teams. The goals of the Skill and Grade Mix Center range from management-level strategies to individual personnel development measures. It is

essential that leadership engages closely with this topic and develops a detailed understanding of it (Lester, 2021). And the main focus must always remain on the care of patients, clients, and residents: “Higher nursing skill mix was significantly associated with improved patient outcomes [10].”

The main aim is to offer caregivers a career program that is suitable for the respective field of activity and their field of activity. In this context, field of action means the needs and requirements of the care recipients in the respective sector and setting. The aspects for educational decisions must also be considered by the decision-makers, e.g. the management of healthcare facilities. Education must be offered in such a way that entry is possible according to existing abilities. Accordingly, measures must be developed in such a way that employees achieve the desired/best possible skills acquisition. With the knowledge and skills they have acquired, they can provide high-quality care and are assigned to an appropriate job profile.

When developing skills, the basic skills (e.g., vocational preparation measures and training) and advanced skills (e.g., further education, training, and studies) that have already been acquired must be considered. Advanced skills are an integral part of all skills areas. The focus is on the principle of skills development. Employees need these skills for their work on, and with, the people they care for. The individually acquired skills lead to the desired qualification (degree)—not the other way around. The avoidance of redundant content in training and further education courses honors the high level of expertise of professional practitioners. Learning success is ensured through the support offered for basic skills (language, individual learning support, etc.). In the area of advanced skills, the permeability and learning support of education must also be taken into account. The focus here is on the mutual creditability of as many courses as possible. Both further training, specialist further training, and studies are important. This has advantages for decision-makers and participants alike.

The individualized consideration of the patients/clients to be cared for is crucial for tailor-made personnel development. The special requirements of the sectors, care settings, and their interfaces in interprofessional/disciplinary cooperation must also be considered and critically analyzed. The creation of concepts for the respective area with the right skill and grade mix is important for each individual care unit and healthcare facility. Monitoring and analysis of daily work processes are the prerequisite for this, on which personnel development can build. Corresponding evaluations based on selected benchmarks are essential. The corresponding job profiles can then make a positive contribution to the satisfaction of nursing staff and improve care.

Depending on the individual possibilities, appropriate learning situations are designed that can be adapted to the premises and everyday processes of the users. Due to the demographic developments described above and the associated need for individualized care for patients/clients, it will be essential for healthcare providers to adapt their educational offerings in the future. A positive error culture, greater motivation to learn, and increased self-confidence among learners can be achieved

through targeted skills training in the context of a skills and grade mix (Patricia Benner et al., 2009).

6.1 New Learning Venue to Support Personnel's Development for the Right Skills and Grade Mix

The skills lab serves as a third learning location for the integration of a practical and transfer-oriented learning process based on the assumptions of constructivism and cognitivism, although it is hardly possible to draw a clear line between the two learning theories. In the design of the individual learning stations, there is often a smooth transition between the assumptions of cognitivism and those of constructivism. Accordingly, learners' knowledge acquisition is based both on their active participation in the problem-oriented learning process and on their previous experience and existing knowledge (Smith & Roehrs, 2009).

An empirically based model for creating complex learning situations is, for example, the 4C/ID model. It provides systematic recommendations for the design of learning situations (Smith & Roehrs, 2009). By incorporating tasks that are designed as authentically as possible, it attempts to reflect the reality of everyday working life.

The four components of the model are explained in more detail below:

Component 1: Learning tasks: These are holistic and authentic tasks that enable learners to build cognitive structures and schemata. These tasks are intended to give learners more confidence and a higher degree of automation in the action sequences.

Component 2: Supporting information: Supporting information creates links between the knowledge learners have already acquired and the new content to be learned. It informs the learner about the organization in a specific task area and explains how to deal with problems that affect the area.

Component 3: Just-in-time information: Just-in-time information is considered to be the information that is specified and scheduled to be released to learners as they work through the learning situation, when they need it. In this context, information can be provided in the skills lab as a case scenario for the simulation or as part of blended learning.

Component 4: Part-task practice: The term part-task practice refers to practicing subtasks that have not yet been practiced in the previous learning process. This form of learning is used to learn critical skills or skills that support many other skills.

Examples include demonstrations or skills training in the skills lab.

6.2 Operationalizing Complex Action Sequences

In order to learn complex action sequences, the skills lab offers methodical arrangements as well as targeted assignments with the help of which the learners deal with the content of the problem situation. Specifically, this is combined in the structured form of the integrative model from the approach in a skills lab and with that of cognitive apprenticeship. This enables learners to experience complex action sequences and problem situations for themselves. As can be seen in the following diagram, in this approach learners are guided from observation, through guidance by experts and independent action, to evaluation and their own reflection (Twigg et al., 2019).

The examination of individual skills and competencies is necessary. Once these have been systematically analyzed, appropriate personnel development measures can be derived. Continuing education to offer ongoing training and development programs to enhance skills and keep up with the latest healthcare practices are necessary, also the management must think about cross-training: Encourage cross-training to increase flexibility and adaptability among the nursing staff.

7 The Implementation of Skill and Grade Mix

The findings are summarized below and suggestions for implementation (strategy and project) are given (Vogel et al., 2017):

1. Analyzing the setting:

- Needs of care of the patients (level, setting, volumes, and patient to staff ratio)
- Status of personal/staff (experience, grades, patient to staff ratio, and collaborations)
- Status of technology/digitalization

2. Analyzing the tasks:

- What kind of tasks are there?
- Who does what kind of tasks?
- How is the staff organized in terms of task distribution?

3. Defining the targets:

- Tasks (description)
- Roles/Competence matrix
- Role clarity (delimitation)/Define responsibilities
- Definition of delegable tasks at various levels
- Cooperation with educational institutions (specific further education and training, skill- and grade-mix centers)

- Consideration of experience! Consideration of qualifications!
- Technology inclusion

Overall, the management has to be transparent in the process. The process of implementing skills- and grade-mix has to be organized in a good change management process to raise the compliance. A continuous improvement/evaluation has to be done!

8 Conclusion

The skill and grade mix in nursing is a crucial element in the delivery of effective, efficient, and high-quality health care. By strategically aligning nursing roles with skills and grades, healthcare organizations can optimize patient care, enhance job satisfaction, and manage costs effectively. While challenges exist, thoughtful planning, continuous training, and fostering a collaborative culture can help overcome these obstacles and ensure the successful implementation of a balanced skill and grade mix.

This chapter provides a foundational understanding of the skill and grade mix in nursing, emphasizing its importance, strategies for implementation, and the potential challenges. In the following chapters, we will delve deeper into specific case studies and explore advanced strategies for optimizing the nursing workforce.

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