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Crossing Borders – Digital Transformation and the U.S. Health Care System

Edited by

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Editorial
Crossing Borders – Digital Transformation and the U.S. Health Care System

Bruce Fried and Andreas Schmid

This publication of student essays resulted from a study tour of the U.S. health care system by University of Bayreuth students and faculty. The basis of this tour is a longstanding exchange program between the Health Economics and Management Program of the University of Bayreuth und the University of North Carolina at Chapel Hill Department of Health Policy and Management. Since 2004, this collaboration has encouraged the exchange of thoughts and ideas between students and faculty from both sides of the Atlantic.

As this volume goes to press, the world is in the midst of the global Sars-Cov-2 pandemic. The situation has highlighted the relevance and importance of the international exchange of information and collaboration. And while the difficulty of transferring experiences and knowledge from one country to another is challenging in normal times, this becomes especially difficult when heterogeneous interests and questionable political motives have at times supported disinformation and distrust. At this difficult time, we have come to appreciate more than ever the need for global ties and the value of sharing knowledge and experiences. While helpful, the value of global connections cannot be duplicated through Zoom, Instagram or Facebook. Thus, despite the difficulties of transatlantic travel, we hope to sustain the personal and professional exchanges between our academic institutions.

During its most recent visit to the U.S., the group from Bayreuth explored the vast diversity of the U.S. health care system and focused particularly on topics related to the digital transformation in healthcare. Looking back, initiatives such as the HITECH Act and the standards developed for the meaningful use of electronic health record information have accelerated the digital transformation of the U.S. health care system. The CMS Quality Payment Program, which provides incentives for physicians to use data in care management, is but one of many initiatives resulting from digitalization. The U.S. has surpassed Germany in digitalization, but the two countries differ in their approach and application of digital technology. While the U.S. has tended to accept certain risks to allow benefits to materialize, Germany has tended to forgo many benefits of digital technology until all potential risks can be addressed and minimized. Despite these differences, both countries struggle with the same challenges to leverage digital potential for the benefit of patients and providers.

Given the tremendous changes that the U.S. health care system has undergone, there is much to learn – for Americans and international visitors alike. In March 2019, 21 health economics and management students and faculty from the University of Bayreuth embarked on a 10-day academic research excursion to the United States to do just that. Organized jointly by faculty and staff at the University of Bayreuth and the University of North Carolina at Chapel Hill (UNC), this excursion provided participants with a wide variety of opportunities to learn about health, health care, and health policymaking in the U.S. The tour started in Chapel Hill, where Bayreuth students and faculty met and interact with UNC faculty. During the first several days, UNC faculty took the time to

provide the Bayreuth visitors with introductory overviews of the U.S. health care system, setting the stage for site visits, presentations, and formal and informal group discussions. The tour then moved from Chapel Hill to Washington, D.C.
During their time in the U.S. the Bayreuth group met and engaged in discussions with many knowledgeable and thoughtful people including:

Chris Ellington	President of UNC Health Care Network Hospitals and Executive Vice President and CFO at University of North Carolina Hospitals
Jeff Strickler	Vice President, UNC Hospitals, Hillsborough Campus Tour at UNC Hospital in Hillsborough
Cheryl Allen	Healthcare Program Developer, Blue Cross Blue Shield of North Carolina (BCNC)
Janet McCauley	Senior Medical Director, BCNC
Melissa Speck	Director, Health Policy, BCNC
Jennifer Anderson	Executive Director, North Carolina Healthcare Information and Communications Alliance (NCHICA)
Angela Yochem	Executive Vice President, Chief Digital and Tech Officer, Novant Health (Charlotte, NC)
Karen Smith	Primary Care Physician, Raeford, NC
Sid Thakur	Director, College of Veterinary Medicine, NC State University
Beth Lovette	Acting Director, Division of Public Health, NC Department of Health and Human Services
Virginia Niehaus	Director of Legal and Regulatory Affairs, NC Division of Public Health
Joe Kelley	VP, Global Government Affairs, Eli Lilly
David Talbot	Sr. Director, International Government Affairs, Eli Lilly
Mark Esherick	Government Affairs and Policy, Siemens Healthineers
Michele M. Lynch	International Relations Manager, Public Policy and Government Relations, Google
Adam Borden	Director, Policy and Reimbursement, Siemens Healthineers
Margaret A. Murray	CEO of the Association for Community Affiliated Plans (ACAP)
Elanor Kerr	Government Affairs and Policy, Siemens Healthineers
Shawn Maree Bishop	VP, Advancing Medicare and Controlling Healthcare Costs, Commonwealth Fund
Mohsin Hashmi	Senior Project Manager, Kaiser Permanente Center for Total Health

The 16 student essays in this edited volume provide insights into the many topics discussed during the group's visit to the U.S. While these essays are not intended to provide a comprehensive overview of the U.S. health care system of the early 21st century, they describe innovative ideas and emerging trends in the delivery and financing of health care in the U.S.

Bruce Fried
(University of North Carolina at Chapel Hill)

Andreas Schmid
(University of Bayreuth)

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Lilly

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Damit die Praxis läuft.

alumni RW Recht & Wirtschaft in Bayreuth

AKGM
Arbeitskreis für Gesundheitsökonomie und -management e.V.

The study tour was organized by Prof. Dr. Andreas Schmid, Assistant Professor Health Management, University of Bayreuth in close collaboration with Prof. Dr. Bruce Fried, Associate Professor, Department of Health Policy and Management, University of North Carolina School of Public Health.

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MG Management im Gesundheitswesen

Part 1: The U.S. Health Care System – a System in Transformation?

Health Care Reform 2020 – The Medicare for All Approach

Verena Schiefelbein

The discussion around reforming health care has become an important part of the election campaigns of Democratic Candidates for the election in 2020. Bernie Sanders endorsed the single-payer Medicare for All Approach. This reform includes a shift from private to public spending mainly financed through tax increases but would decrease the number of underinsured and uninsured people. Different reform approaches are discussed and depending on what factors are included in the study, health care spending varies and leads to uncertainty in discussions. This effects public opinion as people in general support Medicare for All, but support drops when people understand certain impacts. With every health care reform, the status quo is changed, and Medicare for All would not be an incremental change as other health care reforms before, like the Affordable Care Act. Although it is less likely for the Medicare for All Approach to be pursued as its main political supporter Bernie Sanders recently dropped out of the fight of Democratic Nomination. Moreover, Covid-19 and its impact on unemployment rates and hence health care coverage disrupts the current system and could open up possibilities that no one would have thought of.

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1 Health Care Reform in the U.S.

For more than a century, the U.S. has tried to reform health care. The goal is to solve problems regarding access, affordability, and quality of care, and was extended by the goals of cost containment in the 1970s (Obama 2016). Despite the massive efforts made in the last decade to improve health care and make it more affordable and accessible to the population, more than 27 million Americans are uninsured. This amounts to an uninsured rate of 8.5%, with mainly young people between 19 and 44 years being uninsured plus many more people with inadequate access to care (Berchick, Barnett and Upton 2019). This poses a major threat to these people because they are not getting necessary treatments and are not using prevention and promotion services as costs discourage the usage. At the same time, the U.S. spends 18% of its GDP on health care and the per capita health care expenditure is higher than other countries while providing a lower quality of care (Galvani et al. 2020). The disparity among spending a large amount of money for health care but not being able to provide high quality of care to all Americans make health care reform necessary and unavoidable. With the election of Donald Trump in 2016 and his efforts to repeal and replace the Affordable Care Act (ACA), debates have emerged around health care reform and the Medicare for All approach gained attention (Cai et al. 2020). The public interest in this topic has been gaining traction in the past couple of years and influenced the level of effort taken by different candidates to propose health care reform for the election in 2020 (Henry J Kaiser Family Foundation 2020; Oberlander 2019).

This paper gives general information on a single-payer system and analyzes the Medicare for All Act (M4A Act) proposed by Bernie Sanders regarding financing, savings, and coverage expansion. Subsequently, the desirability and feasibility of Medicare for All are analyzed and the paper will conclude with a recommendation.

2 Medicare for All Approach: The M4A Act by Bernie Sanders

Medicare for All is an approach for universal health care reform and is based on a single-payer system aiming for transforming availability and efficiency of healthcare services (Galvani et al. 2020). The term ‘single-payer’ describes a financing mechanism for universal coverage and means that the healthcare system is financed through a single public entity (government) no matter how healthcare services are delivered (Donnelly 2019; Liu and Brook 2017). Legislators use it as a comprehensive reform and single-payer systems have been considered since the early 1990s to improve access and quality under different labels. Health reform proposals that aim for a single-payer system suggest a comprehensive benefits package and negotiation of provider reimbursement and drug prices. Concurrently, private insurance and cost-sharing are eliminated and replaced by a unified government financing that consists of a combination of taxes. In general, a single-payer system aims to reduce administrative costs and decrease drug costs through prize negotiation, however, the scale and time frame is uncertain (Liu and Brook 2017; Cai et al. 2020).

The current multi-payer system is financed through premiums paid by employers and households. Employers spend approximately $536 billion on health care premiums a year (equivalent payroll tax: 12.29%). It would be replaced by a **tax-based system**. M4A Act implements a payroll tax of 10% ($436 billion) to replace the employer premium payments and results in savings for employers. Moreover, the costs for managing the

variety of employee health care plans would drastically decrease. An average household currently pays $5,847 in premiums and out-of-pocket expenditures per year (equivalent tax rate: 9%). Parts of it will remain out-of-pocket and the remaining amount would be covered by a household income tax of 5% ($3,478 per year). This will save households on average $2,369 per year. The surplus gained will be used to create a fund for unexpected events (Galvani et al. 2020). The goal of the tax structure is to redistribute the burden of health care costs in such a way to achieve the highest relief for lower-income households (Pollin et al. 2018). In addition, a Sanders net worth tax of 1% for 0.1% for all households will be implemented (Galvani et al. 2020).
To align differences in patient charges, the M4A Act will apply **Medicare fixed payment rates** to providers across all services for all individuals. By doing so, hospital fees will be reduced by 5.54% ($59 billion) and clinical fees by 7.38% ($23 billion), leading to annual savings of $100 billion (Galvani et al. 2020). The Medicare payment rates for hospitals and physicians are expected to be 60% lower than private insurers payment rates in the first 10 years after implementation and will further decline in the following years. This will reduce provider reimbursement for current privately insured patients and will lead to decreased revenues for health care providers (Blahous 2018).
However, a unified and streamlined payment system would also **simplify administrative payment processes** and would decrease billing and administrative costs for providers by $284 billion. Thus, this will compensate reductions in fees per service and would be the largest source of savings (Cai et al. 2020; Galvani et al. 2020). Administrative savings would result from switching from per-patient billing to global budget (Gaffney et al. 2016). On top of this, administrative overhead costs can be further reduced by consolidating all insurance schemes into one Medicare framework (7% reduction, $217 billion). This could also reduce redundancies in corporate functions but lead to a contradiction of the workforce and where investments are necessary for transition purposes ($61.5 billion) (Galvani et al. 2020). It is unclear whether administrative costs for more patients can be kept on the same level as before, therefore the actual amount of savings as shown in Galvani et al. is questionable (Blahous 2018).
Efforts to reduce fraud and waste could be facilitated by providing comprehensive and consistent clinical encounter data within the single billing system (Cai et al. 2020). Money for fraud detection could be saved as the unification of the system makes it easier to detect fraud due to a comprehensible database of health care charges (4% of total health care expenditure) (Galvani et al. 2020).
Introducing negotiation power for the US Department of Health and Human Services to achieve lower drug prices on behalf of beneficiaries would open up the possibility for price regulation and savings of more than $180 billion a year (Galvani et al. 2020). Lower drug spending could be the second largest source of savings (Cai et al. 2020). Furthermore, the use of generic medications would be beneficial as well because their prices are 70 to 90% lower than of the brand product. However, 85% of all prescription drugs sold are generics and they only account for 10% of total national health expenditures. That is why it is debatable on whether the savings would be as high as predicted (Blahous 2018).
The expansion of health care coverage will reduce the number of uninsured individuals and lead to an increase in health care utilization. Two scenarios are possible. Either, the newly insured population will be compromised of young and healthy adults and the utilization might not grow to or exceed the current level of insured (Cai et al.

2020). Or the newly insured population will be more likely to have undiagnosed comorbidities and conditions that would increase health care spending compared to insured people (Galvani et al. 2020).

3 Evaluating Substantive Desirability: Effects of Medciare for All on the Health Care System

The enactment of the M4A Act could lead to 13% savings in national health care expenditure and thus $458 billion annually. Furthermore, it could save more than 68,000 lives and 1.73 million life-years every year compared to the status quo. Other studies suggest that M4A Act would cost much more and save much less than the estimate (Blahous 2018; Cai et al. 2020).

Financial struggles will be reduced for hospitals serving low-income communities because the burden of unpaid bills will be eliminated through the implementation of fixed reimbursement rates and the relief from administration tasks.

All providers are unified under one financial framework and the in-network and out-of-network structure would be erased. Therefore, there will be no need to turn away or discriminate against individuals based on their insurance status anymore. Additionally, patient choice will be expanded instead of restricted. The adoption would decrease fragmentation and the issues coming along with that such as inefficacy of chronic disease management, and delays in acute care. By disconnecting insurance from employment, it ensures the security of receiving health care services (Galvani et al. 2020).

Universal coverage removes access barriers and provides health insurance coverage for the uninsured and expands covered services (dental, vision, and hearing) for all participants. Avoiding cost-sharing including deductibles, coinsurance, or copayments for individuals further leads to an increased utilization of health care services. The downside is the increase in health care costs and the moral hazard threat emerging out of the increased health insurance coverage (Blahous 2018).

The single-payer system incentivizes the expansion of preventive programs for chronic diseases as it facilitates the continuity of care. High health care costs for latter treatments are avoided and this also leads to positive economic externalities by enhancing workforce productivity. Furthermore, reduced workload in administration leads to a greater focus on patient care and increased career satisfaction. This is necessary because providers need more time to treat the higher demand due to increased insurance coverage (Galvani et al. 2020).

The intervention of the federal government in different areas like health professional education, innovation, and capital expenditures through a national health budget could cause a crowd-out of private-sector investments (Blahous 2018).

4 Evaluating Political Feasibility

4.1 Political Barriers and Opportunities for Enactment

Political barriers and opportunities for enactment are similar to the ones the ACA had experienced and can be seen for any implementation of a system-wide reform. Benefits

package, design, provider reimbursement rates, and scope of the services covered need to be determined (Liu and Brook 2017).
One major political barrier consists of the history of attempts to implement universal health care, which have constantly failed in the past. Reasons for failure include opposition from health care stakeholders, distrust in government, fear of ‘socialized medicine’, and fragmentation of the system. Over time, other systems have been implemented (Medicare, Medicaid, ACA) that now build a well-accustomed status quo and need to be considered when implementing a new system. It is necessary to build based on the complex and fragmented system or replace the system completely. Moreover, the expansion of Medicare, which was the hidden goal when it was implemented, never was accomplished and further lead to a turn away from single-payer reform. The implementation of Medicare for All entails a huge amount of change as it disrupts financing, insurance coverage, and provider payment. This is especially difficult as past health care reforms followed the approach of incrementalism. Therefore, stakeholder opposition and public anxieties will be a lot higher than in prior health care reform approaches (Oberlander 2019).
The American political system regarding health reform is characterized by hyper-partisanship leading to issues for collaborative work in Congress and makes the passing of health care reform incredibly difficult (Obama 2016). A shift of the Democratic party to the left and a new willingness for federal initiatives emerging out of the failed efforts the Trump administration took to repeal and replace the ACA would make Medicare for All more likely. One opportunity to pass Medicare for All lies in a mass movement to break down barriers, but this is less likely. Another opportunity would be that the ACA would be declared unconstitutional and a president supporting Medicare for All has majorities in Congress (Oberlander 2019). Nevertheless, Medicare shows that a single-payer and government-funded health care reform can pass Congress, and can also be widely accepted in the population and political environment (Galvani et al. 2020).

4.2 Stakeholder Analysis and Public Opinion

Medicare for All is a disruptive health care reform approach and therefore receives strong opposition or support from different stakeholders. It is a partisan divided health care reform with 79% of the Democrats favor it and 71% of the Republicans oppose it (Henry J Kaiser Family Foundation 2020).
A study conducted among physicians in four states (New York, Texas, Colorado, Mississippi) found that 43.8% of physicians favored a single-payer system, and that geography may influence attitude towards health care financing options and political beliefs. Their primary concerns are centered around the reduction of provider payments and a rise in workload through the broader insurance pool (Khan, Spooner and Spotts 2018).
At first sight, employers could favor M4A as it reduces the amount of money paid for employees’ health insurance and strengthen the workforce through broader coverage (Galvani et al. 2020). However, they will more likely oppose the M4A Act because they fear higher payments due to tax increases that emerge out of the transfer from a private to a public financed system.
The American Hospital Association opposes Medicare for All and argues that the system relies on private patients to subsidize the care of patients covered by Medicare and

Medicaid, since reimbursement are not sufficient to cover expenses (Galvani et al. 2020).
The public is more likely to support a National Medicare for All Plan (54% in April 2020). Hereby, terminology is important as terms like ‘universal health coverage’ or ‘Medicare for All’ have greater support as they are associated with positive experiences, than the term ‘socialized medicine’. A major risk to this positive public opinion is the uncertainty of approaches of the M4A Act and support drops when understanding certain impacts. For instance, 60% would oppose the reform when it would require most Americans to pay higher taxes. As this is most likely due to the financing of the reform, deeper knowledge about it could change public opinion in an unfavorable way (Henry J Kaiser Family Foundation 2020).
Health insurance companies and pharmaceutical industries typically oppose the health care reform approach as it intends to eliminate private insurance and cut down drug costs (Galvani et al. 2020).

4.3 Costs of the Approach and Finance

Different approaches amount to different federal and national health care spending depending on the design of the health care reform (Blumberg et al. 2019). Galvani et al. suggest that the M4A Act would cost $3,034 billion annually (Galvani et al. 2020). It is unclear whether the Medicare reimbursement rate is sufficient to cover health care costs. Projections say that over 80% of hospitals will lose money by treating Medicare patients, which would increase as every patient is paid under these Medicare rates (Heffler et al. 2018). Losses from Medicare patients that are not fully reimbursed (89% in 2014) cannot be compensated through private insurance reimbursement rates (Blahous 2018). This would lead to a reduced supply of health care services due to higher demand. This could lead to an inadequate supply of services and could affect the quality as well (Liu and Brook 2017). Higher rates can range between current Medicare payment rates and private insurance payment rates, but it remains uncertain whether provider capacity would be sufficient for the increased demand (Thorpe 2016). Blahous predicts that the federal cost of enacting the M4A Act would be so high that even doubling all federal individual and corporate income taxes would be insufficient to fully finance the plan. The plan would not be fully financed even assuming that provider payment rates are reduced by over 40 percent for previous private insured patients. Such large increases in federal taxation or debt would not endure federal commitment (Blahous 2018).
The Urban institute found that federal and national spending would increase. The source of funding would shift from private and state spending to federal spending as the federal government would take over the spending currently provided by employers, households, and state and local governments. National spending would increase through increased utilization by the previous underinsured and uninsured (Blumberg, Holahan and Simpson 2019). Different taxes will finance the federal health care expenditures as huge sources for federal revenues ease away as households, employers, and states, are relieved from Medicare and Medicaid expenditures (Galvani et al. 2020).
Cai et al. conducted a systematic review including 22 single-payer plans. The findings show differences in net savings (7% to 15%) and net costs (2% to 19%) based on different input assumptions in the first year. In the first year, 19 of these analyses estimate decreasing health expenditures and long-term savings through simplified

billing, decreased drug prices, and global budgets. They conclude that a single-payer system reduces health expenditure and achieves lower net health care costs through eliminating private insurance (Cai et al. 2020).

5 Conclusion

A single-payer approach still seemed to be politically unfeasible when the Obama Administration took on the challenge of implementing health care reform in 2010. When Senator Sanders introduced his plan of Medicare for All in his election plan in 2016, the single-payer approached emerged to the center of health care debate (Oberlander 2019). Medicare for All would cover all Americans and would end the fragmentation of the insurance system. The elimination of the insurance-employment relationship is especially important when looking at major health crises like the current COVID-19 pandemic. Unemployment rates are increasing rapidly due to measures taken to flatten the curve, and individuals are losing their insurance coverage and thus, affordable access to care (U.S. Bureau of Labor Statistics 2020). A single-payer system will reduce access barriers and provide patients with necessary services. Therefore, universal health care can improve health outcomes and could result in positive economic outcomes as it contributes to a healthier and more productive workforce.

The government bears the financial responsibility for health care (Blahous 2018). The impact on national health expenditure regarding the implementation of M4A remains unclear, uncertain or varies depending on different approaches taken to estimate costs to set up the single-payer system. Analysts believe that the in the M4A Act proposed funding transfer from private spending to public budgets by Bernie Sanders may not be sufficient to cover the actual costs appearing (Blahous 2018). However, the majority of approaches show a reduction in health care expenditure and an initial 3 and 4% net cost reduction with the possibility of growth over time (Cai et al. 2020). Higher quality can be provided at lower costs within a Medicare for All approach with efficient investments in preventive care, implementation of simplified payment procedures, and increased negotiating power for drugs.

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Assessing the Impact of Alternative Payment Models on Quality and Costs

Corinna Kraus

The United States ranks the highest in the world on health care expenditures, but at the same time, it is ranked amongst the ones with the lowest performance outcomes. The Affordable Care Act of 2010 and the 2015 Medicare Access and CHIP Reauthorization Act aim to implement new ways of providing quality care, push innovation, and lower costs for patients. Alternative payment models promote communication and coordination of care among teams of providers, interoperability, and linking payment and performance. Studies on alternative payment models have found that they lead to an increase in the value in health care by reducing costs and keeping the quality steady.

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1 The Need to Reform Reimbursement

United States (U.S.) health care spending increased 3.9% to reach $3.5 trillion in 2017, which comes up to $10,739 per person (CMS, 2018). With healthcare consuming almost one-fifth of the U.S. economy, the burden of healthcare expenditures continues to crowd out funds for other society essentials like education, infrastructure, and social security programs. Despite the fact that the U.S. ranks the highest in the world on healthcare spending, the U.S. ranks lowest on health performance indicators among eleven comparable nations.

Poor outcomes and continuously growing national health care spending push public and private health care payers, providers, and other stakeholders to find innovative and lower cost ways of providing quality care. To achieve the goal of better care, smarter spending, and healthier people, the U.S. health care system must substantially reform its payment structure to incentivize quality, health outcomes, and value over volume. An alignment like this requires a fundamental change in how health care is organized and delivered and requires the entire health care ecosystem to work together (Chee et al., 2017, p. 2197).

While provider organizations, insurance companies, and government payers have attempted to improve quality and lower cost since the 1990's, the Affordable Care Act (ACA) launched exceptional reforms to improve healthcare value. A wide spectrum of payment models has been introduced that balance financial rewards and risks based on provider performance on specific measures, such as clinical quality, patient experience, and cost (Chee et al., 2017, p. 2200).

In April 2015, Medicare Access and CHIP Reauthorization Act (MACRA) re-pealed the longstanding and unsuccessful Sustainable Growth Rate formula for Medicare and widely adopted alternative payment models (APMs), demonstrating the bilateral and far-reaching commitment to valued-based payment solutions. Many private insurers are closely following Medicare's lead (Jones et al., 2019, p. 723).

This paper first highlights the incentives created by reimbursement systems in health care, which is followed by a presentation Advanced APMs and the Merit-Based Incentive Payment System (MIPS). Subsequently, the impact of APMs on quality and costs will be discussed.

2 Addressing Quality and Costs – The Perfect Reimbursement System

Methods of payment constitute an incentive contract that links the individual physician with the larger organization – be it an insurer, a medical group, or a governmental health benefits program. Therefore, the analysis of physician payment falls within the agency theory - a larger economic literature on contracts and financial incentives. Incentive contracting is the effort by one individual or organization (the principal) to induce and reward certain behaviors by another individual (the agent). There is a variety of mechanisms to initiate the desired behavior, the most notable one being financial rewards. The difference between the level of payment (the total amount expected to be paid by the principal to the agent) and the structure of payment is an important distinction. The latter is the manner in which payment is linked to specific measures of performance. It is designed to provide the highest reward to the agent at the lowest cost to the principal (Robinson, 2001, pp. 150).

Incentives play a major role in creating an effective reimbursement system. The perfect reimbursement system in health care motivates service providers to provide patients with medically necessary and high-quality services. In addition, it should increase efficiency of care by balancing incentives to provide services and to control costs. It should also increase transparency in the provision of services. Ideally, all of these components should be implemented with little administrative effort (Geissler et al., 2012, p. 633).

Before the ACA was introduced in 2010, the U.S. healthcare system was dominated by 'fee-for service' (FFS) payment systems, especially in the outpatient setting (Obama, 2016, p. 525). However, FFS has proven to be one of the worst mechanisms for paying physicians (Robinson, 2001, p. 149). It is a retrospective payment system, which refunds the service provider a fixed reimbursement for each individual service performed. Several services can be billed per patient case and period (Hajen, Paetow, Schumacher, 2017, p. 151). By reimbursing per unit of care provided without accounting for quality of care, the traditional FFS payment system incentivizes volume of services, which may contribute to high healthcare costs without coinciding with good outcomes. Rewarding the provision of inappropriate services results in an input-intensive, gold-plated form of service (Robinson, 2001, p. 149). By paying each provider separately for their services, FFS can encourage fragmented and uncoordinated care that further increases health care costs and care inefficiencies (Dale et al., 2016, p. 2346). It also penalizes healthcare organizations and professionals who find ways to deliver care more efficiently and fails to reward those who improve quality of care (Obama, 2016, p. 525).

Diverse reimbursement methods offer variable incentives that lead to different impacts on quality and costs. Prospective forms of payment lead to a more cost-conscious form of service provision by separating revenues from costs incurred. In the case of a subsequent payment, the supplier bears a low financial risk, which fails to incentivize deliberate use of resources or prevention. By blending elements of prospective and retrospective payment of FFS, salary, capitation, and profit sharing, the American healthcare system exhibits interesting compensation systems to create an effective payment system that benefits all players involved. By mixing price with nonprice mechanisms, incentives that sheer versions of FFS, capitation or salary alone generate, can be balanced and moderated. Therefore, payment mechanisms are embedded in and supported by nonprice mechanisms. Nonprice mechanisms can monitor and motivate behavior that may have financial consequences, but rely more directly on screening, socialization, profiling, promotion, and practice ownership (Robinson, 2001, p. 149).

The ACA is moving the health care system toward 'alternative payment models' that hold health care entities accountable for outcomes. Alternative payment models have already been widely introduced as value-based payment (VBP) systems in Medicare. VBP systems tie FFS payments to the quality and efficiency of care delivered by healthcare organizations and professionals. In addition, there is now increased transparency around the pricing and the quality of care which fosters a more competitive market (Obama, 2016, p. 528).

3 Alternative Payment Models

A reformation of the traditional FFS system was much needed, therefore Alternative APMs were designed. Like the VBP, they reform FFS by tying payments to quality.

They also require communication and coordination of care among teams of providers. While under FFS, each service performed (e.g. each test, visit, or treatment) is reimbursed individually, however, under an APM, payments are organized to promote coordination of care, efficient use of resources, and improvements in quality (Gillen, 2018).

APMs are, according to the Department of Health and Human Services, *"payment approaches, developed in partnership with the clinician community, that provide added incentives to deliver high-quality and cost-efficient care. They can apply to a specific clinical condition, a care episode, or a population."* (Department of Health and Human Services, 2016, p. 77008)

Examples of fundamental concepts of APMs include bundled payments, patient-centered medical homes, and ACOs (Gillen, 2018). A bundled episode payment is a prospective payment method under which the amount received by a provider for all the care related to a specific condition over a specific time is predetermined. It provides a financial incentive to manage a patient's treatment efficiently throughout the entire episode of care across multiple providers. It allows the providers flexibility in the resources they use during the episode. While bundles encourage and support providers to deliver care more efficiently, they could also create incentives for the delivery of more bundles (Muhlestein, Saunders and McClellan, 2017).

A patient-centered primary care medical home focuses on improving the health of communities and populations, while increasing the value of healthcare. This value includes increased quality of care, improved population health, lower cost, and fewer inequalities compared to healthcare systems not based on primary care. This is achieved by integration, coordination, relationships, sustained partnerships, and new ways of organizing health care practice (Stange et al., 2001, p. 601).

Accountable care is an important mechanism used by public and private payers when it comes to aligning health care provider payments with efficient care for defined patient populations. ACOs are groups of doctors, hospitals, and other health care providers that come together to provide coordinated high-quality care to Medicare patients. Coordinated care ensures that patients get the right care at the right time, avoids unnecessary duplication of services and prevents medical errors. The ACO shares savings for the Medicare program when it succeeds both in providing high-quality service and effectively spends health care dollars (CMS, 2019a).

Successful ACOs have used a number of enabling mechanisms to address care coordination and patient safety, thus managing clinical risk. To deliver integrated patient-centered medical care, physicians and other health professionals must work together more closely, share data, and better coordinate care. Additionally, providers must adhere to evidence-based clinical care protocols that manage and minimize risk. Furthermore, ACOs must ensure that they can track and report on quality measures to understand and minimize their clinical risk. The integration of data via electronic health record (EHR) is the key to track and manage clinical risk. EHRs have made it easier for providers and hospitals to assess a patient's medical conditions and ensure that the care provided is appropriate and safe. One of the key goals of the ACA for ACOs is linking any payment or financial incentive to quality measurements and performance requirements to ensure that providers are lowering healthcare costs through delivering improved care without limiting access to necessary care (Lennox-Chhugani, N. et al.,

2015, p. 65). The commonality among APMs are that they promote coordination between providers and reduce of inappropriate services.
While ACOs are important APMs, other APMs with accountability for person- or episode-level outcomes and costs are also expanding. Growing APMs, in addition to shared-savings and shared-risk ACOs, include episode-based models and partially- and fully-capitated payments for patient populations. These trends have been reinforced by the passage of MACRA, which contains new incentives for many physicians to join APMs (Muhlestein, Saunders, McClellan, 2017).
MACRA repealed the Medicare sustainable growth rate methodology and implemented a new approach to payment called the Quality Payment Program (QPP). The QPP is a cost containment strategy aiming to shift Medicare payments from volume to value. Its foundation is high quality, patient-centered care followed by useful feedback in a continuous cycle of improvement. It rewards the delivery of high-quality patient care through two avenues: Advanced APMs and the MIPS (Department of Health and Human Services, 2016, p. 77008). Most providers in the Medicare program are subject to MIPS, though there are exceptions for small practices and providers new to Medicare. Providers in Advanced APMs are not subject to MIPS - they participate in the Advanced APM track of the QPP (Gillen, 2018).
To enable these reforms on the payment system, the Health Care Payment Learning & Action Network (LAN) was established in 2015. It is a collaborative network of public and private stakeholders, including health plans, providers, patients, employers, consumers, states, federal agencies, and other partners within the health care community. The LAN does not only incorporate a common framework and align approaches to payment innovation, but it also shares information about successful models and encourages best practices. This leads to reduced barriers and accelerates the adoption of APMs. The APM Framework classifies four categories: Category 1 includes traditional fee-for-service or other legacy payments not linked to quality; Category 2 includes pay-for-performance or care coordination fees; Categories 3 and 4 contain shared savings, shared risk, bundled payments, or population-based payments (HCP LAN, 2017).
In 2017, 34% of U.S. health care payments were tied to APMs. Shared savings, shared risk, bundled payments, and population-based payments have seen a steady increase from two years ago at 23%. While payments have strongly decreased in Category 1 and slightly in Category 2, there has been an increase in payments in Category 3 and 4 within the past three years (HCP LAN, 2018).

3.1 Merit-Based Incentive Payment System

MIPS is a modified FFS system. It represents a new program for certain Medicare-enrolled practitioners that focuses on quality, clinical practice improvement activities, resource use (cost), and meaningful use of certified electronic health record technology (CEHRT). Its purpose is to support interoperability and advanced quality objectives in a single, cohesive program that avoids redundancies. MIPS was designed to update and consolidate previous programs, including the Physician Quality Reporting System, the Physician VBP Modifier, and the Medicare EHR Incentive Program for Eligible Professionals (Department of Health and Human Services, 2016, pp. 77009).

Performance is measured with the help of the MIPS score, which consists of four components: quality, improvement activities, cost, and meaningful use of CEHRT (also known as promoting interoperability). Each component is weighted differently, with quality being the most heavily weighted module. All components together create a single MIPS score, and then the score is compared to a benchmark to determine whether the eligible clinician receives an upwards or downwards adjustment on their Medicare reimbursements (Gillen, 2018). A downside is the comparison of quality between providers is hindered because the clinicians select their own measures. Therefore, there is no standardization, and reporting is burdensome and complex.

3.2 Advanced Alternative Payment Models

MACRA established significant financial incentives for physicians to participate in advanced APMs. Advanced APMs contribute to better care and smarter spending by allowing physicians and other clinicians to deliver coordinated, customized, and high-quality care to their patients within a lean payment system (Department of Health and Human Services, 2016, p. 77010).

To be considered an advanced APM, an APM must meet all three of the following criteria. Firstly, the APM must require participants to use the CEHRT in order to efficiently capture and share patient data. Secondly, the APM must tie payments for covered professional services to quality measures. And thirdly, the APM must either meet the requirements of a primary care medical home or apply a two-sided risk methodology. A primary care medical home must focus on improving access, communication and care coordination, and assignment of individual to providers. Two-sided risk means that a monetary penalty is enforced if actual expenditures exceed expected expenditures (Gillen, 2018).

APMs that meet the criteria to be advanced APMs provide the pathway by which eligible clinicians who would otherwise participate in MIPS can become Qualifying APM Participants (QPs), and therefore earn incentive payments for their Advanced APM participation. QPs have a certain percentage of their patients or payments through an advanced APM. QPs are excluded from MIPS and receive a 5% incentive payment for a year beginning in 2019 through 2024 (Department of Health and Human Services, 2016, p. 77013).

In 2018, there were nine payment models sponsored by the Centers for Medicare and Medicaid Services (CMS) that qualified as QPP Advanced APMs. One payment model was the Medicare Bundled Payments for Care Improvement Advanced Model (BPCI Advanced). Its overarching goals were redesigning care, increase provider-patient-caregiver engagement, data analysis and feedback, and financial accountability. The BCPI model aims to support healthcare providers who invest in practice innovation and care redesign to better coordinate care, improve quality of care, and reduce expenditures while simultaneously improving the quality of care for Medicare beneficiaries (Gillen, 2018).

Other examples of QPP Advanced APMs from 2018 were Comprehensive Primary Care Plus, Comprehensive Care for Joint Replacement Payment, Medicare Shared Savings Program ACOs, Next Generation ACO Model, and the Oncology Care Model (two-sided Risk Arrangement).

Comprehensive Primary Care Plus is a national advanced primary care medical home model that aims to strengthen primary care through a regionally based multi-payer payment reform and care delivery transformation. It includes two primary care practice tracks with incrementally advanced care delivery requirements and payment options to meet the diverse needs of primary care practices in the U.S. Redesigning the care delivery ensures practices in each track have the infrastructure to deliver better care to ultimately result in a healthier patient population. The multi-payer payment redesign will give practices greater financial resources and flexibility to make appropriate investments to improve the quality and efficiency of care, and reduce unnecessary health care utilization. The model will also provide practices with a robust learning system, as well as actionable patient-level cost and utilization data feedback to guide their decision-making (CMS, 2019b).

4 The Impact of Alternative Payment Models on Quality and Costs

While there is no precise evidence on the implementation and effectiveness of the advanced APMs and MIPS introduced with the QPP, there are studies on other APMs introduced after the ACA such as ACOs or bundled payments.

The most consistent associations between ACO implementation and outcomes were reduced inpatient use, reduced emergency department visits, and improved measures of preventive care and chronic disease management. Studies evaluating patient experience or clinical outcomes of care showed no evidence that ACOs worsen outcomes of care (Kaufmann et al., 2019, p. 255).

In the first year of the ACA, CMS designated over 250 organizations as ACOs. The following entities formed these organizations: multispecialty physician groups, physician–hospital groups and health insurance and provider groups. One of the fundamental assumptions in developing ACOs was that by increasing care coordination, ACOs would help reduce unnecessary medical care and improve health outcomes, leading to a decrease in utilization of acute care services. Initial evidence from ACOs affirmed these assumptions. The original 32 pioneer ACOs were successfully meeting the quality measures, and 25 of them had lower risk-adjusted readmission rates compared to the benchmark rate for all Medicare FFS beneficiaries. In California, a partnership between Blue Shield, Dignity Health System Hospitals, and Hill Physicians Group achieved savings of $20 million through a package of interventions, including integrated discharge planning, care transition support, and patient engagement. There was a 10% reduction in costs per patient compared to members not in the ACO pilot in California in 2010 during the first year of the pilot (Lennox-Chhugani et al., 2015, p. 61).

Kelleher, et al. (2015, pp. e582) examined cost saving and changes in the quality of care for Partners for Kids (PFK), a Pediatric ACO serving an Ohio Medicaid population. They measured the historical cost of care for PFK and gathered comparison statewide Medicaid FFS and managed care cost histories. Between 2008 and 2013, fifteen Agency for Healthcare Research and Quality Pediatric Quality Indicators and four indicators targeted by PFK were used to assess changes in quality of care measures. They concluded that PFK improved the value of care for Medicaid children because it reduced the growth in the cost of care relative to the growth experienced by other Ohio Medicaid enterprises serving children. At the same time, quality of care measures held steady, with a mix of several small improvements and minor declines. Therefore, PFK delivered on the promise of the ACO to reduce the growth rate of health care cost while improving or maintaining the quality of care.

A study on a 2012 established multi-payer Comprehensive Primary Care Initiative investigated whether several forms of support would produce changes in care delivery. The study anticipated that several forms of support would lead to an improved performance and reduced cost of care at 497 primary care practices in seven regions across the U.S. Support included the provision of care-management fees, the opportunity to earn shared savings, and the provision of data feedback and learning support. In 2014, or two years into the program, the practices reported improvements in approaches to the delivery of primary care in areas such as management of the care of high-risk patients and better access to care. Changes in average monthly Medicare expenditures per beneficiary did not differ significantly between initiative and comparison practices when care-management fees were not taken into account. The only significant difference in other measures was a 3% reduction in primary care visits for initiative practices relative to comparison practices. Additionally, two of the six fields of patient experience showed a small improvement in initiative practices relative to comparison practices. After two years, the participating practices reported progress in transforming the delivery of care. But at this point, these practices have not yet shown savings in Medicare expenditures, nor have they shown a significant improvement in the quality of care or patient experience (Dale et al., 2016, p. 2345).

Ems et al. (2018) have shown that quality of care was not compromised under a partial-capitation APM.

A study from Navathe, et al. (2017, pp. 214) followed 3942 patients with lower extremity joint replacement at Baptist Health System (BHS), which participated in Acute Care Episodes and BPCI. They examined average Medicare payments per episode, readmissions, emergency department visits, prolonged length of stay, and hospital savings from changes in internal hospital costs and post-acute care spending (PAC). Between July 2008 and June 2015, average Medicare episode expenditures declined 20.8% for 3738 episodes of joint replacement without complications and declined 13.8% for 204 episodes of joint replacement with complications. Readmissions and emergency department visits dropped by 1.4%, while episodes with continued length of stay decreased 67%. The severity of patient illness remained stable. By 2015, 51.2% of overall hospital savings had come from internal cost reductions, and 48.8% came from PAC spending reductions. Decreases in implant costs were down on average 29% per case and contributed the greatest proportion of hospital savings. Average PAC spending dropped 27% per case, largely from reductions in inpatient rehabilitation and skilled nursing facility spending, but only when bundles included financial responsibility for PAC. During a period in which Medicare payments for joint replacement episodes increased by 5%, bundled payment for procedures at BHS was associated with substantial hospital savings and reduced Medicare payments. Decreases in PAC spending occurred only when it was included in the bundle.

5 Discussion

To date, there is evidence that APMs and ACOs can increase value by lowering expenditures while the quality improves or stays the same. As shown, a wide range of ACOs can improve measured quality, but fewer ACOs have successfully combined quality improvement with significant spending trend reductions. Given the challenges of reforming care delivery to improve outcomes and lower spending, there is an increasingly urgent need for better evidence about what has worked for the variety of successful ACOs. To accelerate progress with ACOs, there is a need for more evidence on which models produce the best results for organizations with different circumstances and characteristics – no matter if the organization is in a rural or urban location, large or small, or physician- or hospital-led (Muhlestein, Saunders and McClellan, 2017). It has also shown that the longer an organization participates as an ACO, the more experience the organization has in how to be efficient, resulting in greater savings. Therefore, results in the newest implemented APMs may only be seen after a couple of years into the program (Kaufmann et al., 2019, p. 269). While APMs and value-based payments offer the promise to deliver quality care with improved coordination at reduced cost, they also introduce the possibility of under treatment.

As APMs spread, more health care organizations are operating under multiple APMs. One common overlap is the use of bundled episode payments for specific services within an ACO arrangement. Evidence suggests that bundles improve efficiency within a defined episode, while ACOs can help improve population health and decrease overall health care spend. For example, a joint replacement bundle could support the orthopedic surgeon to coordinate care for the episode and provide an efficient, high-quality intervention, while the ACO program would encourage the broader organization to address the patient's disease progression through primary care and care coordination, and ensure the patient only receives the surgery when necessary.

APMs that feature increasing accountability for improving patient care and lowering costs continue to expand. Their impact will likely grow as providers are subject to greater risk and develop the competencies to succeed. However, the payment model is not an end in itself. To achieve better value across the American health care system, more progress is needed to refine and align APMs, and to help all types of health care providers develop the capabilities needed to succeed (Muhlestein, Saunders and McClellan, 2017). QPP is a great step in increasing overall value and learning effects of APMs as payments. It is also helpful in learning that two-sided risk arrangements promote the implementation of CEHRT, communication and coordination of care among teams of providers, efficient use of resources and quality (Gillen, 2018).

6 Conclusion

A reform in the provider payment system in the U.S. health care was much needed. The ACA and the MACRA solidified the role of value-based payment in Medicare. Modifying FFS in the outpatient setting to incentivize quality and cost savings was an important step in increasing value in health care. Moving away from a supply-driven health care system organized around physicians and redirecting to a patient-centered system organized around what patients need shifts the focus from the volume and profitability of services provided to the final patient outcome. The majority of APMs rely on FFS Payment with shared savings and shared risk payment structures. Additionally, mixing price with nonprice mechanisms is important to contain undesirable incentives. APMs embed payment mechanisms and support them by nonprice mechanisms. The nonprice mechanisms monitor and motivate appropriate behavior that may have financial consequences, but rely more directly on screening, profiling, promotion, and practice ownership.

The key cost saving is coordinating care and also tracking and using data. APMs support these mechanisms and therefore lead to a greater value in health care. APMs do in fact lead to cost savings, but an improvement in quality could not be proven. Measuring quality in health care will always be challenging, because outcomes often rely on the participation and cooperation of the patient and the severity and acuity of the patients' illness.

APMs undoubtedly have a positive impact on the delivery of health care services. Going forward, it will be important to continue monitoring and using data analysis to evaluate its effectiveness in health care so that APMs can be extended into the private payer sector.

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Strengths and Weaknesses of Administrated Innovations: The CMS Innovation Center

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This paper analyses the extent of innovation of the Center for Medicare and Medicaid Innovation (Innovation Center). The paper also classifies innovations and clarifies the requirements to be innovative, which include willingness, freedom, ability to innovate, and innovation management. The Innovation Center has a wide range of innovations through its classifications. When analyzing the innovation requirements, the willingness to innovate can be expected but not approved. Furthermore, the Innovation Center seems to have a high freedom to innovate through the power to expand models and construct them mandatory. Nevertheless, the freedom is restricted due to the political influences on the Innovation Center. Through the broad internal and external knowledge and its financial resources, the ability to innovate is fulfilled to a large extent. Moreover, the innovation management seems to be well-developed, as the concept includes all of the necessary steps. Even though the Innovation Center fulfils the requirements to run innovations to a large extent, the search through one big player in the payer space leads to some disadvantages, e.g. the participation of many companies enables a more diverse search. However, as this leads to higher overall costs and further disadvantages, it seems reasonable to have one central player, and the Innovation Center seems to be a good candidate. Nevertheless, there is a necessity to include stakeholders in the process of inventions.

Contents

1 Introduction

In 2010, the health expenditures of the United States amounted to 16.4% of the gross domestic product. Compared to other countries of the Organisation for Economic Co-operation and Development (OECD), this is an extremely high percentage. Additionally, key figures show that the health status of people in the US was worse than in many other OECD-countries (cf. OECD, 2018). Given these statistics, one of the actions described by the Affordable Care Act (ACA) was the implementation of the Center for Medicare and Medicaid Innovation (Innovation Center) by including §1115A in the Social Security Act (SSA) (cf. ACA, Sec. 3021(a)). This Innovation Center is part of the Center for Medicare and Medicaid Services (CMS), which is a subagency of the U.S. Department of Health and Human Services (HHS). CMS organises the oversight of Medicare and the federal part of Medicaid and engages with topics surrounding the health care of Medicare and Medicaid beneficiaries (cf. Office of the Federal Register, 2019).

The Innovation Center was implemented to achieve more innovations, therefore, the purpose of this paper is to focus on what extent the Innovation Center can meet the requirements of being innovative by classifying innovations and clarifying which requirements need to be fulfilled by an organisation to be innovative. Chapter 2 will highlight a general background of innovations, while Chapter 3 describes the working area of the Innovation Center. Chapter 4 will then assess the Innovation Center innovative capability and how it can meet the requirements of innovation. Finally, the discussion evaluates to what extent the Innovation Center is capable of developing innovations compared to other players in the health care system. In the conclusion section, this paper will summarize how the Innovation Center meets the requirements to be innovative and its strengths and weaknesses compared to other stakeholders.

2 General Background of Innovations

2.1 Differentiation of Innovations

In general, innovations can be understood as the implementation of new combinations (cf. Schumpeter, 1964, p. 100). The term ‘innovation’ can either describe the process of renewing, or the result of such a process (cf. Marr, 1980, p. 947).

The invention can be seen as the first step of an innovation and describes a new idea. This step is followed by the actual innovation. Here, the invention is used economically, which means that the invention is offered to the market or used within the organisation (cf. Burr, 2004, pp. 25-26). Literature discusses whether this action already describes the end of an innovation or whether the further use and the diffusion is also a part of the process. It seems reasonable to consider the innovation process as complete when the daily routine starts (cf. Hauschildt and Salomo, 2011, p. 20). Nevertheless, it can be argued that the process of an innovation starts at an earlier point. Marr (1980, p. 951) also includes the definition and analysis of a problem prior to the invention as steps of the innovation.

The result of such an innovation process can be differentiated in many ways. Useful criteria can be the *object area*, the *trigger*, the *level of the novelty* and the *scope of change* (cf. Vahs and Burmester, 2002, p. 73). The *object area* of an innovation can be a new or better product, a new process within an organisation, a new sales or procurement strategy, or new structures in an organisation. A further object area is a cultural innovation, which describes a change in the social interaction between individuals between and within organisations (cf. Disselkamp, 2012, pp. 21-30). When referencing the *trigger* of an innovation, there is a distinction between pull-innovations and push-innovations. While innovations based on the need of market participants are referred to as pull-innovations, innovations through research and development are designated as push-innovations (cf. Vahs and Burmester, 2002, p. 79). In addition to the differentiation in areas and triggers, *the level of novelty* is also a useful differentiation. Innovations can be basic, which includes new principles of organisation. Moreover, they can also be an advancement, a customisation, an imitation or a fake innovation, which means that they do not really have a use (cf. Pleschak and Sabisch, 1996, p. 4). Besides those possibilities to differentiate, innovations can be classified through their *scope of change*. Innovations that do not use an absolutely new principle are called incremental innovations, whereas those that are using an absolutely new principle are called radical innovations (cf. Pleschak and Sabisch, 1996, p. 3).

2.2 Requirements for Innovations

In order to achieve an innovation, various prerequisites need to be fulfilled. Those prerequisites can be designated as *willingness* to innovate, *freedom* to innovate, *ability* to innovate, and *innovation management* (cf. Disselkamp, 2012, p. 61).

The *willingness* to innovate often depends on resistance within an organisation. Innovations are usually connected to uncertainties and risks, therefore individuals, groups, or whole organisations can refuse and oppose them. Therefore, the innovation culture (the attitude towards change) plays a critical role in successfully implementing innovations, (cf. Jones and Bouncken, 2008, pp. 824-825). The *freedom* to innovate depends on the climate for innovations and the focus on innovations. The freedom requires openness, structures, and processes, which enable individuals to develop innovations (cf. Jones and Bouncken, 2008, pp. 826-827). The *ability* to innovate depends on the structure of the organisation, which should give the possibility to implement innovations in an organisation. On the other hand, it depends on the employees and their ideas (cf. Jones and Bouncken, 2008, pp. 828-830). However, in this context, the qualification of the employees is substantial (cf. Disselkamp, 2012, p. 83). Furthermore, innovations require many resources, particularly financial resources (cf. Schumpeter, 1964, pp. 102-103).

As willingness, freedom, and ability help empower organisations to innovate, *innovation management* is necessary to realise an innovation. This includes the identification and selection of ideas, as well as the preparation, realisation, and reflection of the implementation (cf. Disselkamp, 2012, pp. 84-85).

3 The Center for Medicare and Medicaid Innovation (Innovation Center)

3.1 Duties of the Innovation Center

As described in the introduction, the aim of the Innovation Center is to improve the health care system of the United States. Therefore, the Center tests innovative health care models. These models should focus on cost reduction and improvement of quality of care. In §1115a (b)(2) of the SSA, the legislator identifies possible areas for such models, such as patient-centred medical home models, care delivery models, salary based payment models, models of community-based health teams, funding of home health providers for chronic care management, and models to push the Electronical Health Records forward. To fulfil their tasks, the Innovation Center is required to collaborate with federal agencies. Furthermore, §1115a (a)(3) SSA should integrate experts and interested parties. The same legislator also identified several factors which should be taken into account when selecting models. It seems useful that the model includes the monitoring of patient care plans, in-person contact, and the model even puts the individuals at the center of the model. Furthermore, it is desirable that the models use technology to coordinate the care. Two other preferred factors identified by the legislator include the possibility to share information and the link to other payment models (cf. SSA, §1115a (b)(2)(C)). If a model meets certain requirements, it can also be expanded in duration and scope by the Secretary of the Innovation Center (cf. SSA, §1115a (c)).

In this context, the innovations run by the Innovation Center can be structured in two main types: new payment models and new care-delivery models. An example for a new payment model is the *bundled payments for care improvement initiative*. This initiative tests four models which link payments for the multiple services received by a patient during an episode of care. The aim of this initiative is to improve the coordination among providers and across health care settings (cf. Innovation Center, 2019b). An example for a new care delivery model is the *Federally Qualified Health Center Advanced Primary Care Practice Demonstration*. This innovation was established to improve the coordination of primary health care through patient-centred medical homes. These homes provide continuous, comprehensive, coordinated and patient-centred medical care in order to reduce costs and improve quality of care and patient health of Medicare beneficiaries. In order to enable this change, the providers received financial support, technical assistance, and feedback reports (cf. Kahn et al., 2016, pp. 1-2).

3.2 Classification of the Innovations Run by the Innovation Center

Activities of the Innovation Center can be classified within the process of innovation. The Innovation Center searches for new ideas and also develops innovations until they can be used by organisations. It is apparent that the Center fulfils the core steps of the process, since it presents the invention and innovation. As the ACA identifies problems, it can be assumed that the previous steps of defining and analysing the problem are complete. The Innovation Center seems to influence the diffusion of an innovation as it can expand the models under certain conditions.

The Innovation Center models can also be classified in different innovation categories. As described above, models of the Center often have the goal to change the interaction of the persons and institutions involved in the process of care. Furthermore, they are often supposed to lead to changes in the structure. Consequently, the Innovation Center should focus on innovations that can be located in the *object area* of structural and cultural innovations. The *trigger* of innovations can be the need of a market participant because interested parties are taken into account. Innovations can also originate in a new development within the Innovation Center. Hence, push- and pull-innovations are possible. When analysing the achievable *level of novelty* of the innovations run by the Innovation Center, it can be assumed that different levels of novelty can be achieved. For example, bundled payments might only be an advancement of existing kinds of payments, but new forms can have more far-reaching characteristics (cf. Carter Clement et al., 2017, pp. 227-229). Even if some models can accomplish a high level of novelty, some of the models run by the Innovation Center might end up with a lower level of innovation. For example, some models may not have a statistically verifiable effect on quality or spendings, resulting in a lower level of innovation (cf. L&M Policy Research, 2016, p. 39). Such innovations can be classified as 'fake innovations'. Depending on the model, it is expected that the *scope of innovations* can differ from incremental to radical. To summarize, payment and care delivery models can be innovations from a wide range of categories.

4 Innovation Capability of the Innovation Center

4.1 Willingness

Some indicators suggest that the Innovation Center is willing to innovate. Both Medicare and Medicaid expenditures approximately tripled from 2000 to 2017 (cf. CMS, 2018). This increase in expenditure led to the expectation that the U.S. government has to further develop the health care system. The establishment of the Innovation Center seems to be an indicator of willingness to innovate quality and cost expenditure within the healthcare system.
Despite these red flags, it cannot be confirmed that the Innovation Center has the willingness to be innovative. The innovative acting of an organisation is highly dependent on the individual behaviour of the employees within the organisation. Models of the innovation process describe what individuals are supposed to do, but they do not explain the behaviour of these individuals (cf. Klusemann, 2003, p. 60). Given this lack of information, it is necessary to analyse the innovation willingness of the individuals working for the Innovation Center. Within the framework of this paper, it is not possible to analyse this. Therefore, it cannot be proved that the Innovation Center has the willingness to innovate.

4.2 Freedom

Besides willingness to innovate, the freedom to innovate is an important factor as well. Particularly for radical innovations, it seems necessary to have the ability to develop these beyond everyday processes (cf. Jones and Bouncken, 2008, p. 819). As the innovations by the Innovation Center might also include radical innovations, it seems

necessary to develop those innovations separate from the everyday processes. Furthermore, the establishment of an organisation which focuses only on the development of innovations creates more freedom within the development process.
Another factor that gives the Innovation Center the freedom to innovate is the freedom to fulfil the steps of the innovation process. The secretary of the Innovation Center obtains the competence to expand scope and duration of running models through the ACA if the expansion is expected to improve quality without an increase in costs or if it is expected to decrease costs without a decline in quality. Furthermore, the Chief Actuary of the CMS is required to confirm that the expansion will not increase the net program spending and the coverage or provision of benefits will not be denied or limited (cf. SSA, §1115a (c)). This change reduced barriers existing in previous procedures (cf. United States Government Accountability Office, 2018, pp. 5-6). The possibility to expand models seems to grant the Innovation Center more freedom to drive innovations forward.
Additionally, the Innovation Center has the possibility to construct models mandatory for participants (cf. United States Government Accountability Office, 2018, p. 14). This competence gives the Innovation Center the freedom to fulfil the necessary steps of implementing innovations. In summary, it seems reasonable to assume that the Innovation Center has the necessary freedom to be innovative. During its implementation, it was already expected to contribute to significant innovations due to it being well equipped with power and flexibility (cf. McKinney, 2010).
Nevertheless, the promotion of innovations through an organisation seems to have some disadvantages. If governmental figures are involved in the innovation process, political considerations influence decisions (cf. Vahs and Burmester, 2002, p. 31). The fact that this applies to the Innovation Center shows the great uncertainty during the shift from the Obama administration to the Trump administration. This political shift influenced the behaviour of the Innovation Center - some models were even ceased because of the new political direction (cf. Twome, 2018, pp. 1-3). Therefore, the openness to develop innovations is not always given.

4.3 Ability

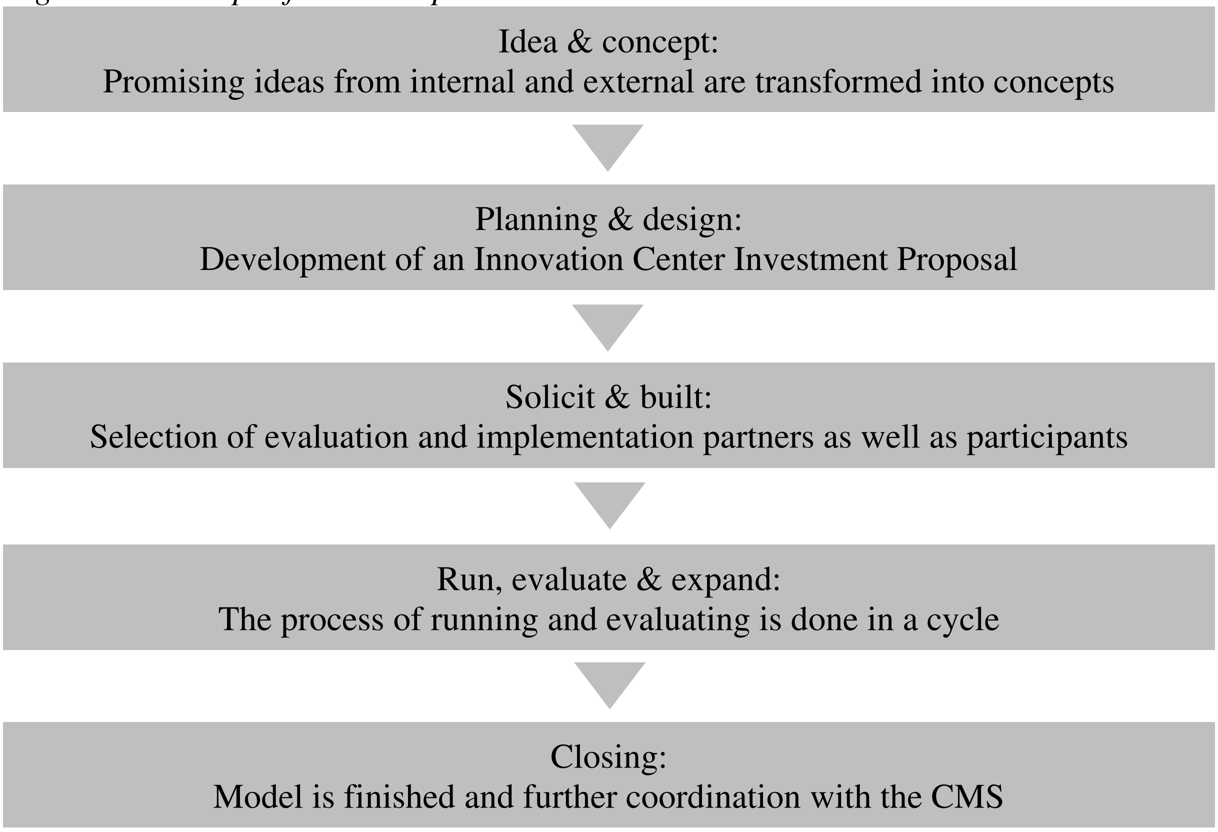
It is often assumed that governmental organisations do not have sufficient knowledge to be innovative (cf. Welsch, 2005, p. 310), and instead, people think that innovations originate from companies (cf. Nelson and Rosenberg, 2009, p. 58). Nevertheless, it is important to identify the ability of the Innovation Center to drive innovations forward. One important prerequisite for the ability to innovate is the qualification of the employees, which is described in section 2.2. In order to fulfil this, the selection of personnel was highly monitored from the beginning, ensuring the hiring of employees from within CMS and practice. The Innovation Center had 54% of its employees from within the CMS and 46% from external sources (the private sector) (cf. United States Government Accountability Office, 2012, p. 16). Besides the qualification of the employees, it is also beneficial that the Innovation Center can rely on an extremely large amount of experience from these projects due to the large number of innovation models carried out. The Innovation Center then integrates these innovation models into new projects (cf. United States Government Accountability Office, 2018, p. 19).

In addition to the diverse knowledge within the Innovation Center, systems to incorporate expertise from outside the organisation were implemented. In fact, many stakeholders' meetings were held and a method to submit ideas of innovations was added onto the Center's website (cf. Innovation Center, 2019a). The interaction of internal and external knowledge is a signficant strength of the Center. While basic innovations are often push-innovations, advancement innovations are usually pull-innovations (cf. Macharzina and Wolf, 2018, p. 740). For this reason, the implemented system enables the Innovation Center to run different levels of innovations.
Moreover, the availability of sufficient financial resources is an important factor. From 2011 to 2019, the Innovation Center was provided with $10 billion in total, and after 2019 the Center will receive $10 billion each decade (cf. United States Government Accountability Office, 2018, p. 2). The Innovation Center can freely use this budget, which leads to a high degree of flexibility in implementing models (cf. Twome, 2018, p. 1). If smaller care providers, as community-based groups, are involved in the models, it seems especially necessary to provide them with sufficient financial resources (cf. Mechanic, 2016, p. 760).
Another important factor to be considered are the stakeholders of the innovation. Each model needs participants, and whether an innovation succeeds or not depends on the providers included. It is unclear on how well the providers fulfill the requirements to be innovative, therefore further research is necessary. Especially with respect to the diffusion of an innovation, it is important to understand that the Innovation Center can urge providers to adopt innovations. Currently, the Innovation Center is limited in obliging providers (cf. Twome, 2018, p. 3), which restricts the Innovation Center from achieving innovations.
Overall, it can be said that the Innovation Center is equipped with the ability to innovate. In particular, the great number of models and the large financial budget are strengths of the Innovation Center.

4.4 Management

A concept for managing the process of innovation was developed for the models run by the Innovation Center. As Figure 1 shows, the first step is the collection of ideas and the creation of a concept. The Center has established different approaches to collect ideas from internal sources, such as CMS or HHS, and other external sources. After collection, these ideas are analysed and evaluated, and the most promising ones are transformed into concepts afterwards. The second step involves the planning and designing of the model. The model then needs to be approved through CMS, HHS and the Office of Management and Budget, followed by its announcement. Contractual partners are then selected for evaluation and implementation of the model. Following the evaluation and implementation, possible participants are informed, and agreements are completed with suitable participants. Subsequently, the model is evaluated, and the results gained from the evaluation are reported to the participants to report out key takeaways. If the model performs well, it can be expanded. In the closing step, the running and evaluation of the model is completed, and a possible proceeding is coordinated with CMS (cf. United States Government Accountability Office, 2018, pp. 28-31).

Figure 1: Concept of model implementation in the Innovation Center



Source: Own presentation based on United States Government Accountability Office, 2018, p. 10.

This concept meets all of the requirements presented in chapter 3.2. It includes a systematic process to identify and select ideas and contains process steps for the preparation, realisation and reflection of the models. Therefore, the innovation management of the Innovation Center is well-developed.

5 Discussion

The Innovation Center is capable to innovate the payment and care delivery models. At this point, the main question is if the Innovation Center is more qualified to drive innovations forward than other players. Regarding innovations in general, it seems reasonable to identify the most promising innovations through a wide variety of attempts in the market (cf. Welsch, 2005, p. 199). An advantage in doing so is the diverse search process, given so many participating companies participate (cf. Welsch, 2005, p. 313). In the American health care system, a lot of initiatives exist which originate through multiple different stakeholders. For example, a project of providers for the responsible handling of resources is completed. Another example is of a partnership between providers and payers to increase efficiency in care (cf. Smith et al., 2013, p. 124).
A disadvantage of a broad search through many participants is the higher overall economic costs for a broad search. On the contrary, the Innovation Center runs an innovation policy, which is characterised by a central player that manages the process of searching. Here, the costs for searching innovations are lower and parallel research can be avoided. This again could comprise the whole process and lead to a great amount risk (cf. Welsch, 2005, pp. 313-314).

An issue with payment projects run by market players is that a change can only be achieved if it is also lucrative for providers. A prerequisite for payment projects is the inclusion of a sufficiently large number of patients into the project with sufficient support (cf. Mechanic, 2016, pp. 756-760). As shown in chapter 4, the Innovation Center has supportive financial resources and through its innovation management, the Center can ensure cooperation. Additionally, 19.3% of the U.S. population is insured through Medicaid and further 17.2% through Medicare (cf. Berchick, Hood, Barnett, 2018, p. 1). Therefore, projects through the Innovation Center can potentially include more than one third of the US-population.
The process of innovation run by the CMS has advantages and disadvantages. The analysis performed in this paper highlights the organisational structure. Based on the steps of the innovation process, this paper concludes that the Innovation Center meets several requirements. However, there are other possibilities to analyse the capability to innovate. For instance, Utterback (1971, pp. 80-84) points out the importance of the environment, firm, and transfer between those trying to achieve innovations. Focusing on the analysis of these three factors might lead to different results when evaluating the Innovation Center. Nevertheless, even Utterback mentions that the analysis of the organisational structure of the firm is necessary to investigate the innovation capability. Consequently, the structure of the analysis utilised in this paper gives a good basis for further research on the innovation capability of the Innovation Center.

6 Conclusion

As described in this paper, the Innovation Center has several strengths and weaknesses with regards to the achievement of innovations. When analysing the extent to which the Innovation Center can meet the requirements to be innovative, it was shown that the Innovation Center fulfils many requirements which ultimately indicate that the Center is in fact innovative.
The ability to run innovations seems to be possible through different factors. First, the diverse personnel and the processes, which were implemented to collect and evaluate ideas from internal and external sources, provide the Innovation Center with a broad basis for innovations. Furthermore, it is important to note the experiences from numerous models and its vast number of financial resources. Therefore, it can be concluded that the Innovation Center has a high ability, but the success of a model also depends on the providers involved and their ability to be innovative. Second, the Innovation Center fulfils the requirement to manage innovations. As shown, there is a well-developed system of managing innovations - the system includes identifying ideas, selecting ideas, and the reflection of a model. Third, it can be concluded that the freedom to run innovations can be fulfilled on a large scale, as the Innovation Center develops innovations beyond everyday processes and is equipped with the necessary power to fulfil the steps toward innovation.
Nevertheless, the Innovation Center has some limitations in its freedom to run innovations. The political influences on the Innovation Center in particular can affect its freedom to innovate. Therefore, the politics need to be considered when evaluating how flexible the Innovation Center can be in the future. Moreover, the paper has displayed that it is important to encourage further research within the capability to innovate. In this paper, it was only possible through assumptions to show that the Innovation Center

has a willingness to be innovative, however, it was not possible to prove this willingness. It is necessary to further analyse the willingness of the employees within the organisation.

Besides the promotion of innovations through a governmental organization such as the Innovation Center, the opportunity to search for new payment and care delivery models through other stakeholders could be meaningful. Using other stakeholders could allow for a broader process of searching for innovations. However, it should be noted that such a process could be accompanied by higher overall economic costs. For that reason, it seems substantiated to control the process of searching through a central actor, such as the Innovation Center. To still allow for a broad invention search process, the strategy of including stakeholders in the process should be used as much as possible. This will allow for a broader search process at lower costs, in order to achieve the ultimate goal to "[r]educe the growth of health care costs while promoting high-value, effective care" (cf. HHS, 2010, p. 27) in the long run.

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Changes in Health Care Market Structure post ACA

Tina Zeilner

Before 2010, many U.S. citizens did not have access to affordable health care coverage. Therefore, high uninsured rates could be observed. This situation motivated the former Democratic President Barack Obama to introduce the Affordable Care Act (ACA) in 2010. One of the main objectives of this health reform was to offer citizens access to affordable care and to encourage them to get covered. After implementation of the ACA, the uninsured rate decreased, partly because of the newly designed health insurance marketplaces and partly due to the expansion of Medicaid programs in many states.

Contents

1 Introduction

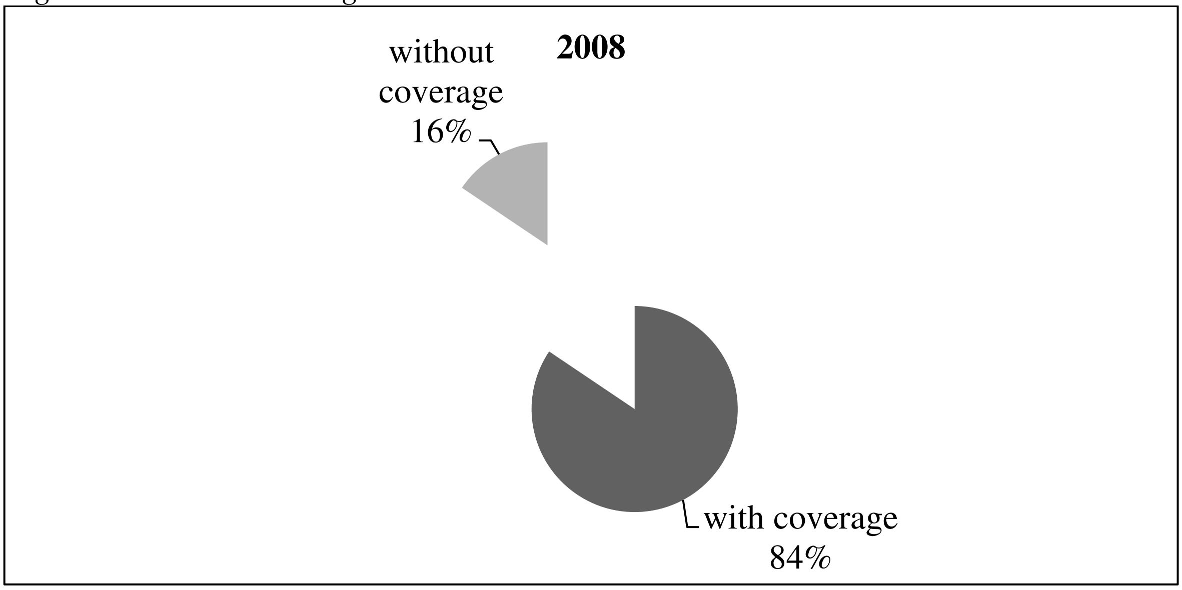
Before President Barack Obama signed the Affordable Care Act (ACA) in March, 10 2010, it was challenging for citizens to get access to affordable health insurance. The two public programs of Medicaid and Medicare were only open for people who met certain categorical criteria, such as age (Medicare) or socioeconomic status in combination with other factors (Medicaid) (Bodenheimer und Grumbach, 2016). People who did not qualify for the public programs had the choice to join a private health insurance either through their employer or as an individual (Whitmore et al., 2011, p. 595). Otherwise, there was the possibility to remain uninsured. The latter was not uncommon because especially for a risk-rated and/or sick individual, private health insurance was extremely expensive (Herring, Pauly, 2006). Consequently, people with poor health status could often not afford health coverage and had to pay medical treatment out of pocket. Unfortunately, this often led to personal bankruptcy because medical treatment in the U.S. is very expensive (Weiß 2013, p. 1292). On this account, the Democratic Party under President Obama decided to ease the situation by implementing the ACA, also called 'Obamacare'. In addition to access to affordable health coverage, the ACA aimed to facilitate the comparison between different insurance options (McKillop et al., 2018, p. 2). This resulted in improved transparency by the Health Insurance Marketplaces (HIM). The aim of this paper is to sum up how HIM affected the demand for health coverage. There will be a comparison of the number of insured people before and after the introduction of the ACA. In the following chapter, there will be an outline of the insurance structure pre-ACA. The term HIM will be defined and there will be a comparison between the insurance structures pre- and post-ACA.

2 Insurance Structure Pre-ACA

As mentioned in the introduction, there were several possibilities to get insured in the years before the ACA was implemented. There were primarily two public programs, Medicare and Medicaid, that have existed since 1965. Medicare is for elderly people who are 65 or older. To become eligible for Medicaid, an individual’s income must be very low and the person needs to meet one of several categorical criteria: having kids, being pregnant, or being a part of the elderly population (Bodenheimer und Grumbach, 2016). In 2008, there were 87.4 million residents who were covered by governmental insurance (DeNavas-Walt et al., 2009, p. 20). For people who did not qualify for these programs, there was the possibility to get insurance either by an employer, or to purchase a private health insurance plan (Whitmore et al., 2011, p. 595; Villegas, 2009). Many people were covered by their employer's health insurance; in 2008, about 58.5 percent (176.3 million citizens) were covered by their employer's health insurance (DeNavas-Walt et al., 2009, p. 20). The extent of coverage was not dependent on the employee's position in the enterprise, in fact all employees, regardless of health status and age, received equal conditions (Herring, Pauly, 2001, p. 43; Whitmore et al., 2011, p. 595). However, employers were not obligated to offer health coverage for their staff (Rice et al., 2018, p. 699). People who were not covered through their employer and were not eligible for government programs had the choice either to purchase individual private health insurance or to forego health coverage with a financial penalty. Premiums of private health insurance were dependent on health status or the previous medical history

(Gruber, 2011, p. 4). Approximately 8.9 percent were enrolled in an individual private health plan in 2008. Overall, as shown in Figure 1, about 16 percent did not have any health insurance coverage (DeNavas-Walt et al., 2009, p. 20).

Figure 1: Health coverage in 2008



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3 The Introduction of the ACA and Health Insurance Marketplaces

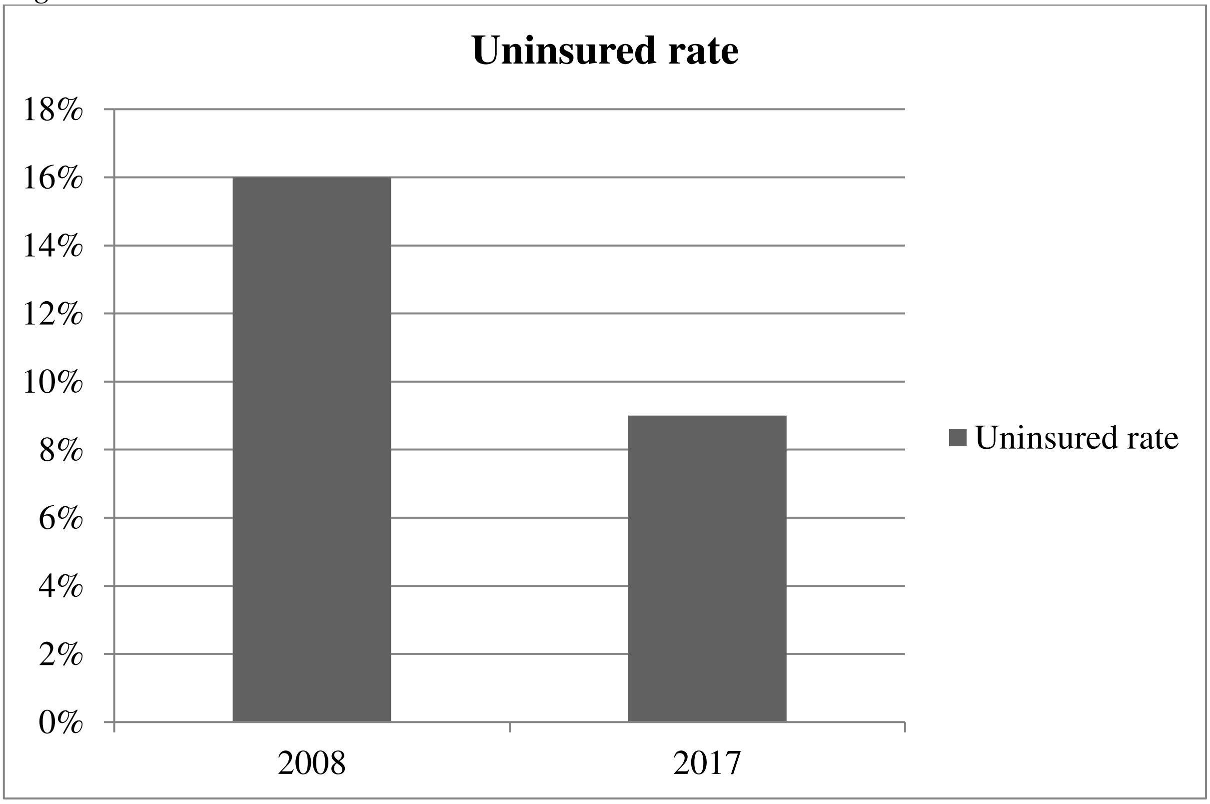
With the objective of ensuring access to affordable health insurance to fight the increasing numbers of uninsured people and avoid situations of total private bankruptcy due to extreme out of pocket expenditures, the democrats enforced their health reform called ACA. In addition to the objectives named above, the transparency of insurance policies offered should be improved. Therefore, people should easily be able to compare different coverage options (McKillop et al., 2018, p. 2). This intention should be implemented by HIM. Furthermore, these HIM are supposed to generate a clearly distinctive competition between health insurance companies. Thus, HIM should also have positive effects on the pricing of insurance policies (McKillop et al., 2018, p. 2; BMG 2018). The HIM are generally operated by the federal government, but the states could also opt to run their own HIM (Internal Revenue Service, 2019).

4 Effects of HIMs and the ACA on the Demand of Insurance Coverage

The health reform strengthened the position of insured people. This development can be traced back to stately regulated premiums: individual insurance policies were no longer determined by factors like health status or medical history. Instead, they were determined based on factors like geographic region, tobacco use, or age. For example, the pricing based on age is assessed by a federally established age curve. Four states use their own age curve to calculate premium levels based on age (McKillop et al., 2018, p. 2). These circumstances had a notable impact on the demand of health insurance policies; in 2017, there were just 28.5 million (nearly 9 percent) citizens without health insurance coverage. About 56 percent were covered by an employer-based insurance, 36.5 percent received coverage by the public health programs (Berchick et al., 2018,

p. 1). Therefore, the rate of uninsured decreased considerably. Figure 2 shows the comparison of the uninsured rate of 2008 and 2017. However, one has to bear in mind that this was also caused by the expansion of Medicaid in many states and cannot be fully attributed to the HIM.

Figure 2: Uninsured rates 2008 vs. 2017



Source: Own presentation.

5 Discussion

As shown in the chapters before, the introduction of HIM as part of the ACA facilitated the access to affordable health insurance policies. This can be observed in the decrease of the uninsured rates which were outlined and compared in chapter 4. Nevertheless, it is important to note that still about 9 percent of the American population was without insurance coverage. This might be attributed to the very low penalty that citizens who refused to purchase an insurance policy were required to pay. A penalty level of about 2.5 percent of the income was not an insurmountable barrier for citizens. Later, the penalty was completely waived (McKillop et al. 2018, p. 2). A reason behind why those citizens refused to get insured might be the lack of understanding of how the system works or underestimation of health risks (Weiß 2013, p. 1292). However, the expansion of Medicaid contributed heavily to the decrease of uninsured rates. However, American states were not obligated to offer a Medicaid expansion (Price, Eibner 2013, p. 1030). Consequently, the intention of the expansion was to make health insurance affordable for more citizens, but it failed in the states which did not join the expansion.

6 Conclusion

On the basis of statistics, it is clear that the health reform resulted a decrease of the uninsured rates in the U.S. Overall, the ACA achieved its intent to help citizens obtain affordable health insurance. The ACA offers affordable insurance coverage to a significant number of citizens who could not afford health coverage before the introduction of the ACA, particularly citizens who had a bad health status.

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Part 2: Digital Transformation – A Perspective of Different Stakeholders

Structure of the EHR Vendor Market and its Innovation Power

Alexandra Lehmann

The federal government has introduced substantial incentives for health care providers to adopt electronic health records (EHRs) through the 2009 Health Information Technology for Economic and Clinical Health Act (HITECH) after realizing that EHRs will be an important tool to deliver health care more efficiently. In order to take advantage of these incentives, hospitals and other health care providers must use EHR systems that meet the criteria of Meaningful Use (MU). As a result of these new requirements, the supply side of the EHR market changed and has led to a growing demand for EHR products. Therefore, it is important to understand how the HITECH Act influenced the structure of the EHR vendor market and its innovation power to provide meaningful EHR systems to hospitals. This paper investigates these influences with particular attention to the innovation power of the EHR systems. The analysis for the product market and geographic market shows that the EHR vendor market structure does not change through large vendors such as Epic, Cerner, and Meditech. However, this is the case with small vendors who deliver EHR systems to smaller-sized hospitals. Regarding to the development of the innovation power, no valid conclusion can be drawn due to insufficient research and contradictory study results.

Contents

1 Introduction

The health care sector has lagged behind all other major industries in the implementation of information technology, but it is finally beginning to catch up (Classen and Bates, 2011, p. 855). After the realization that electronic health records (EHR) will be an important foundational tool to improve safety and quality of care and to reduce health care expenditures, the federal government has finally implemented substantial incentives for health care providers to adopt EHR through the Health Information Technology for Economic and Clinical Health (HITECH) Act (Classen and Bates, 2011, p. 855). In order to take advantage of these incentives, hospitals and other providers must use EHR systems that meet the criteria of Meaningful Use (MU). Due to these new requirements, the supply side of the EHR market has changed and has led to growing demand for EHR products (Castillo, Sirbu and Davis, 2018, p. 2).

Therefore, it is important to understand how the HITECH Act of 2009 has influenced the EHR vendor market. For example, a decreasing number of EHR vendors could indicate that some aspects of the certification process are too challenging or that market forces naturally lead to market consolidation. On the other hand, increasing numbers of vendors could imply more competition, better alignment with market needs, or a valuable certification process (Seth et al., 2014, p. 735). Most studies focus on the impact of the HITECH Act for hospitals and physicians or on adoption rates and the associated Health Information Exchange (HIE) among providers. Only a small number of studies have investigated changes in the EHR vendor market. In addition, there is limited research analyzing the extent to which the new requirements through the HITECH Act and the market structure of EHR vendors have stimulated or slowed down innovations by EHR vendors.

The aim of this paper is to analyze how the HITECH Act influenced the structure of the EHR vendor market and its innovation power to provide meaningful EHR systems to hospitals, with a focus on the innovation power of the EHR systems among the vendor market. In the first section, the relationship between market structure and innovation power will be examined. Then the paper will discuss the main features of the EHR vendor market before and after the HITECH Act was passed. Based on this analysis, possible ways the HITECH Act altered the innovation power from the EHR vendors will be covered.

2 The Relationship Between the Market Structure and its Innovation Power

In a competitive environment three types of market structures exist. First, in a perfectly competitive market (also called polypoly), the market price and output are determined by the interaction of demand and supply (Davis and Garcés, 2012, p. 37). Firms will be sensitive to competitors' strategic variables, such as price or product quality. Second, an oligopoly market is described by only a few firms that compete in the same product market and have only few demanders for these products. In principle, each of the suppliers have some control over prices, but they have to take their competitors' predicted behavior into account (Kolmar, 2017, p. 50). Third, in a monopoly, the market is determined by a single firm that has the power to choose the total quantity to produce (Davis and Garcés, 2012, p. 44). With regard to theories of the firm, the monopoly structure is socially inefficient and prevents economic growth (Kumar and Siddharthan, 1997, p. 67). Most governments counter monopolies and have enacted legislation to control the emergence of monopolies. For example, the US government has enacted anti-trust laws to avoid monopolies (Kumar and Siddharthan, 1997, p. 67).

Innovation or innovative activities are difficult to define, which is why a variety of definitions exists in the literature. Joseph Schumpeter is often regarded as the first economist who raised attention to the importance of innovations (Rogers, 1998, p. 6). He has defined five types of innovations (Ganzer, Chais and Olea, 2017, p. 322):

- The introduction of a new product or a qualitative change in an existing product
- New processes in the industry
- The opening of a new market
- The development of new sources of supply for raw materials and other inputs
- Changes in industrial organization

According to Schumpeter, innovation is a result of the implementation of inventions and the knowledge available to firms to achieve a competitive advantage (Ganzer, Chais and Olea, 2017, p. 322). Innovations are about transformation because they represent discontinuity or a disconnect with the past (Jalonen, 2012, p. 4). Schumpeter's theory about how firms look for new opportunities and competitive advantages over current or potential competitors still have a great influence on the conceptual foundations today (OECD, 2018, p. 45). Produced by the OECD, the Oslo Manual (2018) distinguishes between innovation activities (a process) and innovations (limited to outcomes). The definitions of these terms are as follows:

> "**Innovation activities** include all developmental, financial and commercial activities undertaken by a firm that are intended to result in an innovation for the firm." (OECD, 2018, p. 68).

Therefore, innovation activities can result in an innovation, which is defined below:

> "A **business innovation** is a new or improved product or business process (or combination thereof) that differs significantly from the firm's previous products or business processes and that has been introduced on the market or brought into use by the firm." (OECD, 2018, p. 68).

Examples of characteristics of improved business functionality include increased effectiveness, resource efficiency, reliability and resilience, affordability and ease of use for those involved in the business process (OECD, 2018, p. 72).

According to economic development literature, the market structure and the size of a firm are important influences of creating innovations. At this point it is crucial to understand that market power and a firms' size do not have the same meaning. However, it is not always easy to separate them, because these two are correlated. Therefore, it is not always clear which effects of innovation power rely on the market power versus the firm's size (Vossen, 1998, pp. 88-89):

Market power refers to the ability of a firm to consistently charge prices of its products above the competitive level (Davis and Garcés, 2012, p. 162). A firm has limited market power when several substitutes exist in the same market. Furthermore, the more narrowly the market is defined, the more likely a firm will have greater market power (Massey, 2000, p. 310). Typically, a high degree of market power is associated with monopolies that have too few competitors to guarantee a competitive market price (Tremblay and Tremblay, 2012, p. 138). The most common measurements of market power are sales data to approximate the market share, and concentration measures such as the Herfindahl-Hirschman Index (HHI) (Nicholas, 2003, pp. 1037-1038). Relevant factors to determine market power of a firm are also the product market and the geographic market (Davis and Garcés, 2012, p. 163). Thereby the definition of the product and geographic market should be made together in order to ascertain how buyers respond to a price increase by switching to alternative products or alternative locations. Schumpeter has formulated two broad hypotheses regarding to the relationship between market structure and innovation: First, there is a positive relationship between market power and innovation (Kamien and Schwartz, 1982, p. 22). Monopolies generally achieve surplus profits, because they use better methods, which are not available to competitors. Therefore, monopolies can invest their superior profits in R&D activities to develop innovations, which help them to maintain the monopoly position (Kamien and Schwartz, 1982, p. 28). Compared to a competitive firm that has no superplus profits to invest, the monopolists cost curve and the product portfolio is superior (Kamien and Schwartz, 1982, p. 67). However, this argument ignores the fact that competitive pressure can provide strong incentives for innovation (Fritsch, 2018, p. 199). Because this impulse is relatively low for firms with market power, this can also lead to a correspondingly low level of innovation. Many studies have attempted to determine the relationship between market power and innovation power. The identification of such a correlation is difficult due to the fact that both the market structure and the level of innovation power can hardly be measured (Fritsch, 2018, p. 199). Such measurement problems could be responsible in that many empirical studies could not identify a statistically significant correlation. This could mean that variables other than market power have a much stronger impact on the extent of innovation activity (Fritsch, 2018, p. 200). Second, large firms are proportionaly more innovative than small firms. But Schumpeter's focus lies primarily on the effects of market power in a dynamic process of creative destruction (Kamien and Schwartz, 1982, p. 22; Vossen, 1998, pp. 88-89). He argues that things must be seen and done differently in order to achieve long-term economic growth. For example, he argues that innovation creates new structures by destroying the old ones, which is called the progress of creative destruction (Jalonen, 2012, p. 4). His second hypothesis has been extensively debated in the literature. Recent empirical research has shown that small firms tend to carry out relatively risk-free innovations in small steps (Fritsch, 2018, p. 196). An example of this includes improvements in the form of minor changes in constructions or production methods. However, regarding to a rising start-up market, this hypothesis is not applicable. Start-ups develop disruptive innovations and therefore face high risk to penetrate and remain in the market (Spencer and Kirchhoff, 2006, p. 145). Nowadays, small and large firms are often innovative in different ways. The relationship between large and small firms is particularly influenced by the characteristics of the respective market. Small and medium-sized firms can be especially successful in relatively young markets that are in early stages of the product life cycle (Fritsch, 2018, p. 197). Markets in the early phase of the product life cycle also can offer a good opportunity for successful establishment of new companies. On the other hand, large firms have a strong position in existing well-established markets and are therefore in the later phases of the product life cycle (Fritsch, 2018, p. 198). Evidence has shown that large firms are more likely to create process innovations, such as improved production efficiency, than new major changes innovations (Spencer and Kirchhoff, 2006, p. 148).

Through a shift to international markets, the process of network dynamics can also be seen as an innovation and as a further development of innovation theory. Therefore, the origin and implementation of innovation has changed from the single firm to a group of networked firms (Perks and Jeffery, 2006, p. 67). When referring to the internationalization of markets, Schumpeter's theory no longer applicable in some instances because his theory's focus was primarily on geographically limited markets. For example, there are almost no pure monopolies that prohibit monopolistic positions due to the geographical expansion, the digitization of markets, or laws (Jaekel, 2017, p. 47). Greater intellectual depth, monitoring of opportunities, competence enhancement, and value-added solutions are required to reach economic growth in the long run (Perks and Jeffery, 2006, p. 68). Studies show that cooperation is particularly useful in industries where a rapid obsolescence of technology and a significant barrier to accessing these technological developments exist, such as information and communication technology. The progress of innovation development is not limited to one actor but is a collective and interactive process that includes a wide variety of actors. Examples include companies, non-companies, and organizations such as universities and government agencies (Sun and Grimes, 2015, p. 18).

According to the definition of a business innovation, important elements include the implementation in the market and the importance of understanding how network effects function when launching an innovation. Products or services with network effects are relatively difficult to get started. For example, in the information and communication industry, the first customer of the product will see no benefit because there is no adopter to communicate with. Customers will benefit from the product only when other people start to use the interoperable service (Choi, Kim and Lee, 2005, pp. 170-171). Several studies have shown that network structures play a moderating role in the relationship between network effects and innovation diffusion.

The last section in this chapter will elaborate on indicators or measures for determining the innovation power. Some studies considered measuring the input for innovation activities like expenditures of R&D activity, whereas other studies preferred measuring the output of R&D through the obtained patent data (Kumar and Siddharthan, 1997, p. 55). However, both indicators have their drawbacks. By counting the patent data, the innovation of the content and its value is not truly captured. R&D expenditures only partially represent the expenditures on technology purchases and informative innovative activity does not get captured (Kumar and Siddharthan, 1997, pp. 55). Nevertheless, in the company environment, innovations are often measured by the amount and relative percentage of R&D expenditures. The immediate problem is that innovation is something novel by definition, and therefore it is quite difficult to measure. Despite the established measures, new indicators have been created to analyze the innovation power through different types of surveys (Smith, 2005, pp. 160-161). The complexity of innovation makes it impossible to have a concise measurement of innovation power that is suitable for all firms (Rogers, 1998, p. 21). Different firms will use different methods of innovation, and even the same firm will need to adapt and improve its innovation methods over time. The evaluation of measures leads to the conclusion that each measure has some validity, but none of them can act as a single innovation measure (Rogers, 1998, p. 21).

3 Overview of the EHR Vendor Market Before and After the HITECH Act of 2009

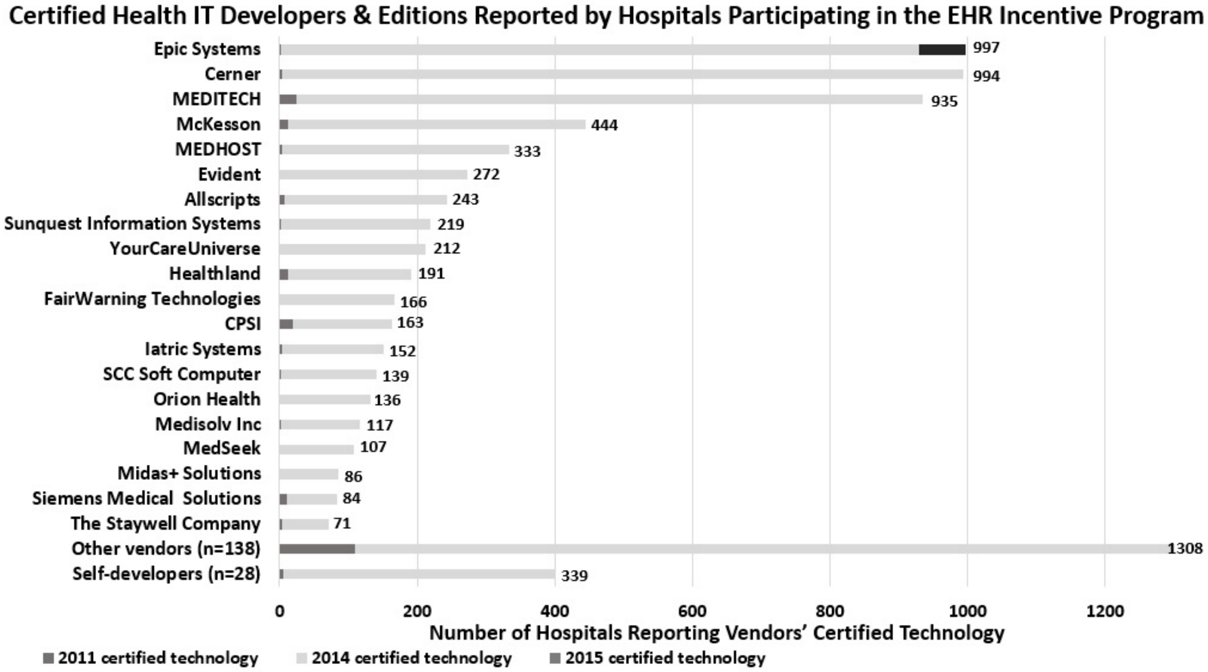
3.1 Trends in the Product Market of EHR Vendor

In 2005, the EHR vendor market was dominated by only a few large vendors who sold their products primarily to health care providers with sufficient margin and capital to make considerable investments (Middleton et al., 2005, p. 14). Most of the EHR vendors had started developing a relatively small application with information technology, and then extended their offering to several independent applications, which were then integrated into a common architecture (Quinn, 2008, p. 2). Many vendors also grew by purchasing products from other vendors or by acquiring the entire small vendor, such as Siemens, who then used this mechanism to expand. In contrast, large vendors such as Epic, Cerner or MEDITECH grew almost exclusively through internally funded growth (Quinn, 2008, p. 2). However, there was also a large number of highly unstable small vendors with a relatively short lifespan of their EHR products. This may have created a barrier for hospitals to adopt EHR systems because there was uncertainty regarding the provider's existence and the high costs for EHR products. The EHR vendor market paid little attention to functional, data representation, or interoperability standards and instead focused more on products to fulfill niche requirements from just a few customers (Middleton et al., 2005, p. 15). Due to the fact that there were few entry barriers and there was an absence of a viable market, the lack of clarity concerning basic product definition, relevant standards, and market segments further complicated the demand. In addition, no certification process for EHR products existed, which led to a low interoperability because only a few customers requested HIE with other providers (Middleton et al., 2005, pp. 14-16). Many vendors only offered stand-alone EHR products, which have since been financially unsuccessful. Therefore, numerous products and vendors are no longer in existence (Tang et al., 2006, p. 125).

After enacting the HITECH Act, the product market concentrated on providing meaningful EHR systems for all U.S. hospitals. Meaningful use includes the use of an EHR in a 'meaningful manner', which focuses on collecting critical data electronically in a coded form, sharing key information with other health care providers, and reporting clinical quality measures and public health information to the government (Blumenthal, 2010, pp. 383-384). Hospitals could receive monetary incentives due to the HITECH Act if the EHR system was certified to provide MU by the Department of Health and Human Services (Castillo, Sirbu and Davis, 2018, p. 2). EHR vendors had to ensure in the certification process that the functionality, security, and interoperability of products met the standards and certification criteria (Blumenthal, 2010, p. 384).

However, it is important to note that almost all EHR vendors certified their products in the program year 2014 (Figure 1). This may be due to the fact that new rules were established in this year, which allowed more flexibility in the certification process (CMS, 2014). By providing this flexibility, more providers were able to participate. Additionally, the EHRs fulfilled the certification requirements such as including MU objectives (for example, drug interaction and drug allergy checks), providing clinical summaries to patients, and reporting on key public health data and quality measures (CMS, 2014). Regardless of the certification years, Epic, Cerner and Meditech offer the most certified EHR products in the entire EHR vendor market. Compared to McKesson or MEDHOST, they offered more than twice as many EHR products.

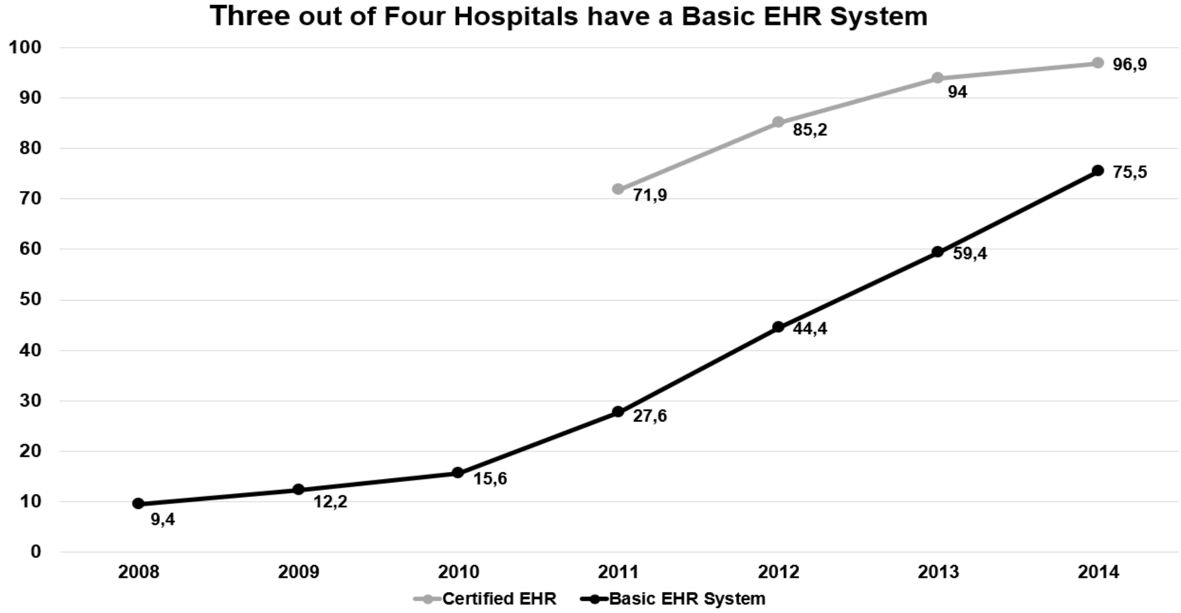
Figure 1: Certified Health IT Vendors and Editions reported by Hospitals participating in the Incentive Program



Source: ONC, 2017.

The study from Castillo, Sirbu and Davis found similar results: the three EHR vendors Epic, Cerner and Meditech controlled 58% of the hospital market in the study cohort (Castillo, Sirbu and Davis, 2018, p. 6). In addition, the study showed that hospitals using an Epic EHR system exchange significantly more health information, while hospitals using Cerner or Meditech share significantly less (Castillo, Sirbu and Davis, 2018, p. 6). The criteria for certification transformed the supply side of the EHR vendor market. Due to the altered demand, about 76% hospitals had introduced at least one Basic EPA system, which represents an increase by 27% compared to 2013 and an eightfold increase compared to 2008 (Figure 2) (Charles, Gabriel and Searcy, 2015, p. 1). The Basic EHR represents a minimum use of core functionality like clinical notes, whereas the certified EHR meets the technological capability, functionality, and security requirements adopted by the government (Charles, Gabriel and Searcy, 2015, p. 1). Almost all reported hospitals (97%) had a certified EHR technology in 2014, which was an increase of 35% since 2011. Hospitals were seeking for EHR systems that were interoperable with other systems to exchange information to further health care provider (Everson and Adler-Milstein, 2016, pp. 1286). Therefore, some vendors made it easier to exchange information to the competitive system. However, concerns were raised that EHR vendors might have strategically implemented these communication barriers across different vendor systems (Everson and Adler-Milstein, 2016, pp. 1287).

Figure 2: Percent of non-Federal acute care hospitals with adoption a Basic EHR and possession of a certified EHR

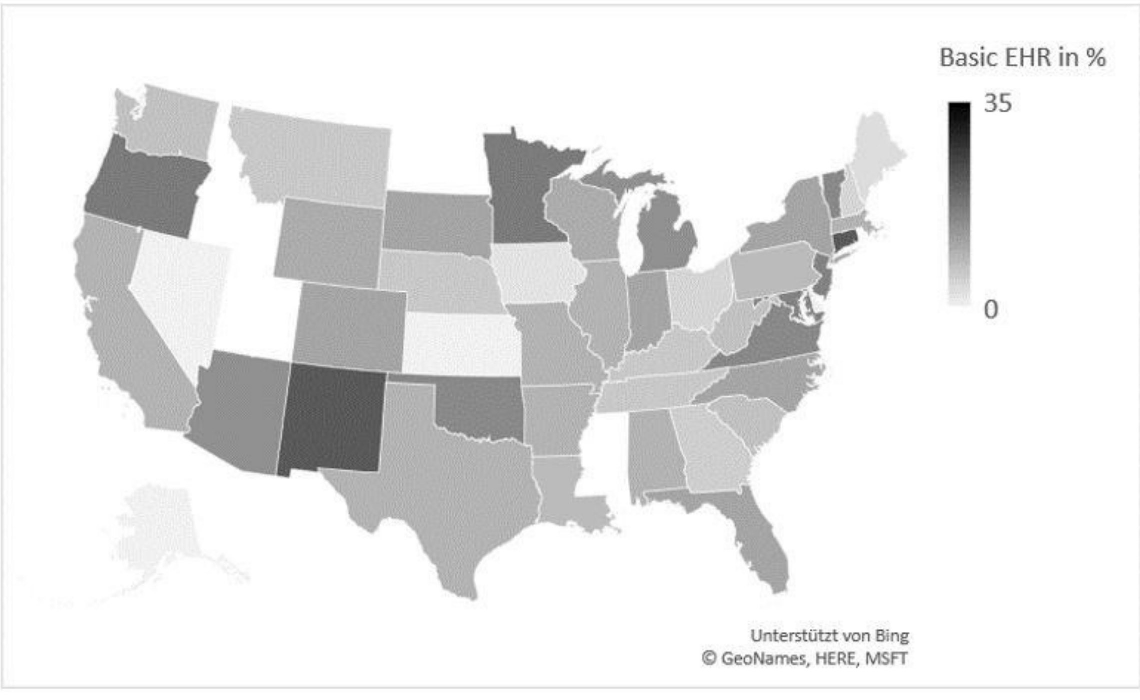


Source: Charles, Gabriel and Searcy, 2015, p. 1.

3.2 Trends in the Geographic Market of EHR Vendors

As shown in Figure 3, the adoption rates of EHR systems in the U.S. were very low prior to the HITECH Act. Only New Mexico and Connecticut had adoption rates of 20% in 2008 (Charles, Gabriel and Searcy, 2015, p. 3). Therefore, EHR vendors did not have a high demand for their products at that time.

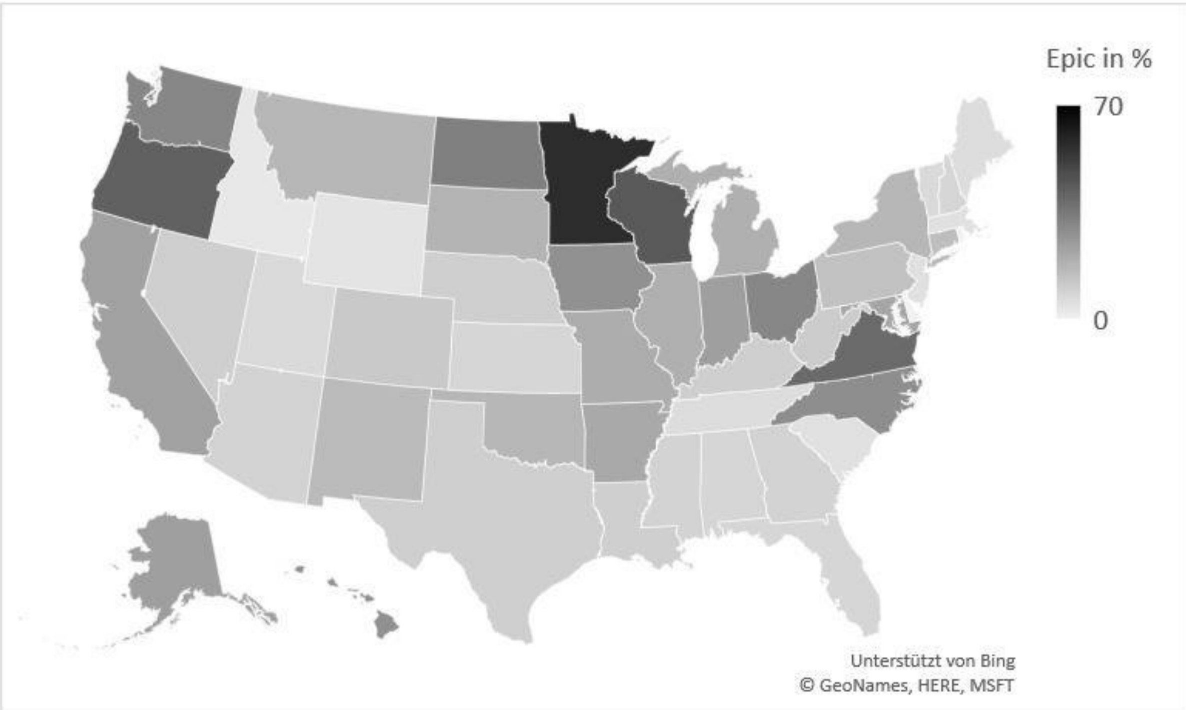
Figure 3: Percent of non-federal acute care hospitals with adoption of at least a Basic EHR system in 2008.



Source: Charles, Gabriel and Searcy, 2015, p. 3.

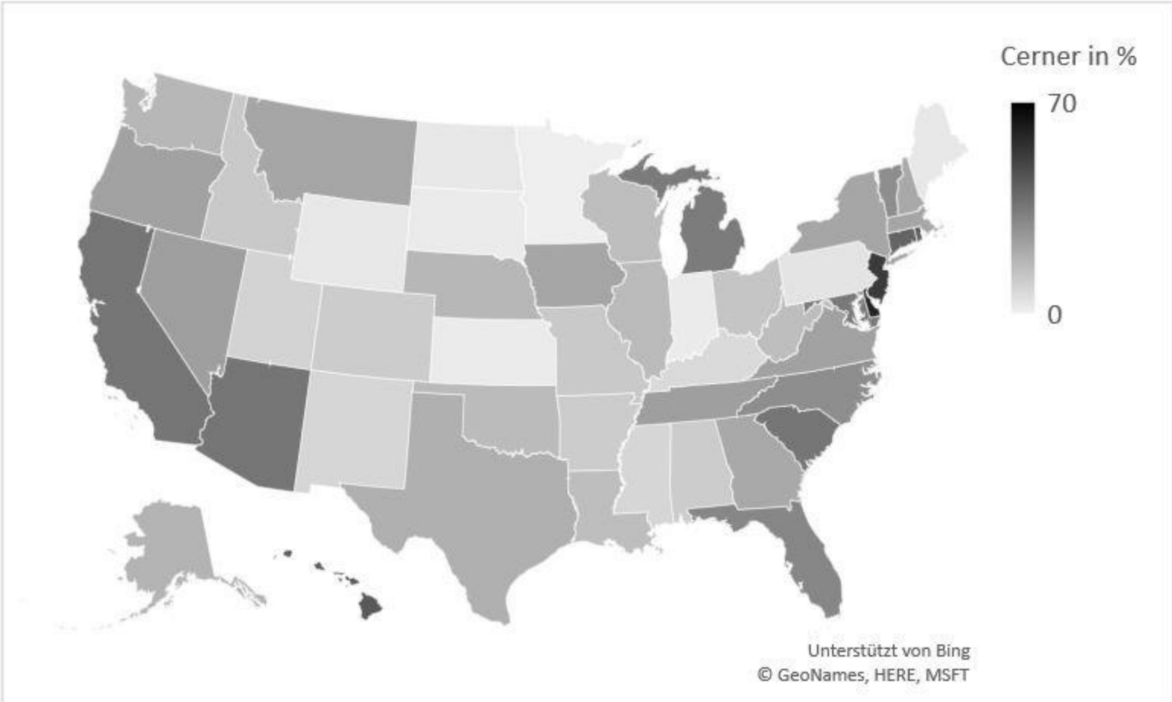
The development of the geographic EHR vendor market from 2006 to 2010 were investigated by Vest, Yoon and Bossak. The authors used Hospital Referral Regions (HRR) to define the local American geographical EHR vendor market. HRRs divide the country into distinct areas and have been used in several health care research studies to define the market area (Vest, Yoon and Bossak, 2013, p. 228). However, the focus of this paper is on state-level. Out of 306 total HRRs, 305 were represented in the study cohort. In order to measure the market power of the EHR vendors, the study applied the HHI in its analysis, which is the sum of each vendor's market share squared (Vest, Yoon and Bossak, 2013, p. 228). In this context, an increasing HHI value indicates a trend toward EHR vendor market power, while decreased HHI scores demonstrate increasing competition. Whereas the competition increased in half of the markets from 2006 to 2010, signaled by a decrease of the mean HHI by 13.4 points, in about a quarter of the markets the competition level did not change significantly (Vest, Yoon and Bossak, 2013, p. 230). Increasing vendor numbers were observed in Alabama, Hawaii, Idaho, Kansas, Montana, Nebraska, Ohio, Oklahoma and Wyoming. The HHI increased by 27.2% of the markets, signaling less competition between EHR vendors.
After enacting the HITECH Act, EHR systems were required to be certified in order to receive monetary incentives from the Centers for Medicare & Medicaid. Therefore, the market share of selected EHR providers were concentrated only in the market for certified EHR products. Figures 4 to 6 show the market shares for Epic, Cerner and MEDITECH in the geographical regions in America in 2015, six years after the HITECH Act passed. These vendors were selected due to their high market share.

Figure 4: Percent of Hospitals Participating in the Incentive Program using Epic in 2015.



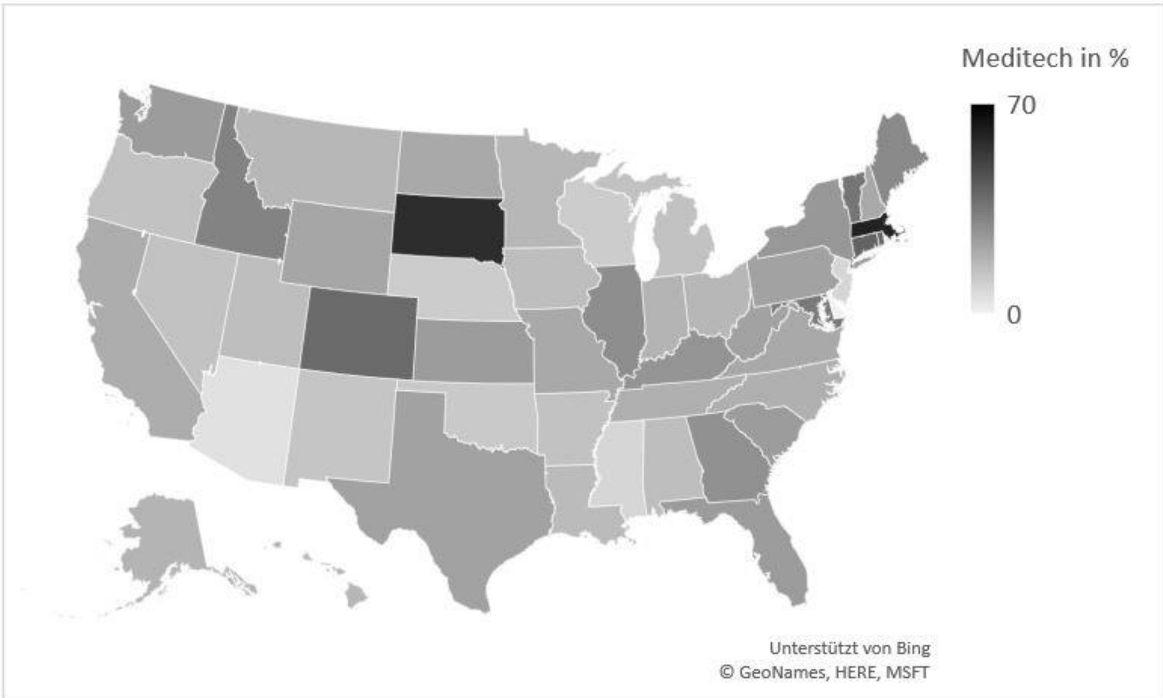
Source: ONC, 2016.

Figure 5: Percent of Hospitals Participating in the Incentive Program using Cerner in 2015.



Source: ONC, 2016.

Figure 6: Percent of Hospitals Participating the Incentive Program using Meditech in 2015



Source: ONC, 2016.

Comparing the market shares, it can be noted that Epic, Cerner and MEDITECH together have a large market power in each county. For example, in Wisconsin, about 84% of the hospitals use products from the large three vendors. This indicates that the market competition did not increase. Even though the number of vendors increased, this does not necessarily lead to more competition because the existing large vendors could have also gained more market share (Vest, Yoon and Bossak, 2013, p. 231). However, there are no additional studies available after 2010 that examine the market concentration by HHI on the HRR or on the state-level.

4 Discussion of EHR Vendor Market with Regard to its Innovation Power

After analyzing the EHR market with regards to the geographic and product market changes, it was evident that the market structure of the large EHR vendors such as Epic, Meditech and Cerner did not change significantly through the HITECH Act. These vendors still maintained strong market power. This could be due to the fact that large and medium-sized hospitals are customers from these vendors. In 2018, Epic and Cerner had a combined market share of 85% among 500-bed U.S. hospitals, with Epic holding 58% of the market share (Landi, 2019). However, empirical studies have shown changes in the EHR vendor market for small hospitals with fewer than 100 beds (Vest, Yoon and Bossak, 2013, p. 229).

The regulation to provide EHR with MU affected the EHR vendors' products. The products must include key functionalities for the certification process to enable hospitals to improve their safety, quality, and patient outcomes (Classen and Bates, 2011, p. 856). The idea was to build on the foundation of MU to spur innovation and achieve rapid learning and technological advancement (ONC, 2015, p. 5). However, flexible certification requirements spurred 'innovation' in the vendor market by using information-blocking techniques that strengthen the market position from the EHR vendor (Gold and McLaughlin, 2016, pp. 670-671). The information-blocking technique makes it more difficult for health care providers to share information with those using other vendors' products. EHR providers can improve their own performance by charging high fees for HIE and can also benefit from making cross-vendor connectivity more difficult by increasing the likelihood that providers will choose their product (Adler-Milstein and Pfeifer, 2017, p. 118). Adler-Milstein and Pfeifer, who conducted a national survey of leaders of HIE, found out that half of the respondents reported that EHR vendors routinely engage in information blocking. The most common motivation for information blocking is to achieve a market advantage (Adler-Milstein and Pfeifer, 2017, p. 126). However, if some products are less competitive, no provider will use those EHRs. Thus, the vendor will be withdrawn from the market in the long-run. Furthermore, this innovation is only valuable for the EHR vendors and legislation could prohibit this technique to protect healthcare providers. Therefore, it is questionable whether this technique can be identified as an innovation.

Only a limited number of studies are available that analyze the innovation power from the EHR market driven by the HITECH Act. Therefore, all health care providers are included in the investigation of the innovation power of the EHR providers. Seth et al. tried to measure innovation by assessing if the type of EHR technology is web-based or a traditional software. The authors argued that they choose these two measures because web-based technology generally enables more flexible business models over traditional software (Seth et al., 2014, p. 736). The results show an increase of web-based technology between 9.9% and 19.5% among providers who adopted EHR in 2011. Web-based technology was used more frequently (15.0%-34.5%) in small-sized practices in

the study cohort. On the other hand, providers in medium and large practices selected traditional software-based EHR (Seth et al., 2014, p. 737). Nevertheless, it is doubtful that these single indicators are reliable in order to measure innovation power. Furthermore, the selection and justification for the selection is random. In order to get a better validity about the development of innovative power, a criteria catalog and a validated survey from theory should be analysed.
Another study conducted 47 in-depth qualitative interviews from different health care stakeholders to examine if the HITECH Act has driven or slowed down the innovation power (Sheikh, Sood and Bates, 2015, p. 849). Some study participants believed that the HITECH Act disrupted normal market forces leading to limited competition in the vendor market (Sheikh, Sood and Bates, 2015, p. 852). Due to the limited competition, EHR vendors have no incentive to invest in technological innovation or to elaborate on advanced EHR systems. One interviewee argued that the HITECH has been responsible for eliminating niche and specialty vendors (Sheikh, Sood and Bates, 2015, p. 852). In addition, the criteria for MU that EHR systems were required for certification were criticized by both physicians and vendors. A physician argued in the interview: "[…] and then vendors have been so focused on only meeting Meaningful Use criteria that they don't do other creative development things." (Sheikh, Sood and Bates, 2015, p. 852). In particular, the experts highlighted the need to stimulate competition on the vendor market and the need to develop a coherent national policy to promote HIE and more interoperability (Sheikh, Sood and Bates, 2015, p. 854). Slight et al. agreed that the MU criteria inhibited innovations for the EHR vendor market because vendors were largely focused on implementing basic MU criteria, which discouraged from addressing other local problems and creating innovative solutions (Sligth et al., 2015, p. 8).
In conclusion, no clear result could be found how the HITECH Act influenced the innovation power. This is because of the limited studies conducted in research and their contradictory results. However, both studies that investigated the innovation power have strengths and limitations. Therefore, more research should be done to promote the measurement of innovation power in the EHR vendor market.
This paper gives an overview of the vendor market with a particular attention on large EHR vendors, such as Epic and Cerner. If the focus were on small vendors, the results would show that in this market segment there exists more competition and a higher variation of the products' lifespan. Furthermore, the development in the EHR vendor market driven by the HITECH Act concentrates only on the geographic and product market. In order to conduct a detailed analysis of the market structure, further data such as sales figures, R&D expenditures, and patent data should be gathered at the firm level.

5 Conclusion

This paper analyzes how the HITECH Act influenced the structure of the EHR vendor market and its innovation power to provide meaningful EHR systems to hospitals. As the analysis showed, the EHR vendor structure did not change by large vendors such as Epic, Cerner and Meditech. However, changes can be seen by small vendors that deliver EHR systems to small-sized hospitals. Therefore, if the focus of the paper had not been focused on the large EHR vendors, the analysis of the development in the EHR market structure likely would have led to a different result. Regarding to the development of the innovation power, no valid conclusion can be drawn due to insufficient research in this field and contradictory study results. However, two studies address that the HITECH Act had a negative impact with regard to developing innovation because EHR vendors were focused on targeting the criteria for MU and therefore all of their manpower was spent on the certification of the EHR products and less on innovation.

To conclude, the introduction of the HITECH Act did achieve one of its goals: to increase EHR adoption by U.S. hospitals. Further policy decisions should target creating more competition among EHR vendors in order to give hospitals more freedom to choose the vendor by their own decision and not on the basis of limited interoperability and HIE with systems from other vendors. In addition, more competition could also lead to more innovative activities and collaborations with health care practitioners, with the aim to improve EHR systems in addressing the needs of customers. More scientific research should be conducted in order to provide further implications for the policy to stimulate innovation in the EHR vendor market.

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The Digital Transformation in the Pharmaceutical Industry

Lukas Höllrich

Digitisation is progressing in all areas of the working world. This means major changes, but also the potential to steer these changes in a positive direction. The healthcare industry – more specifically the pharmaceutical industry - is also affected by the changes brought about by this digital development. This industry is characterised by strong competition and a high pace of scientific research. The strong competition then results in a great intrinsic motivation to use digital solutions to increase efficiency. This paper provides an insight into these digital changes. The purpose of this paper is to investigate the disruptive potential of digital M-Health applications for patient care within the pharmaceutical industry. Relevant literature is collected via a semi-systematic literature overview, which includes the literature databases SpringerLink, PubMed, LIVIVO and GoogleScholar. M-Health applications have an enormous disruptive potential for patient care in the pharmaceutical industry. They can play a decisive role in the developments from a product-oriented to a patient-oriented business model, despite non negligible data privacy and socio-ethical issues. However, the complete penetration of the industry with digital applications will yet take several years.

Contents

1 Introduction

Digitisation, referred to as the fourth industrial revolution, originated in the dotcom phase in 1998/99. Although the dotcom bubble burst in 2000, it was the beginning of a comprehensive digitisation of the world and its economic processes (Becker, Reynolds and Knop, 2015, pp. 1–2). Since then but particularly for the past decade, society has been in the midst of transformation from a service-based society to a knowledge- and information-based society. On the one hand, this development can be traced back to the process of globalization, but on the other hand it can also be traced back to increasing global digital connectivity. All sectors of economy, among those in the pharmaceutical industry, have to deal with these changes (Huber, Dachtler and Edinger, 2017, p. 242).
This paper will investigate the disruptive potential of digital M-Health applications for patient care within the pharmaceutical industry. Given this background, this paper will first look at digitisation in more detail. In particular, two phases concerning the dissemination of digitisation will be discussed. Furthermore, the developments within the pharmaceutical industry will be examined. The explanation of the developments of the pharmaceutical industry serves as a basis to understand current climate and changes in the industry, particularly dealings with the major market-related changes. This work focuses on the effects of digitisation of patient management, and possible contributions to changes within patient management through the use of M-Health applications are considered. Additionally, this paper will examine the extent to which these digital applications contribute to changing the business model in pharmaceutical industry and the resulting opportunities. The problematic aspects must be highlighted, followed by the most important barriers of digital applications. The discussion will summarize the most important results, followed by the limitations of the work and will end with a final conclusion.

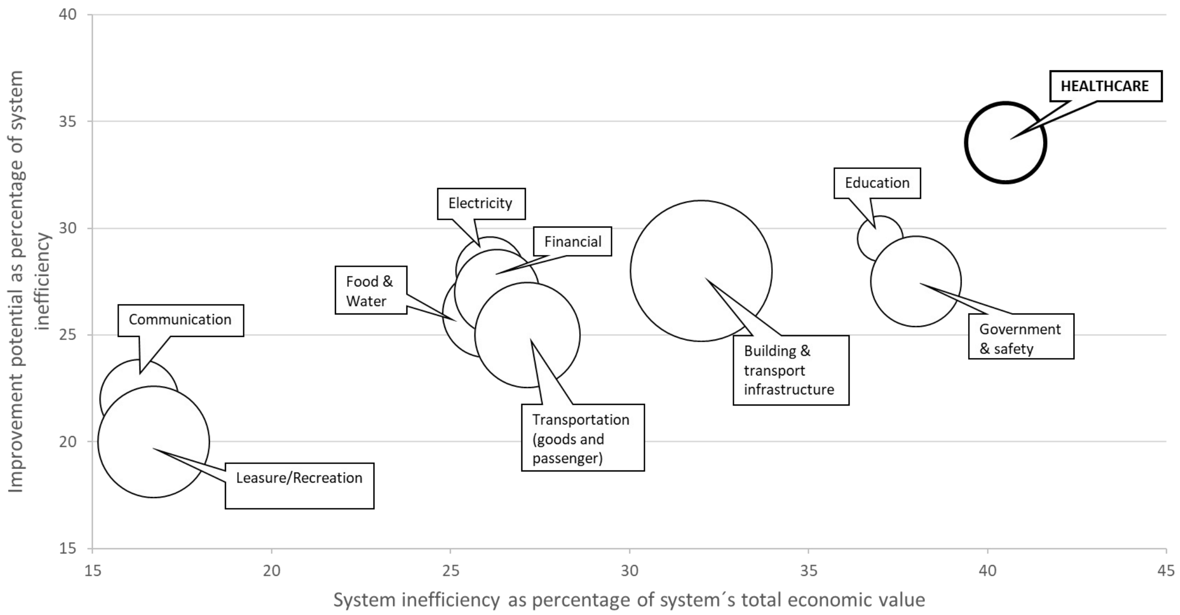
2 Fundamentals

2.1 Digitisation

Digitisation is "the conversion of analogue information into digitally stored and used information" (Baierlein, 2017, p. 1).
The term digitisation is omnipresent in today's socio-political discussions. It is associated with significant changes and development perspectives whose consequences are hardly predictable. This is based on the rapid technological development of recent years, in which the performance of hardware has risen as drastically as its price has fallen (Hirsch-Kreinsen and Hompel, 2018, pp. 13–14).
Two phases of digitisation should be distinguished. In the first phase, which began in the 1990s, this process was established in those economic sectors in which production and communication were based directly on the use of data and information. Examples for this are the service sector or the music industry. The second and current phase has focused on linking digitisation with physical objects. This includes devices, vehicles, machines, but also entire logistics and management processes. One focus of the second phase is the digitisation of industrial production, which is subsumed under the term Industry 4.0 (Hirsch-Kreinsen and Hompel, 2018, p. 15). Thus, it is not only about the pure transfer of analogue information to a digital medium, but about the transfer of

humankind in its living and working environment to a digital level (Hamidian and Kraijo, 2013, p. 5). This translation leads to major changes in the work environment. It is expected that digitisation will lead to significant job losses in the upcoming years due to automation in the areas of low-skilled jobs. On the other hand, positive growth conditions are expected to increase the overall number of employees. Accordingly, there will be a change in the demands placed on the tasks and qualifications of employees in all sectors of the economy (Hirsch-Kreinsen and Hompel, 2018, pp. 17–18).
The industrial sector is subject to constant change and progress. Every company that wants to survive in the long-term must understand and react to progress in technical developments (Pfeiffer, 1971, p. 17). This means that even the healthcare sector, which has a long adaptation phase for major innovations, will not remain unaffected by these new developments. Healthcare is characterized by a relatively high degree of inefficiency and also a high potential for improvement in comparison to other industries (see Figure 1). It is clear that improving with the help of digital business model innovations is prioritized among healthcare companies (Halecker and Hölzle, 2015, pp. 69–70).

Figure 1: Inefficiencies in various industries



Source: Own presentation based on IBM, 2010, p. 5.

2.2 Evolution of the Pharmaceutical Industry

Within the healthcare sector, the pharmaceutical industry is at the forefront of digitisation. This industry is characterized by strong competition and fast paced scientific research due to limited patent terms. The patent terms end up resulting in a great intrinsic motivation to use digital solutions to increase efficiency (Suwelack and Klaus, 2017, p. 167).
The developments within the pharmaceutical industry can be divided into three phases. The first phase is characterised by 'blockbuster drugs' and their patenting (Huber, Dachtler and Edinger, 2017, pp. 244–245). 'Blockbuster drugs' are products whose turnover is greater than one billion dollars, regardless of the time period (Fischer and Breitenbach, 2013, p. 15). The market launches were preceded by years of costly

research and development. As a result, pharmaceutical companies protected these products, their intellectual property, with patents. Patent protection is particularly important in the pharmaceutical industry, where the innovator has an unfavourable relationship between high innovation costs but low imitation costs. Furthermore, it is important for the innovator to bear in mind that after patent protection has expired, there is usually a drastic decline in sales and profits of the original drug due to significantly cheaper generics by other pharmaceutical companies (Raasch and Schöffski, 2008, pp. 215–216).

Today's phase (phase 2) is characterized by a decline in innovations and the patent cliff. The patent cliff refers to the expiration of many blockbuster patents in the past or in the upcoming years, as well as the missing pipeline in many pharmaceutical companies to fill the gap. This poses great difficulties for companies, since the growth of the pharmaceutical industry depends to a large extent on the introduction and acceptance of new, patented drug therapies. In response to these developments, this phase is driven by programs for cost reduction, improving operational efficiencies, and diversifying product market models (Aitken, Fricke and Reichelt, 2008, p. 446; Huber, Dachtler and Edinger, 2017, p. 245).

Future developments, or the third phase, will be characterized by a change in the pharmaceutical industry from the exclusive supply of a drug for a specific disease to the holistic supply of medication and information. This holistic approach will then contribute to an optimized influence on therapy success. The decisive factor for the recovery of a patient is no longer the drug alone, but the therapy strategy chosen, which can include additional services such as infrastructure, information, and data connectivity. This means that it is no longer just a question of the efficacy of a drug, but of interacting with the patient to satisfy his or her needs. In the new business models, digital information is the currency. In the future, the success of pharmaceutical companies will depend on the extent to which relevant digital information from various sources can best be aggregated (Huber, Dachtler and Edinger, 2017, pp. 244–245).

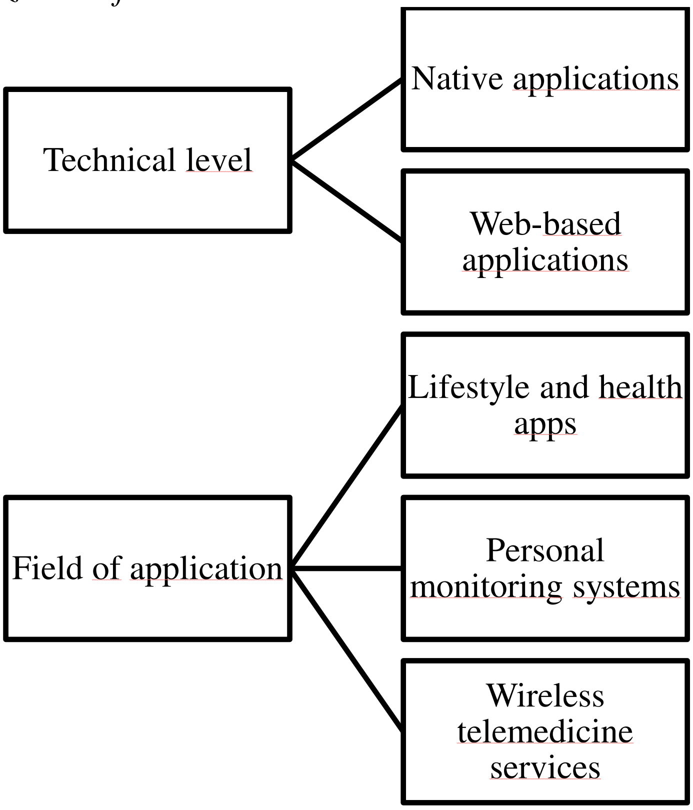
3 Patient Management in the Pharmaceutical Industry

3.1 Mobile-Health – Digital Applications for Patient Care

M-Health can be considered a further development of Electronic-Health (E-Health). E-Health refers to devices that are used as stand-alone devices in medical practices or as home-use applications by patients. Thus, there is practically no networking of devices and use of digital data (Huber, Dachtler and Edinger, 2017, p. 243).

M-Health, on the other hand, implies the use of mobile devices such as wearables or smartphones in medical care or public healthcare. Wearables are electronic devices that are worn on the wrist, head, ears, clothing or skin and can be connected directly to the web via wireless technology (e.g. Bluetooth) through a smartphone or tablet. M-Health applications can be categorized into two levels (see Figure 2). The first level represents the technical level. Here a distinction can be made between applications that have been developed for a specific operating system, e.g. Internetwork Operating System (iOS), and applications that are web-based. The second level represents the field of application, which is divided into three categories. The first category covers lifestyle and health tips. Apps within this category can be linked with medical devices or sensors (e.g. in wristbands or watches) to measure vital signs such as pulse or blood pressure. The second category includes personal monitoring systems, which could contain reminders to take medication. The third category includes wireless telemedicine services that provide location or environment dependent support in acute medical situations (Jäschke, 2017, pp. 176–179).

Figure 2: Categorization of M-Health



Source: Own presentation based on Jäschke, 2017, pp. 178–179.

All three categories offer many opportunities for better management of health. Long-term monitoring, which analyses relevant data from patients' everyday lives and makes it available to the physician, has the potential to individually optimize the course of therapy and the patient's compliance. As the ‘point-of-care’ shifts closer to a point-of-need’, reaction times are shortened due to the earlier recognition of deterioration tendencies. Early intervention in high-risk situations is possible due to mobile technology. Patients become more involved in their own treatment process and have the opportunity to actively participate in their health journey. In this way, health profiles and health processes can be evaluated individually for the benefit and in the interest of the patient (Strotbaum and Reiß, 2017, p. 360).

3.2 Developments in Patient Management

Many apps related to health or medical practice are available in the M-Health market. According to estimates, there were about 103,000 different health and medical apps in the app stores (Google Play Store, Apple AppStore, etc.) in 2015. The two largest app stores on Google and Apple alone each have more than 70,000 apps from the health sector. This number is now likely to be significantly higher, as new apps essentially come onto the market every day (Strotbaum and Reiß, 2017, p. 359).

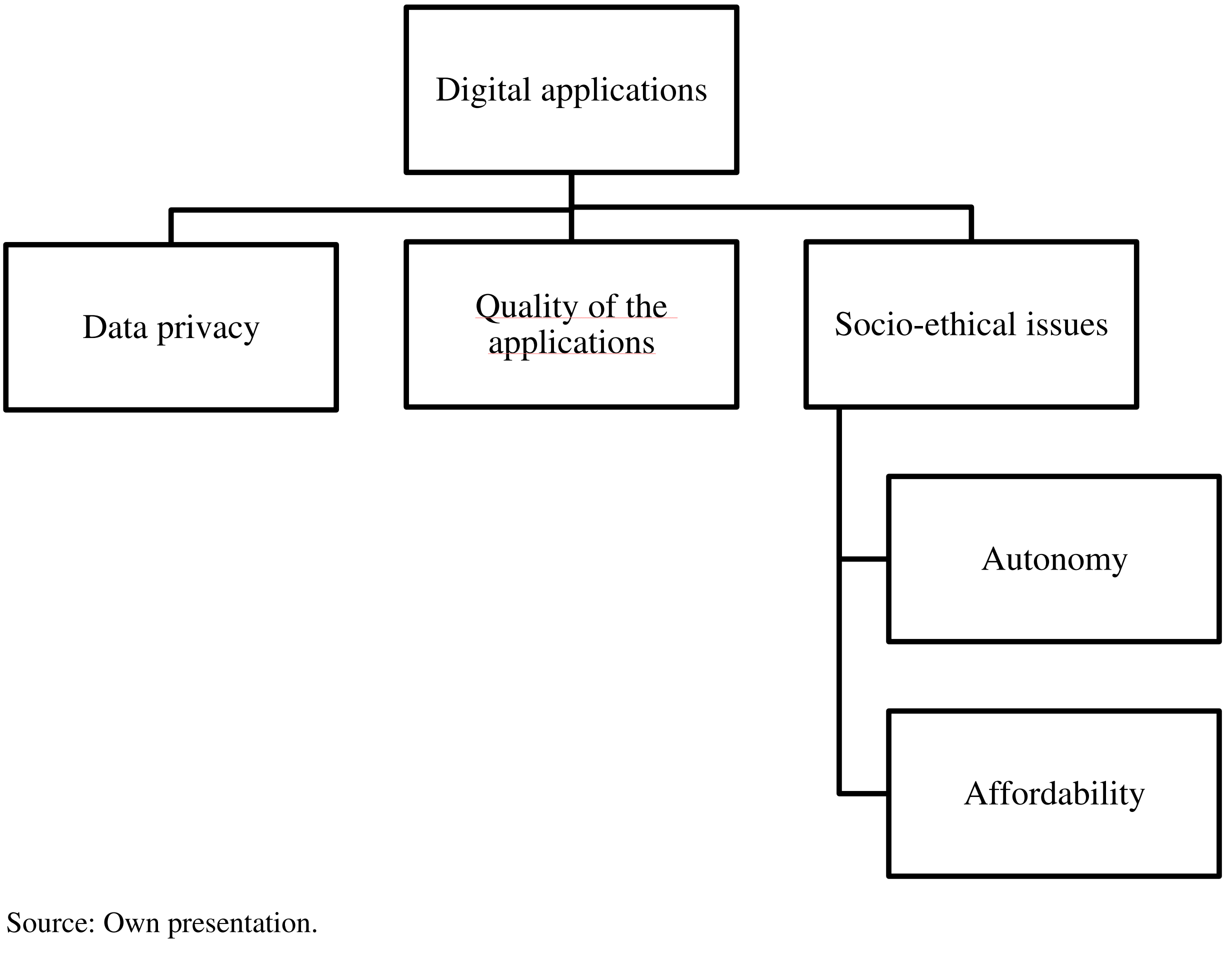
The pharmaceutical industry has also recognized the potential for digitisation and M-Health applications. There is a noticeable, albeit slow, but steady change from a product-oriented business model to a customer- and patient-oriented business model in which mobile applications play an important role (Gombocz, 2013, pp. 9–10). Between 2013 and 2014 alone, the number of health apps published by pharmaceutical companies rose by over 60% (Statista Research Department, 2015).
The current product-oriented business model focuses on the interaction between the pharmaceutical industry and health care institutions. Patient empowerment is at the centre of all change towards a patient-oriented business model within the pharmaceutical industry. This refers to the power and control that makes a patient able to control his or her health-related decisions. Patient empowerment enables a patient step into the foreground as the addressee of their health (Anwar, Chowdhry and Prasad, 2018, pp. 77–80; Lassnig, et al., 2017, pp. 38–40). One reason behind these changes is that in the future, there is the threat of only being suppliers to other branches of industry that have understood how to network with the environment in time. In the past, health data was reserved for healthcare institutions, but this is gradually changing. Today, competitors are entering the market with an enormous budget for research and development. Competitors include Apple, IBM, and Samsung. Venture capital companies are also becoming increasingly interested in digital healthcare. Over the past four years, US venture s have quadrupled their investment in the digital healthcare system to a volume of over $5 billion in 2014 (Champagne, Hung and Leclerc, 2015, p. 2; Huber, Dachtler and Edinger, 2017, p. 248). Pharmaceutical companies react differently to these changes. On the one hand, they try sealing themselves off from these competitors and develop their own ideas, but on the other hand, the pressure of competition also gives rise to radical cooperation. For example, Bayer is cooperating with Nintendo on a blood glucose meter for children and combining blood glucose monitoring with an adventure game. The player receives extra points for regular blood glucose monitoring and is rewarded with additional bonus points for values in the normal range (Huber, Dachtler and Edinger, 2017, p. 245).
The key to continued success of pharmaceutical companies is a broad exchange of data and connectivity to end users. For the pharmaceutical industry, this means that it is no longer sufficient to provide only one drug but needs to offer a holistic therapy concept that provides an infrastructure that includes additional services and data connectivity along with the actual medication. Thus, the reasons for the change from a product-oriented business model to a customer-oriented business model can be seen mainly in two developments. The increased possibilities for patients to obtain information as a result of digitalization are leading to a shift in knowledge and a strengthening of patients' market position. The appearance of competitors with great know-how in digital applications increases the pressure for quick progress (Huber, Dachtler and Edinger, 2017, p. 253).

3.3 Issues of Digital Applications

In addition to the many opportunities that arise from the use of digital applications, there are also a number of issues that need to be considered (see Figure 3).
One of the most important issues with digital health is data protection and interference with the privacy of users of digital applications. Data is increasingly being collected

from users without their knowledge or control over this process (Barbry, 2012, pp. 92–94). M-Health applications use highly sensitive personal data due to the nature of the application, application context and functionality. However, there is generally a significant lack of transparency regarding the storage, use, and disclosure of this data to third parties. While the patient is usually protected by the medical practitioner's duty of confidentiality, this cannot be guaranteed in a digital context. Particularly in the case when applications that are available free of charge, private business models are based on the collection, transmission, and evaluation of data (Strotbaum and Reiß, 2017, p. 365). On the one hand, the user cannot therefore intervene in a regulatory manner in the processing of his personal data, and on the other hand, the user is unable to correctly assess the future value of his/her personal data. Typically, the user cannot make an decision as to whether or not to entrust the developer of this application with his/her personal data. This inequality between developer and user leads to the fear of a transparent patient whose data is processed uncontrollably (Buck, et al., 2018, p. 303). The security of digital applications is also immensely important in this context. As already mentioned, the collection of health data is highly sensitive and if these data are not sufficiently protected, unauthorized persons could gain access to them. Therefore, adequate protection against unauthorized groups like phishers and hackers should be an essential component in the development of these applications (Royakkers, et al., 2018, pp. 133–134).

Figure 3: Issues of digital applications



Source: Own presentation.

Furthermore, it must be taken into account that digital ecosystems and thus app markets are not regulated markets. Although marketplace operators have mechanisms in place to check the release of newly offered apps, these mechanisms are very opaque and technical. Conversely, this means that an application´s recommendations, plans, and instructions may not be professionally vetted and could be flawed. As there is no way to validate or certify institutions yet, the quality of the application's content is hardly verifiable by the user. Even under the assumption that pharmaceutical companies bring applications onto the market in line with the latest scientific findings, the user himself represents a potential source of danger. Incorrect operation of these applications, without adequate support, can result in health risks (Buck, et al., 2018, pp. 302–303).
Socio-ethical aspects also play a decisive role in the use of digital applications. As far as autonomy goes, one risk of using digital applications is the emergence of technological paternalism. Technological paternalism is when an application may suggest to the user that decisions about the user´s health stated by the application are better than those of the user himself (Hilty, 2015, p. 54). This could occur when a person uses an application without critical questioning. This then leads to the fact that the manufacturers of these applications can influence the behavior of a user, which leads to the possibility of a manipulation of a user. When creating digital applications, pharmaceutical companies could give greater priority to company interests than to patient health (Royakkers, et al., 2018, pp. 131–133). But the financial framework conditions for the acquisition of M-Health applications must also be taken into account, as there is a risk that health inequalities will increase due to social status. This does not affect apps that much, as they are usually available free of charge or at a reasonable price in the app stores. However, financial framework conditions could affect other applications such as wearables. For socially disadvantaged population groups, the purchase of applications is more difficult due to financial limitations. The lack of availability of these applications results in less knowledge or perceived knowledge about one's own state of health. This poses a danger that digital inequality could also lead to health inequality (Dockweiler and Razum, 2016, pp. 6–7).

4 Discussion

Digitisation has the potential to completely change the world as we know it. The expansion has been gradual and uneven across different industries. It is already spread far and wide into industries where regulations are less strict. In healthcare, however, there are major barriers to change because patient´s health is at stake. The pharmaceutical industry, as part of the health care system, is also affected by these regulations. At the moment, the pharmaceutical industry is undergoing a transformation from a manufacturer of a drug to a service provider for the entire treatment process, and digital applications play a crucial role in achieving these changes. With the help of these applications, it is possible to collect and process large amounts of patient data. In this context, M-Health applications offer the advantage of mobility and thus, continuous availability. The previous product-oriented business model of the pharmaceutical industry is increasingly turning into a patient-oriented business model. Patient empowerment plays a decisive role here, as the patient is now at the centre of attention, not the product. M-Health applications should lead to the patient being involved in the collection of data on his or her state of health. This results in closer cooperation between pharmaceutical companies and patients. Pharmaceutical companies are developing different strategies to respond to change. Some companies try to develop their own ideas for the patient-oriented business model, while others enter into unusual partnerships to achieve these goals.

This paper provides an overview of digital developments in the field of patient management, and therefore does not address country-specific distinctions. This is also due to the fact that pharmaceutical companies are usually internationally operating companies. Regulators of digital applications analyse apps diversely in different countries, which in turn limits the development possibilities and leads to different degrees of digitisation in the individual health systems, to which pharmaceutical companies have to adapt in the respective markets. Furthermore, this paper only examines the influence of digital transformation on patient management in the pharmaceutical industry. But the areas of preclinical research and development, clinical research, regulatory affairs and market access, production, marketing, and sales remain unconsidered. The respective areas differ in their digital penetration (Suwelack and Klaus, 2017, pp. 167–171). For an assessment of the overall digital penetration of the pharmaceutical industry, all business and production areas need to be considered. In the area of patient management, only the subarea of M-Health applications is considered in this paper. The other areas of patient management are E-health applications and telemedicine. The difference between the areas lies in mobility and the knowledge required to operate the applications. However, the boundaries between these areas will become increasingly blurred in the future (Huber, Dachtler and Edinger, 2017, pp. 242–249).

With all of the positive aspects that these changes entail, the negative aspects must also be considered. Among other things, data protection and the invasion of a patient´s privacy play a decisive role. The processing of sensitive personal data in healthcare requires special protection. Another critical point is the quality that M-Health applications offer. It is difficult for the patient to assess the applications reliably. One way for a patient to check the quality of the available health app is to tighten up the certification of the apps by a central certification body. Even if there are already possibilities for the certification of health apps, their quality is presently not objectively comprehensible. The implementation of a central certification body should focus on the data protection and medical correctness of the information. Ultimately, socio-ethical aspects also play a central role. Thus, the autonomy of the user must not be lost when using an M-Health application, nor must financial limitations be the reason for excluding population groups from these far-reaching changes.

Ultimately, digitisation has an enormous disruptive potential to revolutionize the pharmaceutical industry, which is even accompanied by the development of a new business model approach. M-Health applications in patient management have the potential to become an important part of the development towards a patient-oriented business model in the pharmaceutical industry. The reluctance of the pharmaceutical industry to expand these technologies is due to the problems of digital applications. Looking at the subdivision of developments in the pharmaceutical industry in this paper, it can be said that we are currently in the transition from the second phase, the problems posed by patent cliff, to the third phase, the holistic approach to care beyond the provision of medication. Even though many developments of the third phase can already be observed today, many experts agree that the pharmaceutical industry still needs some time to fully adapt to this trend. It is predicted that digitisation will only unfold its full potential in this industry in about 15 years, i.e. around the year 2030 (Lassnig, et al., 2017, p. 42). Thus, right now we can speak of a great potential, but not of a great exhaustion of the possibilities of digitisation within the pharmaceutical industry.

5 Conclusion

The aim of this paper is to identify the disruptive potential of digital applications in patient management in the pharmaceutical industry. The pharmaceutical industry, like all other industries, is subject to constant change. Digitalization, however, has the potential to completely redesign this industry. Pharmaceutical companies should take a very close look at the opportunities, but also the risks, that arise from digitisation. Business models must adapt to developments in the environment.

The use of digital applications in connection with the pharmaceutical industry is ultimately aimed at improving and monitoring the health status of patients. Patients should be more involved in this process and should be given the opportunity to take more responsibility for their own health. It will be several years before the issues with these new technologies are adequately resolved and the full disruptive potential of digitisation is revealed. Pharmaceutical companies need to be aware of their special responsibilities in this regard and continue to progress towards digitisation. The other areas of pharmaceutical service supply must also be taken into account in the expansion of digitisation. In the health sector in particular, it is essential that uncertainties are avoided as far as possible and that patient confidence in these new technologies is strengthened. Even if the problems discussed in this paper are solved, the patient still must use these applications.

In conclusion, it can be said that the entry of digitisation into the pharmaceutical industry, despite not negligible problems, has the enormous potential to make the entire system safer and more efficient for everyone. The question does not seem to be whether digitisation will change the pharmaceutical industry, but when.

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Aims and Strategies of Health Insurances with Regard to Digitizing Health Care

Anna-Maria Zierenberg

Using electronic health records is associated with improvements in healthcare quality, patient safety, and cost savings. For this reason, the Centers for Medicare and Medicaid Services designed incentive programs for eligible healthcare providers to promote high adoption rates. This paper investigates goals and strategies that health insurance companies pursue electronic health records and how they handle implementations. The Diffusion of Innovations Theory by Rogers is used as a conceptual framework to analyze how these activities affect the diffusion process of electronic health records. After the implementation of the Medicaid and Medicare Incentive Programs for eligible professionals and hospitals in 2011, electronic health record adoptions were realised among 642,600 participants by 2018. Although 80 percent of the eligible office-based physicians have adopted, and 96 percent of the eligible hospitals have adopted a certified electronic health record in 2017, challenges remain particularly with interoperability and usability of the electronic health records. Findings report that the Centers for Medicare and Medicaid Services achieved high diffusion rates through their strategic approaches. By assessing provider-specific characteristics, communication behaviors, and technology application barriers, studies found that these might help to draft tailor-made strategies to advance certified electronic health record usage. However, not only does the exchange of data between eligible providers need to be driven forward, but it needs to be driven forward among all stakeholders, including public health agencies or registries. As a result, public health insurance companies should focus on the development of a standardized electronic health record infrastructure as a prerequisite to provide access to high quality care and provide health care at lower costs.

Contents

1 The Diffusion of EHRs in Healthcare

As information technology capabilities rise, policymakers seek strategic approaches to systematically integrate these innovations into healthcare delivery. By passing the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009, the US Government intended to drive widespread electronic health record (EHR) adoption in hospitals and physician practices to realize quality and efficiency benefits. The Act authorized the Centers for Medicare & Medicaid Services (CMS) to implement incentive payment programs to promote the adoption and use of EHRs through financial, administrative, and technical support.

The purpose of this paper is to investigate aims and strategies that public health insurance companies pursue regarding the implementation of EHRs and how these affect the diffusion process of EHRs. Therefore, the Diffusion of Innovations Theory by Rogers is used as a conceptual framework. The core elements of the theory will be explained after an overview of the programs that CMS has initiated since the enactment of HITECH. Then, the way CMS integrates both its aims and strategies into the programs is analysed.

To date, about $30 billion has been made available to physicians and hospitals (Blumenthal and Tavenner, 2010, p. 501). While adoption has been realized among 642,600 program participants (CMS, 2019d), challenges remain especially regarding health data exchange and usability. In order to give recommendations for future actions, the extent of influence on EHR adoptions among different types of healthcare providers is discussed and barriers are identified. These barriers should be addressed to progress nationwide EHR diffusion and ultimately provide access to high quality care.

2 Theoretical and Legislative Framework

2.1 Programs Established by CMS with Respect to EHRs

In 2011, CMS introduced the Medicare and Medicaid EHR Incentive Programs that reward eligible professionals (e.g. physicians), eligible hospitals, and critical access hospitals for successfully adopting, implementing, upgrading, and demonstrating Meaningful Use (MU) of certified EHR technology (CMS, 2019f).

MU of certified EHR technology includes three main aspects: use of an EHR a) in a meaningful manner (e.g. e-prescribing), b) for electronic health information exchange, and c) to submit clinical quality and other measures (CMS, 2019e).

Whereas the Medicaid EHR Incentive Program is run by individual states and ends in 2021 (ONC, 2018), the CMS-run Medicare EHR Incentive Program was partially replaced by the Promoting Interoperability Category. Since 2017, it belongs to the Merit-based Incentive Payment System, a Quality Payment Program that was implemented by CMS required under the Medicare Access and CHIP Reauthorization Act of 2015 (QPP, 2019). In this program, eligible clinicians report on a set of measures and are scored based on their performance on the measures in the four categories: promoting interoperability, quality, cost, and improvement activities. A final score is calculated based on the weighted performance in each category and compared to a threshold to determine payment adjustments (AAFP, 2019).

In April 2018, CMS renamed the EHR Incentive Programs to the Promoting Interoperability (PI) Programs, which correspondents to the new content focus: interoperability and improved patient access to healthcare data (CMS, 2019f). From 2019 onwards, all eligible professionals, (dual-) eligible hospitals and critical access hospitals in both the Medicare and Medicaid PI Program must demonstrate usage of 2015 Edition Certified EHR Technology (CMS, 2019a; 2019b).

2.2 Diffusion of Innovation Theory

The Diffusion of Innovations Theory seeks to explain the process of dissemination of innovations in a society. Its origin is considered to be the work 'Diffusion of Innovations' by the American sociologist Everett M. Rogers (1962). He defines an Innovation as '…an idea, practice, or object that is perceived as new by an individual or other unit of adoption' and understands Diffusion as the process '…in which an **innovation** is communicated through certain **channels** over **time** among the members of a **social system**' (Rogers, 1983, pp. 10-11). Figure 1 shows the four key elements of the diffusion process and their components.

Figure 1: Four Key Elements of the Diffusion of Innovations

Innovation	Communication channel	Time	Social system
• Relative Advantage • Compatibility • Complexity • Trialability • Observability • Reinvention	• Mass media channels • Interpersonal channels	• Knowledge • Persuasion • Decision • Implemen-tation • Confirmation	• Optional • Collective & • Authority innovation-decisions

Source: Own presentation based on European Public Health, 2016.

The Innovation-Decision Process describes the individual adoption of an innovation and can ideally be categorized into the five stages: knowledge, persuasion, decision, implementation, and confirmation (Rogers, 2013, pp. 164-165). At the knowledge stage, the individual (or other decision-making unit) becomes aware of the innovation's existence and develops an understanding of its function. At the persuasion stage, an opinion is formed whether the innovation is favourable or not. The individual decides to adopt or reject the innovation at the decision stage. In case of adoption, the innovation is put into use at stage four, the implementation stage. At the confirmation stage, the individual decides whether the innovation will continue to be used or not (Rogers, 2003, p. 164). The rate of adoption, defined as '…the relative speed with which an innovation is adopted by members of a social system' (Rogers, 1983, p. 23), depends on the individual's perception of an innovation's characteristics. Rogers (1983, p. 35) states the relevant six attributes: relative advantage, compatibility, complexity, trialability,

observability, and reinvention. He argues that these influence the decision-making process, especially at the persuasion stage (Rogers, 1983, p. 165).
Messages reach individuals via communication channels; these can be distinguished between mass media channels in which a particular spread knowledge of innovations and interpersonal channels alters attitudes towards them (Rogers, 1983, p. 35). Aside from the innovation's characteristics, the decision also depends on the influence from within the social system. If an individual decides independently of other system members, it is an optional innovation-decision. Instead, collective innovation-decisions are made by consensus among the members, whereas relatively few individuals in a system make authority innovation-decisions on whether to adopt or reject innovations (Rogers, 1983, pp. 29-30).

3 EHR Diffusion – Aims and Strategies of CMS

3.1 Aims Connected to EHR Usage

The HITECH Act called for healthcare providers not only to install but also to demonstrate MU of a certified EHR system. The HITECH Act's administrative realization is led by CMS and the Office of the National Coordinator for Health Information Technology (ONC). The concept of MU is based on five overarching goals for health outcomes (CMS, 2010a, p. 2):

1) Improve quality, safety, efficiency, and reduce health disparities
2) Engage patients and families in their health
3) Improve care coordination
4) Improve population and public health
5) Ensure privacy and security protection for personal health information

How these general goals are put into practice can be demonstrated by the MU objectives. CMS has established them for all providers to report MU and show they apply their EHR in a way that can positively affect patient care (CMS, 2010b, pp. 19-39; CMS, 2012, p. 35-42). For example, goal 1 (improve quality, safety, efficiency, and reduce health disparities) could be realized through the objective *implement one clinical decision support rule*, whereas the objective *provide patients with an electronic copy of their health information* helped to attain goal 2. The third goal could be achieved through the objective *capability to exchange key clinical information among providers of care and patient-authorized entities electronically* and goal 5 through the objective *protect electronic health information*. All objectives mentioned are so-called core objectives. There were 15 core objectives for eligible professionals and 14 core objectives for eligible hospitals that had be fulfilled at Stage 1 of the program. Providers also had to complete 5 out of 10 objectives from a menu set including at least one public health-related objective. It helped to achieve goal 4 and could be the objective *submit electronic syndromic surveillance data to public health agencies* (CMS, 2012, p. 61). Additionally, professionals had to report 6 and hospitals 15 Clinical Quality Measures (e.g. blood pressure measurement; CMS, 2010a, p. 6).

The MU objectives differed as the programs progressed (CMS, 2019f). This allowed CMS to tailor the requirements with regard to its own goals, but also to respond to unexpected events in terms of providers' difficulties in meeting the criteria or EHR market changes (HHS, 2018b). Renaming the EHR Incentive Program to the Promoting Interoperability Program reflects CMS's focus on improved health data exchange between providers and patients and patient access to health information. Therefore, participants in the Medicare PI Program in 2019, for example, must attest to CMS four objectives:

1) Generate and transmit permissible discharge prescriptions electronically
2) Encourage and leverage interoperability on a broader scale and promote health IT-based care coordination
3) Provide patients electronic access to their health information
4) Be in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using certified EHR technology (CMS, 2019b)

3.2 Strategies for EHR Implementations

To achieve nationwide EHR diffusion, CMS designed various strategic approaches which can be summarized as follows:

Develop programs and offer implementation assistance

As previously noted, public health insurances pursue several interests with EHRs. In order to accelerate their broad implementation process, the US Government authorized CMS to establish appropriate programs for healthcare providers. In October 2018, CMS reported that more than 642,600 professionals, hospitals, and critical access hospitals were registered in the Medicare and Medicaid PI Programs (CMS, 2019d). For eligible providers, CMS issues comprehensive work sheets to guide them through MU reporting (CMS, 2019a; 2019b), and supports the states through regional offices to achieve adoption of EHR technology (ONC, 2011, p.10). CMS also collaborates with the ONC, which provides funding for technical assistance (e.g. vendor selection, workflow redesign) and educational programs for health IT workers (CMS, 2010a, pp. 31-32).

Divide the programs into Stages allowing long-term running and program adjustments

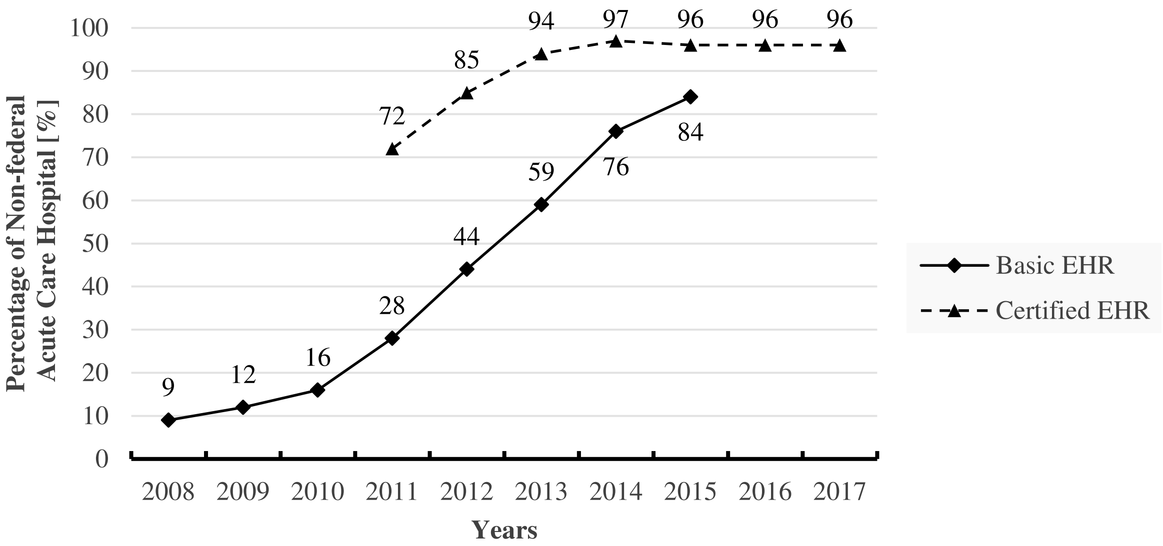
The Medicare and Medicaid EHR Incentive Programs consist of 3 stages, each with its own specific objectives, measures, and standards. Stage 1 focuses on collecting medical data electronically and obliges the providers to report MU objectives. Stage 2 includes some changes to the core and menu objectives to improve processes and ensure that quality goals are met. Stage 3 uses certified EHR technology to improve health outcomes. The stages build on each other and are constantly modified to enable the participants to fulfil the requirements progressively (CMS, 2012, p. 40; CMS, 2019f). For example, the Medicaid EHR Incentive Program modification of 2018 was estimated as an increase in flexibility and response to concerns from providers by putting off required use of 2015 Edition Certified EHR Technology until the 2019 reporting year (AAP, 2018).

Establish MU criteria and demand certified technology
The HITECH Act demands that healthcare providers use their EHR in a meaningful way by meeting a series of objectives. These objectives were defined by CMS and put their broader healthcare aims into a measurable operating criterion. MU is also a precondition for claiming incentive payments. Next to the MU requirements, all PI Program participants are obligated to install 2015 Edition Certified EHR Technology from 2019 onwards. The certification ensures the software's technological capability, functionality, and security to its users. Furthermore, CMS sets standards and other criteria that EHRs must observe, such as storing data in a structured format for an improved data transfer. According to the Medicare Access and CHIP Reauthorization Act, participants must attest that they are not limiting nor restricting the compatibility or interoperability of their certified EHR technology (CMS, 2019c). This information blocking occurs, for example, if a fee for data exchange is requested (ONC, 2019a).
Provide financial incentives and payments reductions
Professionals participating in the Medicare EHR Incentive Program were reimbursed up to $44,000 over 5 years, if they met this program's requirements (CMS, 2012, p. 15). Eligible providers who did not enrol in this program until 2014, became subject to payment adjustments starting in 2015 (CMS, 2015, p. 1). In contrast, no penalties resulted from eligible providers who do not take part in the ongoing Medicaid EHR Incentive Program, where participants could receive up to $63,750 over six years in total (CMS, 2012, p. 15). However, professionals who were eligible for both programs had to prove Meaningful EHR Use in order to avoid being subject to payment adjustments (CMS, 2012, p. 20). This was done by reporting measures for a pre-defined period (e.g. 90 consecutive days in the first participation year; CMS, 2012, p. 33). In October 2018, CMS announced that more than 546,644 participants obtained payments. Since 2011, Medicare paid more than $24.8 billion and Medicaid more than $6 billion for their EHR Incentive Programs (CMS, 2019d).

3.3 The Diffusion of EHRs in the Context of the CMS Incentive Programs

CMS awards MU of EHRs only for a limited period. The year 2014 was the last year to initiate participation in the Medicare EHR Incentive Program, followed by a last incentive payment in 2016. In the Medicaid EHR Incentive Program, the last year to initiate participation was in 2016 following a last payment in 2021 (ONC, 2018). In 2016, more than 95 percent of all eligible hospitals and critical access hospitals have demonstrated MU of certified EHR technology (ONC, 2017a). As part of the eligible professionals, over 60 percent of all office-based physicians have MU certified EHR technology in 2016 (ONC, 2017c). Regarding eligible hospitals, 84 percent of non-federal acute care hospitals were using basic EHR technology in 2015, and 96 percent have possessed a certified EHR system (defined as having an agreement with an EHR vendor, which is not equivalent to adoption) through 2017 (ONC, 2017b). The development of basic EHR adoption (2008-2015) and certified EHR possession (2011-2017) is shown in figure 2. The ONC certification program began in 2011, therefore data on certified EHRs exists since 2011.

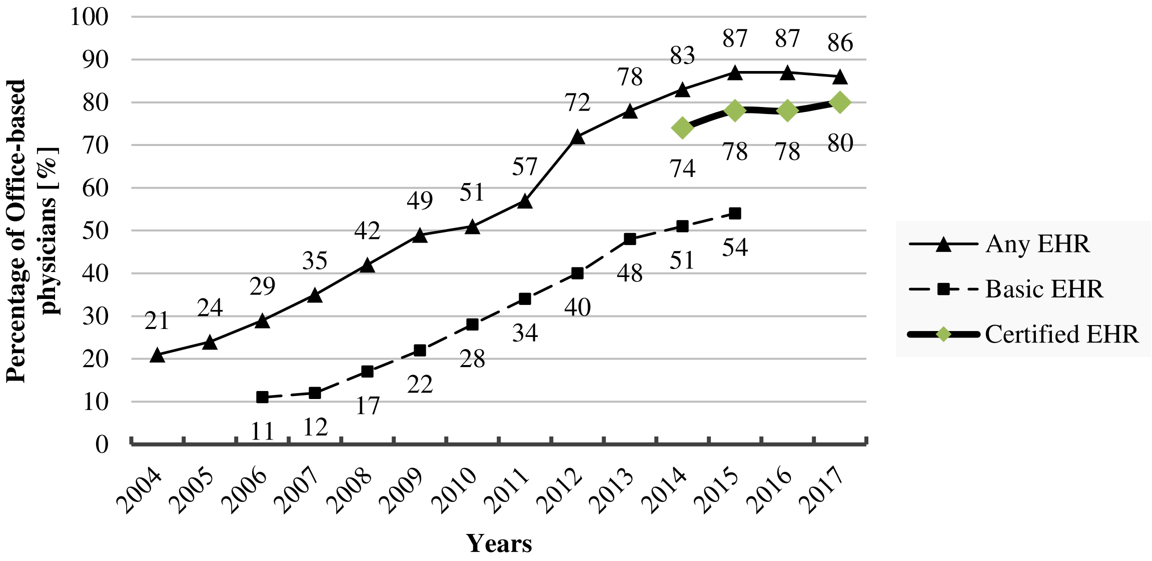
Figure 2: Percentage of Non-federal Acute Care Hospital EHR Adoption from 2008 to 2017



Source: Own presentation based on ONC, 2017b.

Regarding eligible physicians, 54 percent of office-based physicians were using basic EHR technology in 2015. According to the ONC and figures from the National Center for Health Statistics, 86 percent of office-based physicians had adopted an EHR (defined as a medical or health record system that is either all or partially electronic), and 80 percent had adopted a certified EHR in 2017 (ONC, 2019b). Figure 3 shows the development of any (2004-2017), basic (2006-2015), and certified (2014-2017) EHR adoption among office-based physicians. The ONC started tracking adoption of certified EHRs by office-based physicians in 2014. Data on basic EHR adoption (defined as EHRs that report patient demographics, patient problem lists, medication lists, clinician notes, medication orders, laboratory and imaging results) for both eligible hospitals and professionals was collected until year 2015 (HHS, 2018a, p. 18).

Figure 3: Percentage of Office-based Physician EHR Adoption from 2004 to 2017



Source: Own presentation based on ONC, 2019b.

4 Implications for Public Health Insurances

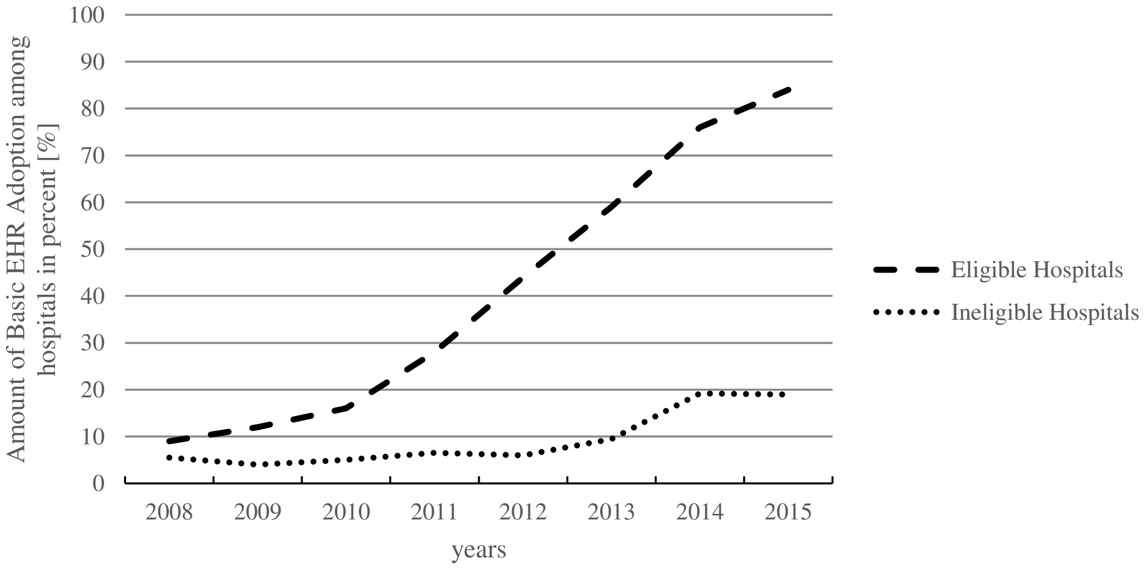
According to the ONC figures 2 and 3, integrated data from the American Hospital Association's annual survey of EHR Adoption, and the National EHRs Survey, hospitals and office-based physicians have constantly adopted basic EHR since 2008. After CMS introduced the Incentive Programs in 2011, hospitals' adoption of certified EHR technology increased from 72 to 96 percent in 2017. In 2014, the ONC began tracking adoption of certified EHRs by office-based physicians. At that time, 74 percent of office-based physicians had already adopted a certified EHR. This figure rose by 6 percent until 2017.

The extent to which the adoption of EHRs by hospitals or physicians was influenced by the HITECH Act of 2009 initialising the CMS Incentive Programs is uncertain and debated. The former National Health Information Technology Coordinator, David Brailer, refers to the trend of increasing EHR implementations before the Act. Healthcare providers would have continued to adopt EHRs independently due to market changes (Woskie, 2015, p. 108). In fact, considering figure 3, a constant rise in any EHR (by 27 percent since 2004) and basic EHR adoption (by 11 percent since 2006) by office-based physicians until 2009 is noticeable (ONC, 2019b). Nevertheless, both figures' graphs increase constantly after the enactment, which indicates a potential influence after the changed legislation.

Considering the Diffusion of Innovation Theory and the data mentioned, the choice to adopt an EHR before the HITECH Act was an optional innovation decision for healthcare providers. They independently gained knowledge of EHRs and their functions via interpersonal exchanges (such as personal exchange among single providers) and mass media channels (such as professional journals). After CMS introduced the EHR Incentive Programs, eligible providers expected financial disadvantages if they did not implement and use EHRs according to the guidelines provided. Thus, the decision became almost a collective innovation-decision, because the members of a system (CMS as a federal agency) reached consensus to promote the

diffusion of EHRs. However, since there is no legal obligation to adopt an EHR, the decision was up to the individual provider.
Researchers like Adler-Milstein and Jha (2017) examine whether policy changes and incentives paid by public health insurances advance EHR adoption. Since incentives are only granted to eligible providers, such as acute care hospitals, the authors compare acute care hospital annual EHR adoption rates before and after the Incentive Programs' introduction in 2011 to long-term acute care, psychiatric, and rehabilitation facilities without access to financial incentives (Adler-Milstein and Jha, 2017, p. 1417). Among 4,268 eligible hospitals included in the study, EHR adoption increased on average from 3.2 percent in the pre-period (2008-2010) to 14.2 percent in the post-period (2011-2015). In contrast, annual adoption rates for the 851 ineligible hospitals rose less rapidly from 0.1 percent before and 3.3 percent after the reform. The results are presented in figure 4. In conclusion, the authors find evidence that the HITECH Act and the incentives did in fact trigger EHR adoption.

Figure 4: Percentage of Basic EHR Adoption among Hospitals by Eligibility for CMS-Incentives from 2008 to 2015



Source: Own presentation based on Adler-Milstein and Jha, 2017, p. 1419.

Similar results regarding the gap between eligible and ineligible hospitals in adopting basic EHRs were found by Walker et al. (2016, p. 497) for the period of 2009-2013. Without financial incentives, long-term care, psychiatric, and rehabilitation hospitals' basic EHR adoption was significantly slower (15 percent in average) until 2013 than eligible hospitals (59 percent). The authors report that ineligible providers might benefit indirectly from an expanding EHR market as its technical developments and expertise grow. Generating vertically integrated health care systems and collaborating with hospital systems could be other reasons for EHR implementations among ineligible providers (Walker et al., 2016, p. 498). According to research on EHR adoptions from 2006 to 2011, physicians in health maintenance organizations adopted EHRs more frequently than solo practitioners (Xierali et al., 2013, p. 391). This can be explained by the diffusion effect that occurs when members of a peer network decide to adopt or reject an innovation, thus putting increasing pressure on the individual to make the same decision about the innovation (Rogers, 1983, p. 234).

According to the Diffusion of Innovations Theory, optional decisions are usually made quicker than collective ones (Rogers, 1983, p. 30). But considering figure 4, the rate of EHR adoption was faster among eligible providers after CMS made a collective decision to push EHR implementation compared to ineligible providers who decide optionally. Thus, CMS was able to extend its programs to ineligible providers to close the technology gap, thereby minimizing potential healthcare inequalities. As CMS links EHRs with higher quality care, patients that go to hospitals or practices that do not adopt EHRs might be systematically disadvantaged (Jung et al., 2015, p. 1036).

As shown in figure 3, 74 percent of office-based physicians (all specialities) had a certified EHR in 2014 (ONC, 2019b). The same year, the adoption rate among primary care physicians (general practitioners, internists, pediatricians, obstetricians, gynaecologists) was 79 percent, whereas nonprimary care physicians' adoption rate was 70 percent (Jamoom et al., 2016, p. 1). Accordingly, EHR adoption by specialists is lower than by primary care physicians. The Diffusion of Innovation Theory predicts that different providers adopt innovations at different rates (Rogers, 1983, p. 246). Specialty physicians might face specialty-specific challenges like workflows (e.g. combination of outpatient and surgical practice) or certain information needed (e.g. image integration) that become barriers to EHR adoption (Grinspan et al., 2013, p. 231). Furthermore, the organizational capability to respond quickly to regulations could be an advantage for hospitals in contrast to ambulatory practices (Adler-Milstein and Jha, 2017, p. 1421), which could explain the higher EHR diffusion rates among eligible hospitals compared to professionals (see fig. 2, 3). A study on New York State physicians found that physicians in practices with more physicians were more likely to participate in the EHR Incentive Programs than those in smaller practices or solo practitioners (Jung et al., 2015, p. 1038). The latter might lack resources and staff to implement and maintain EHRs (Xierali et al., 2013, p. 391). It is possible that the setting determines the time needed for an EHR adoption rather than the actual decision of whether or not to adopt (Castillo et al., 2018, p. 2).

Other aspects CMS might consider if EHRs are to be extended include the knowledge and persuasion stage of the element of time of the Diffusion of Innovations Theory (see fig. 1). By disseminating knowledge and convincing potential users of the benefits, CMS influences the first two stages of the Innovation-Decision Process. If providers form a favourable attitude toward EHRs, they likely opt for an application. A targeted use of communication channels can also affect this decision. For example, messages received through interpersonal channels are especially persuasive due to their subjective nature (Rogers, 1983, p. 18). Besides spreading knowledge, CMS provides monetary, administrative, and technical support as part of the Incentive Programs to decimate factors hindering the diffusion process. One reason for the general upward trend of EHR installation among both eligible hospitals and professionals could be CMS's strategy to offer financial incentives to help overcome some of the high implementation costs. This policy seems to be crucial for a large-scale EHR installation, because initial costs were stated most often in a systematic literature review about EHR adoption barriers (Kruse et al., 2016, p. 5).

However, these results do not imply success in every respect. For example, the ONC reported 96 percent of hospitals possessed a certified EHR (ONC, 2017b), but this does

not indicate whether all hospitals use these systems and if they met the MU criteria. In parallel, ineligible providers implement technology that match their individual and organisational characteristics, disregarding the specifications of the Incentive Programs. Therefore, their EHRs may not meet the functionality criteria of a basic EHR (Walker et al., 2016, p. 497). Certain challenges remain, particularly regarding EHR interoperability between providers. To address these, CMS modified the PI Programs (CMS, 2019f). The ONC monitors the development of four interoperability domains: sending, receiving, finding, and integrating electronic health information among acute care hospitals. Recent data show that hospitals engaged in all domains increased by 41 percent since 2016. However, the findings also highlight challenges, especially in integrating or receiving health information notably for small, rural, and critical access hospitals (Pylypchuk et al., 2018, p. 8).
Hospitals also state that multiple vendor platforms are a barrier for exchanging data (Pylypchuk et al., 2018, p. 8). The EHR market remains fragmented and consists of many different vendors. Some of them disturb data exchanges by developing products with limited interoperability (Adler-Milstein and Pfeifer, 2017, p. 118). Through certification criteria for EHRs as part of the PI Programs, CMS tries to counteract these activities (CMS, 2019c). A recent study reveals that vendor choices affect the performance of hospitals in the Incentive Programs, and therefore suggests advancing the EHR certification requirements (Holmgren et al., 2018, p. 658). Seamless data exchange is not only relevant for hospitals or physicians, but also for public health agencies and registries (Blumenthal, 2018, p. 23). Multiple providers using unstandardized EHRs report to surveillance programs which are challenged to integrate the data within their workflow (Birkhead et al., 2015, pp. 350; 356). Next to advances in public health, CMS associates EHRs with improvements in care quality, patient safety, and cost savings. However, the promising benefits and features of EHRs require further efforts of the public health insurances and strategies to tackle the challenges mentioned that hinder realizing the full potential of EHRs.

5 Conclusion

Over the past years, CMS has initiated a widespread transformation of health information technology in the US. However, as the Diffusion of Innovation Theory predicted, different providers adopt innovations at different rates. Assessing provider-specific characteristics and attitudes towards innovations, communication behaviours, and technology application barriers might help to draft tailor-made strategies to further advance certified EHR implementation and usage. Ineligible providers should not be disregarded in the efforts, especially considering CMS's goal apply to these healthcare providers as well. Since the Incentive Programs greatly aided EHR diffusion among eligible providers, others may benefit from program expansions. However, challenges remain, particularly in the domains of interoperability and usability. Patients whose providers have limited or no involvement in the exchange of electronic data could be disadvantaged, leading to inequalities instead of improvements in healthcare delivery. Therefore, public health insurance companies should now focus on closing the gap in EHR adoption and meaningful usage to provide access to high quality healthcare. They should also focus on developing a standardized EHR infrastructure with transparent certification criteria for all stakeholders to realize the full potential of EHRs

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Implementation of Digital Transformation at a Hospital

Dorothea Finzel

As medical institutions in health care, hospitals vary in different characteristics from a company in the classical sense. Despite these differing characteristics, digital technologies offer great potential for hospitals and companies in the course of the digital revolution. For an efficient implementation of digital transformation in hospitals, this paper examines whether hospitals can also be digitally transformed on the basis of the 'Stages to Digital Business Transformation' model developed for business companies. To set the stage, the differentiation of the terms digitization, digitalization and digital transformation is explained in detail. This term paper highlights the presentation of the characteristics of hospitals such as the highly complex bilateral, person-related service, and high proportion of over 56 years old doctors, and also analyses the individual stages in the model of the Five Stages in Digital Business Transformation. Results show that the respective stages of the Five Stages in Digital Business Transformation model focus on various goals and challenges, which in principle can also be implemented in hospitals. Finally, it is important to note that new challenges could arise due to changing characteristics of the hospital which are dependent on the goals and management of each individual hospital. A guideline with an additional checklist should therefore be developed in a further research for the simple implementation of digital transformation in hospitals.

Contents

1 Digital Revolution in Hospitals

Since the 1950s, our society has been in the midst of a technological development. The digital revolution has not only become a trend, it has been spreading or has already spread to more and more areas, according to Rückert (2018, p. 8). Many companies are already taking advantage of digital technologies and are developing into so-called 'digital businesses'. There are many models of Digital Business Transformation and can be used for a structured implementation (Matt, Hess and Benlian, 2015, pp. 339–340).
Although there is obvious potential for digital transformation in hospitals, the execution in this space has not yet advanced (Krüger-Brand, 2017, p. 2258). A cause of the lack of advancement could be that despite operating economically like a business company in the classical sense (Klimpe, 2015, p. 192), the hospital as a medical facility has various special characteristics such as the category of the products (Jäschke and Richard, pp. 7–9). An efficient introduction of digital opportunities would be an advantage if hospitals could apply existing strategies typically designed for non-healthcare companies.
The aim of this thesis is to investigate whether digital transformations developed for business companies can also be applied to hospitals (given their unique business structure) in order to implement a complete digitalization in the hospital.
To complete a comprehensive analysis, the model of the Stages in Digital Business Transformation of Berghaus and Back (2016) was applied. This model was designed on the basis of a wide range of individual companies and therefore represents many of the digital transformation of companies.
It is important to define the terminology for a general and uniform understanding. Therefore this paper will define digitization, digitalization, and digital transformation. Subsequently, the structure of the maturity model of Berghaus and Back (2016) is described in detail. Following the maturity model, the special challenges and characteristics of hospitals are characterized in order to analyze selected elements of the Stages in Digital Business Transformation to a hospital. The results will then be discussed and summarized. Overall, this paper focuses primarily on the Five Stages in Digital Transformation in hospitals.

2 Terminology of Digital Transformation

Although the terms *digitization*, *digitalization* and *digital transformation* are a central component of terminology in the field of digital change, there are often uncertainties regarding which one to use. The difficulty in correctly identifying which one to use is further reinforced by the lack of 'official' and 'uniform' definitions. Accordingly, terms in literature have different meanings and ways of use depending on context and author (Bloomberg, 2018).

2.1 Digitization

The definition of *digitization*, according to Steinhubl and Topol (2015, p. 1489) is „the process of changing data into a digital form that can be easily read and processed by a computer.“ On the other hand, according to Carayannis (2013, p. 538), this process leads to a replacement product and not to a real novelty. For example, the transformation of analogue books to digital ebooks creates a new way of reading or a new method of

communicating information. *Digitization* as a simple transformation process, defined by Gassmann, Frankenberger and Csik (2014, p. 6) as more than a business model that has the "ability to turn existing products or services into digital variants".
For a uniform and comprehensible understanding, *digitization* is defined in this paper according to Gartner's Glossary (2019) as „the process of changing from analog to digital form, also known as digital enablement. […], *digitization* takes an analog process and changes it to a digital form without any different-in-kind changes to the process itself."

2.2 Digitalization and Digital Transformation

Digitalization is also a complex term, therefore there are many different interpretations of this word depending on context and author. In some cases, the terms *digitization* and *digitalization* are not distinguished and are therefore assumed synonyms (BarNir, Gallaugher and Auger, 2003, p. 791; Cooley, 2018, p. 2). Brennen and Kreiss (2019) offer a basic differentiation between the words *digitization* and *digitalization*. The authors provide the following definition of *digitalization*: "the adoption or increase in use of digital or computer technology by an organization, industry, country, etc." Additionally, Brennen and Kreiss (2019) concluded that *digitalization* is strongly linked to social life and as a result, many areas of social life are being restructured around digital communication and media infrastructures.
Gartner (2019) defines *digitalization* as "[...] the use of digital technologies to change a business model and provide new revenue and value-producing opportunities; it is the process of moving to a digital business." In this context, Garter highlights the change within companies through the use of digital technologies. However, his description already resembles the definition of *digital transformation*. Parviainen et. al (2017, p. 64) describe *digital transformation* as "[...] changes in ways of working, roles, and business offering caused by adoption of digital technologies in an organization, or in the operation environment of the organization." In another definition of *digital transformation*, Mazzone (2014, p. 8) also stresses that digital change should be implied both strategically and tactically.
In order to differentiate the terms *digitalization* and *digital transformation* more precisely, this paper analyses the following definitions by Bloomberg (2018): *digitalization* through digital technologies influences the processes and structures that make up a company's operations, and *digital transformation* is related to digital change with the entire company and its corporate strategy and management.
According to the Roland Berger's 2015 study on digital transformation in the industry 'Die digitale Transformation der Industrie', *digital transformation* is influenced by four different levers. The first lever effect results from digital data, which provides the basis for better predictions and decisions through acquisition, processing, and evaluation. Furthermore, a guiding dimension of digital transformation is the automatization of systems and processes resulting from new technologies in connection with artificial intelligence. Moreover, the mobile networking of all participants in the value chain positively changes the digital transformation of a company. As a fourth leverage effect, a customer can access new digital technologies, which results in an improved customer experience (Bloching, et al., 2015, pp. 18–20).

3 Implementation of the Five Stages in Digital Business Transformation at a Hospital

3.1 The Unique Characteristics of a Hospital

A hospital's management structures and daily tasks economically operate in a similar way that non-healthcare companies operate (Klimpe, 2015, p. 192). However, a medical facility is characterized by special characteristics, such as the category of the products, the personal situations, and unique challenges (Jäschke and Richard, pp. 7–8).

The product of the hospital, the change of the state of health, is classified as a highly complex, bilateral, and person-specific service. The characteristics of the provision of services in hospitals implies various characteristics. In principle, a service can only be provided to the customers or patients, and as a result, service provision and service delivery arise simultaneously. This has the consequence that activities of the hospital staff are mostly bound to the hospital by working with patients. In addition, the individuality of the person or patient makes it difficult to standardize patient-centred work in the hospital (Sibbel, 2004, pp. 22–25).

Standardization of treatment processes bring fundamental and important advantages in terms of costs and quality assurance. Therefore, despite the heterogeneity of the treatment spectrum and the individuality of patients in a hospital, the goal in hospitals is to standardize homogeneous clinical manifestations through clinical pathways. (Schlüchtermann, 2016, p. 81).

In addition, staffing shortages among nursing and doctors due to a decrease in the working population and resulting increase in workload for each of these professions pose a significant challenge (Hellmann, Hasebrook and Beushausen, 2016, p. 14). Doctors in the USA are also characterized by a high proportion of over 56-year-olds. Approximately 46% of practicing physicians are 56 years old or older (The Physicians Foundation, 2019).

Working with people's health also creates special requirements for the protection of privacy and thus, for protection of patient data. In the USA, requirements for data protection in hospitals are regulated in the Health Insurance Portability and Accountability Act (HIPPA). The primary objective of this policy is to provide continuous flow of health information needed while the individuals' health information is properly protected (OCR, 2003, p. 1).

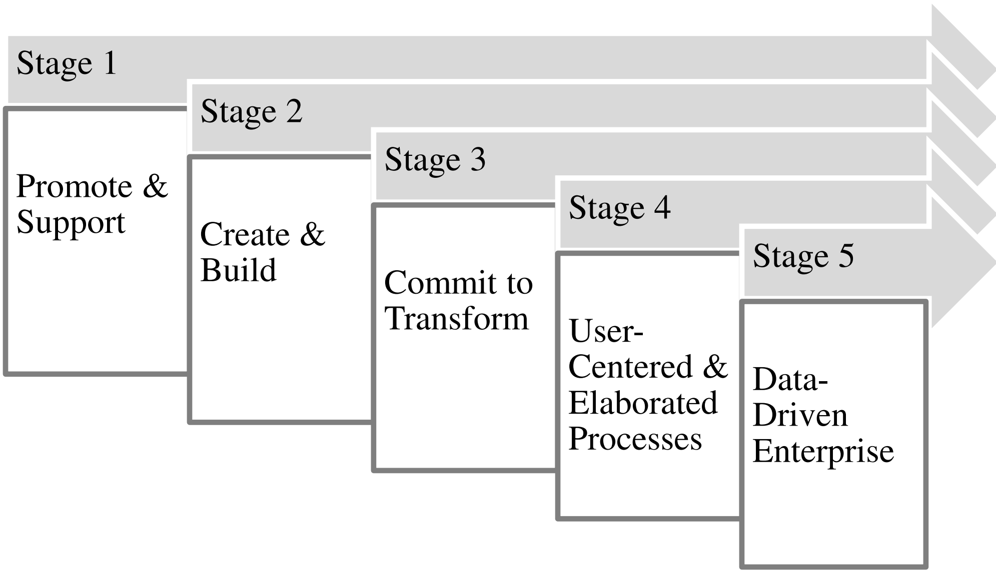
3.2 The Five Stages in Digital Business Transformation

3.2.1 The Model of Stages in Digital Business Transformation

Berghaus and Back (2016, pp. 4–5) divided the affected areas of the company for their model of stages in Digital Business Transformation in the following nine dimensions: Customer Experience, Product Innovation, Strategy, Organization, Process Digitization, Collaboration, Information Technology, Culture & Expertise, and Transformation Management. Berghaus and Back therefore extended the leverage model of the Roland Berger study to include the general areas of human resources, strategy & management and product (innovations).

The model used in the study on the digital transformation of Berghaus and Back is a maturity model. This is a common approach to assess the implementation of techniques or concepts. For the maturity model, the application process is separated into different stages and the dimensions are assigned in one of the defined stages (Bogaschewsky, et al., 2016, p. 97). The nine dimensions and the corresponding items were analyzed in the present study according to difficulty, priority and implementation. They were then assigned to the following five stages in Digital Transformation: Business Promote & Support, Create & Build, Commit to Transform, User-Centered & Elaborated Processes and Data-Driven Enterprise (see Figure 1) (Berghaus and Back, 2016, p. 6).

Figure 1: Five Stages in Digital Business Transformation



Source: Own presentation based on Berghaus and Back, 2016, p. 6-10.

3.2.2 Stage 1: Promote & Support

In the first stage of the Digital Business Transformation, awareness of digitization and digitalization need to be raised in companies and hospitals with regard to management and personnel. Therefore, strategic prioritization, flexible work, and management support of digital transformation need to be implemented, according to Berghaus und Back (2016, pp. 6–7).

First, management must adopt a digital transformation as continual strategic project. Additionally, the high value of a digital business should be considered in the overall strategy. This means that management needs to promote and prioritize digital treatment methods and other digital technologies to improve internal processes. Moreover, medical or organizational departments with promising digital success should be selected and promoted for digitization and digitalization (Berghaus and Back, 2016, pp. 6–7). Since the management in hospitals is also responsible for strategic and innovative decisions, these implementations are feasible (Hellmann, Hasebrook and Beushausen, 2016, p. 117).

This stage also affects the collaboration of personnel and their involvement in the digital transformation. It is important that employees are familiar with digital products, however this could become especially difficult for doctors of older generations. Because of their lack of training to rapidly evolving technologies, their digital affinity could be low and therefore have to receive additional digital education (Bayerischer Industrie- und Handelskammertag e.V., 2018, p. 3). In addition, the existing time pressure in nursing due to a lack of labour leads to a high number of sick days (Hofmann, 2012, p. 1166). There could be some time driven issues to implement trainings session for efficient and correct use of digital equipment. It is also important to note that at this stage, flexible work conditions for employers are recommended. As previously stated, since the specialty of the hospital product, the change of the state of health, requires personnel to work stationary at the hospital, there are flexible working possibilities curtailed. Only some duties can be managed from home or from flexible working spaces. For example, there is a possibility that coders, billing, and account receivable staff etc. could accomplish their jobs from their preferred workspace or location (Relias Media, 2017). Similar to some of the off-site imaging services such as evaluations of x-ray, Computed Tomography (CT) and Magnetic Resonance Tomography (MRT), some jobs can be done from offside offices (medavis GmbH, 2011).

In addition, it is human nature that people are in principle afraid of change and prefer their usual working methods (Goepfert and Conrad, 2013, pp. 185–186). For this reason, a fundamental change in treatment methods through new digital technologies or through the digitalisation of the previous processes could potentially result in interpersonal conflict.

3.2.3 Stage 2: Create & Build

The central content of this stage is the development and implementation of digital innovations and technologies. Regular systematic evaluations for technical potential in all internal partial and overall processes are carried out on a strategic level. Moreover, resources such as time and budget are released by management for development and implementation of innovations. In order to generate a ready-to-use environment for new innovations, digital competences of all participants and digital activities will be strengthened in this stage. In addition, liaising with external partners such as start-ups, universities, etc. will also help with the development and implementation of digital innovations and technologies (Berghaus and Back, 2016, pp. 7–8).

Another important dimension of the second stage is the digitization of existing processes. This includes that previous analogue communication now mainly takes place via digital channels (Berghaus and Back, 2016, p. 7). Parts of this networking and digitization of existing processes and corresponding departments can already be fundamentally achieved in hospitals with so-called ‘hospital information systems’ (HIS). These systems offer a platform for numerous tasks of hospitals. For example, with HIS, patient-oriented digital features can be built in order to create a consistent customer experience and smooth communication via various channels. During their stay in the hospital, patients can be informed digitally about current waiting times, preliminary findings, or general recommendations for a healthy behavior. Furthermore, HIS offer digital possibilities for internal communication or detailed documentation of costs and other relevant key indicators (Benthin and Koch-Büttner, 2018, pp. 13–14).

Constructive error management is also important for successful implementation and use of digital innovations in hospitals (Berghaus and Back, 2016, p. 7). In order to improve the application of digital novelties, errors must first be detected. This is particularly true in hospitals because the recognition of errors is critical, particularly because there is a historical expectation of error-free work (Sexton, Thomas and Helmreich, 2000, p. 747).

3.2.4 Stage 3: Commit to Transform

Changes in the third stage focus on the dimensions of Culture & Expertise, Organization and Transformation Management, where mainly internal structures are modified by digitization and digitalization (Berghaus and Back, 2016, p. 8).
At this point of digital transformation, a systematic transformation management is implied. This means that responsibilities are developed and allocated through defined task and decision areas and are allocated contact people (Berghaus and Back, 2016, p. 8). A structured system of representatives for special areas of responsibility is common in hospitals, particularly for minimizing liability-related risks and increasing patient safety (Felber, 2011, p. 361).
In this stage, hospital management is also able to define a strategic plan, which is to be used as basis for structured implementation of digital transformation. In 2016, already about 83% of hospitals implemented a systematic strategic management, therefore it is possible to develop strategic plans in context of a digital transformation in hospitals (Deutsches Krankenhausinstitut e.V., 2016, p. 9).
It is also important to note that employee culture is changing in this stage: Digital knowledge and experience become a main component in search for employees (Berghaus and Back, 2016, p. 8). However, there is currently a severe shortage of qualified personnel among hospital staff, especially nurses. According to the US Bureau of Labor Statistics, 1.1 million more nurses are needed to control the increasing shortage (Haddad and Toney-Butler, 2019). Therefore, qualified medical staff are already rare and additional conditions attached to recruitment could minimize potential employees.
The dimension of process digitization will also be further developed in this phase. This is where automated routine processes emerge. At this point, a distinction can be made at companies and hospitals between main services (primary processes) and auxiliary services (secondary and tertiary processes). In hospitals, the main service is a positive change in the state of health and thus all associated diagnostic, therapeutic, and nursing services. In order for this service to be carried out smoothly, support services such as purchasing, logistics and laboratory services are required (Schlüchtermann, 2016, pp. 90–91). As already discussed, a standardization by clinical pathways is aimed at in medical processes, where the individuality of patient must always be considered in the treatment plan. In administrative auxiliary processes in hospitals (e.g. in purchasing), processes can be precisely simplified and improved with the help of automatic digital technologies (Richard, 2016, p. 16).

3.2.5 Stage 4: User-Centered & Elaborated Processes

Objectives of the fourth stage focus on involving customers or patients in further development of the processes to create a personalized customer experience. Additionally, digital changes and goals already achieved in this phase are regularly monitored, evaluated and improved, e.g. on the basis of selected key performance indicators (KPIs) (Berghaus and Back, 2016, p. 9).

Various tools can be used for target control. These include the KPIs, which can be displayed collectively via the company-wide or hospital-wide Balanced Scorecard, and thus present a well-structured summary of indicators for selected goals (Fernandes, Raja and Whalley, 2006, p. 623). This collection, presentation, and analysis of the KPIs is also possible in hospitals in digital form using HIS for example (Benthin and Koch-Büttner, 2018, p. 14).

3.2.6 Stage 5: Data-Driven Enterprise

During stage 5, data is collected during interactions with customers or patients through internal or external processes. The Big Data are then analyzed with advanced data analytics technologies and used purposefully for decision support, product development, and process development. A prerequisite for this stage is appropriate technical and digital equipment and internal expertise (Berghaus and Back, 2016, pp. 9–10).
At this stage of digital transformation, customer and interaction data are measured across multiple channels. The aim is to analyze and process the collected data in real time. For the analysis and processing of customer or patient data in real time, a form of the HIS discussed above could be used. The aim of this stage is also possible in hospitals (Benthin and Koch-Büttner, 2018, p. 14).

4 Discussion

In summary, hospitals have special factors that distinguish them from a traditional company. The product of hospitals is the change in the state of health of a patient, which represents a highly complex, bilateral, patient-centric service. Despite these individual services, a standardization of medical processes in the form of clinical pathways is necessary. Furthermore, there are notable issues in the realm of hospital personnel. For instance, there is a high proportion of doctors who are over the age of 56. In addition, there are far-reaching bottlenecks in personnel, especially in nursing staff. Another notable issue is data protection in general, especially in health care and hospitals specifically. Since this concerns sensitive health data of the patients, special caution is required in this industry.
Stage 1 of the Digital Business Transformation model promotes the importance of digital transformation in hospitals. As already mentioned, the changes by management and in personnel can be carried out on basis of the company-like conditions, only with minor individual challenges like the conversion of advanced training, for example. *Stage 2* focuses on the development and implementation of digital innovations and technologies. The associated process of digitization can be carried out in hospitals with the help of HIS. The required error management is also already an integral part of patient security in many hospitals. Consequently, *Stage 3* focuses on a change of inner structures. This means that representatives are assigned to various tasks and strategic management, which is largely present in hospitals, and develop a strategic and structured plan for digital transformation. In addition, automatic routine processes are also be created in hospitals for administrative processes. The set objectives are reviewed regularly and structured in *Stage 4*. This target control can be quantified by KPIs. The last stage is *Stage 5,* which discusses with the analysis and processing of collected data from internal and external sources in real time. In this stage too, the HIS for hospitals offers a suitable

platform. Nevertheless, in this stage, as in the previous ones, appropriate data protection must always be ensured.
If one considers the implemented dimensions of the Five Stages in Digital Business Transformation on the basis of the characteristics in hospitals, all tasks, with exception of acquisition of personnel with a digital affinity, can be carried out in hospitals. It should be noted that, in addition to the items listed in the model, other tasks related to digitization and digitalization also arise, such as stricter error management since the focus is on patient protection and security (Bundesärztekammer, 2019). Despite the special character of the product, digital transformation is possible, but it also creates new challenges such as the development of automatic routine processes.
Therefore, it can be stated that hospitals, as healthcare companies, can also be digitally transformed using a model of digital transformation developed on basis of other non-healthcare companies. However, other country-specific requirements arise whereby results could also change correspondingly, such as in data protection. In addition, there are countless possibilities to carry out a digital transformation of business companies. Therefore, there is not one true approach, and instead depends on the structure and goal of individual company (Matt, Hess and Benlian, 2015, pp. 339–340).
This process was selected in advance of the analysis because it offers a simple and structured approach based on actual digital transformation. The model is divided into different stages, but tasks and objectives of phase can lead to smooth transitions. The analysis is also limited by the scope of the work. Only a superficial analysis of individual selected dimensions could be completed, and based on this, conclusions could be drawn about the entire implementation of a stage in hospitals. The definition of a completely digitalized hospital is also difficult to implement, since the field of digital technologies and innovations is developing rapidly (Talin, 2017).

5 Conclusion

The aim of this thesis was to investigate whether the concept of digital transformation originally developed for business companies can also be applied to hospitals in order to implement a complete digitalization in the hospital. The following has been concluded about a digital business transformation strategy in hospitals: In principle, this thesis can be answered in the affirmative, since many of considered items of different dimensions can also be implemented in the structure of a hospital. It has been shown, for example, that management can adapt and implement hospital strategies to finally adopt a digital transformation. In addition, it can be concluded that digitization and digitalization for many of the internal processes in hospitals is also possible. Nevertheless, it is important to note that due to the special structures of hospitals, some dimensions cannot be fully implemented, and additional challenges can arise in certain dimensions of the Five Stages in Digital Business Transformation. Furthermore, this model is only a pioneer model and not a fixed structure. Thus, depending on the goals and management of hospitals, there may be a different outcome on the research result.
In order to maximize the potential of a digital business, many smaller companies and hospitals need support. Another research could focus on creating an additional checklist to follow guidelines for a digital transformation at a hospital. This could be developed on the basis of a more detailed and systematic analysis of the implementation of the Five Stages in Digital Business Transformation model for a hospital.

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Part 3: Digital Transformation – Users' View

Choosing Wisely vs. Endless Options: Differences in Attitudes towards Innovative Technology in the U.S. and Germany

Christian Horvat

Electronic Health Documentation (EHD) is not yet widely used in Germany in comparison to the US. A possible reason for this could be due to healthcare professionals attitudes regarding innovative technologies, such as EHD. This paper investigates the extent to which differences in effort and performance expectations lead to lesser use of EHD amongst German and American nurses. An innovation scheme derived and the relevant decisional system was selected by building on the terminological key terms and related theoretical concepts. Nurses' individual determinants of adoption were derived from the Unified Theory of Acceptance and Use of Technology (UTAUT). Relevant empirical findings were selected and analysed when meeting inclusion criteria. Impact on nurses' intention and real use behavior was explained through the variables for expectancies and the associated moderating factors. Due to a small number of findings and methodological limitations, a clear conclusion was not possible. The studies showed more valid results for German and American nurse expectancies than for social influence and conditions which are facilitating the use of EHD.

Contents

1 Introduction

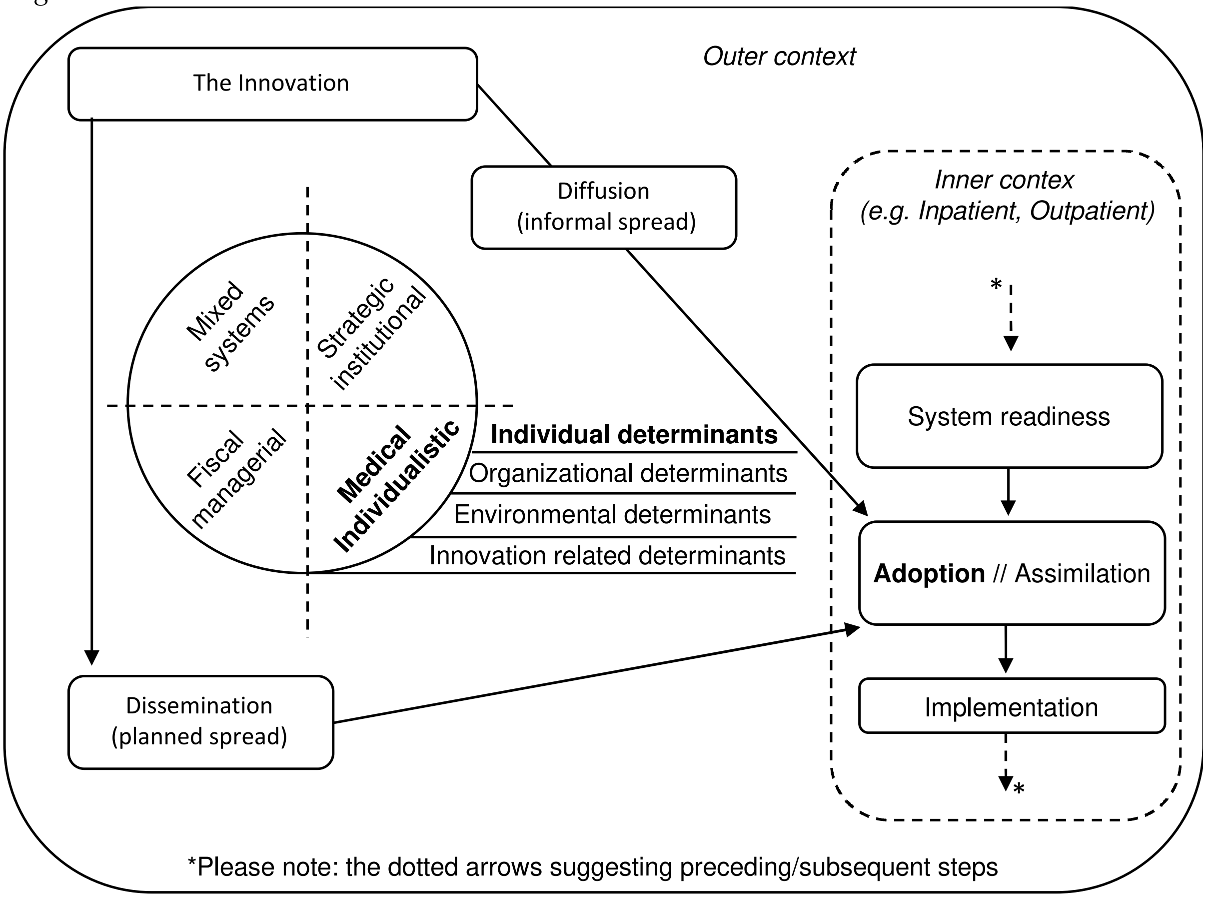
The American Recovery and Reinvestment Act enforced a basis to create an interoperable and digital health care system in the US. One aim of the law was to connect health care providers through the implementation of Electronic Health Documentation (EHD) (cf. Sherer, Meyerhoefer and Peng, 2016, pp.571). In 2009, there was low usage of EHD in the US due to various barriers, partly linked to the resistance of Health Care Professionals (HCP) (cf. Jha et al., 2009, pp.1631). However, in 2015, over 75% of US hospitals adopted an EHD System (cf. Adler-Milstein et al., 2015, pp.2176). In 2016, Germany passed an important law scoping the introduction of electronic health, which has built the basis for a digital and interoperable health care infrastructure (cf. Ber-tram et al., 2019, p.4). Presently, the relatively high distribution rates in the US are contrasting Germanys low rankings in implementation of EHDs (cf. Amelung et al., 2017, pp.28).
The example from the US shows that the implementation of innovative systems such as EHD is accompanied by barriers in different decisional systems. Understanding a HCPs adoption behavior seems to be an essential precondition to introduce EHD successfully (cf. Dockweiler, 2016, p.259).
It can be conjectured that differences in implementation EHD can be driven by an individual's adoption behavior and may vary among US and German HCPs (cf. Dockweiler, 2016, p. 262). Physicians are often known to be the most important group of care providers when it comes to decision-making on whether or not to adopt innovative technologies in healthcare (cf. Varabyova et al., 2017, p.241). But in case of EHD, which is not linked to a single device used for treating or diagnosing patients, this may be different.
Additionally, there seems to be an upcoming nursing shortage in the US (cf. Buerhaus et al., 2017, pp.40), and also a current shortage in Germany (cf. Ka-ragiannidis et al., 2019, pp.329; Fischer, Aust and Krämer, 2016, p.11; Ausserhofer et al., 2014, pp.131). Additionally, it is assumed that a greater need of care will be needed within the next decades. This leads to a necessity to creating more effective and efficient care in order to reduce the workload of nurses and ensure quality of care for patients (cf. WHO, 2016, pp.8). Studies have shown that EHDs could be a feasible solution to reach those goals (cf. Wang, Zhang and Lin, 2016, pp.13; Perotte et al., 2015, p.879). Therefore, this paper will address to which extent differences in expectancy lead to lower Use Behavior (UB) in EHD among German nurses in comparison to US nurses. In doing so, this may help shed light on nurses' perceptions towards EHD and whether the assumed differences can be seen as a greater barrier, possibly a reason behind the lagging adoption of EHD in Germany.

2 The Terminological and Theoretical Framework

2.1 The Terminological Framework of Innovation

Innovation not only represents an incremental change, but also discontinued newness (cf. Greenhalgh et al., 2005, p.26). This change can be seen as an unsteady process within the innovations development itself and the innovations spreading. When combining the perceptions of Greenhalgh et al. (2005, p.201) and the four decisional systems and their determinants from Varabyova et al. (2017, p.239), a scheme (shown in Figure 1) arises which specifies the field of medical individualistic adoption and its determinants.

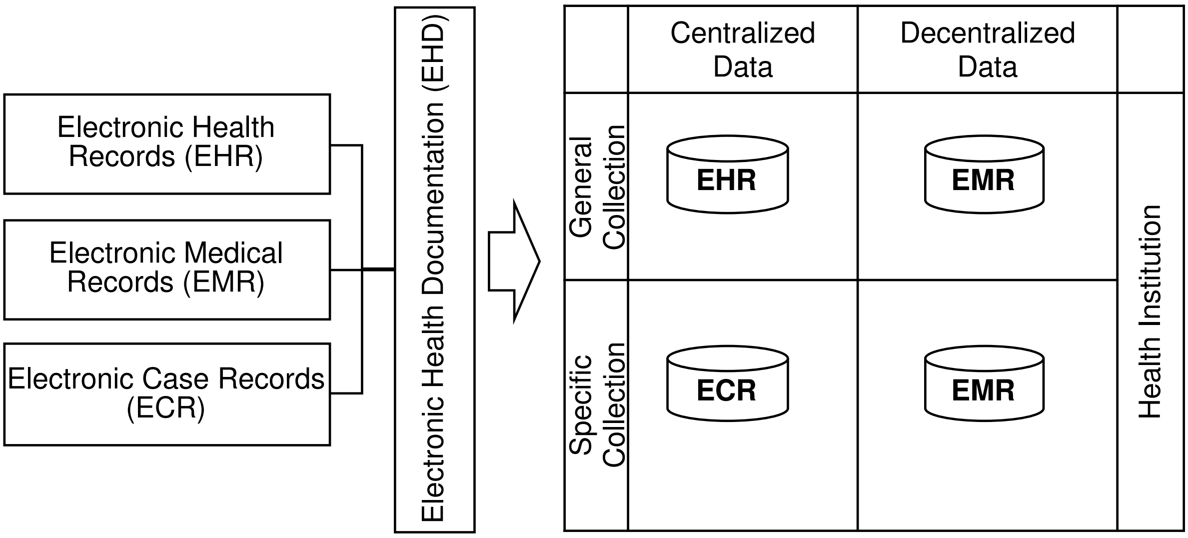
Figure 1: The innovation scheme and its determinants



Source: Own presentation based on Greenhalgh et al., 2005, pp.6; Varabyova et al., 2017, pp.233.

The spread of an innovation is often differentiated by whether it happens on an organizational or individual level. On an individual level, a single person is making a decision regarding an innovation. For the healthcare sector, this individual can be a physician, nurse, or physiotherapist that decides whether or not to use a new technology. In addition, other stakeholders for example healthcare managers, also make decisions when it comes to the implementation of innovative technologies (cf. Varabyova et al., 2017, p.231). At this point it is important to differentiate the two processes of diffusion and dissemination, and thus the individual adoption and the organizational assimilation of innovation. Even though while differentiating those processes a mutual relationship exists, because HCPs are often embedded in organizational structures (for example, medical associations, hospitals, or primary care organization) and organizational decisions are driven by its decider's personal factors (cf. Frambach and Schillewaert, 2002, pp.164). Within the medical individualistic system, a single HCP either adopts a new technology or chooses not to adopt. Beside their individual determinants, HCPs are influenced by the organizational structure he or she is integrated in and by the innovation itself. The individual determinants on which this work continuous to focus are described in the following chapter.
Following the classifications by Dünnebeil et al. (2010) and Haas (2016, pp.187), four EHD types can be categorized by covering the maintenance and administration perspective, the storage location perspective, and the targeted audience (see Figure 2).

Figure 2: EHD classification



Source: Own presentation based on Dünnebeil et al., 2010 and Haas, 2016, pp.187.

As this paper examines the adoption of EHD which represents the innovative element, it is important to understand that innovation in this context is not related to specific devices, such as personal computers or cell phones. It is more the realization of the opportunity to digitize, collect, crosslink, share, and evaluate health-related information and making it accessible for different stakeholders (cf. Fischer, Aust and Krämer, 2016, pp.9), which ultimately changes the processes of treating patients. Electronic Medical Records (EMR) are used by a single medical institution, whereas Electronic Health Records (EHR) shares medical documentation via different health care providers treating a patient. Electronic Case Records (ECR) are used only for a specific medical case by several care providers. Since the adoption behavior of patients is not the objective of this paper, the Personal Health Record is not listed in Figure 2. While Varabyova et al. (2017, p.241) considered physicians as being the most important group of HCPs within this decisional system, the group of nurses in fact outnumbers physicians nearly all over the world (cf. OECD/EU, 2018, p.180) and documents more than any other HCP group in acute and post acute care (cf. Weaver and O'Brien, 2016, p.18).
Recognising this, nurses' individual determinants of adopting EHDs are crucial when implementing such systems in ambulatory care, primary care, or hospitals (cf. Behkami and Daim, 2016, p.11). The process of implementing and developing innovations on an individual level is not steady (cf. Coleman, Katz and Menzel, 1957, p.268) and individuals' attitudes towards innovative technologies are crucial to exploit technological potential (cf. Dockweiler, 2016, p.259). Therefore, innovation should be constantly accompanied by research in adoption behavior. A deeper investigation into adoption theory is covered in the next chapter, which will help shed light on which factors influence nurses in EHD adoption.

2.2 The Theoretical Framework of Adoption Behavior

The adoption and the use of innovative technology has been investigated since the 1960s by various scientific disciplines. The Theory of Diffusion of Innovations in particular can be seen as a major work in this field (cf. Rogers, 2003, p.47). The Davis study remains a milestone by explaining individual adoption behavior and formed the Technology Acceptance Model (TAM) (1989, pp.319). Some studies have shown inconsistencies within the constructs of the TAM Model (cf. Legris, Ingham and Collerette, 2003, pp.202; Sun and Zhang, 2006, pp.64).

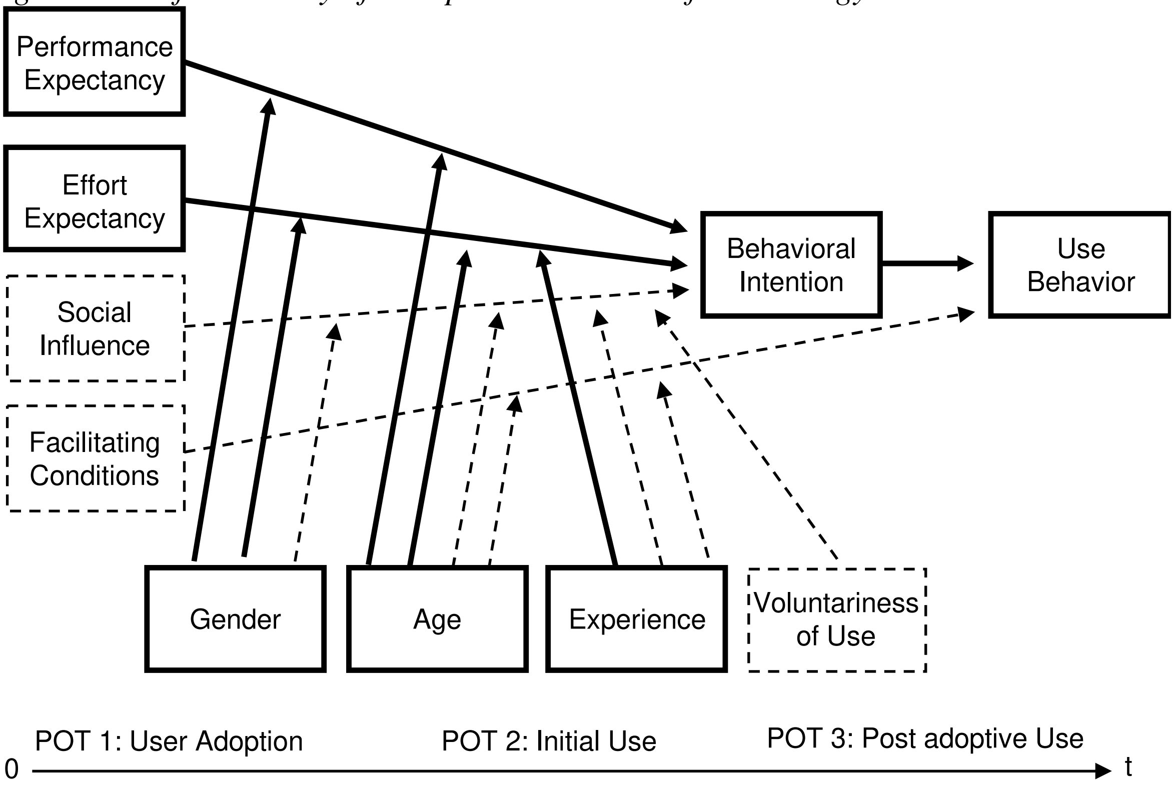
Venkatesh et al. (2003) developed the Unified Theory of Acceptance and Use of Technology (UTAUT), which integrates and draws upon eight different models related to technology acceptance and use. UTAUT was further developed by Venkatesh, Thong and Xu (2012), who then created UTAUT 2.

However, most of the studies conducted in the field of information technology have been using TAM to explain adoption behavior of HCPs (cf. Holden and Karsh, 2010, pp.165; Gagnon et al. 2016, p.214). Additionally, more recent investigations are still using TAM as a partly theoretical basis of their studies and specific TAM models and have been developed to investigate in a specific decisional system (cf. Venkatesh and Bala, 2008, p.273). Nevertheless, an extensive and normative framework arises from the UTAUT model to investigate in the different fields of technical adoption behaviour (cf. Venkatesh, Thong and Xu, 2016, p.350).

Therefore, using the initial UTAUT Model seems to be an appropriate trade-off to cover the current research status and recent model developments. Furthermore, the UTAUT Model has led to a sufficient number of empirical findings. This paper focuses on the two UTAUT variables Performance Expectancy (PE) and Effort Expectancy (EE), which are highlighted in Figure 3.

The UTAUT theory relies on the assumption that the independent variables PE, EE, and Social Influence (SI) are affecting the dependent variable Behavioral Intention (BI). BI and the independent variable Facilitating Conditions (FC) determine the UB of a nurse. PE positively affects a nurses BI to use an EHD. The more a nurse expects an increase in performance, the higher is his/her intention to use this EHD, and vice versa. Initially, EE scale-items where formulated positively (Venkatesh et al., 2003, p.450). Therefore, high values in this dimension stand for less effort using EHD.

Figure 3: Unified Theory of Acceptance and Use of Technology



Source: Own presentation based on Venkatesh et al. 2003, p.447.

EE consists of 'Ease of Use' and 'Complexity,' and PE consists of 'Perceived Usefulness', 'Extrinsic Motivation', 'Job-Fit', 'Relative Advantage' and 'Outcome Expectations' (Davis, 1989; Thompson, Higgins and Howell, 1991; Moore and Benbasat, 1991). These constructs have been finally operationalized by four items each, which can be found in Figure 3. The variables SI and FC are not primary subjects of this paper, however their importance will be discussed briefly in section four. FC in this context means to which extent a nurse is convinced to that he or she has the required resources and knowledge to use the EHD. Contrastingly, EHD compatibility with systems already being used and the possibility to receive support when needed, encloses this dimension. The variable SI includes a nurses' perception on how important others think he or she should or should not use an EHD. Also, organizational efforts and management support are related to this dimension (cf. Venkatesh et al., 2003, p.460). Nurse demographics such as age, gender, their technology experience level, as well as the voluntary use of technology are moderating the independent variables. Their contextual characteristics will be further described in section three. Following the UTAUT specifications, the use of EHD should be measured within four different Periods of Time (POT). Within those POT, different measurements should be performed (cf. Venkatesh et al., 2003, p.437).

Figure 4: Operationalization of PE and EE

Performance Expectancy	U6: I would find the system useful in my job. RA1: Using the system enables me to accomplish tasks more quickly RA 5: Using the system inceases my productivity OE 7: If I use the system, I will increase my chances of getting a raise.
Effort Expectancy	EOU3: My interaction with the system would be clear and understandable. EOU5: It would be easy for me to become skillful at using the system. EOU6: I would find the system easy to use. EU4: Learning to operate the system is ease for me.

Source: Own presentation based on Venkatesh et al., 2003, p.460.

BI and UB both originate from Fishbein and Ajzen (1975) and Davis (1989). Venkatesh et al. (2003) have not defined BI or UB but have measured BI by using items from TAM which have been used in previous acceptance research (cf. Venkatesh et al., 2003, p.438), and measured UB by tracking real usage logs.

3 The Nursing Workforce in Germany and the U.S.

The German nursing workforce can be differentiated by their training levels. In the past decades, nurses were trained according to their later primary field of work: geriatric care, pediatric nursing, and adult nursing. By 2020, vocational nursing training will be provided in a generalized form and will no longer follow this trisection (cf. Hatziliadis, 2019, p.155). The completion of a three-year vocational training is a prerequisite which culminated by a national examination (KrPflAPrV, §§ 1). Once the vocational training and two years of professional experience have been completed, extra-occupational specializations in nursing are possible such as intensive, emergency or palliative care. Nursing staff with three-year vocational training represent the largest subgroup of the nursing workforce in Germany at over 90% (cf. Destatis, 2017). In Germany, the one- or two-year vocational training of nursing assistants is regulated by the 16 federal states. The educational attainment among the assistants ranges between a lower or upper secondary school level (cf. Laxer et al., 2016, p. 68). This group accounts for around 10 percent of the German nursing workforce (cf. Destatis, 2017). In 2003, the first pilot projects for academic nursing were launched in Germany. Since 2017, initial academic education in nursing has also been legally anchored in the Nursing Care Reform Act of 2017 (cf. Darmann-Finck and Reuschenbach, 2018, p. 163). However, the vast majority of care is still provided by vocational nurses, as the group does not yet play a major role in the German nursing care sector (cf. Tannen et al., 2017, p. 42).
In order to work as a nurse in the USA, passing the National Council Licensure Examination (NCLEX) is mandatory. The specific requirements for the NCLEX are outlined in the nurse practice act (cf. Russell, 2017 pp. 19), and are determined at a federal level by the board of nursing and the regulatory body (cf. Hou et al., 2019, p. 113). There are also professional groups of nurse practitioners (NP) and registered nurses (RN). In this occupational group, a relevant Bachelor's or Master's degree is

required. Additionally, someone can become a Licensed Vocational Nurse (LVN) or Licensed Practical Nurse (LPN) with a non-academic degree (cf. Texas Board of Nursing, 2017, Section 301.157). Registered Nurses are the largest occupational group in nursing, accounting for around 77% of all nurses. Approximately 20% of the nursing staff are LVNs/LPNs, and approximately 4% of all nurses are PNs (cf. Bureau of Labor Statistics, 2018).

4 Empirical Findings from Germany and the U.S.

The research and selection of empirical findings was determined by the specific technology (EHD), the user group (nurses), the countries in which the studies have been conducted (US respectively Germany), and the used theory model (UTAUT). A literature search was conducted by following Döring and Bortz (2016a, pp.157). Figure 5 shows the characteristics of the identified studies.

Figure 5: Identified studies meeting search criteria

Study	Country	Usage	n	Setting
Dockweiler et al. (2019)	Germany	hypothetical	179	Outpatient
Holtz and Krein (2011)	USA	real	113	Hospital
Vollmer et al. (2016)	Germany/USA	real	122/103	Hospital
Wills, El-Gayar and Bennett (2008)	USA	real	52	Outpatient

Source: Own presentation.

Two studies investigated the adoption behavior of American Nurses through a questionnaire survey. In Michigan, a 5-point likert scale items was used (cf. Holtz and Krein, 2011, pp.250) and South Dakota, a 7-point likert scale items was used (cf. Willis, El-Gayar and Bennett, 2008, pp. 398).
A study examined the hypothetical adoptive behavior of nurses and apprenticing nurses throughout Germany through an online questionnaire survey using a 4-point likert scale (cf. Dockweiler et al., 2019, p. 89). For better comparability, the results of the latter group were not taken into account. One study investigated the adoption behavior of nursing staff working either at the University Hospital, Erlangen, or Intermountain Medical Center Hospital, Utah through a paper-based questionnaire using the 5-point likert scale items (cf. Vollmer et al., 2016, p. 119).
Furthermore, the differences in PE and EE, possible moderating effects of age, and gender and experience among German and US nurses will be outlined as well as their impact on BI and on UB. The relations between the variables, as determined by the studies, can be found in Figure 6 and will be described in the following sections.

Figure 6: Strength and direction of effects

Direction of effects	**USA**	**Germany**
PE -> BI	*Vollmer et al. (2016):* msr = 3.7451 (p=0.000)* *Holtz and Krein (2011):* β = 0.17 (p=0.05) *Wills El-Gayar and Bennet (2008):* β = 0.269 (p>0.1)	*Vollmer et al. (2016):* msr = 2.4350 (p=0.000)* *Dockweiler et al. (2019):* s.i. = OR 3.430 (p=0.015)*
EE -> BI	*Vollmer et al. (2016):* msr = 3.7516 (p=0.000)* *Holtz and Krein (2011):* β = 0.11 (p=0.11) *Wills, El-Gayar and Bennet (2008):* β = 0.245 (p>0.1)	*Vollmer et al. (2016):* msr = 2.7479 (p=0.000)* *Dockweiler et al. (2019):* s.i. = OR 0.313 (p=0.014)* s.i. = OR 0.217 (p=0.002)*
SI -> BI	*Vollmer et al. (2016):* msr = 2.9462 (p=0.303) *Holtz and Krein (2011):* β = 0.32 (p=0.001) *Wills, El-Gayar and Bennet (2008):* β = 0.324 (p>0.05)*	*Vollmer et al.* msr = 3.1871 (p=0.303) *Dockweiler et al. (2019):* n.a.
BI	*Vollmer et al. (2016):* n.a. *Holtz and Krein (2011)*: $R^2 = 0.28$ *Wills, El-Gayar and Bennet (2008):* $R^2 = 0.511$	*Vollmer et al. (2016):* n.a. *Dockweiler et al. (2019):* $R^2 = 0.561$
BI -> UB	*Vollmer et al. (2016):* n.a. *Holtz and Krein (2011):* n.a. *Wills El-Gayar and Bennet (2008):* β = 0.329 (p>0.001)*	*Vollmer et al. (2016):* n.a. *Dockweiler et al. (2019):* n.a.
FC -> UB	*Vollmer et al. (2016):* msr = 3.8176 (p=0.933) *Holtz and Krein (2011):* n.a. Wills, El-Gayar and Bennett (2008): β = 0.247 (p>0.1)*	*Vollmer et al. (2016):* msr = 3.8174 (p=0.933) *Dockweiler et al. (2019):* s.i. = OR 4.797 (p=0.003)* s.i. = OR 2.556 (p=0.014)*
UB	*Vollmer et al. (2016):* UB for specific EHD parts: diagnosis: 71.7% (p=0.001)* goals: 80.4 (p=0.000)* interventions: 81.8% assessments 81.8% handover: 66.7% *Wills,* El-Gayar and Bennett *(2008):* $R^2 = 0.287$ *Holtz and Krein (2011):* n.a.	*Vollmer et al. (2016):* UB for specific EHD parts diagnosis 38.65% (p=0.001)* goals 45.6% (p=0.000)* interventions 86.0% assessments 96.0% handover 5.3% *Dockweiler et al. (2019):* n.a.

msr= mean scale rating; n.a.= not available; *= significant result; s.i.= single item

Source: Own presentation

4.1 The Performance Expectancy of Nurses

All underlying studies showed statistically significant positive relationship either for single scale items, or between the aggregate variables PE and BI for nurses in Germany as well as in the US, except one study. This outlier showed positive but not significant effects of PE (cf. Willis, El-Gayar and Bennett, 2008, p.399).
German nurses assume a more transparent nursing process, improvements in physician cooperation, and better information exchange among their own professional group. They otherwise do not see much potential of EHD to reduce workload for their own occupational group (cf. Dockweiler et al., 2019, p.91). Additionally, in accordance with Vollmer et al. (2016, p.121), German nurses' rating scales were significantly lower in comparison to the US occupational group, as they do not believe that the use of an EHD System enables them to complete their duties faster.
Contrastingly, US nurses stated that EHD systems can be seen as useful instruments in hospitals which could help to streamline nursing processes. US nurses perceived positive effects on the quality of care (cf. Holtz and Klein, 2011, p.258).

4.2 The Effort Expectancy of Nurses

In contrast to PE, the studies come up with a less consistent picture with regards to EE. There was no uniform statistical significance between the EE of nurses and their BI to use EHD. Vollmer et al. (2016, p.121) showed a positive statistical significance between EE and BI for German and US nurses, but higher statistical significance for US nurses. Therefore, it is expected that German nurses show more efforts to use an EHD than their American colleagues.
Wills, El-Gayar, and Bennett (2008, p.399) also showed a positive but not a significant relationship between EE and BI for US nurses. In terms of scale item ratings, US nurses rated EE at a mean of 3.75, whereas German Nurses rated EE at a mean of 2.75 (cf. Vollmer et al., 2016, p.120). Likewise, a German study presented statistical significance for EE, showing low reservations among German nurses. It states that they assume minimal issues integrating EHD into their daily nursing routine and do not believe it would take much time away in their patient interaction. The study also highlights that high costs and technology dependence were the nurses strongest perceived efforts with an approval rating of approximately 80% and 70%, respectively (cf. Dockweiler et al., 2019, p.94).
Additionally, increased perceived training efforts determines the BI of German nurses negatively (cf. Dockweiler et al., 2019, p.92). An additional US study found no statistical significance between EE and BI among US nurses. This indicates that this variable could be less important compared to other theory constructs that were investigated (cf. Holtz and Krein, 2011, p.254).

4.3 The Moderating Effects of Age, Gender and Experience among Nurses

As shown in Figure 3, an individual's age, gender, and experience are assumed to determine his/her behavioral intention to use a technology by moderating the independent variables PE and EE.

Only two studies presented results related to these findings, even though all studies queried and described the socio-demographic characteristics of the study groups (cf. Dockweiler et al., 2019, p.89; Vollmer et al., 2016, p.120, Holtz and Krein, 2011, pp.252; Wills, El-Gayar and Bennett, 2008, p.398). Vollmer et al. (2016, p.120) found potential cofounding effects, as the study groups differed by age and gender. However, when outlining the study results, differences among US and German nurses can be found for the moderating variable experiences.

First, Dockweiler et al. (2019, p.91) and Holtz and Krein (2011, p.254) show PE is significant, suggesting that the relationship between PE and BI is moderated by German and US nurses experiences, even though this is not supported by initial theory (cf. Venkatesh et al., 2003, p.468). Regarding US nurses, Holtz and Krein (2011, p.254) showed negative moderating effects of experience, because nurses with less than ten years of hospital affiliation found the EHD system significantly more helpful compared to nurses with more experience. For German nurses, Dockweiler et al. (2019, p.91) showed positive moderating effects of experience, because nurses who had participated in an EHD educational training showed significantly more conviction towards EHD potential to coordinate care and integrate EHD into care processes.

Secondly, Holtz and Krein (2011, p.255) found that nurses' EE was not affected by their age or educational level, but by their professional experience. Thus, individuals who had less than 15 years of experience found it easier to learn and use the EHD compared to nurses with 15 years or more of work experience. Likewise, German nurses with less work experience or such who participated fewer in further education trainings significantly perceived more efforts towards their patient-relationship when using EHD (cf. Dockweiler et al., 2019, p.92). Additionally, none of the studies performed regression analysis for moderating variables.

4.4 The Behavioral Intention of Nurses to Use Electronic Health Documentation

Within this section, results related to SI are presented as they are directly linked to BI. From a US perspective the theoretical construct of UTAUT showed positive correlations between PE and BI, EE and BI, and SI and BI. Holtz and Klein (2011, p.253) showed for a group of American nurses that the strongest link to their BI in respect to EHD was SI (correlation 0.55), followed by their PE (correlation 0.48), and then and EE (correlation 0.46). Those results were significant at a 0.01 level and therefore represent high statistical accuracy. Findings by Willis, El-Gayar, and Bennet (2008, p.399) are supporting this ranking on a lower level of correlation.

Dockweiler et al. (2019, p.94) showed statistical significance with regard to German nurses for one single scale item of the PE dimension (0.015 at a 0.05 level) and for two items of the EE dimension (0.014 and 0.002 at a 0.005 level), but no statistical significance for SI. The previous studies investigated in the field of adoption, either in Germany or the US, to figure out nurses' adoption behavior on a national level. Vollmer et al. (2016) primarily addressed differences between German and US nurses. The results of this study showed significantly lower mean scale ratings of German nurses for EE and PE, suggesting (but not tested for) higher BI among US nurses.

4.5 From Behavioral Intention to Real Use Behavior

Figure 3 shows that the factors BI (which roots from PE, EE, and SI) and FC are both influencing the UB of an individual. Holtz and Krein (2011, p.251) did not analyze FC, because their measurements were performed prior the implementation of the EHD in the US. Vollmer et al. (2016, p.121) found high FC ratings for US nurses and German nurses, and therefore rejected the hypothesis. They concluded that better technical and organizational infrastructure was needed to support the EHD use of US nurses.
However, Dockweiler et al. (2019, p.94) found two scale items linked to the construct FC are significant. He stated that data transparency and technical knowledge are important aspects for German nurses and stated high senior management support.
The research question - to which extent differences in performance and effort expectancy are leading to lower UB in EHD among German nurses in comparison to US nurses - can be answered in a tendency. Vollmer et al. (2016, p.121) showed significant higher mean ratings among US nurses regarding their UB towards particular functions of an EHD. This study also showed significant higher PE and EE ratings among US nurses (cf. Section 3.1 and 3.2) but did not analyze the intermediate construct BI.
Additionally, Holtz and Krein (2011, p.254), Wills, and El-Gayar and Bennett (2008, p.399) performed regression analysis for BI and provided a limited explanation (R^2= 0.28 respectively R^2= 0.51). Wills, El-Gayar and Bennett were able to show that BI has significant influence on US nurses UB (β=0.329, p>0.001), explaining nearly 30% of their UB by BI and FC. Dockweiler et al. (2019, p.93) explained over 50% of variance among German nurses BI towards the use of EHD but were not able to analyze UB because nurses' perceptions were related to a hypothetical EHD, meaning that there was no UB at all.

5 Discussion

The study results as shown in Figure 6 and the methodical approach of the studies should to be taken into account first. As stated in Section 3.4, SI seems to have a substantial impact on US nurses rather than PE and EE. Given this fact, the internal consistency of the studies needs to be considered. As shown in Figure 7, the internal consistency for the variables SI and FC are lower than for the variables PE and EE, except for the measurements by Wills, El-Gayar, and Bennett (2008) and therefore undercut sufficient reliability (cf. Döring and Bortz, 2016b, p.443). Not all studies listed items and rather replaced or omitted original items partly (cf. Dockweiler et al., 2019, p.91). Consequently, a profound comparison on an item-level was not possible.

Figure 7: Internal consistencies of the studies

Study	UTAUT item reliability expressed as Cronbach's Alpha			
	PE	EE	SI	FC
Dockweiler et al. (2019)	α=0,91	α=0,86	α=0,66	α=0,80
Vollmer et al. (2016)	α=0,86	α=0,87	α=0,64	α=0,68
Holtz and Krein (2011)	α=0.80	α=0.82	α=0,79 // 0,87	n.a.**
Study	UTAUT AVE scores and correlation of latent variables for UB			
Wills, El-Gayar and Bennett (2008)*	0.360	0.592	0.510	0.470

***Please note: Study used a different approach verifying good internal consistency; **not analyzed**

Source: Own presentation based on the shown studies.

Discussing the importance of the variables on a model-independent level, Sadoughi, Khodaveisi, and Ahmadi (2018) displayed more significant dependencies for dimensions related to PE and EE when considering proximity between TAM and UTAUT. Kim et al. (2016) showed this proximity for EHR adoption behavior of HCPs between PE and Perceived Usefulness (PU) as well as EE and Perceived Ease of Use (PEOU). Taking this connection into account, additional studies showed the importance of PE and EE for EHD among nurses (cf. Dharmarajan and Gangadharan, 2013, p.2628; Strudwick and McGillis Hall, 2015, pp.599). Investigations in other fields of digital innovation in healthcare showed non-significance of relationships between SI and BI (cf. Sezgin, Yildirim and Yildirim, 2018, p.160).

Especially for the variable FC, Li et al. (2013) showed a much larger cluster of possible relevant aspects in comparison to PE and EE, rooting the difficulty to relate the variable with a user's BI. These reflections relativize the results and shows the need for additional research in the field of SI and FC among nurses. As shown in section 3.5, differences in PE and EE among German and US nurses can hardly be assessed.

Therefore, international results are useful to help frame the situation. Tubaishat (2018, pp.383) showed nearly equal mean scale ratings among Jordanian nurses (mean ratings at a 3.9 and 3.7 level) compared to US nurses (cf. Section 3.2 and 3.3). This supports the US results, even though the group of Jordanian nurses were on average younger and included more men in comparison to the US and German nurse groups.

As described in section 3.3, the role of moderating variables complicates the comparability, as nurse populations differ by age, gender, and experience. Venkatesh and Morris (2000, pp.128) revealed that men in comparison to women more heavily consider the aspect performance when deciding to use or not to use new technology. Women, by contrast, consider effort aspects more than men when considering use of a new technology. Even though German and US studies are unable to provide such insights from a quantitative perspective, similar gender-specific effects have been shown by Tubaishat (2018, pp.385) for the group of Jordan nurses as well.

Initially, the role of experience can be seen contractionary for US and German nurses. Experience seems to negatively affect PE for US nurses, whereas experience positively affects PE for German nurses. Taking a closer look, these differences may be driven by the studies' different meanings of the term experience. For the US nurses, the time of hospital affiliation was summed under this term by Holtz and Krein (2011, pp.254). However, for German nurses, their educational level was also summed up by Dockweiler et al. (2019, p.91). Tubaishat (2018, p.385) findings support educational training as a positive predictor, showing significant positive effects for Jordan nurses. As their PU increased, the more years of EHR specific experience the nurses gained. Holtz and Krein (2011, p.255) also showed that EE was not affected by US nurses' age, which is supported by Tubaishat's findings (2018, p.385). A lower educational level and work experience was related to more EE of German nurses, (cf. Dockweiler et al., 2019, p.91) which was also supported by Tubaishat (2018, p.385).

Furthermore, some studies showed methodological inconsistencies, for example using items which have not been assessed qualitatively before (cf. Dockweiler, 2019, p.92).

It should be noted that more than a decade separates the oldest from the most current study (cf. Wills, El-Gayar and Bennett, 2008; Dockweiler et al. 2019). As innovation in information technology covers processes that are relatively faster than in other sectors (cf. Fichman, Dos Santos and Zheng, 2014, p.338), the implementation and use of EHD could be differ at the time of investigation if the technical developments are considered. Additionally, most studies did not specify the EHD technology in particular. Referring to Figure 2, most of the studies investigated the field of EMR without differentiating whether or not there was a general collection of data. Therefore, fewer insights were derived related to current aspects, such as cross-linking HCPs and sharing health data among them. This could be improved when assuming centralized and general data collection (cf. Roth and Groß, 2018, p.57).

None of the included studies collected longitudinal data as suggested by Venkatesh et al. (2003, p.438). When considering the definition of innovation as given in section 2.1, the studies were able to provide fragmented insights, but were missing the process of innovation while performing one-time measurements. Nevertheless, implementation contexts are different and research activities are time-consuming and costly. Therefore, researchers should specify the research field they are investigating in by covering the specific technology (e.g. EHR, EMR), the POT, and its corresponding measurements and the related user group (nurses, physicians, etc.) perform more focused research when using the UTAUT model.

Besides these findings, it is not clear to which extent nurses become involved in implementation processes. In hospitals, there may be an indirect impact from care managers, senior nurses, or superusers representing their own interests. Little is known how decisions are reached within ambulatory nursing services.

6 Conclusion

Terminological distinctions, as shown by Greenhalgh et al. (2005, p.201), are useful to define the research area and to avoid misapplication of theory models (for example, operationalization of variables). The differentiation between formal and informal spread of technology may not be a crucial factor for EHD. However, it can be useful when investigating more device-related technologies such as mobile health. The theoretical

basis of many models such as TAM and UTAUT and their further developments are based on the diffusion of innovation theory. However, the extensive systematic review by Greenhalgh et al. (2005) shows limited transferability of those product innovation concepts to process innovations in healthcare (cf. Ward, 2013, p.225). Likewise, this paper showed such limitations too by identifying lower internal validity of FC and SI.
In a nutshell, a direct conclusion from nurses' PE and EE to their UB is not possible as longitudinal data have not been available and have lead to a intermediate function of BI. As discussed, BI seems to be influenced by nurses SI, but this relation has not been tested successfully for nurses. This seems to be similar for FC affecting UB. Therefore, even though Vollmer et al. (2016) identified differences that indicate lower PE and EE of German nurses, the study missed the link from BI to UB. Future research is needed to examine HCP adoption behavior more accurately, particularly in Germany.

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Differentiating Benefits of Electronic Health Records (EHR) from a Physician's Perspective

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The Health Information Technology for Economic and Clinical Health Act, which came into effect in 2009, launched an initiative to promote the dissemination of health informatics. The aim was to increase the motivation of physicians to implement electronic health records in order to improve the quality of care and reduce overall health expenditure. Since then, there has been a continuous increase in the implementation rates of electronic health record systems in hospitals and among office-based physicians. In 2017, almost all large hospitals introduced a certified electronic health record system and approximately 80 percent of office-based physicians used a certified electronic health record system. This paper focuses on identifying the potential benefits for physicians who carry out the implementation of an electronic health record. The physician's acceptance of the new technology is an essential prerequisite for the potential benefits to actually materialize. At this point, it is important also to take a look at the potential disadvantages of the implementation of an electronic health record.

Contents

1 Current Situation of the Dissemination of Electronic Health Records in the U.S.

Since the early 2000s, the electronic health record (EHR) has been a hot topic of discussion in the United States (U.S.). While EHRs collect and store all of a patient's health-related information, EHR systems are also designed to go beyond the collection of the usual clinical data and enable exchange of data with other physicians involved in the treatment of patients (cf. The Office of the National Coordinator for Health Information Technology, 2019). The expansion of these functionalities enables the exchange of information among the treating physicians, and should contribute to an improvement in the quality of care (cf. Menachemi and Collum, 2011, p. 47) and to a reduction in health expenditure (cf. Chaudhry et al., 2006, pp. 747-748).

At the beginning, many doctors were skeptical about the implementation of EHR systems. Before 2008, less than half of the physicians were convinced of using EHR (cf. The Office of the National Coordinator for Health Information Technology, 2019). With the introduction of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009, an initiative was launched to further advance the implementation of EHR systems. Since then, the acceptance of EHRs by office-based physicians has more than doubled. By 2017, nine out of ten office-based physicians had already implemented an EHR system and almost four out of five had adopted a certified EHR (cf. The Office of the National Coordinator for Health Information Technology, 2019). Implementation is also rising in hospitals. By 2017, 99 percent of large hospitals and 97 percent of medium-sized hospitals had already introduced a certified EHR system (cf. The Office of the National Coordinator for Health Information Technology, 2018b). Despite the high implementation rates, some physicians, especially older physicians, remain skeptical about the use of EHR systems. High implementation costs and the perceived questionable data protection are arguments that results in the vote against the implementation of an EHR system, among other things. In addition, physicians fear that the functions of the EHR system will be overburdening (cf. Hatton, Schmidt and Jelenc, 2012, p. 710).

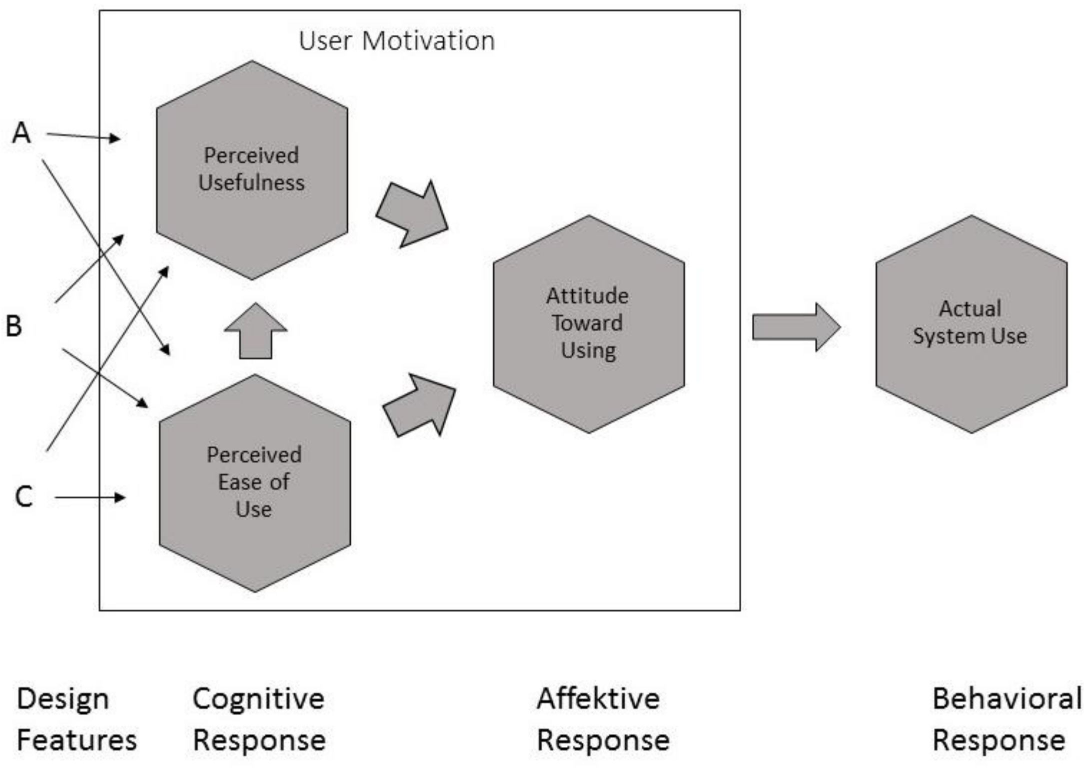
Within the framework of this paper, the advantages and disadvantages of implementing an EHR system are identified. The aim of this paper is to investigate to what extent EHR systems could relieve the physician's burdens in their daily work. To start, data and facts about EHR systems will be presented, important terms will be defined, and the current situation of EHR use will be examined. Subsequently, the individual benefits of EHR systems from a medical point of view will be discussed. This will be followed by a discussion that includes the Technology Acceptance Model by Davis to explain the acceptance by physicians regarding the implementation of an EHR system and to identify important disadvantages of EHR use. Finally, the most important findings are summarized in the conclusion.

2 Facts and Figures on Electronic Health Record Systems

2.1 The Idea of the Technology Acceptance Model

The *Technology Acceptance Model* (TAM) by Davis from 1989 is one of the best-known acceptance models. According to the model, acceptance depends on two factors. The first factor is perceived usefulness and is defined as "the degree to which an individual believes that using a particular system would enhance his or her job performance" (Davis, 1985, p. 26). The second factor is the perceived ease of use and means "the degree to which an individual believes that using a particular system would be free of physical and mental effort" (Davis, 1985, p. 26). Accordingly, the user's acceptance depends on the benefit of the new technology and its usability. The greater the benefit and the easier the usability, the higher the user's acceptance of the new technology. External factors may influence perceived usefulness and perceived ease of use (cf. Davis, 1985, pp. 24-25). For instance, system properties, development processes, or training can be used as possible external variables. The effects of these variables can be used to convey the intention to use, the perceived benefit, and the perceived user-friendliness because these variables influence each other. The easier a system is to use, the more useful it is perceived. However, the variable of perceived usefulness is a slightly stronger determinant than perceived ease of use (cf. Venkatesh and Davis, 2000, p. 187). Due to the limited scope of this work, the focus in the discussion chapter lies primarily on the variable of perceived usefulness. Figure 1 shows the Technology Acceptance Model. In the following, the concept of EHR is discussed.

Figure 1: Technology Acceptance Model



Source: Own presentation based on Davis 1985, p. 24.

2.2 The Concept of Electronic Health Record

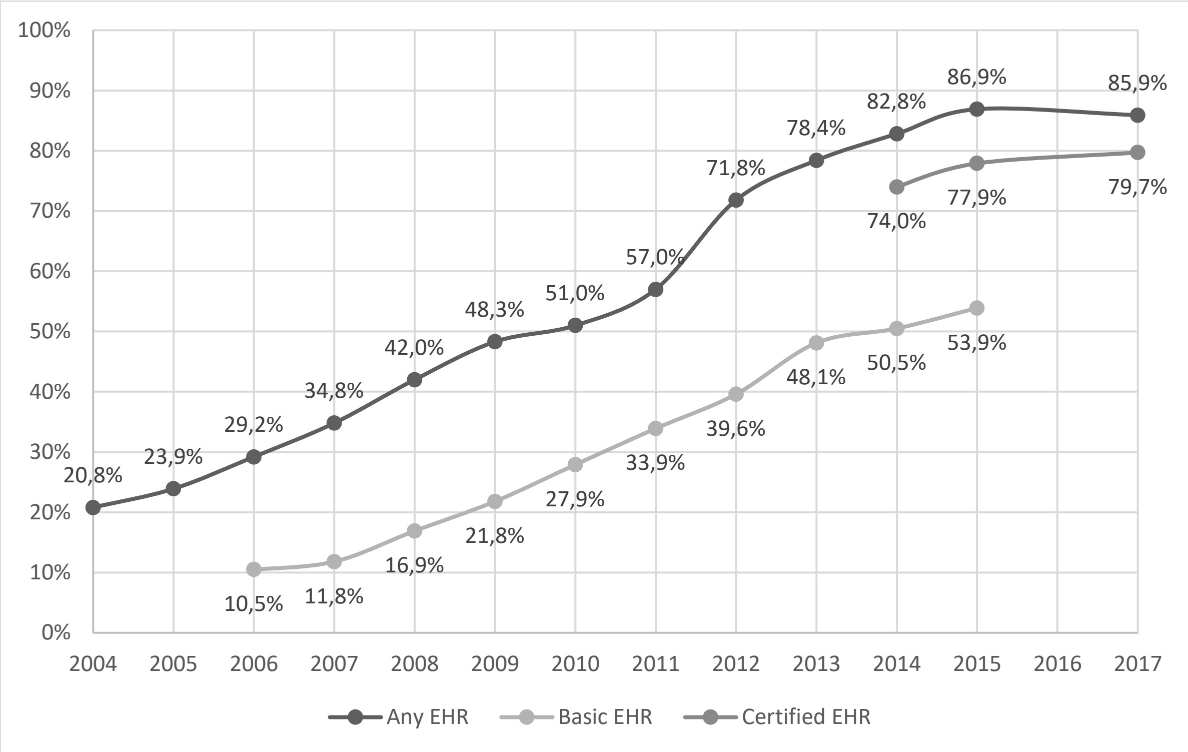
The term *electronic health record* is often used as a synonym to *electronic medical record* (EMR), however, there are some differences between these two terms. The term EMR describes a digital version of a patient's paper record. Medical information of a patient such as diagnoses, medication, and treatment plans are recorded. However, this information is the property of an institution, and can only be viewed and used by it. If necessary, the patient can request a printout of this information to share the information with a specialist, for example (cf. Garrett and Seidman, 2011).

The EHR collects medical information, such as the EMR, and furthermore provides the patients with the ability to add information to the EHR. This collected information can be exchanged with other healthcare personnel, such as laboratories or specialists, in order to have access to the information from all physicians and providers involved in the care of the patient. Thus, EHRs are designed in such a way that not only all persons involved in patients care have access, but also the patients themselves. Another special feature is that patients, as the owner of the EHR, can decide for themselves with whom they want to share their data (cf. Garrett and Seidman, 2011: The Office of the National Coordinator for Health Information Technology, 2018a).

2.3 Users and Application of Electronic Health Records

The HITECH Act in 2009, as part of the American Recovery and Reinvestment Act, was enacted with the goal of motivating providers, such as hospitals and office-based physicians, to adopt EHR systems. The aim was to promote the diffusion of health information technology to improve the delivery of health services and health outcomes (cf. Gold and Mc Laughlin, 2016, p. 655). The EHR incentive programs of Medicare and Medicaid offered hospitals and office-based physicians financial subsidies if they could prove *meaningful use* (cf. King et al., 2014, pp. 392-393). The specific program that physicians could participate in depended on the number of patients insured through Medicare or Medicaid. For example, if office-based physicians treat more patients who are insured through Medicare, they can participate in the Medicare program. Participation in both programs is not possible. There are some differences between these programs: for example, Medicaid provides a higher financial grant than Medicare, and doctors do not have to prove its usefulness until the second year. In the Medicare program, physicians must prove meaningful use in the first year (cf. Bruen et al., 2011, p. 473). A lack of proof of meaningful use or a late implementation of an EHR system resulted in a financial punishment (cf. Atasoy, Greenwood and McCullough, 2019, p. 489). Proof of meaningful use was provided if the implemented EHR system had functionalities such as clinical decision support (CDS) tools, computerized physician order entry (CPOE) and health information exchange (HIE). A CDS system supports the provider in making decisions regarding patients care. A functionality of a CDS system can be the provision of the latest information about a drug. Based on this information, the computer warns physicians if the patient is allergic to a drug or if drug interactions could occur. CPOE systems allow physicians to place orders such as laboratory tests or physiotherapy on a computer rather than on paper. Additionally, HIE enables the exchange of electronic health information at the patient level between different facilities (cf. Menachemi and Collum, 2011, p. 48). Figure 2 shows effects of the HITECH Act and how the implementation of EHR systems by office-based physicians has developed since then.

Figure 2: Office-based Physicians with Electronic Health Record Adoption



Source: Own presentation based on The Office of the National Coordinator for Health Information Technology (2019).

A Basic EHR is based on the physicians' report and includes all of the following computer-assisted functions performed in the practice: patient demographics, patient problem lists, electronic lists of medications taken by patients, clinician notes, medication orders, viewing laboratory results, and displays of imaging results. Any EHR system is a medical or health-related recording system that is either fully or partially electronic and excludes only billing systems. A Certified EHR is a system that meets the requirements of the U.S. Department of Health (cf. The Office of the National Coordinator for Health Information Technology, 2019). The graph above clearly shows the impact of the HITECH Act on implementation rates. The increase in the number of Certified EHR systems in particular indicates that physicians are making extensive use of the EHR.

3 Advantages of Electronic Health Records for Physicians

EHR systems can benefit physicians in many ways, whether they are working in a hospital or in an office-based practice. An EHR system has many potential capabilities. In view of the meaningful use required by the HITECH Act, functionalities such as CDS tools, CPOE, and HIE must be demonstrated. These functionalities are highlighted in this paper to explain the individual advantages for physicians.

Guidelines are a basis for physicians to avoid harm to the health of their patients. However, this is linked to the condition that doctors know all the guidelines and are also up to date on their medical knowledge. In practice, however, this may look different.

Some physicians may not be aware that there is a guideline for a particular disease, or the physicians may not recognize that a certain guideline applies to a specific patient. The physicians lack of ample time can also be a reason that the treatment of the patient does not follow current guidelines (cf. Menachemi and Collum, 2011, p. 49). The functionality of the CDS system can provide a solution to those problems. This system alerts physicians that the patient may experience an allergic reaction to the prescribed medication due to a new composition of the medication that was previously unknown to the physician. This function is very useful for the doctors, but moreso for the patient's health. Furthermore, the system warns the physician of drug interactions (cf. Menachemi and Collum, 2011, p. 48). This function could prevent damage to the patient's health and contribute to safer and more efficient care. The lack of time in everyday practice can lead doctors to overlook critical laboratory values, and as a result, could affect patient care. This problem can be counteracted by this system because the system can warn the physician of potential drug errors and display critical laboratory values (cf. Menachemi and Collum, 2011, p. 49). King et al. used data from two representative surveys in 2014 where physicians were asked about their attitudes and experience with EHRs. The results show that physicians greatly appreciate the features of the CDS system. In fact, 65 percent of the physicians surveyed found the function of paying attention to possible medication errors to be helpful and 62 percent found the function of paying attention to critical laboratory values to be helpful (cf. pp. 394-395).

CPOE systems also benefit both physicians and patients. A fundamental advantage for physicians is that they can easily access computerized records. This avoids the problem of illegible handwriting that often occurs with paper-based patient records (cf. Menachemi and Collum, 2011, p. 48). In the inpatient sector, poor handwriting of physicians with instructions for the nursing staff could lead to an incorrect medication or an incorrect dosage of the medication being administered. Illegibility in handwritten prescriptions for example, can also lead to medication errors in the outpatient area. This can result in a serious damage to the patient's health. With the process of digitalization, potentially dangerous medical errors can be eliminated. CPOE systems can also facilitate communication among employees. In the past, notes were written by hand to provide information to colleagues. Often, they were ignored due to poor handwriting or the notes getting lost. EHR provides an internal system for sending and receiving information between colleagues (cf. Hatton, Schmidt and Jelenc, 2012, p. 711), helping to ensure that important information does not get lost and reaches all colleagues involved in the process. This could contribute to improved communication within the medical team.

The functionalities of the HIE also have advantages for doctors. Patient data has thus far been stored at different locations, like the family doctor, the specialist, or the hospital. This means that a lot of data accumulates in different places over the course of a patient's life. Before the introduction of an EHR, findings and relevant patient information had to be sent by fax or post to the attending physicians (cf. Menachemi and Collum, 2011, p. 48). As a result, it was not possible to act promptly when values were poor. HIE, and therefore remote access, offers a solution to this problem, because secure and timely access to patient data can help the attending physicians act quickly and initiate the necessary therapeutic measures promptly. The findings here also coincide with the survey conducted by King et al. in 2014. The survey found that 81 percent of the

physicians find remote access as helpful and are convinced that it can contribute to improved patient care (cf. p. 397).
Due to the timely exchange of patient information between doctors, duplicate examinations can also be avoided (cf. Atasoy, Greenwood and McCullough, 2019, p. 490). A treating physician who refers a patient to a specialist often does not receive a letter with the examination results until days later. Furthermore, often only the results requested by the referring physicians can be found in this letter. If the specialist has carried out any relevant laboratory tests, for example, the referring physician might not receive this information. Then the attending physician could, in some circumstances, have this laboratory test carried out again. Since EHR provides all physicians involved in the patient's care access to all of the necessary information, this issue could be avoided. Thus, EHR systems save repeat labs and imaging costs and generate more effective care (cf. Menachemi and Collum, 2011, p. 48).
EHR systems could also be financially benefit physicians. As early as 2003, Erstad stated that these systems help eliminate billing errors and inaccurate coding (cf. 2003, pp. 54-55). Hatton, Schmidt and Jelenc conducted interviews with physicians in 2012. The physicians expressed that working with an EHR system is cheaper and more efficient because EHR systems help to achieve more precise coding and more uniform recording of fees for services rendered, which facilitates the administrative process (cf. p. 711). Consequently, the use of an EHR system could contribute to an increase in cash flow and turnover.
Patient access to their own medical information stored in the health record can be seen as another benefit for physicians. For patients, the ability to view their own medical data is an incentive to read the information stored there. If the information provided is not clear or comprehensible, patients may tend to obtain further information until they understand it. For physicians, this can be seen as an advantage because the patient is better-informed. This in turn could lead to improved care and better patient health outcomes (cf. Neves et al., 2018, pp. 1-2). Furthermore, patients access to personal medical data could help to increase patient satisfaction and result in an improved doctor-patient relationship (cf. Davis Giardina et al., 2014, p. 738).

4 Discussion

The introduction of the HITECH Act in 2009 has succeeded in motivating many physicians in office-based practice to implement an EHR system. The requirements of meaningful use also represent a positive aspect, as many advantages can be attributed to the functionalities of the required systems. The effects of the HITECH Act are also reflected in the increase in registered doctors who have introduced a certified system. An essential prerequisite for the benefits listed above to actually realize them is acceptance by medical professionals. Acceptance can also be a critical factor for successful implementation (cf. Ludwick, Manca and Doucette, 2010, pp. 43-44). In the following, an attempt will be made to explain the acceptance of physicians on EHR systems on the basis of Davis' Technology Acceptance Model.
Due to the limited scope of this work, this is based on literature only, which has advantages and disadvantages. Since studies, surveys, and systematic reviews were mainly used in this work, topicality is a central disadvantage. Studies and systematic reviews can take up to two years to be published.

Changes in our lives are a natural phenomenon but are often approached with fear and skepticism. For most people, it is important to have a daily routine in life (cf. Folaron, 2005, p. 40). The fields of information technology (IT) and medicine are particularly well known for the fact that they are constantly confronted with new innovations. If a new technology is introduced in a hospital or in a medical practice, such as an EHR system, the medical staff is obliged to use it and cannot avoid its use. Skepticism about change is a natural process. Here it is particularly important to identify the factors that can lead to the rejection or acceptance of IT.

Using Davis' TAM is an appropriate approach to predict and explain physicians' responses to EHR systems. This model is also particularly suitable for use in the field of health IT, as it focuses on perceived usefulness and perceived ease of use as two specific variables that influence the use of IT. Users' intentions to behave depend on their attitude and is determined by a subjective norm (cf. Bodur, Brinberg and Coupey, 2000, pp. 17-18). Furthermore, the variables of perceived usefulness and perceived ease of use are influenced by external variables, as well as human and social factors, which indirectly influence the attitude towards technology acceptance. Accordingly, the acceptance of using an EHR system is influenced by three constructs.

The question to which extent the individual physician in office-based practice recognises a facilitation of work and an improvement of work performance through an EHR system cannot be substantiated here. However, the advantages mentioned indicate some positive processes which are certainly accompanied by improved work performance for physicians. Ultimately, however, any kind of expected general improvement, whether in quality of care, administrative procedures or doctor-patient communication, could be perceived as a higher benefit. But these views depend heavily on the attitude of the individual. If physicians have a positive attitude towards an EHR system, than they will also perceive the perceived usefulness more readily than someone who has a negative attitude towards EHR systems.

In technological innovation, the question of technical capabilities is also important. An older physician who lacks technological skills will be more skeptical about a computer-based system than a younger physician with decent technological skills. The acceptance by physicians in office-based practices who have been using a paper-guided system in their medical practices for years and have few technical capabilities is significantly lower, since they have a benefit from the previous system and can also cope with its operability. In order to increase the acceptance by physicians in relation to the implementation of an EHR system, it is important to highlight the benefits. So that computer skills do not represent a barrier to the acceptance of an implementation of an EHR system, comprehensive training courses are important regarding the handling of the functionalities of the EHR system.

Higher acceptance could also be related to the extent to which physicians already have gained experience with EHR systems. Physicians who have already implemented a basic EHR in their practice will be more optimistic about expanding the functionalities of the system. The skepticism about making health information available in the system, collecting it, and sharing it with other treating physicians will be significantly lower than of physicians who have worked with a paper-based system to date and have no experience at all with EHR systems. This means that physicians who already have experience with EHR systems will be more likely to see a benefit for themselves in everyday practice and be more optimistic about expanding the functionalities of the EHR system.

Besides the previously mentioned advantages of the different EHR functionalities, the literature also shows possible disadvantages in connection with this technology. It is not without reason that there are still individual physicians who will be skeptical about implementing an EHR system. Despite the financial incentives provided by the HITECH Act, the high adoption and implementation costs and the ongoing maintenance costs represent good reason for staying with the old system. Furthermore, privacy and security concerns, the concerns physicians about the loss of decision-making autonomy, and the problem of limited interoperability are among the potential drawbacks or consequences that may arise from EHR systems.

The adoption, implementation costs, and ongoing maintenance costs are a huge obstacle for hospitals and office-based physicians to introduce and implement an EHR system. The adoption and implementation costs consist of the purchase and installation of hardware and software, the conversion of paper files into electronic files, and the training of employees. The purchase and installation of hardware and software involves the replacement of hardware and regular updating of the software is necessary. These high costs for the user must not be underestimated (cf. Menachemi and Collum, 2011, p. 51). Continuous employee training throughout the entire implementation phase is also important. Only if employees are familiar with the newly introduced system, the fear of the technology will be reduced, and the system's functionalities will be used comprehensively; however, training of employees can cause a temporary loss of productivity because the occupied training time again leads to interruptions in the work processes while carrying out everyday activities. The implementation could even result in lost sales (cf. Menachemi and Collum, 2011, p. 52). Furthermore, if a new system is introduced, system malfunctions could occur more frequently, which could hinder the work process; and also lead to temporary productivity losses.

Another negative aspect is the issue of data protection. Due to the increasing amount of electronically exchanged health information, the risk of violations of patient privacy is increasing (cf. Westin, 2005, pp. 1-2: Fernández-Alemán et al., 2013, pp. 559-560). Although legislation prescribes that patient data should be protected, electronic data cannot be guaranteed to be 100 percent secure (cf. Parver and Thompson-Hoffman, 2009, pp. 5-6). According to a survey, this is also a major concern of doctors (cf. Wright et al., 2010, p. 68) because confidential health data can attract hackers. EHR systems must have a specific feature that allows system operators to identify any person who has access to the health record. Doctors also express concerns that healthcare professionals may be inclined to carelessly handle medical information since it will be easy to access on the EHR. Concerns are also expressed about if companies, such as life insurance companies, or employers gained access to data and begin to use health data for business purposes. Furthermore, there are concerns among physicians that authorities such as national health insurers will use the data to derive information about potential savings or structural changes by identifying physicians who are causing above-average health expenditure (cf. Steininger et al., 2014, pp. 2,774-2,775).

Another weakness of EHR systems is when they advise the treating physicians which medications to prescribe to the patients. The concern that may arise for physicians is the loss of their autonomy in decision-making. Also, excessive reliance on technology can become problematic for physicians as they rely on it more and more. Hospitals and general practitioners should ensure that primary health care can be provided without technology (cf. Menachemi and Collum, 2011, p. 52). In the event of a system failure, advancing technology could pose a threat to patient health.

Furthermore, many of the current EHR systems are only interoperable to a limited extent and therefore cannot communicate directly with each other (cf. Atasoy, Greenwood and McCullough, 2019, pp. 493-494). HIE systems offer a possible measure for this problem. They enable the exchange of health information between treating physicians even if they have EHR systems that are not compatible with each other. Although HIE systems have many advantages for physicians, it can be observed that the prevalence of these systems is rather low. Possible reasons include a lack of incentives for doctors to share medical information. The doctors also strategically refrain from sharing information to avoid losing patients. In view of these reasons, more information and incentives should be provided surrounding the advantages of a HIE system in order to convince physicians to use it.

5 Conclusion

A major hurdle for the implementation of an EHR system was cleared with the introduction of the HITECH Act in 2009. The financial incentives and technical support were able to persuade many physicians to implement an EHR system. The proof of meaningful use is a positive aspect, since the functionalities required by the proof offer many advantages for physicians. For instance, warnings about a patient having allergies on a particular drug due to a new composition, the avoidance of medication errors due to poor handwriting, or the avoidance of duplicate examinations through a HIE system can be demonstrated. The spectrum of advantages of an EHR system contribute to the fact that physician workload is alleviated. Physicians are often faced with a lack of time in their daily practice and lack of time in the inpatient and outpatient area, which can contribute to inadequate patient care. Overlooking a critical laboratory value as a possible consequence of the lack of time can have serious consequences for the health of a patient. EHR systems display warnings to alert physicians to review a laboratory reading, which can help improve the physician workflow and improve patient care.

Physician acceptance is a critical factor for successful EHR implementation. Only if a technology is accepted and used extensively by the medical staff are the advantages mentioned above realized. A lack of technical capability, especially among older physicians, is often the reason why physicians are skeptical about implementing an EHR system. In addition, there are high implementation and adoption costs as well as the concern about data protection. In order to promote acceptance with regard to the use of the EHR, comprehensive staff training for the use of the functionalities of the EHR system is important. Training reduces fears of the EHR and increases the likelihood that the EHR system will be used in its full functionality. If an EHR system is used in its full functionality, physicians will also be more likely to recognize the benefits of this system for themselves and perceive this as a relief in their everyday practice.

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The Impact of Digitization on Physician’s Documentation Workload

Lara Schmidt

Background: One of the most important issues that physicians are facing today is the digitization in the health care sector. Digitization can help them to improve the prevention, diagnosis, and treatment of patients by providing a real-time access to patient data. However, digitization also entails new challenges for physicians. Objective: The aim of the following term paper is to provide an overview of the impact of Electronic Health Records (EHR) on the mental health of physicians in the USA. The phenomenon of ‘burnout’ will be considered. References are made to the job satisfaction and the workload of the physicians. With the help of exiting studies and surveys, references are made to job satisfaction and the workload of physicians. Advantages and disadvantages of EHR are also considered and discussed. Results: An increased bureaucracy could be determined by more structured data input, the associated time pressure of the physicians, and also a simplified access of the patient’s data. Due to the time pressure mentioned above, about half of the physicians in America who use EHR already suffer from stress and burnout. However, EHRs can be a reliable, higher quality data input that can provide improved communication with patients. Conclusion: It can be concluded that increased stress, work-life balance, and insufficient job satisfaction can lead to increased burnout among physicians. By adapting the digitization tool to the clinical routine of physicians, EHR can provide support in healthcare.

Contents

1 Health Care in the Course of Digitization

Healthcare providers around the world are facing the challenge of having to improve patients' overall health, while at the same time reducing the costs. Therefore, the digital change in the health care system can help manage this challenge through the integration of new technologies, such as artificial and operational intelligence. The integration can be used to improve diagnoses, prevention, and patient treatment and can help doctors and nurses to make faster clinical decisions. It also ensures a more efficient use of resources and services in the health care sector, which results in cost-savings in the long term (cf. Gopal et al., 2018, p. 328). Scientists have already been dealing with the topic of digitization in the health care system for a very long time. The first information technologies were already integrated into hospitals in the 1960s. However, technologies such as Electronic Health Records (EHR) and telemedicine have only spread to the health care sector recently. These technologies provide physicians with a variety of options, such as immediate access to patient data and its processing regardless of location and time, more transparency of the data, and an improved exchange of information with patients and physicians (cf. Atasoy et al., 2019, p. 488). The United States in particular is regarded as a pioneer in this space, given its shift towards digitization in the health service. Companies such as Google, Apple, and Microsoft have a great influence on new technologies, both as sponsors and in development and data backup, which is why these top companies have become new players in the health care system. Their aim is to launch new (digital) offers for patients and physicians and thus advance a digital health care system in the USA (cf. Schmitt-Sausen, 2018, pp. A1319ff.). Due to the growing complexity in primary care through the use of EHR, the burden on physicians is increasing. A reason for the increased burden is the combination of personal and non-personal care with administrative tasks such as billing, performance measurement, and coding. Studies have shown that physicians spend an average of six hours per day on documentation (cf. Arndt et al., 2017, pp. 419ff.).

Due to the increasing number of physicians with mental illnesses (currently 40%) in the United States, this paper will discuss the relationship between Electronic Health Records and the phenomenon of physician burnout (cf. Locke, 2019). The effects of increasing digitalization in the health care system on the mental health of physicians will be analyzed. This raises the following question: *To what extent does digitized documentation such as Electronic Health Records impact the mental health of physicians?*

In order to establish an initial understanding of the following topic, chapter 2 explains mental health and burnout in detail. To explain burnout, the burnout-prophylaxis model by Hans Kernen is used. This is then followed by the relevance of digitization in healthcare and its application. The chapter also includes a definition of the digitization tool of Electronic Health Records. Furthermore, the next section provides an explanation of the 5-stage model to classify Electronic Health Records in the electronic patient documentation. Following the description of the used method is the main part of the term paper. The primary section is intended to illustrate the implications of the use of EHRs in terms of workload and job satisfaction. The burnout-prophylaxis-model is also referenced. In the final chapter, the results are discussed and recommendations are provided. Finally, the paper concludes with limitations of the term paper along with the final conclusion.

2 Theoretical Background

2.1 Mental Health

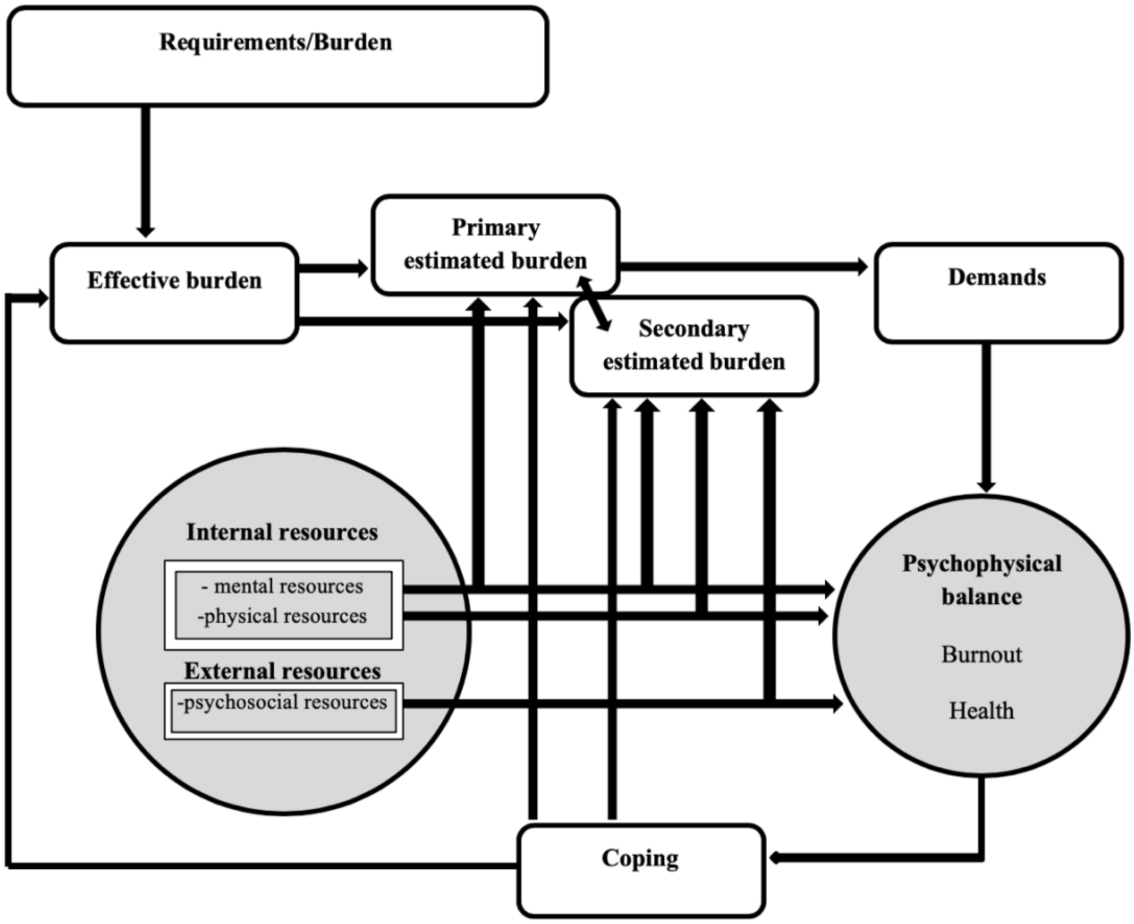
In 1951, the World Health Organization (WHO) defined mental health as "the capacity of the individual to form harmonious relations with others and to participate in, or contribute constructively to, changes in is social or physical environment" (WHO, 1951, p. 4). Today, mental health is used as a positive term that indicates the condition of psychological well-being. However, it is also often used to point out to a person's mental health problem. Mental health as a positive vitality is responsible for enjoying life and overcoming burdens, such as pain and disappointment (cf. Pilgrim, 2017, pp. 3f.). According to DIN EN ISO 10075-1, mental stress is defined as all external factors that encounter a person and affect them on a psychological level. The social context and the individual coping strategies are dependent on if external burdens have a positive or negative effect, depends on (cf. Pilgrim, 2017, pp. 3f.).
The topic mental health has become very important in today's society. The number of mentally ill people is continuously rising. Nearly 46.6 million people in the United States in 2017 live with a mental disorder (cf. NIH, 2019). A reason for this can be the rising sensitivity of perception and the naming of psychosocial problems. Because of the rising sensitivity and naming, public awareness of the symptomatology has increased in recent years (cf. Schneider, 2011, pp. 6f.). Mental health is also becoming an increasingly important aspect in the working area for physicians. The reasons behind this include the growing work intensification at clinics with the simultaneously rising shortage of physicians, time pressure, as well as the use of new technologies with increased quality discussions (cf. Angerer et al., 2011, pp. A832f.).

2.2 Burnout

The medical meaning of the term 'burnout' was affected in 1974 by the psychoanalyst Herbert Freudenberger and is frequently used in research literature and publications. He interprets burnout as a process that represents the exhaustion of one's own physical and mental reserves. This is reflected by symptoms such as chronic tiredness, impatience, indifference, cynicism or even psychosomatic disorders (cf. Freudenberger, 1983, p. 34). Burnout usually occurs in motivated people who give off more energy than they can handle over a longer period of time. This happens as a creeping process over several months and years. Therefore, in the beginning, many people hardly notice that they become noticeably weaker. Causes of burnout can be different and are characterized by several factors. In scientific publications, there are two explanatory approaches. These focus on external factors, but also on the internal disposition; in most cases, both factors coincide (cf. Berndt, 2011, pp. 15ff.). A further explanatory approach is offered by the burnout-prophylaxis-model (BPM) by Kernen.
This salutogenetic model shows the interaction between resources and the burnout disease. Kernen´s model (Figure 1) is based on the assumption that the resources of an individual contain health, and thus prevent burnout. This arises questions such as, 'through which stages does the individual go through while coping with a burden', and 'to which extent can certain resources help to overcome these burdens?' The process, shown in figure 1, starts with the requirements and burdens of the individual's

transactions with the environment. All individuals are exposed to requirements and burdens in every situation. A burden is defined as all external factors affecting the organism (cf. Semmer, 1999, pp. 744ff.). The individual has to select between relevant and irrelevant factors, which are perceived as subjectively effective that occur constantly. It is the result of factors such as external components, the sum of behaviors by which the individual reacts to stress, and internal components that have manifested themselves in psychological well-being as a result of previous adaptation achievements. These components are mostly dependent on each other and appear together. The next stage is the primarily estimated burden. In this case, the effective burden is differentiated from the individual and evaluated relative to the resource-building or resource-consuming impact. It constitutes a combination of the effective burdens and their assessment (cf. Kernen, 1999, pp. 51ff.). According to Lazarus and Launier (1981, pp. 213ff.), the primary burden can be interpreted as irrelevant, positive, damaging, threatening or challenging. This is followed by the secondary estimated burden. A comparison is made between primary effective burdens and the available resources which are provided to the respective subjective assessment. Stress is considered as all effects of the burdens on the organism. It has to be considered that each individual reacts differently to the same load. With regards to the BPM, the stress results from the comparison of the primary and secondary estimated burdens. In order to cope with this strain, the resources of the individual must be activated. In some cases, depending on the stress level, this can lead to a loss of energy, while in other cases the energy level can remain the same. The preservation of a psychophysical balance serves to prevent the reduction of resources. The psychophysical balance is the state of homeostasis, or a well-functioning regulation. If resources are overused over a long period of time, the ability to adapt becomes limited. This can result in a reduction or preservation of the resources. There is a burnout risk, which can then lead to a burnout syndrome after a period of time. The internal and external factors affect the individuum as an additional factor. The ability to perceive possible indicators of effects as first early warning signs, combined with the willingness to perform, is considered as a central prophylaxis factor of the BPM. Depending on the psychophysical balance, different coping strategies become visible. In ideal circumstances, an adaptation takes place combined with the available resources (Coping). In the BPM, this affects the environment, and then burdens can be managed or reduced. Thus, coping is a transaction as a part of an overall regulation, connected with the internal regulation of the individual (cf. Kernen, 1999, pp. 52ff.).

Figure 1: Burnout-prophylaxis model (BPM)



Reference: Own presentation based on Kernen, 1999, p. 49.

2.3 Digitization in Health Care Sector

New technologies and the associated digitization are emerging concepts in the health care sector. According to the American Telemedicine Association, more than 60% of US hospitals already use telemedicine services. In 2015, about 87% of the physicians in established telemedicine practices in the United States, and more than 90% of the clinics were using this technology (cf. Schmitt-Sausen, 2018, pp. A1319ff.). From the patient and physician point of view, digitized applications primarily conduce to improve the patient care. From the communal and political perspective, an optimized use of resources could generate economic savings (cf. Haas, 2006, p. 1f.). The aim is to prevent multiple examinations or incorrect medication through incorrect information. The improved quality of care results from the fact that research and treatment of uncommon diseases can be carried out more easily through intelligent and cross-institutional integration. A further value is the digital interconnection of physicians in order to provide the best possible supply of information. Therefore, tools such as Electronic Health Records, in which all relevant patient data is available in one file, are particularly valuable. Through the use of EHRs, a better relationship between physician and patient can be maintained (cf. Lux et al., 2017, p. 690f.).

The term ‘Electronic Health Record’ is not well-defined in the national and international literature. The best-known definition of Electronic Health Records was given by Peter Waegemann in 1999, who defined EHR as a “computer-stored collection of health information about one person linked by a person identifier." These can be related to institutions, as a Medical Records or independent, as a Patient Record (cf. Waegemann, 1999, pp. 116ff.). EHRs have the capability to improve the quality of health services (cf. DesRoches, 2008, p. 54). The aim is to provide authorized persons with the information in the desired form, independent of time and place. By using the electronic documentation tool, larger amounts of information can be illustrated in a more clear and structured way (cf. Leiner et al., 1999, p. 69). Data is captured and saved according to uniform classification criteria. There is a problem-oriented transparency of the patient's medical history, which guarantees the best possible care (cf. GVG, 2004, p. 9). Electronic Health Records are used by various providers and administrative staff of the health care system. This includes doctors, nurses, radiologists, pharmacists, laboratory technicians, and radiologists. In addition to these users, patients have the possibility to use EHRs. Special fields of application in the health care system include primary care and inpatient care (cf. Häyrinen et al., 2008, p. 296).

3 Implications on the Physicians' Mental Health

3.1 Effects on Documentation Workload

EHRs have a considerable effect on the workload of physicians in primary and inpatient care and can be both positive and negative. The effect depends on the size of the doctor´s office, working hours per week, and the specialization of the physician. Studies and surveys have found that electronic documentation improves the general workflow and thus supports patient care. The ease of access, independent of time and place, simplifies the communication between physicians and their staff and among other stakeholders. Misunderstandings are more preventable, and problems can be directly treated (cf. Harris et al., 2018, pp. 38ff.). On the other hand, other studies describe that the requirements and burdens are increasing due to constant availability and higher pressure of time. A reason for this is that the documentation must be conducted according to a certain structure, which can be time-consuming and circuitous. Other negative aspects include the non-intuitive user interfaces that can be difficult to use, especially for older physicians who used to work with the paper-based documentation. Many physicians also report that the electronic documentation quality is worse than paper-based methods because of the inflexbility of template-based notes and the interoperability of the different electronic systems (cf. Collier, 2017, pp. E1405f.).
Other studies refute these findings. They mention that documentation is not possible at the patient's bedside, as otherwise communication with the patient would not take place. The documentation has to be written up in the office afterwards. However, many physicians consider the electronic documentation of patients' health data to be more reliable than the manual input on paper. Through a more accurate and structured approach to input patient data, the result ends up saving time because it circumvents the process of searching for documents in a paper-based patient documentation system. Many physicians also rate the data input by the patient or the patient's parents as 'good'. This enables a different view of a possible diagnosis, as further (non-medical) information appear. The issue with this is that different terminology is used. The number of submissions from different players can lead to an information overload (cf. Häyrinen et al., 2008, pp. 297ff.).

Further studies highlight the positive impact of EHR on the quality of clinical decisions by providing physicians a real-time access to medical records. The previously mentioned structured data input helps to avoid medication errors. In this way, patient care and the associated preventive care can be provided more efficiently in long-term. A negative aspect is the data protection and the possibility to manipulate it by other parties (cf. DesRoches et al., 2008, pp. 54ff.).
Overall, the introduction of the EHR leads to an increasing bureaucracy for physicians. For many, especially for older practitioners, the use of electronic documentation is a challenge and therefore a major change that can lead to frustration and stress quickly. However, a large number of physicians perceive the EHR in a positive light because of its structure and accessibility.

3.2 Effects on the Job Satisfaction

Regarding EHRs and physician general job satisfaction, the studies and opinions of the physicians overlap. It is presumed that the main cause of dissatisfaction is due to physician burnout. Thus, the prevalence of burnout syndrome among physicians who use EHR is 27.2%, while physicians who do not use EHR have a prevalence of only 13.6%. There are also differences in gender; women are more vulnerable to the burnout syndrome than male physicians (cf. Gardner et al., 2018, pp. 106ff.). Many doctors report that they cannot cope with the documentation during working hours. Because of this, they spend a lot of time documenting patient data at home. This time is not paid out to them, which leads to increased frustration with the profession (cf. Harris et al., 2018, pp. 38ff.). The rising attendance on the screen for data entry reduces personal communication with colleagues. The personal interaction with the patients decreases, since this time is needed for the data documentation. This results in the physicians feeling lonelier during their working hours (cf. Collier, 2017, pp. E1405f.).
During the implementation of EHR, many physicians underestimated the duration and costs of implementation. This leads to a double workload, as they have to devote themselves to the applications and to the operation of EHR beyond their normal working lives (cf. Häyrinen et al., 2008, pp. 297ff.). The current job satisfaction of the 70% of physicians who use EHR is quite low. The satisfaction of the workload depends on the physician's area of expertise. While general practitioners and urologists are increasingly dissatisfied, pathologists and radiologists benefit from the application of EHR. Approximately 40% of overall physicians are satisfied with the use of EHR across all specialties. In case of psychological overload, more than the health of the physicians is endangered by the occurrence of the burnout syndrome. The quality of patient care can also be impaired by the physicians' lack of concentration, as the frequency of mistakes on the patient increases (cf. Shanafelt et al., 2016, pp. 839ff.). The physicians get the inclination to leave the practice. This also increases the fluctuation in clinics and medical practices and the lack of practitioners (cf. Arndt et al., 2017, pp. 424f.).

Reference to the burnout-prophylaxis-model

In order to demonstrate the relevance of the impacts listed above, one of the effects will be applied to the burnout-prophylaxis-model of Kernen.[1] The increased bureaucracy with the resultant time pressure is a requirement and burden from the environment. The requirement is that physicians have to work with a new instrument, the EHR. The potential for mistakes in the documentation and excessive demands on documentation during the patient care, can result in excess pressure, which can be burdensome for the physicians. This effective burden is primarily estimated by relevance. In this process, attention is intuitively paid to whether the mentioned burdens establish the resources (positive) or endanger them (negative). As a secondary estimated burden, all available resources that can serve as compensation for time pressure are compared. By comparing the primary and secondary burdens, the respective burdens arise such as comparing the required and available time for the documentation of patient data. In this case, the organism is affected by the resulting frustration and stress, which causes the consumption of energy. The organism tries to establish a psychophysical balance by using all available resources, which then leads to more stress. This stress cannot be avoided by the physicians, otherwise they would disregard their work. A negative psychophysical balance takes place and in the long-term, a burnout-risk is the result. To cope with this, many physicians take work home with them, and as a consequence, their personal lives can be negatively impacted. If the physicians do not learn to cope with this situation, they will continue to fall into a process of resource depletion, which can result in burnout.

4 Discussion and Limitations

The different opinions of the physicians of the various studies are striking. On the one hand, the reduced workload of physicians due to the structured presentation of data and simplified access is discussed. On the other hand, studies highlight the increasing workload due to bureaucracy and complicated operations. In this case, the different ages of the physicians, who express the different opinions, are particularly noticeable. While older physicians have problems using the EHR, younger ones are more adaptable to the digitization tool. There are also clear differences of opinions between the physicians regarding to the communication with human beings. While some mention the simplified communication with their colleagues, others refer to the insufficient personal touch during communication with their colleagues and patients. These opinions depend on the specialization of the particular physician. For this reason, the conclusion that the EHR deteriorates personal communication cannot be drawn. The studies agree on the more complex and correct input of patient data, which leads to enormous time pressure and increased home-based work for all practitioners. The consequences were frustration, stress, and psychological problems, which have already led to burnout by many physicians.

To counter this, measures must be taken to increase the job satisfaction of the physicians through EHR. It is recommended that EHR providers cooperate more closely with physicians. That way, the physicians' wishes and suggestions can be taken into account

[1] The reference to the listed impacts on the BPM also applies to all other impacts. In view of the repetition and time, the example only refers to a selected combination of effects.

and the systems can be shaped in a more palatable way for the physicians. The operation of EHR can thus be better integrated into the physicians' workflow so that no additional time needs to be spent on documentation from home. In particular, older physicians need to gain a new understanding of their work, as digitalization will become a basic element of their work in the future (cf. Collier, 2017, pp. E1405f.). In addition to better communication between providers and users of EHR, face-to-face communication with patients and staff should also be restored. One option is to integrate a computer into the doctor's office so that patient documentation is done during interaction with the patient. In order to reduce the physician's workload, it could be possible to set up medical writers who deal exclusively with the documentation during treatment. This increases the satisfaction and efficiency of the practitioner. Training courses, especially designed for the applicability of the EHR, also provide assistance in making documentation faster (cf. Shanafelt, et al., 2016, pp. 844ff.). An international consistent terminology of the different electronic systems is necessary to achieve semantic interoperability (cf. Häyrinen et al., 2008, pp. 300f.).
The work represents some limitations; limited access to databases results in a limited number of studies and publications that could be accessed on this topic. For this reason, literature that has existed for ten years has also been used. Due to this time lag, some information may no longer be up to date. Furthermore, only the effects of EHR in the USA are considered. This is because the US is most advanced in the digitization process so far. This means that the results cannot be generalized to every country. Therefore, there is a need for research on the application of EHR and its long-term impact on other countries. A particular difference should be made in the system's applicability. Most important is the research on the avoidance of negative effects so that mental illnesses can be prevented, such as burnout.

5 Conclusion

The aim of the thesis is to investigate the implications of Electronic Health Records on the mental health of physicians with a focus on the USA. In this country, EHR already have a very large influence on the functioning of physicians. Their job satisfaction decreases due to the complicated user interface, the new way of functioning, and the enormous time pressure to which they are exposed. Since the documentation of patient data is very structured and therefore time-consuming, doctors take their work back home, which affects work-life balance. This leads to psychological consequences, such as burnout. In long-term, EHRs could have a positive impact on physician workload if it is adapted to the everyday clinical practice of physicians. The structured presentation of patient data, the ability to view the diagnoses of all physicians to find possible contacts, and the ability to view the data regardless of time and place will improve patient care and efficiency. However, this will require further research and measures in the area of health digitization, especially in relation to the causes of their negative effects. It can be concluded that EHR tend to have a negative impact on the mental health of physicians in America due to insufficient job satisfaction, which typically results in burnout. Nevertheless, EHRs do have the potential to become a suitable and helpful long-term digitization tool for physicians in the health care sector.

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Accepting and Embracing Digital Innovations – Differences in Physicians' Attitudes between Germany and the U.S.

Tizian Juschkat

In the healthcare sector, digitalization and digital innovations are currently seen as 'problem solvers' for demographic change, rising healthcare costs, and the decline in the number of physicians. When considering discussions or studies on the subject of digitization, Germany represents the role of a laggard, while the United States is viewed as a pioneer of digital innovation. Therefore, the aim of this paper is to investigate to what extent the German and the American healthcare systems differ with respect to acceptance and implementation of innovations such as electronic health records and telemedicine. The diffusion theory of Rogers (2003) is applied to the users of digital innovations' electronic health records and telemedicine, both from Germany and the United States. Moreover, the digital innovation users are classified into the following categories: innovators, early adopters, early majority, late majority and laggards. A closer look at the results shows that digital innovations are accepted and were implemented earlier in the United States than in Germany. In addition, the efforts to introduce innovations generally appear to be greater. However, with regard to Germany, the term 'laggard' should be highlighted. In Germany, there seems to be certain areas in which the introduction of digital innovations lags behind, but there are also other areas where Germany is on the forefront of digital innovation.

Contents

1 Germany vs. U.S.: Differences in the Acceptance of Innovations

In Germany, the digitization rate of all economic sectors has increased, but the growth of the health sectors´ digitization rate was the lowest in Germany (cf. Baierlein, 2017, pp.3–4). In comparison to other European countries, according to the European Commission, Germany is lagging behind the average in digital medical innovations (cf. Sabes-Figuera et al., 2013, pp.21–23). In addition, innovations are perceived as problem solvers for demographic change, rising healthcare costs, and the decline in the number of doctors (cf. Mestres, 2017, pp.8–9). A common obstacle for the implementation or adoption of digital innovations is the interaction of political and organizational structures, like data security (cf. Nohl-Deryk et al., 2018, pp.940–942; Baierlein, 2017, pp.6–7). The United States of America (U.S.) is known to be the pioneer in the field of digitization. With the attributes of speed, flexibility and user-friendliness, many American companies are investing in digitization, particularly in the healthcare sector (cf. Kaeser, 2015, pp.6, 35). Under $157.4 billion of investments were made in 2016, while national health care expenditure was approximately $3,337.2 billion (cf. NCHS, 2018, p.xii). Even the largest technology companies like Apple, Amazon, Facebook and Google are entering into the healthcare space (cf. Kramer and Vollmar, 2017, p.473).
The following paper discusses Germany and the U.S.'s exploration into new digital innovations in the outpatient sector. The question to be answered is: To what extent do the German and the American healthcare systems differ in terms of acceptance and implementation of innovations like electronic health records (EHR) and telemedicine? This paper first outlines the outpatient sectors of Germany and the U.S. Additionally, Rogers´ diffusion theory will be explained, which forms a basis for the analysis. Rogers' diffusion theory model will then be applied to the users of both innovations, and a distinction will be made between Germany and the U.S. The results will be compared and discussed, and finally the paper will close with a conclusion.

2 Outpatient Care Systems and the Diffusion Theory

2.1 Outpatient Care in the German Health Care System

This paper will focus on the supply market whose main sectors are outpatient and inpatient care (cf. Preusker, 2015, p.118). In the outpatient sector, sectoral segregation is very strong because they have different organizational forms and criteria for evaluation and remuneration (cf. Busse et al., 2017, pp.45–46). Most health expenditure in 2016 accounts in the area of outpatient care, at around €180 billion (cf. Statista, 2018). Regarding the costs, the outpatient sector is most important in the German health care system. It contains an outpatient general practitioner (GP), specialist, psychotherapeutic, and dental care. In comparison to inpatient care, patients cannot be hospitalized (cf. Preusker, 2015, p.120). Ambulatory treatments in German hospitals are only allowed if the treatment is highly specialized, in combination with a Desease Management Program (DMP) or in the case of undersupply (cf. ibid., pp.121–122). When choosing practitioners, the patients are free to choose their own practitioner, but if they want to see a specialist, a referral by a contract doctors is necessary for insurance coverage. Thus, accredited GPs have the task of coordinating health care for statutory health insurance (SHI) insured patients (cf. Jung et al., p.580).

Outpatient care can be divided into primary care and specialist care. Specialist care includes anesthetists, ENT doctors, dermatologists, etc. In Germany, there is a trend of specialization most noticeable in rural areas. In 2012 financial incentives were implemented to make subsidiaries more attractive for GPs (cf. Busse et al., 2017, pp.194–197). The inpatient care is defined as the medical and nursing care provided in a hospital. In addition, accommodation and board is part of the inpatient care as well (cf. Preusker, 2015, p.136). In the German health care system, hospitals are mostly responsible for inpatient specialist care. In the other systems, the outpatient specialist care is mostly taken over by hospitals as well. In Germany, these tasks are performed by specialists in outpatient practices, but today more and more hospitals offer outpatient care such as emergency department services, outpatient surgery, and treatments in connection with DMP (cf. ibid., p.137).

2.2 Outpatient Care in the United States

The structure of outpatient and inpatient care can be found in the American healthcare system as well, but without strict separation like in Germany. The structure of the two sectors was influenced by various external factors such as policies, practices, and payers. Thus, the American healthcare system can be described as fragmented, disorganized and inefficient (cf. Kovner et al., 2011, p.181). Nowadays, many hospitals provide outpatient care as well as inpatient care. New treatment methods have decreased patient length of stay in hospitals and have changed reimbursement which has made the outpatient market more attractive. Moreover, patients prefer home and community-based settings rather than being admitted to the hospital. Therefore, outpatient care is also provided in hospitals, outpatient clinics, freestanding facilities such as CVS or Walmart (cf. Shi and Singh, 2017, pp.171–176). Given the various options of the treatment in the ambulatory range, the impression given is that patients can decide freely as to which provider to see. However, besides the case of special circumstances such as work-related accidents or invalids, there is not particularly a free choice of physicians. Additionally, the choice of hospital is fairly limited by payer as well. With Medicare, a choice of provider is possible, however, the patient may have to pay a co-payments (cf. Beske et al., 2005, pp.191–193). Accordingly, access to medical care depends mainly on insurance coverage (cf. Kovner et al., 2011, p.182). A major difference between the US and German system is that German doctors working in hospitals are also allowed to provide outpatient services. Most family practitioners, general internists and pediatricians have privileges which enable them to access hospital resources and provide outpatient care (cf. Jonas, 1998, pp.64–65).

Health care delivered in the outpatient sector can be described as primary care. Primary care is provided by GPs, which mostly includes general internists, family practitioner and pediatricians. According to the Institute of Medicine, primary care is an integrated care service provided by physicians that meets a large proportion of personal health needs. A sustainable partnership with patients as well as practicing in the context of family and community is important (cf. Kovner et al., 2011, p.183). The physicians providing primary care serve as gatekeepers. They should be the patients´ first contact of ongoing wellness care and health issues (cf. ibid., 2011, p.15).

2.3 Diffusion of Digital Innovation

Diffusion or acceptance of digital innovations like the EHR or telemedicine is very abstract. A diffusion model is used to make the success in use of telemedicine and EHRs more tangible. The basic model, which describes the acceptance of digital innovations, is known as the diffusion theory and was published by Everett Rogers in 1962. In this paper, the rates of adoption of the users of EHRs and telecardiology will be determined and classified in the adopter categories afterwards.

Rogers describes diffusion as a process of communication of innovations through different channels, which gradually reaches different members within a social system (cf. Rogers, 2003, pp.5–6). Innovation, communication channels, time, and the social system are highlighted as the four main elements (cf. ibid., p.11). Innovation is defined as an idea, practice, or subject that individuals and other application units have not been exposed to before (cf. Spil, 2006, pp.2–3). If the idea is new to the person, it is innovation. It is not important whether the idea already existed before (cf. ibid., p.37).

Rogers different rates of adoption begin with the **relative advantage**, which describes to what extent the innovation might be better than the existing idea. Objective arguments are less important than the perceived arguments. **Compatibility** explains the importance of consistence with existing values, past experiences, and needs of adopters of the innovation. Incompatibility with existing values will extend the process, because a new value system is required. Third, **complexity** characterizes how difficult the innovation is to understand. To adopt the innovations faster, the aim should be to make them as easy to understand as possible. Furthermore, **trialability** describes to what extend the innovation has been tried before. Testing the innovation reduces any uncertainties an individual may have. Lastly, **observability** describes the process of making the result of the innovation visible to prospects (cf. ibid., pp.15–16).

Individuals do not always adopt innovations at the same time because find out about the innovation at different times (cf. Roßnagel, 2009, p.33). Correspondingly, adopters can be classified in different adopter categories depending on when they adopt the innovation. **Innovators** are the first individuals who come up with the innovation. Moreover, innovators are often described as venturesome because they experience a high degree of uncertainty. Innovators are considered as gatekeepers because they start the innovation process. **Early adopters** are more integrated in the social system and have the highest degree of opinion leadership in most systems. In addition, they reduce uncertainty and apply it through the use of innovation. Therefore, early adopters can highly influence the speed of diffusion. **Early majorities** are mainly influenced by the early adopters. Their position is very important because they link the early adopters with the late majority. Moreover, they can be described as deliberate, because they weigh the pros and cons before adoption since they do not want to be the first, but also not the last. The **late majority** adopts the innovation just after the average members and represents one third of members of a system, as well as the early majority. Their long waiting time is caused by the skepticism, and they decide to wait so that most of the uncertainty can be eliminated prior to adoption. Finally, the **laggards** are very traditional. They seem to live in the past and finally decide to adopt the innovation when most of the other individuals no longer see the new idea as an innovation. This gives the laggards an isolated position in their system (cf. Rogers, 2003, pp.282–285).

3 Digital Innovations and their Acceptance in Outpatient Care

3.1 Digitization in the German Healthcare System

3.1.1 The Elektronische Patientenakte

In order to ensure the most important goals like patient safety, quality, effectiveness, and equitable care, a standardized system such as an elektronische Patientenakte (ePA) is helpful (cf. Haas, 2016, pp.183–184). The ePA refers to an IT-supported, structured documentation that collects and summarizes health data of a person. Giving a precise definition is difficult because the term ePA is used in different ways (cf. ibid., p.188). The ePA is not implemented yet, but according to the current coalition agreement, it should be introduced by 2021 (cf. Bertram et al., 2019, p.4). To enable a meaningful classification into the diffusion theory of Rogers, the use of the cross-institutional ePA (eEPA) will be discussed. The innovation users will be classified to the rate of adoption stages, and then an adopter category will be assigned to them.

The relative advantages of the eEPA can be described in contrast to the existing documentation programs. Due to the lack of direct communication between physicians, the current system is very fragmented (cf. ibid., p.5). The eEPA is intended to counteract this and improve communication and coordination between doctors. This can eventually lead to a decrease of double or follow-up treatments. Moreover, the transparency of information and patient-centered care will increase. Furthermore, better recognition of interrelations will increase the drug therapy safety. In combination with patients' access, the understanding of disease and the treatment adherence can increase (cf. ibid., p.6). Secondly, compatibility of the eEPA concerns existing values, past experiences, and needs. Moreover, the data sovereignty as well as ethical and legal aspects should be discussed (cf. Haas and Bertelsmann Stiftung, 2017, pp.134,171,203). Regarding complexity, the eEPA seems to be very complex and non-transparent, because the word eEPA is used in many ways (cf. ibid., p.47). The trialability of the eEPA for patients is low. It is only available if the patients participate in an experiment like the a German health insurer, Barmer Krankenversicherung in 2007 (cf. ibid., p.143). Physicians and other players are limited to demonstrations at trade fairs or similar. The classification of the eEPA's observability is very difficult for the German health care system, but compared to other countries like Estonia and Denmark, it shows that the acceptance is very high (cf. Haas, 2016, pp.8–12).

Because the eEPA is not implemented yet in the German health care system, the user's classification in an adopter category of Rogers is not yet possible. Compared to other European countries, Germany might be considered to be in the late majority category. The late majority includes skeptical individuals who need most uncertainty removed prior to adoption - this description fits to the German mindset.

3.1.2 The Use of Telemedicine

Telemedicine can be described as a providing care across spatial distances or time offset. Care includes diagnostics, therapy, rehabilitation, and even medical decision counselling. To give care across spatial distances and time offset, information and communication technologies must be used (cf. BÄK, 2015, p.334). The care of stroke patients is an example of the current use of telemedicine in Germany (cf. Beske, 2016, pp.90–91). To enable a meaningful classification, the use of telemedicine will be limited to the area of telecardiology. It is one of three types which are financed within the framework of compensation catalogs or explicit statutory regulations (cf. Marx and Beckers, 2015, p.1053). The users of the innovation will be classified to the rate of adoption stages as follows, and then an adopter category is assigned to them.

An advantage of telecardiology is that the distance between patients and physicians becomes less relevant, which is important for elderly patients with many co-morbidities (cf. Schmid, 2016, p.15). Moreover, the reduction of physicians in rural areas can be counteracted with the use of telemonitoring and cardiology (cf. Diedrich et al., 2018, pp.307–308). The German Medical Association (BÄK) has also mentioned that positive effects are expected in the bridging of treatment breaks from inpatient to outpatient care. In addition, telemedicine results in an increase in quality, since teleconferencing can lead to a higher level of specialists' knowledge (cf. BÄK, 2015, pp.3–4). Compatibility is predominantly given in the context of telecardiology. The adoption of telecardiology creates a higher level of trust because a high number of users proves that the use of the system makes sense. However, for nationwide use, a developed telematic infrastructure is necessary (cf. GKV-Spitzenverband, 2016, p.7). Telemedicine's complexities are difficult to determine because the term telemedicine also summarizes different applications. Patients understand the lower complexity applications because of the continual use and the simplicity. The degree of trialability is also related to health fairs for future implications of telemedicine. The telecardiology is available at physicians who support its infrastructure, and the patients can get important results from the attending physician. Therefore, the observability of already existing telemedicine technologies is high and covers all sides of players.

The classification of the users in an adopter category will be limited to the telecardiology, especially in relation to the evaluation of cardiac pacemaker's data (cf. van den Berg et al., 2015, p.372). In the case of telecardiology, they can be classified as the early adopters. In the overall context, the users of telecardiology are taking a pioneering role. They show the positive developments and could thus pave the way for other areas within telemedicine. Moreover, German physicians typically regard the wide range of telemedicine in a positive light (cf. Dockweiler, 2016, pp.263–264).

3.2 'Medicine 4.0' in the United States?

3.2.1 The Electronic Health Record

The EHR is described as a digital version of the existing patients paper charts with information which are made instantly available for any authorized user. They contain a patient's medical history, diagnoses, medications, treatment plans, immunization dates, etc. Moreover, providers can access evidence-based tools that they can use to make decisions about a patient's care and automate and streamline provider workflow (cf. ONC, 2018). Through the use of the HER, the Office of the National Coordinator for Health Information (ONC) improved patient care, increased patient participation, improved coordination of care, increased the number of accurate diagnoses, improved patient outcomes, improved practice efficiency, and increased cost savings (cf. ONC, 2017).

Considering the basic type of EHRs, all rate of adoption characteristics can be clarified. EHR systems are designed to be supportive regarding the core activities of primary care physicians and other players in the ambulatory care setting and can be seen as a major relative advantage. Moreover, EHRs can support the realization and coordination of patient-centered care to ultimately increase quality of care by enabling the exchange of clinical information between providers of care (cf. Raymond et al., 2019, p.72). Thus, the three main goals of health care can be accomplished through the use of EHRs. (cf. Barker and Heisey-Grove, 2015, pp.898–899). Furthermore, EHRs can improve higher quality in ambulatory care (cf. HITEC Investigators et al., 2013, p.502).

Compatibility of the implementation is mainly given because the use of an electronic documentation and information exchange fulfills the existing values and needs. Moreover, the EHR adds features that simplify and support processes, but it requires a change in work flow and practice redesign. The fact that the EHR system mainly transferred the paper-based system into a digital documentation allows the understanding to be easy, but the complexity of the whole system cannot be underestimated (cf. Morton and Wiedenbeck, 2010, p.6). The trialability for institutions and practices which have not adopted the EHR system is high, because around 63% of primary care practices have already adopted an EHR (cf. Barker and Heisey-Grove, 2015, p.896). Observability is high due to a high number of users, positive effects of patient care, high level of quality of care, and increased patient satisfaction as reported by physicians (cf. DesRoches et al., 2008, p.50).

The users of EHRs can be described as early adopters, because the United Kingdom (UK) as well as Canada were more active in using EHRs (cf. Raymond et al., 2019, p.72). As a result, the push for widespread EHR use within the U.S. become a national priority. Approximately $29 billion in federal incentives were invested in the adoption (cf. HITEC Investigators et al., 2013, p.496).

3.2.2 Using Telemedicine in the United States

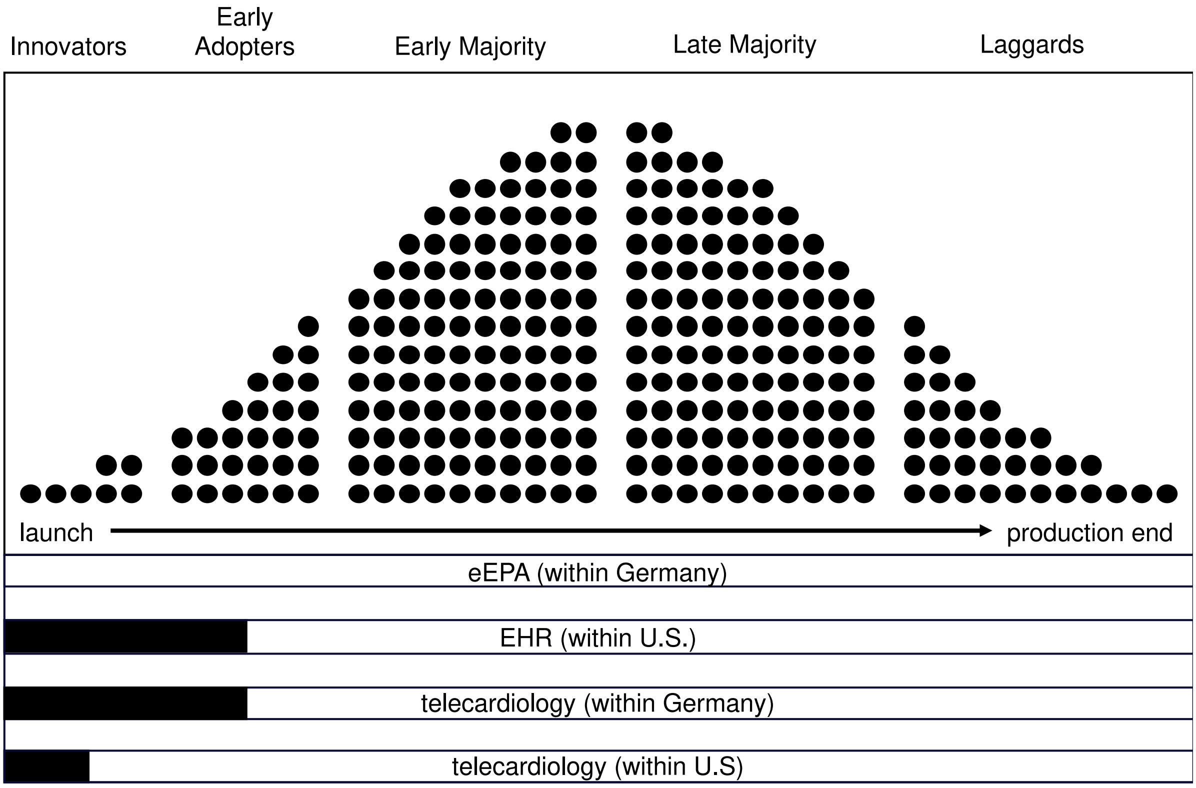
Since the 1950s, telemedicine was implemented in medical services. The first company in the U.S. that used telemedicine was the National Aeronautics and Space Administration. They mostly monitored health factors and evolved the field of telemedicine over time. Telemedicine improved access to care, resource efficiency, and decreased costs for a routine office visit when compared to traditional office visits. Additionally, more than 50% of acute care facilities are using telemedicine in some ways. Accordingly, the telemedicine market is expected to reach the value of $30 billion dollars by 2019 (cf. Williams et al., 2018, pp.1–2). According to the Institute of Medicine, telemedicine can be defined as the use of electronic information and communications technologies to provide and support health care when distance separates the participants. Telemedicine contains teleconferencing, consultation, mentoring, presence, and monitoring services (cf. Field and Institute of Medicine, 1996, p.27). In order to facilitate comparability, telecardiology will be focused. Telecardiology is one of several possibilities in the U.S. to treat acute conditions such as asthma, psychotic episodes, heart failure, stroke, neonatal cardiology, and leukemia (cf. Swanson Kazley et al., 2012, p.160).

An increase of high-quality care and travel time are advantages in the context of telecardiology cost savings (cf. Swanson Kazley et al., 2012, p.160). Especially in the instance of face-to-face care, the use of telecardiology can replace physical care for 7% of internist visits and up to 47% of nursing home visits (cf. Ray et al., 2015, p. 572). Moreover, telemedicine or telecardiology can be very helpful in rural areas and in areas with a lack of specialists because it these areas can be covered as well (cf. Aneja et al., 2011, pp.2306–2307). The fact that telecardiology reduces waiting and travel time for affected patients mostly satisfies the need of potential adopters. Moreover, the fact that home visits and inpatient care can be reduced shows a high compatibility of telecardiology (cf. Swanson Kazley et al., 2012, p.160). Half of the physicians not currently using a telecardiological technology should try the different possibilities and directly ask for the opinions of users who already adopted them. The observability of results is not necessarily noticeable for the user, but some studies show positive and negative effects of telemedicine and telecardiology (cf. Summe et al., 2018, pp.344–347).

Various acute care facilities have already adopted telemedicine innovations. Their users can be described as innovators, early adopters, and early majority. Accordingly, the other 50% of physicians who have not yet adopted the technology are allocated to the late majority and laggards. Since the first uses of telemedicine were already made in the 1950s, the users in the U.S. can be classified as innovators or early adopters in an international comparison.

4 Discussion

Figure 1: Classification of users of innovations into the adopter categorization by Rogers



Source: Own presentation based on Rogers, 2003, p.281.

After applying the diffusion theory to the users of digital innovations, the results are compared and analyzed in detail. As shown in Figure 1, the difference regarding the adoption of eEPA/EHRs by their users differ significantly between Germany and the U.S. The main difference is that the eEPA is not implemented in the German health system yet. Discussions on the implementation have been going on at various levels, but without any development for several years. Fundamental questions of how implementation should take place are still being discussed. The exact definition of the EPA, the associated tasks and requirements, and the importance of data security are all possible reasons for the hesitations. It concerns particularly sensitive and personal data, therefore these hesitations are justified. Furthermore, it is unclear whether the positive aspects of eEPA will materialize at all, since they depend strongly on the actual implementation and a reasonable telematic infrastructure is required first. In terms of implementation and use, it could be oriented towards countries that have already successfully implemented them, such as Sweden or Denmark (cf. Haas and Bertelsmann Stiftung, 2017, pp.161–168). Doctors are predominantly opposed to eEPA because they fear transparency, more bureaucracy, considerable additional costs, and not many benefits for the patient (cf. ibid., p.145).

In the U.S. the EHR is not implemented in every area of the healthcare system. The successful use of EHRs in the UK and Canada have led to a strong increase in using EHRs in the U.S. Even the government attempted to quickly advance the introduction nationwide by offering financial incentives and cuts in remuneration. With the help of the Health Information Technology for Economic and Clinical Health Act (HITECH),

$29 billion federal incentives were offered. Following these changes, many hospitals implemented EHRs. The support of the HITECH was not enough, because many practices and smaller hospitals were not able to pay the large expense of an EHR system. To provide effective and high-quality care, practices must have IT facilities, but their implementation is very costly. Thus, now mostly bigger hospitals use EHRs (cf. HITEC Investigators et al., 2013, p.496). Even in America, the use of an EHR does not always insinuate positive effects. The quality of ambulatory care was improved, but simultaneously the work burden increased as well (cf. Howard et al., 2013, p.112). Furthermore, the gap between the functionalities of the EHR system and those actually used can significantly reduce the positive effects (cf. Raymond et al., 2019, p.72).

In Germany, the use of telecardiology is more established than the eEPA. Accordingly, the physicians who use telecardiological techniques are described as early adopters, as shown in Figure 1. Telecardiology, is already financed within the framework of compensation catalogs or explicit statutory regulations (cf. Marx and Beckers, 2015, p.1053). The acceptance of physicians seems to be very high, as they see potential benefits in the area of quality improvements and in the prevention of gaps in care. Moreover, telecardiology is one of the most mature areas of telemedicine and has proven its worth by their users (cf. Franke et al., 2012, p.291). However, there are not only positive effects in the field of telemedicine. The BÄK states that there is a trend towards the supply-driven implementation of health services. Furthermore, telemedicine in the standard remuneration system is difficult because of the differentiation between technologies which digitize existing processes and those who represent a new supply process (cf. BÄK, 2015, p.1).

Compared to Germany, more studies on the actual benefits of digital innovation can be found in the U.S. (cf. Ray et al., 2015, p.572). Furthermore, the fact that the telemedicine market in the U.S. will reach the value of $30 billion dollars by 2019 shows the importance of this area (cf. Williams et al., 2018, pp.1–2). However, this does not exclude the possibility that some forms of telemedicine may not always be cost-effective. Teleconsultations can often be more costly than conventional consultations (cf. Swanson Kazley et al., 2012, p.160). Also, Americans should be concerned about quality of care, security, and technical issues when it comes to telemedicine (cf. AP-NORC Center for Public Affairs Research, 2018, p.4).

Some limitations of this paper are notable. Germany and the U.S. focus on outpatient doctors, which is not completely possible because there are not enough studies in the specific field. The mentioned aspects in the medical field can be transferred to the ambulatory physicians as well. Moreover, the classification of users into adoption categories was limited because some of the involved technologies have not been implemented yet.

5 Conclusion

In conclusion, the U.S. is more open to the introduction of digital innovations to potential users and is faster in its implementation. However, it is not ideal in the U.S. or Germany, since implementation and practical control depend on the individual states. However, uniform standards are very important. One reason for the faster implementation and acceptance is certainly the type of payment model in America, because it makes it possible to bear the costs of new digital innovations. In addition, the

Americans' have an open attitude towards new technologies, both in the private and the public health sector, which plays an important role in their adoption speed. German adopters have a more skeptical attitude. Data protection is very important in Germany. Technical innovations also plays a dominant role within the use of eEPA and telemedicine, and makes a large impact when introducing suitable telematics infrastructure. In addition to the debate on data protection, the implementation of digital innovations is also limited by the financing model in Germany. There are presently no possibilities to include telemedical innovations or the use of eEPA in the framework of compensation catalogs. However, the difference in the widespread use of digital innovations, such as EHR or telemedicine, is not as strong as expected.
In the future, it would be necessary to establish global interoperability for telemedicine and EPA to improve comparability. The implementation of an EPA in a portal would be target-oriented, because they unfold their potential in interaction with other telemedical applications - otherwise the advantages are invalid. In addition, global networking should be achieved in the area of telemedicine. This would make it possible to exchange knowledge in real time on a global scale and could significantly improve the quality of care. However, legal and ethical aspects must also be considered. In conclusion, both the patient and the doctor play a key role in the introduction of any digital innovation. Patients and physicians are the ones that will mostly use the technologies and for whom the benefits of new digital innovations should essentially outweigh the costs. If this is the case, the advantages can outweigh rising costs and demographic change.

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Part 4: Digital Transformation – Applications

The Adoption of RTLS in Healthcare

Moritz Reinsch

The paper aims to assess the current adoption of real-time location systems (RTLS) within healthcare settings and to evaluate why the current penetration rate is lagging behind former estimations. The research methodology chosen to examine the adoption of RTLS in healthcare is literature review, supported by interviews of various primary respondents, including key industry participants, consultants, and market studies. Rogers' 'Diffusion of Innovations Theory' was adapted to estimate the current state of the technology along the diffusion process, and to discuss barriers that might have decreased the adoption rate in the market. Rogers' theory provided a suitable underlying framework for the purpose of this paper. RTLS was adopted by both social groups: innovators and early adopters. However, the diffusion rate has since slowed down because the early majority group has been more skeptical if the outcome is worth the investment. Many solutions are perceived as expensive surveillance systems that do not live up to the customer's expectations of a balance between accuracy, efficiency, and cost. Current market trends such as hybrid systems and the decreasing costs of hardware are still to show their impact on the adoption in the market. The existing technological, material, and organizational barriers to RTLS' adoption remain persistent. These obstacles must be removed if hospitals are to leverage the benefits these solutions provide and move from a niche product to mainstream.

Contents

1 Introduction

Hospital operations are considered to be among the most complex systems with constant movement of people and goods (Carr, 2017, p. 1). Many hospitals must deal with efficiency losses due to staff looking for missing or lost equipment or due to hospitals on average purchasing 10-20% more items than actually required to maintain an efficient workflow (Kamel Boulos and Berry, 2012, p. 7). Real-time location systems (RTLS) have been proven to be successful in healthcare applications, not only in asset management to provide equipment retrieval, but also in workflow optimization and improving patient and staff safety (Bugge, 2018, pp. 1–3). However, there is still a long way ahead when it comes to diffusion of the technology since the market penetration rate has not yet exceeded 20% (Fisher and Monahan, 2012, p. 706; Lorenzi, 2011, p. 39, 2016, p. 35; MarketsandMarkets, 2014, p. 64; Peck, 2017, p. 1; Vantage Technology Consulting Group, 2018). This paper systematically reviews the literature on the use of RTLS in healthcare to examine RTLS' maturity of diffusion along the innovation-decision process by Rogers (Rogers, 2003, pp. 169–170). Rogers' model has not only been used at both an organizational and individual level, but also presents a theoretical foundation to discuss adoption at a global level (Taherdoost, 2018, pp. 963–964) and was therefore adopted for the purpose of this paper. The paper further evaluates current market trends and characteristics of the RTLS technology by using various market studies, supported by interviews with key industry participants and consultants to conclude why there has not been a rapid adoption of the solution in healthcare as forecasted 10 years ago. Rogers' model integrates three major components: the innovation decision process, adopter characteristics, and characteristics of an innovation (Rogers, 2003) which are described in chapter two. In chapter three, the former components are used to discuss the current state of RTLS technology along the innovation process, whereas the latter component is used to determine any potential barriers that impede RTLS' adoption and potential drivers that will promote its diffusion and uptake in the healthcare market.

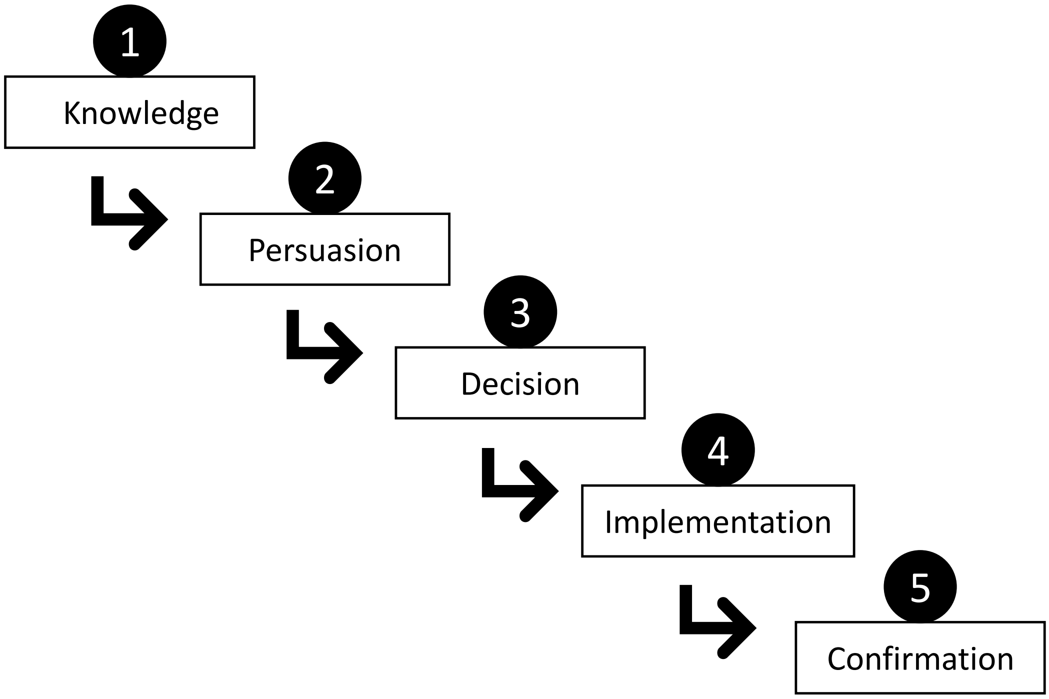
2 Research Methodology and System Characteristics

2.1 Rogers' Diffusion of Innovations Theory

2.1.1 The Innovation Decision Process

Rogers alleges that an individual's decision about an innovation is a process that occurs over time and consists of a distinct series of actions. This innovation-decision process involves five steps: 1. Knowledge, 2. Persuasion, 3. Decision, 4. Implementation, and 5. Confirmation. These stages typically follow each other in a time-ordered manner which is shown in Figure 1.

Five Stages of the Innovation Decision Process



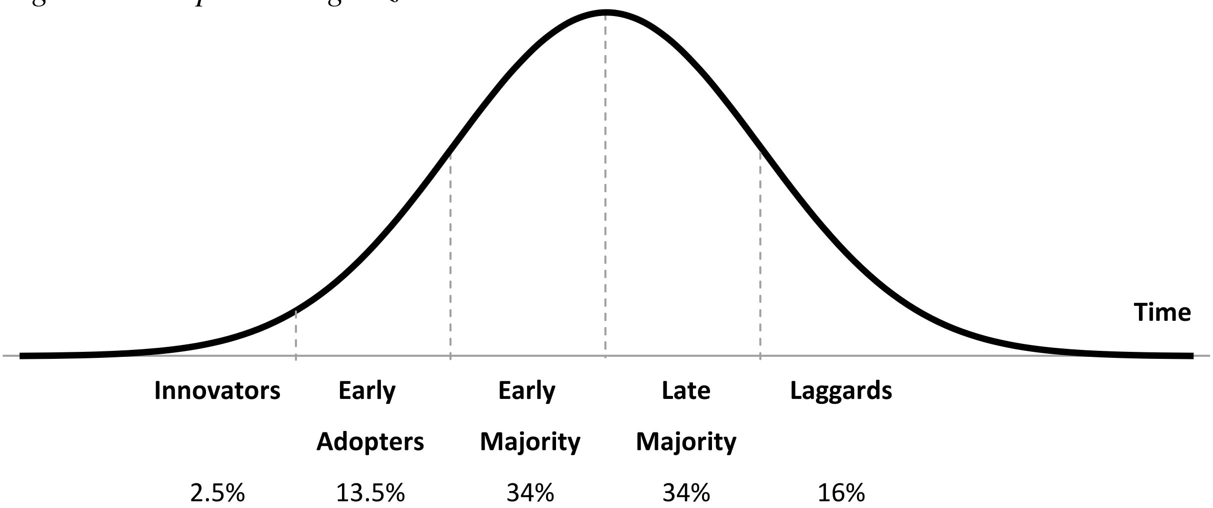
Source: Own presentation based on Rogers, 2003, pp. 169-170.

The innovation-decision process starts with the **knowledge** phase. In this step, a decision-making unit discovers the innovation's existence and seeks information about the innovation to gain some understanding of how it functions. During this phase, it attempts to determine "what the innovation is and how and why it works" (Rogers, 2003, p. 171). After the knowledge phase, the **persuasion** phase begins, where the decision-making unit forms a favorable or unfavorable attitude towards the innovation. In order to shape its attitude more clearly, it continues to search for innovation evaluation information and messages through the decision stage. At the **decision** stage, the decision-making unit engages in activities that yield an adoption or a rejection of the innovation. Of note, rejection is possible at every step in the process. The fourth stage in the innovation-decision process is the **implementation** phase, which occurs when the innovation is put into practice. Uncertainty about the outcomes of the innovation can still be a problem at this stage. Therefore, the implementer might require assistance to reduce the degree of uncertainty regarding the consequences (Sahin, 2006, p. 17). The innovation-decision has already been made, however at the **confirmation** stage, the decision-making unit seeks reinforcement of its decision. According to Rogers (Rogers, 2003, p. 189), this decision can be reversed by the decision-making unit if exposed to conflicting messages about the innovation. Depending on the support for the adoption of the innovation and the attitude of the decision-making unit, later adoption or discontinuance could happen during the confirmation stage.

Adopter Categories

In the context of adopting innovations, Rogers divides the adopters into five categories (Rogers, 2003, p. 281). This classification includes innovators, early adopters, early majority, late majority, and laggards. As figure 2 shows, the distribution of adopters is a normal distribution; each category is defined using a standardized percentage of respondents. For example, the area under the left side of the curve and two standard deviations below the mean is comprised of innovators who adopt an innovation as the first 2.5% of the individuals in the system (Sahin, 2006, p. 19). However, it is worth mentioning that only successful innovations follow this curve over time. Adoption is an atypical outcome, because the vast majority of innovations fail to diffuse (Dearing and Cox, 2018, p. 184).

Figure 2: Adopter Categorization



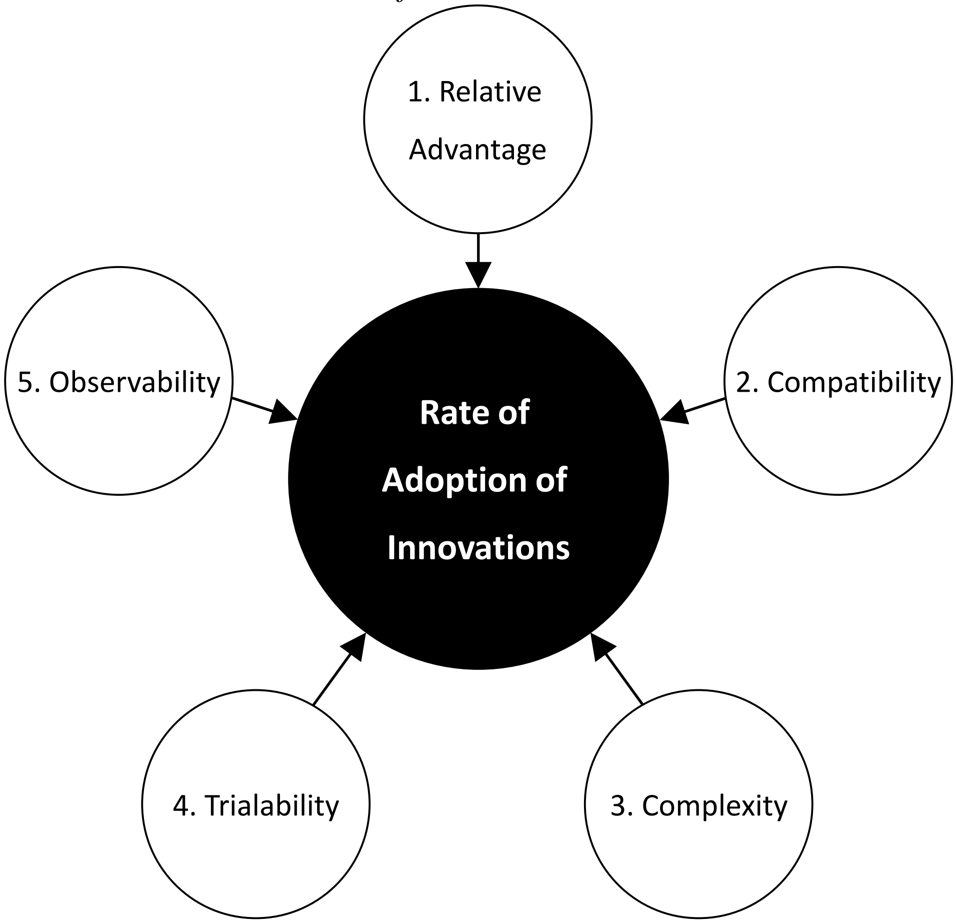
Source: Own presentation based on Rogers, 2003, p. 281.

For Rogers (Rogers, 2003, p. 282), **innovators** are willing to experience new ideas. They do not hesitate to take risks and should be prepared to handle unprofitable and unsuccessful innovations, and a certain degree of uncertainty about the innovation (Sahin, 2006, p. 19). The individuals in this category take a critical role in the diffusion of innovations and their venturesomeness requires innovators to have complex technical knowledge. **Early adopters** are more likely to hold leadership roles in social systems, therefore other members ask them for advice or information about the innovation. Their subjective evaluation of the innovation is crucial in embracing change and diffusion (Sahin, 2006, p. 19). Rogers claims that although the **early majority** has close interpersonal networks, they usually do not execute the leadership type roles that early adopters do. The innovation-decision process takes longer for the early majority in comparison to innovators or early adopters (Değerli, Aytekin and Değerli, 2015, p. 1556). The **late majority** is skeptical about the innovation and its outcomes. Thus, they wait until most of their peers adopt the innovation. Economic necessity and peer pressure might lead them to overcome their skepticism and to adopt the innovation eventually (Sahin, 2006, p. 20). **Laggards** are bound by traditions and are typically very conservative. They approach innovations with suspicion (Değerli, Aytekin and Değerli, 2015, p. 1556) and are often challenged by restricted resources. Moreover, their interpersonal network is limited to other members from their own category and they do not hold leadership roles. Consequently, their innovation-decision process is relatively long (Sahin, 2006, p. 20).

2.1.2 Characteristics of Innovations and the Rate of Adoption

Rogers defined the *rate of adoption* as “the relative speed with which an innovation is adopted by members of a social system” (Rogers, 2003, p. 221). It is generally measured as the number of individuals who adopt the new idea in a defined time period, for example one year. One important factor on the rate of adoption is the perceived attributes of an innovation. Rogers claims that between 49% and 87% of the variance in the rate of adoption can be explained by five attributes (see figure 3): 1. Relative Advantage, 2. Compatibility, 3. Complexity, 4. Trialability, and 5. Observability (Rogers, 2003, pp. 15–16).

Figure 3: Perceived Characteristics of an Innovation



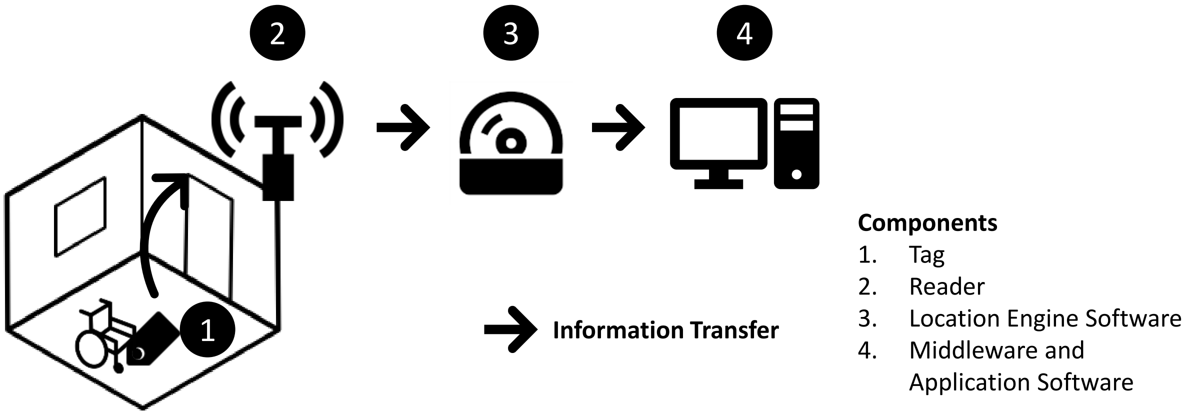
Source: Own presentation based on Rogers, 2003, pp. 15-16.

Relative advantage refers to the degree to which an innovation provides desirable consequences for the adopter compared to other available alternatives, which provides the individual with insights of the innovation's net benefits that will favor the decision to adopt (Rogers, 2003, p. 15). For example, economic profitability, increase of social prestige, and savings of time are elements of relative advantage (Sahin, 2006, p. 17). **Compatibility** is "the degree to which an innovation is perceived as consistent with the existing values, past experiences, and needs of potential stakeholders" (Rogers, 2003, p. 15). The more compatible an innovation is, the less uncertain it is to the individual. Consequently, a highly compatible innovation will require less effort of the decision-maker to assimilate the new technology into the existing landscape (Jeon, Han and Lee, 2006, p. 1914). Contrastingly, **complexity** is negatively correlated with the rate of adoption because if a new technology is difficult to master, it requires the decision-maker to use greater quantities of resources to understand and completely utilize its advantages (Thong, 2015, p. 205). The possibility to test the innovation on a trial basis (**trialability**), allows decision-makers to make experiments with the new technology, explore its upsides and possibilities in advance, and even try to identify and resolve potential downsides before fully committing to adoption (Dwivedi *et al.*, 2009, p. 18). Finally, **observability** might help the decision-maker evaluate the benefits of an innovation more effectively. The results of some ideas are easily observed and communicated to others, whereas some innovations are more difficult to tangibly observe and describe to others (Rogers, 2003, p. 16).

2.2 System Characteristics of RTLS

RTLS is defined as a solution that tracks and identifies the location of objects in real or near-real-time. The various components that are involved in the RTLS are (Kamel Boulos and Berry, 2012, p. 2; Malik, 2009, pp. 9–10) 'Tags' or 'Badges' that are attached to or embedded in the objects to be tracked. Each tag periodically transmits its own unique ID to location sensors. 'Readers' (location sensors) collect and process tag signals, thereby subsequently sending them to the location engine software. The 'location engine' communicates with tags and readers to determine the location of tags. It reports this information to specialized middleware and applications. The 'middleware' is the software that resides among the pure RTLS technology components (tags, location sensors, and location engine) and the applications capable of exploiting the value of the technology. The 'Application' (end-user application) is the software that interacts with the RTLS middleware and aggregates and displays the information received in a user-friendly format (see Figure 4).

Figure 4: Parts that comprise a RTLS



Source: Own presentation based on Malik, 2009, pp. 9-10.

RTLS solutions rely on different wireless technologies to establish the communication between tags and readers including light, camera vision, infrared, sound, ultrasound, Bluetooth (BLE), Wi-Fi, RFID (radio frequency identification) ZigBee, ultra-wideband (UWB), and GPS and Cellular (Curran *et al.*, 2011, p. 2; Liu *et al.*, 2007, p. 1073). RFID tags can be either active, powered by a small internal battery to send out a signal covering a range of up to 100 meters, or passive, which do not require an on-board battery but are limited to communicate only when they are in close proximity to a reader (Chen and Collins, 2012, p. 3853). The differences in cost, power consumption, reliability and accuracy, and range of the most common technologies are summarized in figure 5 (D'Souza, Ma and Notobartolo, 2011, p. 40; MarketsandMarkets, 2018, p. 51). All RTLS technologies share the same objective of determining the location of objects as precisely as needed but differ in terms of the physical phenomena used for location detection, the tag's form factor, power requirements, and range (Kamel Boulos and Berry, 2012, p. 3). There is clearly no 'one size fits all' solution for every application purpose (Clarinox Technologies Pty Ltd, 2009, p. 1). Therefore, a thorough assessment of needs and existing conditions in the healthcare facility is highly recommended before the technology is selected (Lorenzi, 2011, p. 40).

Figure 5: Comparison of RTLS tags based on different technologies

Parameter	Active RFID	Wi-Fi	UWB	BLE	Infrared	Ultrasound	Zigbee
Cost	Low	High	High	Low	High	High	Medium
Power Consumption	Low	High	Low	Low	Medium	Medium	Low
Reliability/Accuracy	Medium	Low	High	Low	High	High	Low
Range	High	High	High	Medium	Low	Medium	Low

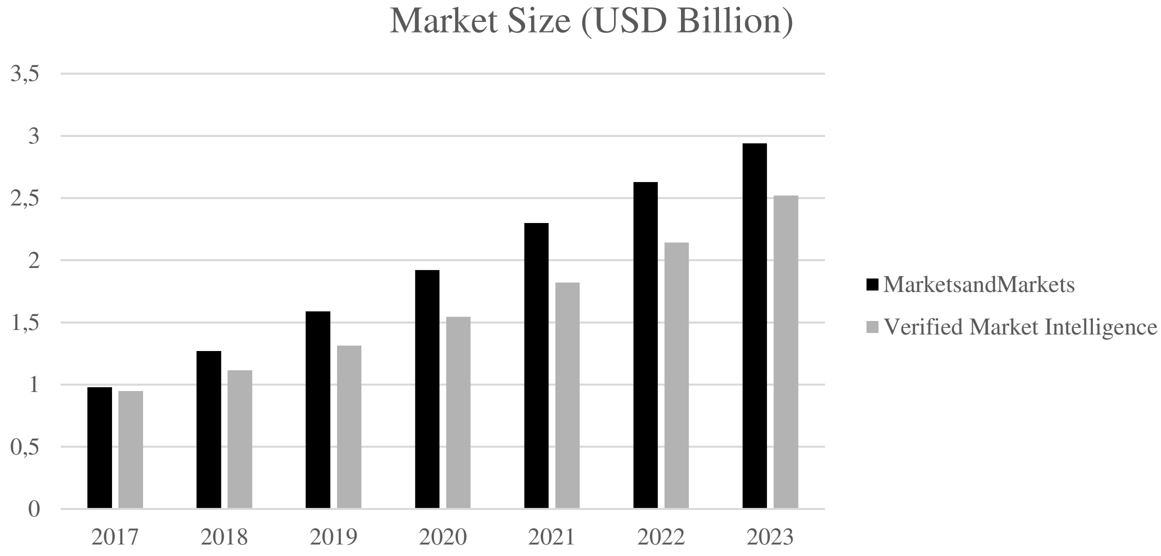
Source: Own presentation based on D'Souza, Ma and Notobartolo, 2011, p. 40; MarketsandMarkets, 2018, p. 51.

3 Results and Discussion

3.1 Current Adoption Status of RTLS

First RTLS implementations in hospital environments started to appear in 2011 and 2012 (Vantage Technology Consulting Group, 2018). Today, several market research companies forecast a very bright future for RTLS applications with steadily rising revenues in the healthcare sector (MarketsandMarkets, 2014, p. 37, 2015, p. 40, 2018, p. 29; Technavio, 2016, p. 5). Although the size and growth rate estimations of the market have differed significantly in the past, the two most recent market studies are very consistent with one another. According to MarketsandMarkets and Verified Market Intelligence, the RTLS market for healthcare is expected to grow from almost USD 1.0 billion in 2017 to USD 2.75 billion by 2023, at a compound annual growth rate (CAGR) of approximately 18% during the forecast period (see Figure 6) (MarketsandMarkets, 2018, p. 29; Verified Market Intelligence, 2019).

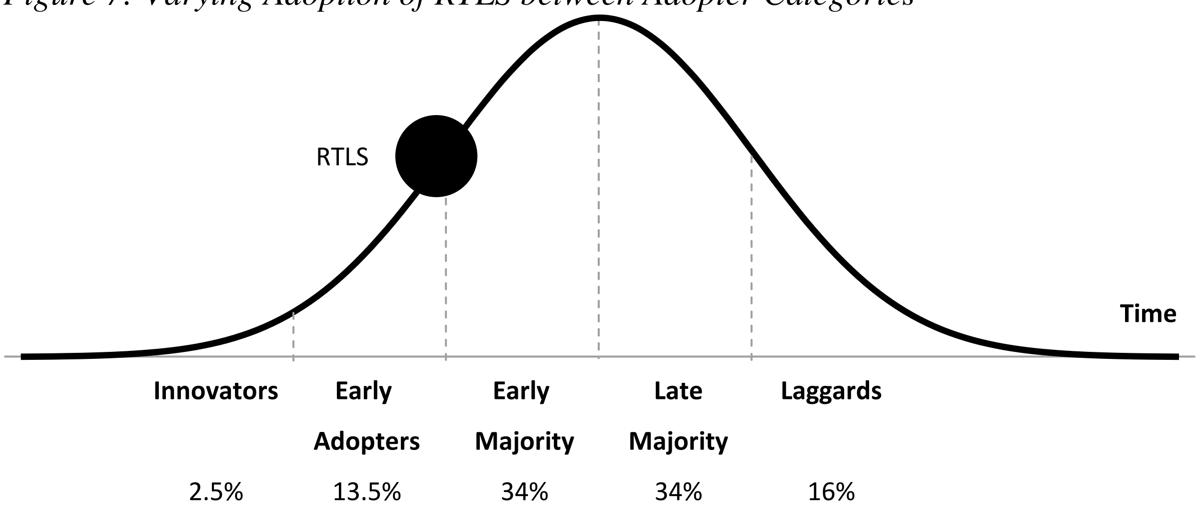
Figure 6: Market Size Forecast for RTLS in Healthcare



Source: MarketsandMarkets, 2018, p. 29; Verified Market Intelligence, 2019.

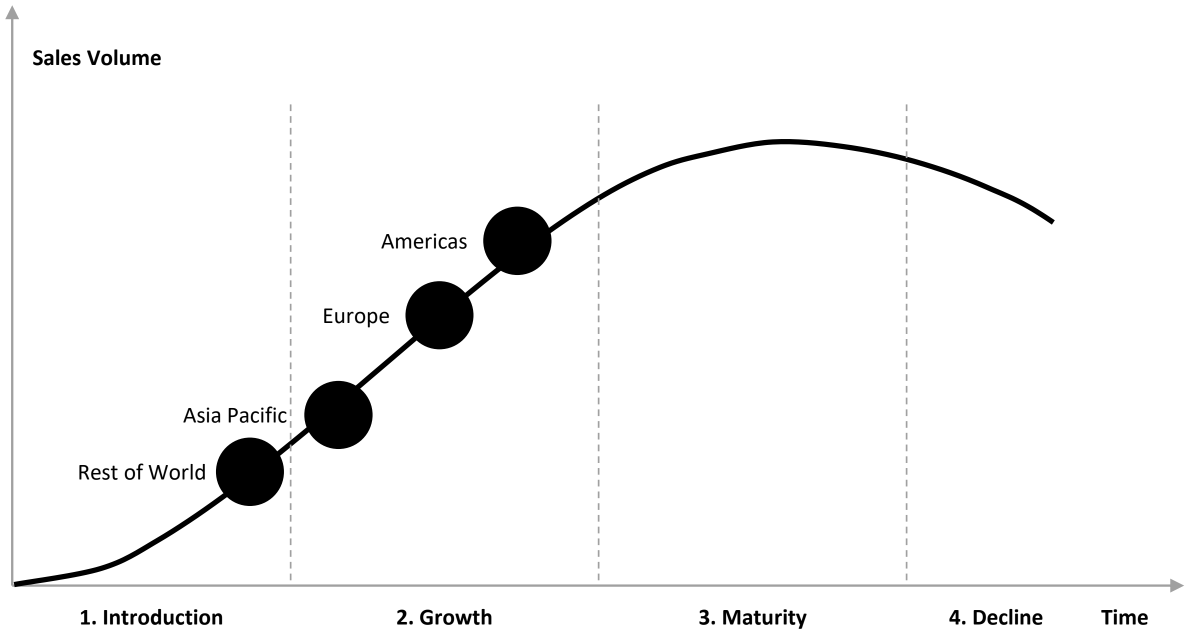
Despite the fact that RTLS has been used in the healthcare market for almost 20 years and that there are optimistic forecasts of market research companies, market penetration at present does not seem to match with these expectations. Experts agree that between 15-20% of healthcare facilities currently use RTLS and that the penetration rate has only marginally increased during the last five years (Fisher and Monahan, 2012, p. 706; Lorenzi, 2011, p. 39, 2016, p. 35; MarketsandMarkets, 2014, p. 64; Peck, 2017, p. 1; Vantage Technology Consulting Group, 2018). Considering Rogers' classification of adopter categories from chapter two, RTLS predominantly appeals to the groups of 'Innovators' and 'Early Adopters' who have successfully adopted the new technology. However, the 'Early Majority' still seems to have reservations about RTLS, since the adoption rate has slowed down noticeably (see Figure 7).

Figure 7: Varying Adoption of RTLS between Adopter Categories



Moreover, penetration differs highly across geographic regions, namely Americas, Europe, Asia Pacific and the rest of the world. As shown in figure 8, Americas is in the later growth stage since RTLS is well known due to the high concentration of RTLS vendors in this region (MarketsandMarkets, 2014, p. 65). Europe is expected to grow at a CAGR less than the Americas, and the markets in APAC and ROW are still in a nascent stage.

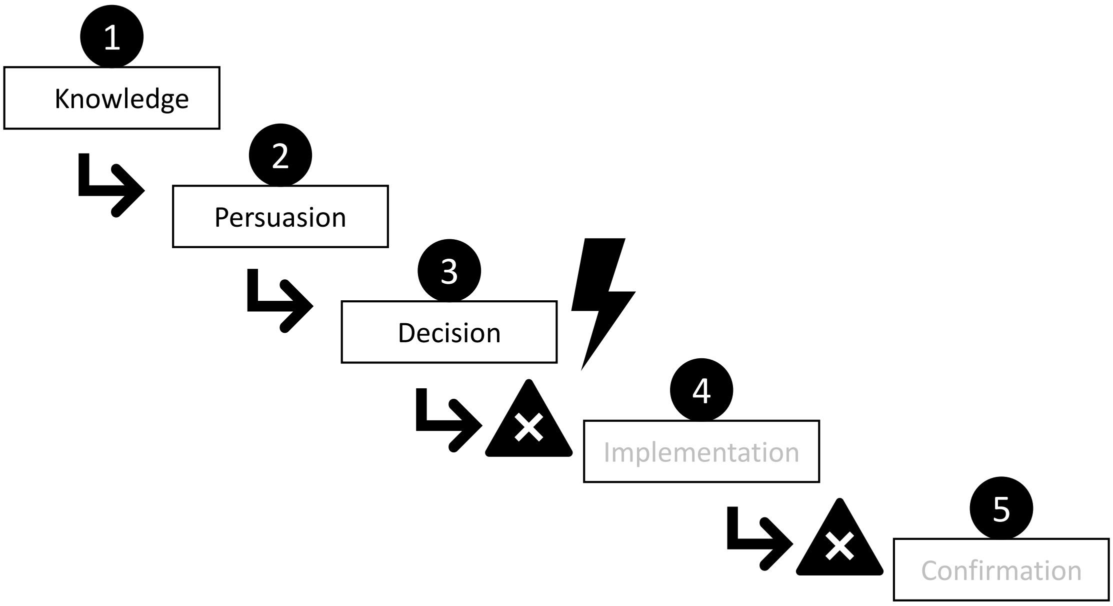
Figure 8: Industry Life Cycle of RTLS across the World



Source: Own presentation based on MarketsandMarkets, 2014, p. 64.

One of the causes of RTLS's adoption absence from the early majority may be that they have difficulties in finding convincing evidence that the innovation works. In reference to Rogers' innovation-decision process, the decision-makers have not formed a favorable attitude towards the technology, which has led to the rejection of RTLS. Consequently, the subsequent phases of implementation and confirmation do not occur due to the interruption of the process and furthermore, the rate of adoption does not increase from this point on (see figure 9). As mentioned earlier in chapter two, Rogers claims that the rate of adoption is highly influenced by five attributes: 1. Relative Advantage, 2. Compatibility, 3. Complexity, 4. Trialability, and 5. Observability. These characteristics shall now be evaluated to find reasons for the relatively low diffusion of RTLS while incorporating current market trends.

Figure 9: The Interruption of RTLS' Innovation Decision Process



3.2 RTLS as Innovation

3.2.1 Relative Advantage

Costs

RTLS has the potential for significant time and cost savings by tracking expensive or shared equipment, such as intensive care unit (ICU) ventilators or intravenous pumps, and reducing equipment theft and accidental loss (Malik, 2009, p. 36). Hospitals are typically large institutions, which makes it difficult for personnel to find portable equipment when it is required. Moreover, the practice of working around the problem by 'hoarding' equipment only exacerbates the problem (Kamel Boulos and Berry, 2012, p. 4). Equipment searches translate into delays for the overall process and have adverse impact on total productivity. By using a RTLS, healthcare facilities can limit their purchases and avoid owning more equipment than necessary. Lower capital expenditure will yield a reduction in the cost of depreciation, whereas fewer assets require less storage and maintenance. It will also help avoid unnecessary rental equipment and machinery. Accordingly, due to RTLS's ability to locate assets more effectively, medical staff can focus on their professional duties, thus increasing productivity and overall staff satisfaction (Yu, Ray and Motoc, 2008, p. 368).

But RTLS not only improves asset utilization, it was also found to be of great help in improving patient and operational processes by actively monitoring asset and patient flow through the hospital. Thus, RTLS can also save costs and improve patient satisfaction (Wicks, Visich and Li, 2006, p. 7). Benefits occur through minimizing non-value-added activities and reducing on-hand inventory at distributed storage locations (Kumar, Livermont and McKewan, 2010, pp. 45–46). First, RTLS helps in identifying bottlenecks in order to tailor appropriate solutions for typical problems; such as increased waiting times, postponed surgeries, and the lack of beds in an ICU (Berg, Longley and Dunitz, 2019, p. 56). By monitoring flow and handoffs between departments and people, the hospital management can decide if there is a need to assign

more staff or equipment to specific departments at various stages of the patient pathway (Malik, 2009, p. 19).
Considerations about the economic profitability of RTLS are fueled by the decreasing costs of RTLS hardware and software, especially of tags (Kaplan, 2018; Thau, 2017). In 2003, a RFID tag was priced at around USD 1. Whereas they now sell for approximately 10 cents (Thau, 2017). Mass production of tags has resulted in a steep decline in prices. Both the cost of hardware and software has been declining at an average of 8-10% p.a. (MarketsandMarkets, 2014, p. 58).
However, even though the costs of most of the RTLS products are falling, the total costs of ownership of a RTLS is very high (Wicks, Visich and Li, 2006, p. 6). Installation costs range between USD 2 to 5 million (MarketsandMarkets, 2018, p. 45), which includes the initial software and hardware, maintenance costs, and additional training for the staff. RTLS requires not only tags and readers, but also additional servers, databases, middleware, and end-user applications. The substantial initial investment seems to be one of the key restraining factors hindering RTLS' adoption in healthcare facilities (MarketsandMarkets, 2015, p. 57).

3.2.2 Compatibility

Safety
RTLS' applications are highly compatible to a key goal of medical institutions, hospitals and pharmaceutical companies: patient and staff safety. They have been used to track the physical movement of patients to ensure their safety. For example, in the case of Alzheimer and dementia patients; if the patient leaves a defined area or gets too close to potential exits, the system will alert staff and pinpoint the location of the patient (Kamel Boulos and Berry, 2012, p. 4). Moreover, RTLS improves the accuracy of patient identification (Cavalleri, Morstabilini and Reni, 2004, p. 3281). Alerts can warn providers of possible human errors, such as leaving items inside a patient's body during surgery or when patients take the prescribed medication incorrectly (Lorenzi, 2011, p. 39). Furthermore, RTLS can also improve staff safety by giving them the ability to request emergency assistance in crisis situations (Kamel Boulos and Berry, 2012, p. 5). Nurses have unacceptably high levels of exposure to violence, which commonly includes verbal abuse but also physical abuse (Chapman et al., 2010, p. 2066). RTLS could help in the timely summoning of assistance.
However, the surveillance possibilities of RTLS can be perceived as 'Big Brother' by the hospital personnel and the patients. Without a clear rationale, the system is not compatible with people's existing values of privacy (Fisher and Monahan, 2012, p. 710). Union members complain that RTLS can be used to monitor specific employees unfairly such as their break time and working hours tracked. The strong potential resistance may jeopardize an entire RTLS implementation (Fisher and Monahan, 2012, p. 710; MarketsandMarkets, 2018, p. 45).
Technology
The increasing technological advancements in RTLS during the last two decades have led to improved accuracy, higher efficiency, and lower cost to match the customer's expectations. Teething troubles such as short battery life of tags have been ruled out almost completely (Fisher and Monahan, 2012, p. 708). Installation time has decreased, reconfiguration of the system has been eased, and moving the application from the

hospital to the cloud removed the complexity of maintaining an on-site installation (Lorenzi, 2016, p. 36). Moreover, a range of hybrid solutions have emerged to tackle some of the major obstacles associated with a single technology based RTLS. Technically, two or more technologies are now combined aiming to be cost-efficient without having to compromise on accuracy (MarketsandMarkets, 2018, p. 46). For example, Wi-Fi is combined with infrared since it can penetrate through walls and floors but fails to pass through glass sliding doors and windows, which infrared is capable of.
However, some technical issues remain. At the moment, the majority of end users of RTLS in healthcare are not pleased with the implementation, since performance-delivered and performance-promised differs widely (Okoniewska et al., 2012, p. 674). For example, the accuracy of Wi-Fi promised by vendors is between 5-15 meters. Unfortunately, in 7 out of 10 cases they fail to achieve this standard (MarketsandMarkets, 2018, p. 46). Likewise, designing hybrid solutions that try to satisfy high accuracy, high range, low power consumption, and low price imposes inequitable trade-off challenges for the vendors, which to date they have not been able to solve completely. Furthermore, the interference of RTLS with the hospital's medical devices and equipment, especially when they share the same frequency or are used in dense wireless networks, remains a problem (van der Togt et al., 2008, p. 2884).

3.2.3 Complexity

Standards

Successfully established standards are a prerequisite for any data exchange (Perlin, 2016, pp. 1667–1668). In the past five years, initiatives have been taken from different organizations and companies such as ISO/IEC (Switzerland), ANSI (U.S.), ETSI (France), and IEEE (U.S.) to establish available standards to agree upon (MarketsandMarkets, 2014, p. 54). Standards like ISO/IEC 24730 and IEEE are a step forward to ensure common standards and interoperability in the market.
However, there is still a definite lack of well-defined technology standards in the market (Technavio, 2016, p. 24). The missing standards make it difficult to integrate available solutions in existing IT landscapes and with each other. Most vendors only rely on a single protocol. Therefore, a variety of different technologies has risen that operate on non-interoperable protocols and frequency bands. Deploying a RTLS project is highly complex and requires a lot of engineering know-how and bespoke on-site adjustments. The vendor has to be present at the customer's site during the whole project and must provide adequate training for the hospital's staff (Lorenzi, 2011, p. 40; MarketsandMarkets, 2018, p. 45).

3.2.4 Trialability

Although vendors offer pilots and demos of their RTLS offerings, trialability is highly limited. Pilots are typically departmental and do not look at the full benefit than can be achieved at the enterprise level (Hoglund, 2011, p. 21). Demonstrations can only show what other facilities have achieved and what the potential customer might be able to expect from an implementation of RTLS. However, every hospital is different, so each deployment of RTLS must be tailored to the individual hospitals' needs and objectives, hence a thorough assessment must be completed before any experiments with the technology can take place (D'Souza, Ma and Notobartolo, 2011, p. 6; Kamel Boulos and Berry, 2012, p. 6). Moreover, the proprietary nature of the RTLS marketplace makes it near-impossible to switch your RTLS provider at a later stage of the project; for example, it is difficult to switch RTLS providers when you want to upgrade your system with offerings from a different vendor (D'Souza, Ma and Notobartolo, 2011, p. 42).

3.2.5 Observability

Many hospitals across the world such as Piedmont Healthcare, Florida Hospital, UT Medical Center, Palmetto Health, Altru Health Systems, Texas Health Resources, Mount Carmel Health, Oklahoma University Medical Center, and Denver Health are using RTLS for a variety of purposes (MarketsandMarkets, 2018, p. 42; Poshywak, 2013, p. 57). Since most of the providers publish their experiences in journals, observability of implementations is present to an extent. Moreover, the increasing use of tags (Technavio, 2016, p. 21) is also noticeable within hospitals from patients, staff, and management of competing health care facilities. However, the advantages of RTLS are hardly visible to others, since the insights from technology are only displayed in the very narrow environment of healthcare facilities and do not target the individual rather the physicians and hospital management. The findings are summarized in Figure 10.

Figure 10: Summary of RTLS' perceived Attributes of Innovation

Attribute	Driver		Challenge
Relative Advantage	Economic profitability and decreasing costs of hardware	vs.	High costs of ownership
Compatibility	Technological advancements		Technological issues
	Safety increase		Privacy issues
	Already existing Wi-Fi network to build on		Low quality of Wi-Fi network
Complexity	Implementation of standards		System incompatibilities and necessity of training
Trialability	Pilots and Demos		RTLS = High involvement products, bound to one vendor
Observability	Increasing number of successful implementations and use of tags		Narrow hospital environment, Target group = Professionals

4 Conclusion and Limitations

The value of RTLS in providing visibility into the real-time location of assets, both equipment and people, has been shown in several case studies in the healthcare sector (Poshywak, 2013, p. 57). However, the diffusion of the technology lacks behind the ambitious expectations 10 years ago. This paper evaluates current market trends and characteristics of the RTLS technology to assess why there has not been a widespread adoption of the solutions in healthcare, and to determine the stage of adoption the technology is in at current state.

A suitable underlying framework for the process of adopting new innovations was adapted from Rogers' 'Diffusion of Innovations', which is also among the most popular and most used in the field. It was shown that both innovators and early adopters have found the innovation to be appealing, but the early majority seems to be more resistant to adopting the technology. Speaking in the terminology of Rogers, the early majority of adopters are not convinced by the existing proof of benefits that ensue by implementing RTLS in hospitals. Thus, they reject the technology.

The reasons for the rejection lie in the technology being used for RTLS. Most of the solutions available come with large costs of ownership. In contrast, the benefits of implementation are not perceived to be worth the high initial investment. Even though the technology aims to increase safety for staff and patients by alerts and the ability to request emergency assistance, it is often perceived as being used as an invasive surveillance system. Moreover, vendors struggle to live up to the customer's expectations in terms of accuracy, efficiency, and cost of the solutions offered. Hybrid solutions try to find a suitable tradeoff between these objectives, which makes the solution even more complicated. Experimenting with RTLS requires a hospital to go through the time-consuming and expensive assessment of its facilities and the increasing use of tags cannot make up for the fact that the advantages of RTLS are hardly visible to others.

This paper has several limitations. Even though some market studies and interviews of industry participants were incorporated in this article, most of the reviewed articles remain academic papers. Thus, the findings may not be completely accurate for the actual RTLS adoption in hospitals. Likewise, Rogers' theory of diffusion has its own limitations. For example, diffusion does not necessarily traverse chronologically through distinct stages and it also might underestimate the socially constructed nature of large technological systems (Lyytinen and Damsgaard, 2001, 179-183).

Since more and more successful RTLS projects are being implemented in hospitals across the globe, it is now much clearer to see how the technology can improve healthcare delivery and it is easier to identify the critical success factors during the implementation. However, further research is required to find solutions for the challenges mentioned in this paper that are hindering the market's ability to leverage the benefits of RTLS.

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Digital Applications as Quality-Management Tools in Primary Care

Julia Kast

Since 2017, the payment of primary care physicians includes the outcome and quality of care based on patient-reported outcomes. The following essay examines the following question: How do patient-reported outcomes influence quality in primary care in the United States? The theoretical principles about quality, value-based remuneration and patient-reported outcomes in primary care are explained and the effects of patient-reported outcomes on the components of quality (structure, process and outcome) are evaluated. Patient-reported outcomes offer a new perspective on healthcare and can therefore act as an initiator of change. Physicians must be convinced that this indicator is valuable and is the key person on whether a patient-reported outcome improves the quality of care or not. Additionally, digital versions of patient-reported outcomes must be sufficiently validated before use. Consequently, quality of care can be positively influenced by using patient-reported outcomes. This can be theoretically intensified by P4P models, but in practice, this is only possible to a limited extent. Further possibilities should be examined in more detail, especially the effects of patient-reported outcomes on quality in primary care.

Contents

1 Quality at the Centre of Care in U.S. Healthcare

Through the introduction of the Affordable Care Act (ACA) in 2010, the American legislative put healthcare outcomes, cost changing behaviour, value-based payment and quality of care at the centre of patient care (Conway, Mostashari and Clancy, 2013, p. 2215). Similarly, the introduction of the Health Information Technology for Economic and Clinical Health Act (HITECH Act) in 2009 represents a milestone in the broad implementation of digital applications in the American healthcare system. Particular focus was placed on the introduction of the electronic health record (EHR) and also the related remuneration (Burde, 2011, p. 174). This rapid progress of technological infrastructure brought the implementation of internet-based applications, touch screen tablets, and EHRs into care (Jensen et al., 2015, p. 153).

Since value-based payments are in the focus of American healthcare (Groves et al., 2013, p. 10), the question arises of how quality of care can be improved and if quality measurements like patient-reported outcomes (PROs) can improve quality of care. Hence, this analysis will discuss the research question: 'How do patient-reported outcomes influence quality in primary care in the U.S.?'

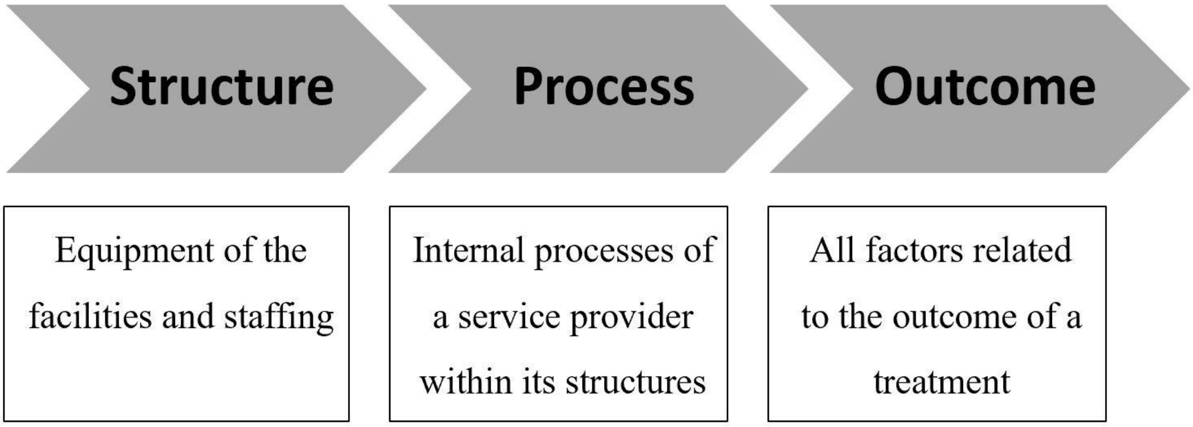
A patient-reported outcome is "a measurement based on a report that comes directly from the patient […] about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else." (FDA-NIH Biomarker Working Group, 2018, pp. 53–54). In the following analysis, the theoretical principles about quality, value-based remuneration, and patient-reported outcomes in primary care will be explained and the effects of patient-reported outcomes on components of quality (structure, process and outcome) will be evaluated. Subsequently, the analysis will conclude that quality of care can be positively influenced by using patient-reported outcomes. This can be theoretically intensified by P4P models, but in practice, this is only possible to a limited extent.

2 Theoretical Principles about Primary Care

2.1 Definition of Quality and Patient Reported Outcome Measurements

The best-known definition of quality in healthcare was shaped by Donabedian (Weigel, 2018, p. 21). Donabedian subdivides quality into the elements structure, process, and outcome (Donabedian, 1966, p. 169).

Figure 1: Definition of Quality (Donabedian, 1966)



Source: Own presentation based on Donabedian (1966), Weigel (2018) and Das, Gopalan and Chandramohan (2016).

The structural quality primarily takes the equipment of the facilities and the staffing into account (Weigel, 2018, p. 21). Examples of structural quality include equipment, infrastructure, communication, drugs, supplies, and transport (Das, Gopalan and Chandramohan, 2016, p. 322). Process quality refers to the internal processes of a service provider within its structures (Weigel, 2018, p. 21). This helps in determining whether services are provided optimally and safely minding the standards of service delivery through technical and non-technical performance (Das, Gopalan and Chandramohan, 2016, p. 322). Therefore, structure and process represent the treatment procedure (Hentschel et al., 2015, pp. 85–86). The third element is the outcome, which includes all factors associated with the outcome of the treatment (Weigel, 2018, p. 21). The quality of the results depends on the quality of structure and process (Weigel, 2018, p. 21).

Quality in patient-care has to be measured (Donabedian, 1966, pp. 167–169), and one way to estimate quality is through ‘Patient-reported Outcomes’ (PROs) (Elsenbeck, Tucker and Dickens, 2018, p. 3). PROs are patient feedback instruments to the physician in which information is not modified (Cella et al., 2015, p. 4). PROs are patient-reported, subjective measurements that focus on the patient's personal experience and how they perceived the treatment (Black, 2013, p. 167). ‘Patient-reported outcome measures’ (PROMs) are standardized questionnaires with regard to a patient's health condition, behavior or health condition (Cella et al., 2015, p. 4) that can be generic or disease specific (Black, 2013, p. 167). If an electronic format of a patient-reported outcome is used, it is called ePRO (Zbrozek et al., 2013, pp. 480–489). In this paper the terms ‘PRO’ and ‘PROM’ will be used synonymously.

2.2 Characteristics of Pay for Performance

As quality was introduced in the previous chapter, this chapter will explain how quality-based remuneration may increase the payment of physicians. Pay for performance (P4P) is a hypernym for diverse types of performance reimbursement, and renumeration is based on quality and efficiency of the treatment (Scheppach, Emmert and Schöffski, 2011, pp. 9–11). Commonly, performance in a P4P program is evaluated by quality of care, usage of services, and overall health outcomes (Das, Gopalan and Chandramohan, 2016, p. 321). The rate of remuneration is connected with previously set aims of care.

Precise quality indicators are set to measure these aims (Scheppach, Emmert and Schöffski, 2011, pp. 10–12). In order to implement P4P successfully, it is necessary to define and measure quality (Scheppach, Emmert and Schöffski, 2011, pp. 9–11). Additionally, performance is rewarded through P4P Programs and is characterized by treatment processes and healthcare outcomes (Hentschel et al., 2015, pp. 84–85). While the process quality can be quantified, the outcome quality is not easily quantifiable and therefore needs to be evaluated more extensively (Hentschel et al., 2015, pp. 83–87).

2.3 Use of Patient-Reported Outcomes as Quality Management Tools in Primary Care in the U.S.

After emphasizing the importance of feedback instruments, it is important to understand how they are applied in practice in the United States. In countries like Great Britain, the adoption of PROs was driven through legislative initiatives, whereas in the United States it was driven through the medical profession concentrated on improving outcomes for patients (Black, 2013, p. 167). In 2015, the Medicare Access and Chip Reauthorization Act of 2015 (MACRA) was introduced and changed the way that Medicare rewards physicians for value over volume (Centers for Medicare and Medicare Services, 2019, p. 1). Primary care providers have to decide for 6 out of 50 to 60 metrics. These metrics are tools to measure quality, not outcomes of quality. As some of these measures are patient-reported, therefore PROs incorporate and are therefore used for quality-based remuneration of physicians. PROs are utilized as quality-management tools in primary care (Mutter et al., 2018, pp. 933–936).

3 Analysis of Patient-Reported Outcomes and their Effects on Quality in Primary Care in the U.S.

3.1 Questionnaires, Collection and Interpretation of Data

One way to collect data is through the use of patient questionnaires. These measurements, PROMs, can be generic or disease specific (Black, 2013, p. 167). Whereas system-specific measures evaluate conditions linked to an explicit body region, disease-specific surveys appraise the effects of a disease on a patient's health and cannot be compared between different diseases (Elsenbeck, Tucker and Dickens, 2018, p. 3). The design of the questionnaires has a fundamental impact on the way PROs are measured. The stakeholders in the health sector have different views on what quality of care means, so their diverse interests should be defined in advance (van der Wees et al., 2014, p. 768). The involvement of patients in the design of PROMs is of central importance. Patients should be involved in the design so that PROMs accurately reflect the patient's point of view on quality of care without bias (Wiering, Boer and Delnoij, 2017, pp. 19–20). One type of PROM are the health-related quality of life questionnaires Short Form (36) Health Survey (SF-36) and Short Form (12) Health Survey (SF-12), which both evaluate the patient’s overall health status in the physical, mental, and social dimensions (Elsenbeck, Tucker and Dickens, 2018, p. 3). Medical and nursing staff should also be involved in the development of PROMs in order to guarantee medical accuracy (van der Wees et al., 2014, pp. 766–767). Additionally, patients should be included. Since patients often do not have any medical knowledge, the questionnaire should be written in lay-terms. Incomprehensible questionnaires can lead patients not understanding the questions, which could lead to distorted results (Philpot et al., 2018, pp. 362–363). Therefore, it is crucial that the various stakeholders are involved in the design of PROMs, that they are comprehensible to the patient, and that it is clear which form the PROM questionnaires should take. This has a profound influence on further steps and thus contributes significantly to the impact of PROMs on assessing quality in patient care (Wiering, Boer and Delnoij, 2017, pp. 19–20).

Another key point is the collection of data. Data can be collected through various methods, all of which have strengths and limitations (Ahern, Ruseckaite and Ackerman, 2017, p. 1455). IT infrastructure plays an important role in the collection of PROM data. If this infrastructure is well-designed, it can make work frictionless for physicians, care staff, and patients (van der Wees et al., 2014, 759, pp. 768-769). For instance, this includes the automatic insertion of the PROMs into the EHR so that the physician and care staff have instant access to the PROMs results, and the data only has to be collected and stored once (van der Wees et al., 2014, pp. 763–768). To increase accessibility, there should be several ways to complete questionnaires, such as digital, paper or web-based versions of PROs (Dobrozsi and Panepinto, 2015, p. 505). This is particularly important in order to address a diverse population and to avoid bias or data skew in the results (Wahl and Yazdany, 2016, p. 364). In most cases, ePROs are preferred by patients with low manual function because they are not as difficult to use in comparison to the dexterity required with pen and paper (Schefte and Hetland, 2010, p. 103). Overall, electronic formats are preferred by participants (Campbell et al., 2015, p. 1949). Moreover, the patient should be given the opportunity to complete the questionnaires during the waiting period before the appointment (van der Wees et al., 2014, p. 765). During the treatment, it is important that the results from PROs are addressed by the physician. Otherwise, the patient's willingness to fill in further questionnaires may decrease (van der Wees et al., 2014, pp. 766–767). In addition, responding to questionnaires too frequently can lead to distortion of the results and patient survey fatigue, ultimately leading to lower response rates overall (Boyce, Browne and Greenhalgh, 2014, p. 513). Another important point is the physician's conviction of PROs. If the physician is not convinced that the PRO is value, he will not require patients to fill out questionnaires (Boyce, Browne and Greenhalgh, 2014, pp. 511–512).

Consequently, data generated must be analyzed, evaluated, and interpreted. Only through evaluation and interpretation actions to improve medical quality can be initiated (Boyce, Browne and Greenhalgh, 2014, pp. 511–512). IT systems can be used as a support to pre-interpret the data and thereby reduce the physician’s workload (Mejdahl et al., 2018, pp. 549–550).

3.2 Effects on Structure

In this paper, Donabedian's definition of quality in healthcare is adopted to evaluate the effects of PROs on structure, process, and outcome.

In the following section, effects of PROs on structure are analyzed. A key point of PRO implementation is the physician's conviction about its value. If physicians do not find PROs beneficial, the outcome of improved quality is at risk. Therefore physicians should be supported in the integration of PROs into their workflows, which can then lead to higher acceptance of PROs (Rotenstein et al., 2017, pp. 966–967). The concordant implementation of PROs proves how challenging it is to successfully collect data, and how particularly difficult it is to implement PROs in small primary care practices (Elsenbeck, Tucker and Dickens, 2018, p. 6). Before implementation, automated systems need to be authorized to collect PROs and patient's experiences in order to improve quality of care and health outcomes (Conway, Mostashari and Clancy, 2013, p. 2215). PROs must be considered in the implementation of EHRs in the form of a patient portal (Sutherland et al., 2016, p. 261). In clinical care, diverse studies have shown that electronic collection is preferred to paper collection, and also results in lower rates of unanswered questions (Jensen et al., 2015, p. 154).

A disadvantage of electronic collection is that a patient may need longer to complete the questionnaires due to a patient's lack of familiarity with electronic devices (MacKenzie et al., 2011, p. 2622). In order to use an electronic version successfully, it has to be validated before use (Campbell et al., 2015, p. 1953). Additionally, it must be evaluated to ensure standard paper-based PROs are equivalent to the electronic format (ePROs). Campbell et al. analysed this issue and found forty-three studies (78%) that approved conformity, two (4%) failed conformity, and ten (18%) where scientist's conclusions where not coherent (Campbell et al., 2015, p. 1951). According to Hollen et al. however, a computerized format can replace the paper form of PROs in the evaluation process (Hollen et al., 2013, p. 171).

3.3 Effects on Process

PROMs play a key part in monitoring improvement or worsening of quality of life, function, and illness (Ahern, Ruseckaite and Ackerman, 2017, p. 1454). Accordingly, its influence on the process must be considered. There was stakeholder support in implementing patient-reported elements into EHR and several primary care settings (Estabrooks et al., 2012, p. 575). Within the process of treatment, PROMs may be collected before or after the invention or the treatment (Ahern, Ruseckaite and Ackerman, 2017, p. 1455). Through PROMs, real-time feedback can be given compared to other patients in the cohort, and it is possible to observe their development against others (Ahern, Ruseckaite and Ackerman, 2017, p. 1454). According to Browne et al., collecting a patient's experience is a crucial step towards dealing and improving the quality of care (Browne et al., 2010, p. 922). The data collected becomes increasingly valuable for all stakeholders because it is used in various ways such as accounting, quality measurement, and evaluation (Browne et al., 2010, p. 923). Upon interviewing patients and clinical staff, both had the opinion that questions could be shortened to decrease the amount of repetition between survey and physician questions (Rotenstein et al., 2017, p. 966). Two issues on collecting PROs are the time constraints and the question of if the PRO really added value (Rotenstein et al., 2017, p. 964). To record needs over time, constant monitoring with PROs combined with feedback and followed up supportive care was advised a potential way to meet a patient's needs (Mitchell, 2013, pp. 220–221). If questions seem irrelevant to patients, it increases the chance of the patient only completing half of the PRO or voiding answers. On the other hand, as collecting PROs becomes a day-to-day business, there is a high chance that collecting valid data is achievable (Estabrooks et al., 2012, p. 579). Patient-experience measures could eventually be impacted by components that are not directly related to quality of processes. For instance, Manary et al. point out that a proportion of patients link their patient care experience to their health status regardless of the actual level of patient care they were given (Manary et al., 2013, p. 202). PROs require certain efforts that the physician must keep track of. In order to reduce the workload for physicians, PROs should be naturally integrated into the appointment (Boyce, Browne and Greenhalgh, 2014, p. 516). The processes for creating questionnaires, collecting data, measuring data, evaluating data, and interpreting data should function as efficiently as possible. Otherwise, the increased workload of doctors and patients will develop into a barrier due to negative attitudes towards PROs (Boyce, Browne and Greenhalgh, 2014, pp. 511–512). In addition, nurses can make a classification of the generated data and thus reduce the physician's workload (Mejdahl et al., 2018, pp. 549–550). Porter states that process measurement is not a replacement for outcome measurement, even though an appropriate measurement for health care institutions itself (Porter, 2010, p. 2478).

3.4 Effects on Outcome

Outcomes are generally the base of healthcare decisions (Huttin, 2019, pp. 111–112). PROMs are "a potentially valuable tool in the assessment and evaluation of clinical outcomes" (Ahern, Ruseckaite and Ackerman, 2017, p. 1454), and in order to improve health outcomes, access to care is a fundamental criterion (Dahl, Peltier and Milne, 2018, p. 562). The goal of PROMs is to ensure the success or reflect the failure of treatments and therapies from the patient's point of view (Ahern, Ruseckaite and Ackerman, 2017, p. 1454). It is important to note that no standalone outcome can capture the results of care sufficiently (Porter, 2010, p. 2477). To record needs over time, constant PRO monitoring combined with feedback and followed up supportive care is recommended as a potential way to meet patient's needs (Boele et al., 2017, p. 158). Several studies found out that patient experience correlates with clinical mechanisms of care for prevention and disease management which leads to improved health outcomes (Browne et al., 2010, p. 922). When physicians act based on PROMs, the full potential of the collected data is used. So far, PROMs are not often recorded in routine care, although PROMs are well suited for monitoring chronic diseases and improving outcomes (Recinos et al., 2017, pp. 460–461). By monitoring chronic diseases, physicians can also intervene in the treatment process through telemedical applications. The goal is to process the collected data in order to have a comprehensive database in the future (Ward, Schiller and Goodman, 2014, p. 63). Outcomes of PROMs in primary care are not well-researched yet, but it is assumed that it will require innovation - especially for patients with long term conditions (Black, 2013, p. 169). Yet, feedback to primary care providers has had only small effects on the process or outcomes of care (Fihn et al., 2004, p. 241).

3.5 Pay for Performance with PROs in Primary Care in the U.S.

Since 2018, hospitals and doctors have been remunerated according to quality standards. In principle, there are two options for doctors to be paid by Medicare. The first is a modified fee-for-service model, the Merit-Based Incentive Program (MIPS), and the other is the Advanced Alternative Payment Model (AAPM), which includes reimbursement within the bundled payment models. MIPS also collects points for services rendered, which are evaluated on the basis of quality indicators (Matthes, 2019, p. 252). MIPS is part of the MACRA and integrates multiple quality programs (Centers for Medicare and Medicare Services, 2019, p. 1). Quality improvements can be remunerated by the score as well as performance improvement in different dimensions. In 2018, a quality-oriented remuneration of +/- 5% was budgeted and is projected to rise to +/- 9% in 2022. Due to this change in law, quality immediately became an issue of utmost interest for leading positions (Matthes, 2019, p. 252). In clinical care, PROs belong to standard of quality-based remuneration for several years and since that outcomes have partially improved. In primary care, similar expectations are cherished forthwith which can be justified by the intersectorality of care (Mutter et al., 2018, pp. 931–937).

4 Discussion

The goals for this paper were to analyze PRO's influence on primary care quality in the U.S. The findings shall be discussed in this section of the paper.

The U.S. health care system is driven towards the 'triple aim' of improved care experiences with higher quality and lower costs; there is a focus is on patient-centric care and optimal outcomes in quality (Berwick, Nolan and Whittington, 2008, pp. 759–769). The primary care practice is an essential factor of digital health information sharing and coordination (Baird and Nowak, 2014, p. 192). Particularly in the treatment of long-term conditions, primary care plays an important role. Therefore, primary and secondary care must be observed to collect data and evidence for PROMs in whole health economies (Black, 2013, p. 169).

Presently, certain stakeholders in health systems have huge interest in the use of PROs to include patient groups in decision making processes; for example: payers, regulators and qualified organizations are all interested (Jensen et al., 2015, pp. 153–159), however this sector of healthcare cannot solely assure best outcomes. The optimal PROM coverage would be capturing all suitable patients across participating settings such as hospitals, clinics, primary care, and aged care as part of regular clinical care (Ahern, Ruseckaite and Ackerman, 2017, p. 1455). The use of PROMs has been more frequent in individual physicians and several hospitals, but is not commonly used in health systems in some parts of the United States (Black, 2013, p. 167). In this case, physicians have a duty to be transparent to their patients about quality and cost (Liao, Emanuel and Navathe, 2016, p. 149). Similarly, the single use of technical attempts like EHR, decision-support systems, or patient-reported outcomes show little or no benefit if only used alone (Fihn et al., 2004, p. 241). Recently, PROM items may also include individual data and computer-adaptive testing, where algorithms are used to select questions (Ahern, Ruseckaite and Ackerman, 2017, p. 1455). Data must not only come from patients, it should also be collected through linkage between databases (Black,

2013, p. 169). The optimal scenario would be integrated systems that meet all requirements.
Concerning the treatment of patients, the automatic insertion of data into the EHR could save costs but could also reduce the error rate during data transfer. If the physician cannot access the questionnaire data during the consultation, the results of the questionnaires will not affect the quality of treatment (van der Wees et al., 2014, pp. 763–764). Additionally, it is still not clear if electronic versions of a PRO can be replaced completely through a digital format. Furthermore, not all PROs are validated in an electronic format (ePROs) for proper use. Additionally, aggregation and data transference leads to uncertainty (Wysham, Abernethy and Cox, 2014, p. 569). Campbell et al. and Gwaltney, Shields and Shiffman come to the conclusion that computerized formats of PROs (ePROs) are as successful as paper-based versions (Campbell et al., 2015, p. 1954; Gwaltney, Shields and Shiffman, 2008, pp. 322–333). In this regard, ePROs have several advantages, such as enhanced data quality, no missing data, lowered bureaucratic burden, and better implementation of work sequences (Zbrozek et al., 2013, p. 482). Nevertheless, further assessments should constantly be done to prove that reliability and validity are comparable to the initial version in order to transfer a PRO instrument into an electronic form (Campbell et al., 2015, p. 1954). Additionally, there is always the risk that even if physicians evolved their processes as a result of the intervention, the outcomes might not have been influenced. Therefore a PRO is not guaranteed to improve a quality of care outcome (Fihn et al., 2004, p. 245). Consequently, patient-reported data can be influenced by factors like race, ethnicity, education, or health status. Hence, data must be analyzed by these characteristics (Browne et al., 2010, p. 923). Due to the large Hispanic population in the US, providers should also make questionnaires available in Spanish (Rotenstein et al., 2017, p. 966).
PROMs must be collected for long periods of time. If only the short term is considered, there might be a risk of misinterpreting data (Black, 2013, p. 170). Monitoring, for example, is important because long periods of time should be measured in order to map the disease properly, especially in the case of chronic diseases (Recinos et al., 2017, pp. 460–462). Studies have shown that the physician is typically the decisive factor whether a PRO is successful or not. Therefore, the physician is at the center of the success of PROs (Rotenstein et al., 2017, pp. 966–967). This is especially the case in primary care, where data collection can only be carried out to a limited extent by external staff and relies heavily on the physician (Huttin, 2019, pp. 111–113).
The use of PROs in primary care in the United States are not well researched yet. Therefore, data from clinical care and clinical trials were used and transferred to primary care. Transmissibility between clinical and primary practice is limited, but as long as no further studies are conducted, this is a way to approach the topic. Methods like PROs will be implemented first in clinical care until it is used in primary care (Huttin, 2019, pp. 111–113). Further limitations of this work were temporal delays in publication of studies and reviews. Additionally, only studies written in English and German were considered, therefore there might be a language bias. There might be a prioritization bias as well. It is important to note that the findings obtained in this work only reflect an overview.

5 Conclusion

There are two separate goals that PROs must achieve - quality management and provider comparisons. Furthermore, data collection methods have to be supported so that PROs will become a part of routine care. Additionally, since it is not possible to spread provider comparisons to all stakeholders, focus treatments and diseases need to be selected. Likewise, it also necessary to address the systematic barriers that continue to be unsettled to guarantee that PROs are used adequately (Black, 2013, p. 170). In order to boost the use of PROs in various disease areas or reward systems, researchers should conduct studies with valid study designs, promote the use of validation methods for the studies, accelerate the digitalization of PROs to ePROs, and regulate the sources of biases through several models of data collection (Huttin, 2019, p. 112). Nevertheless, the extent to which the costs of the implementation are in proportion to the benefits must always be weighed during the implementation process. This also includes the bureaucratic efforts for service providers as well as for system. The concordant implementation of PROs persists challenging, as successful data collection is particularly difficult to implement in small practices. Plus, the diversity of PROs and the deficiency of standardization hardens extensive comparisons. Yet, there is still no consensus on which PRO generates the most valuable data (Elsenbeck, Tucker and Dickens, 2018, p. 6). It is important to note that healthcare delivery involves numerous stakeholders from primary care physicians to single care providers to hospitals, however, none of these is solely responsible for creating value and consequently quality (Porter, 2010, p. 2478). In summary, it can be concluded that PROs offer a new perspective on healthcare and can therefore act as an initiator of necessary change. As a result, quality of care can be positively influenced by using patient-reported outcomes. This can be theoretically intensified by P4P models, but in practice, this is only possible to a limited extent. More attention should be drawn to outpatient care because the hospital sector has so far been the primary focus of research on PROs. In conclusion, the further possibilities of PROs should be examined in more detail, especially the effects of PROs on quality in the primary care sector.

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Use of Decision Support Systems for Medical Diagnosis and Treatment Selection

Theresa Schröder

Clinical Decision Support Systems are capable of assisting physicians in the overall process or solely within the diagnosis or treatment process to help them to find the right medical course of action. These systems calculate the probability of different diagnoses and of the success for the available treatment options. As Decision Support Systems provide different explanatory approaches, physicians benefit from additional arguments that they might not have considered beforehand. The goal of this paper is to illustrate the use of Clinical Decision Support Systems for the diagnosis and treatment selection. Further technological advances must be incorporated into the existing systems in order to improve them, however, these systems must be adapted to fulfill the requirements of the physicians in order to build up an acceptance in the medical profession. The acceptance and use of such Decision Support Systems grows through a significant improvement in the quality of care. Furthermore, these systems potentially protect physicians from treatment errors if connected to patient data. Clinical Decision Support Systems should not be used as a substitute for all diagnostic options. The systems are designed to help physicians form critical opinions. The opportunities offered by CDSSs promise a significant improvement in the inpatient as well as in the outpatient sector. With a correct implementation and use of these systems, it is possible to create positive changes in the healthcare market.

Contents

1 Advancement and Development of Decision Support Systems

Technological innovation has caused a change in society. This change can be considered inexorable (cf. Greenes, 2014b, p.81). The increasing digitalization in connection with societal change promotes the development and spreading of Decision Support Systems (DSS) (cf. Mandzuka et al., 2017, p.121). In particular, the complexity of medicine fascinated developers of computer-based DSSs (cf. Greenes, 2014b, p.83). With the explosion of knowledge coming from the new technological advances, physicians are constantly confronted with new products which are supposed to support diagnosis and treatment decisions. DSSs are designed to effectively preselect information for the physician, so the physician only has to review relevant information for decision-making (cf. Greenes, 2014b, pp.85). Considering the aging population and the increasing prevalence of comorbidities and chronic diseases, the healthcare system is forced to establish modern, technological solutions for improved quality of care (cf. Greenes, 2014b, p.90).

Clinical Decision Support Systems (CDSS) are fundamental to physicians in practice. During a medical decision process, these systems provide diagnostic and treatment possibilities. With the assistance of these systems, physicians are able to rethink decisions and consider new diagnostic tests and alternative treatments. Furthermore, these systems can provide information on the probabilities of success and outcomes of the various treatment alternatives (cf. Greenes, 2014a, p.112). CDSSs, according to Greenes (2014a, p.112), "intend[ed] to interact with and give advice to a human being." CDSSs are also fundamental to society because they help avoid common medication errors and adverse drug events. In addition, the subsequent costs of treatment also result in considerably higher healthcare costs (cf. Kaushal/Bates, 2001, p.59). Patient safety and quality improvements are also promoted by CDSSs. One of the challenges is the established culture of the health care system, in which physicians enjoy complete autonomy (cf. Berner, 2009, p.17).

DSSs have the ability to preselect information. Therefore, it can be considered as an enrichment for physicians. Since an overabundance of information is available on the Internet, preselection is of enormous importance. Irrelevant information to the physician can be filtered out in advance before the physician starts to screen the information. A computer-based DSS uses artificial intelligence (AI) and algorithms to scan information according to criteria such as quality and timeliness (cf. Greenes, 2014b, p.86).

In health care, DSSs were already introduced several years ago and the use is continuously increasing. In 1945, the former director of the *Office of Scientific Research and Development*, Vannevar Bush, published the first article about DSSs called *As We May Think*. The invented future device holds the name *Memex* and is described by Bush as a device capable of storing everything a person hears, sees, or experiences, and making the information available by pushing a button (cf. Bush, 1945, n. p.). Since the publication of this article, enormous scientific progress has been initiated, with DSSs being developed in various industries. In the 1960s the first systematic studies on DSSs were published. Computer-based Decision Support Systems could emerge with the development of small and distributable computers (cf. Power, 2008, p.121). With an increase in digitalization, the daily work routine of physicians is slowly changing. Digitalization will facilitate the quest for information, the exchange of information between different health care providers and the analysis of health data. Even if health

decisions are uncertain, physicians are in the position to accelerate decision-making and minimize uncertainty.
The underlying literature for this paper was selected by various keywords in Google Scholar, PubMed, and the database of the University of Bayreuth. Keywords such as *Clinical Decision Support System* and *Diagnosis Decision Support System* were used for the search operation. The results were reviewed and sorted based on the abstracts. Multiple systematic reviews are used for the analysis of the effectiveness of Decision Support Systems. After a preliminary literature search and review, the following two research questions were elaborated. The research questions were *How do Decision Support Systems influence physicians' treatment decisions?* and *How do Decision Support Systems influence the quality of care?* After narrowing down the topic, a more detailed literature search was conducted.
DSSs can be used in a wide variety of areas. In the healthcare sector, patients and physicians are able to use support systems. However, in this paper, the focus is on the opportunities and risks for physicians' decision-making. In addition, the paper will be focused on the American healthcare market. This focus was set with a view to the excursion and intercultural exchange that took place. The paper then discusses the effectiveness of DSSs in practice. The paper closes with a conclusion, which elaborate upon the research questions and summarize the paper.

2 Fundamentals of Clinical Decision Support Systems

2.1 Clinical Decision Support Systems

This paper examines the application of DSSs in the medical area. Decision Support Systems are computer-based information systems using AI to support the decision-making process with all available information (cf. Shortliffe, 1986, p.830). In the medical sector, the technology is used to assist physicians during the decision-making process. These Clinical Decision Support Systems are designed to influence physicians' decision-making process and are intended to support the diagnosis and treatment processes in particular (cf. Berner/La Lande, 2007, p.3). In order to use a CDSS, an electronic health record (EHR) is necessary. This is the only way the system is able to provide suggestions and warnings for individual patients and their needs (cf. Nanji et al., 2014, p.487).
CDSSs can be divided into the term's *clinical decision* and *support*. In the following paper, the term *clinical decision* is understood as a decision which deals exclusively with the control of the health and health care of an individual patient. The term *support* only includes assistance in decision-making. The physicians' decision-making is influenced by the rapid availability of patient data, different treatment tools and different treatment alternatives (cf. Greenes, 2014a, p.8). In addition, CDSSs can assist the physician in diagnosing a disease through AI. The system provides evidence-based medical information and functions as a control system for diagnostic examinations which are performed and used for the individual treatment steps by physicians or other healthcare professionals (cf. Zwack, 2018, p.4). CDSS is defined by Kawamoto et al. (2005, p.65) as "any electronic or non-electronic system designed to aid directly in clinical decision-making." The Diagnosis Decision Support System (DDSS) can be defined as a computer-based algorithm that supports the physician during the diagnostic

process (cf. Miller/Geissbuhler, 2007, p.101). CDSSs can have a passive, a semi-active, or an active layout. The passive systems only respond to a specific request from the physician. The semi-active systems elaborate the information in the background but submits data solely upon request. Active systems automatically reveal data and proposed solutions (cf. Mandzuka et al., 2017, p.121). In literature, the term *Diagnosis Decision Support System* is generally equated with the term *Clinical Decision Support System*. In the following parts of the paper, the term CDSS is primarily used, including terms like Medical Decision Support System or Diagnosis Decision Support System, as mentioned in various literature.
It is important to be clear about the definition of DSSs by Thornett. According to Thornett (cf. 2001, p.40), DSSs are consultation systems in which AI uses collected knowledge to make it available to physicians. Furthermore, there are two levels of Clinical Decision Support Systems, which can be differentiated into the *rule-based system* and the *expert system*. The first level is *rule-based* and supports physicians with their decisions. These systems force physicians to logically rethink all decision options. The decision options are determined by the data entered into the system (cf. Thornett, 2001, pp.41). The second level, which equals the *expert system*, is answering queries about any medicine aspects. These systems offer a variety of diagnostic and treatment possibilities tailored to the individual patient (cf. Thornett, 2001, p.41).

2.2 Theory of Medical Decision Making

Theories about human decision-making have been part of economic research for over 150 years. According to Felder and Mayrhofer (2017, p.1), it is not possible to determine with certainty which alternative is the best when deciding. *Medical Decision Making* (MDM) is defined by Whang (2013, p.1209) as a process “by which a diagnosis or treatment plan is formulated from the available test information, often with the incorporation of known patient preferences.” In addition, Greenes (2014c, p.121) defines requirements for MDM. For instance, a physician should apply gathered knowledge to a specific subset of patient information in order to make a decision about diagnosis or treatment. Hence, the theory of MDM explains the process of decision-making in the medical and healthcare sector (cf. Felder/Mayrhofer, 2017, p.1). As early as 1919, Bleuler defined *Medical Decision Making* as a consideration of probabilities of benefit and harm (cf. Bleuler, 1919, p.89). Decisions made by a physician have a direct impact on a patients’ health status. In allocating time to different patients, physicians need to decide which patient needs to be prioritized. However, physicians do not only have to decide on the order of patients' treatments, but they are also required to make decisions about their individual therapies. With the decision for or against a specific therapy, the effect on the patient must be considered carefully (cf. Felder/Mayrhofer, 2017, pp.1). Every decision concerning the medical health of patients is burdened with uncertainties of different natures. For instance, it is uncertain whether the diagnosis is correct or how therapy affects a patient (cf. Hunink et al., 2014, p.3). With the help of a CDSS, *Medical Decision Making* is able to derive treatment options or possibilities to prevent the disease. DSSs should attempt to outline the health benefits and probable outcomes of each decision option (cf. Whang, 2013, p.1209).
However, societal change forces patients to participate in medical decisions and take responsibility for their health. In addition, this change promotes the involvement of

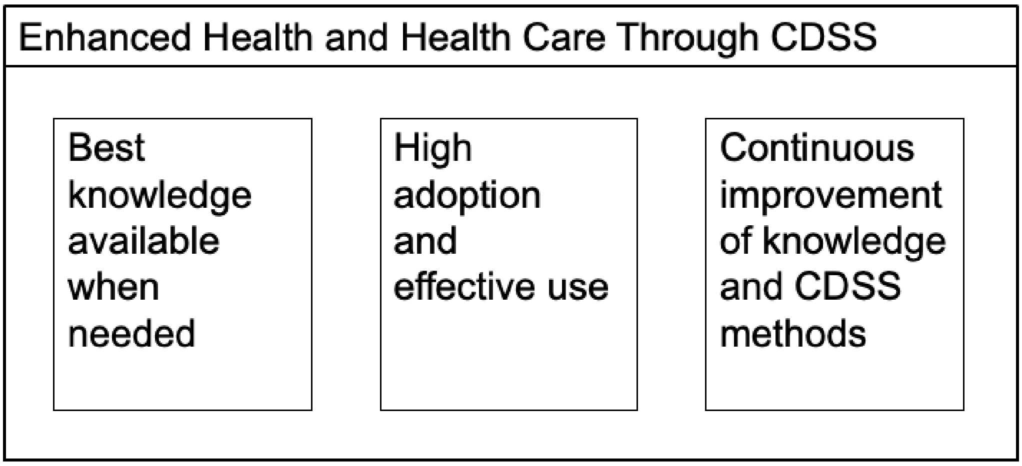
patients in medical decision-making. The so-called shared MDM is the ideal decision-making method, according to Strull et al. (1984, p.2990). Through this method, physicians are able to empower patients to participate in the decision-making process. Physicians are expected to respect patients' preferences, although access to CDSSs for patients is not possible, because these systems are usually developed only for larger companies. Shared decision-making influences the way physicians predict clinical decisions. By including patients, physicians are no longer able to make decisions on their own or solely based on proposals from CDSSs. Besides the suggestions of the CDSS, the opinions and preferences of patients should be taken into account as well (cf. Shay/Lafata, 2014, pp.295; cf. Edmonds, 2014, p.526). Shared decision-making has been identified as one of six key factors for high-quality treatment (cf. Institute of Medicine, 2001, p.43). A shared decision-making approach in conjunction with a clinical DSS not only increases patient satisfaction, but also improves risk perception and treatment quality (cf. Edmonds, 2014, p.526). Furthermore, through a shared-decision approach the relationship between patients and physicians can be improved. These support systems unite patients and physicians, especially when several well-founded treatment options exist (cf. Mandzuka et al., 2017, p.121). Each treatment option is characterized by different benefits and harms. Moreover, CDSSs also supplements the information with the probabilities of results for the various options depending on the risk potential of the respective patient. However, it should be noted that the optimal decision-making process does not necessarily lead to an optimal decision (cf. Edmonds, 2014, pp.525).

3 Application Areas of Clinical Decision Support Systems

3.1 Realization Requirements

In 2007, the American Medical Informatics Association (AMIA) published requirements for CDSSs. With this publication, the AMIA responded to a request by the *Office of the National Coordinator for Health Information Technology* in 2005. The AMIA is concerned with the improvement of Clinical Decision Support Systems within the American health market. Within the framework of health information strategies, other countries are also further developing CDSSs (cf. Osheroff, 2007, p.142). AMIA developed various strategies for the continuous improvement of CDSSs. A three-pillar model has been developed to ensure an effective implementation. This model is designed to improve health care in the United States. As shown in Figure 1, the model is based on these three pillars: 1. *Best Knowledge Available When Needed*, 2. *High Adoption and Effective Use* and 3. *Continuous Improvement of Knowledge and CDS Methods* (cf. Osheroff, 2007, p.143).

Figure 1: The three pillars for realizing CDSS



Source: Own presentation based on Osheroff et al., 2007, p.143.

The first pillar is characterized by a simplified presentation of medical knowledge and data for medical professionals. This allows medical users to quickly capture and evaluate data and information and incorporate it into the diagnosis and treatment process. Furthermore, a simplified search for specific or complementary information is considered to be one of the main requirements for a CDSS (cf. Osheroff et al., 2007, pp.142). The second pillar is high acceptance and effective use, and focuses on the removal of legal, financial, and political limitations and obstacles. In addition, CDSSs should have a significant clinical value for users. The support system is intended to provide financial and operational value to the acquirer. A constant improvement of the system is considered necessary by the AMIA, as well as the continuous development of a simple application (cf. Osheroff et al., 2007, pp.142). In the third area, AMIA has committed a steadily improvement of the knowledge base and the method of the Clinical Decision Support System. Modifications are expected from CDSSs interventions and clinical knowledge. Improvements should be based on experience, feedback, and newly collected data. Therefore, national experiences and data of the interventions should be integrated. The AMIA regards the integration of EHR as indispensable for increasing clinical knowledge and improving health management (cf. Osheroff et al., 2007, pp.142).

3.2 Diagnosis Decision Support Systems

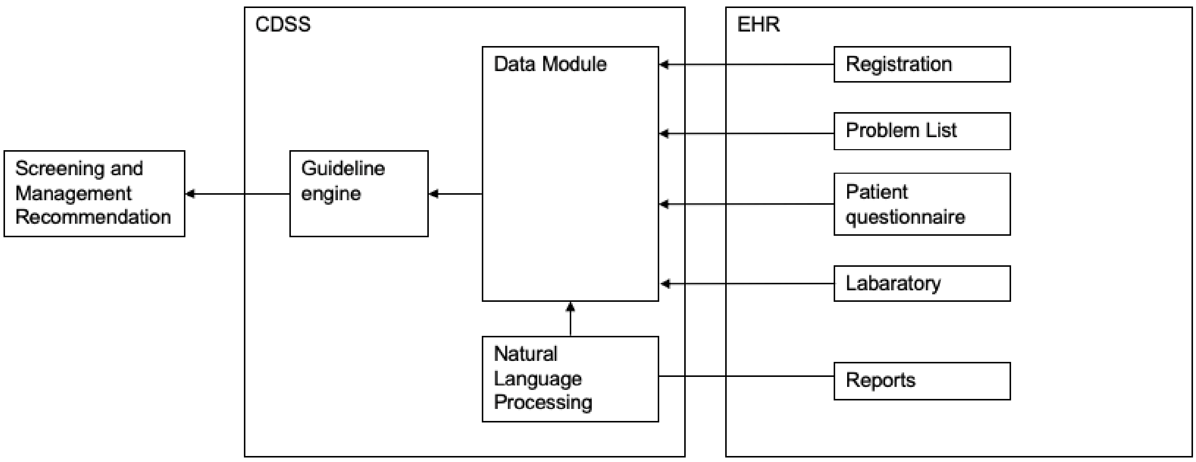
Diagnostic Decision Support Systems are one of the first innovative medical informatic systems. In particular, diagnostic errors lead to medical errors and undesirable side effects. Mandzuka et al. (2017, p.121) mention the fact by which 32% of medical errors are due to an insufficient amount of time to evaluate the patient's condition. In addition to AI, the systems use statistical pattern recognition models. In most cases, physicians are forced to follow a predefined vocabulary list when entering patient-relevant data (cf. Berner, 2006, p.1167). For this reason, different DSSs use *Natural Language Processing* (NLP). Most CDSSs force physicians to adhere to a specific vocabulary list when entering patient-relevant data. NLP allows physicians to use a variety of terms when adding these data to a CDSS or DDSS (see Figure 2, chapter 3.3).

Various DDSSs are already integrated into clinical routine. The *Ada DX* system provides an example of a Diagnostic Decision Support System which is currently still a research prototype of the company *Ada Health*. In this system, physicians are able to enter patients' symptoms and receive two ranked lists of differential diagnoses. One list displays common diseases, and the other displays rare diseases. Moreover, the different probabilities of disease occurrence are also indicated (cf. Ronicke et al., 2019, p.3). According to Ronicke et al. (2019, p.3), this prototype is not yet suitable for daily use. However, it is currently being optimized and further research will be conducted. *Ada Health* offers also a diagnostic system for patients. Using an app, patients are able to track symptoms and make them available to physicians during a consultation. The app uses a personal health profile and a chatbot to interview the patient about their symptoms (cf. Hirsch, 2018, p.20).

3.3 Decision Support Systems for Treatment Decisions

During the treatments, CDSSs can also assist physicians in the administration of medication. Among other things, they provide information on dosages and medication guidelines. Moreover, CDSSs can identify drug-drug interactions, possible drug allergies, and can provide reminders on follow-on prescriptions (cf. Kaushal/Bates, 2001, p.59). However, these systems do not function entirely in a smooth or error-free manner. Physicians have to accept and integrate these systems into the treatment process. Nanji et al. (2014, p.487) investigated the functioning and acceptance of physicians in relation to alert systems for drug prescriptions. They discovered that many warnings from the system are ignored and overridden by the physicians. Too many warnings can result in error warning fatigue (cf. Nanji et al., 2014, pp.487). Nanji et al. also researched specific reasons for not heeding warnings. Most physicians, for instance, indicated in warnings about drug allergies or age-based suggestions that patients had already tolerated the drugs successfully in the past (cf. Nanji et al., 2014, pp.488).

Figure 2: Architecture of a CDSS



Source: Own presentation based on Wagholikar et al., 2013, p.750.

Figure 2 shows a CDSS developed by Wagholikar et al. (2013, p.750). This system extracts all patient-relevant information from the EHR. Furthermore, physicians are able to enter more information into the system. The system uses treatment guidelines, medical databases and all patient-relevant information to develop proposals. With the

NLP program, physicians are not limited to certain terms and can enter their entries freely into the EHR. It is of particular importance if physician reports or similar can be entered directly into the system in order to avoid additional work (cf. Wagholikar et al., 2013, p.750).

4 Effectiveness of Clinical Decision Support Systems

4.1 Effective Usage

Evaluation of Clinical Decision Support Systems is very important to measure the impact and output of these systems for physicians and patients (cf. Potts/Wyatt/Altmann, 2001, p.456). A CDSS can only be used effectively by physicians if the databases are updated regularly. Decision-making processes in medicine are highly dependent on empirical knowledge (cf. Ehtesham et al., 2019, n. p.). This is where Ehtesham et al. (2019, n. p.) see the superiority of CDSSs, as they could learn from previous decisions and disease processes with the use of AI. Nonetheless, a CDSS can only be as effective as physicians' attention to detail. Overriding the CDSSs warning can cause the system to be labeled as ineffective (cf. Nanji et al., 2013, p.489). According to Pawloski et al. (2019, p.331) DSSs have the ability to improve measures in the health care process.

4.2 Diagnostic and Medication Area

Diagnosis Decision Support Systems are especially effective for medical diagnostics, which function case-oriented. It is advantageous if the system incorporates previous decisions (cf. Ehtesham et al., 2019, n. p.). According to Pastore et al. (2019, p.2), CDSSs should be user-friendly and easy to access. Otherwise, physicians may not use DDSSs to support their diagnostic process. The DDSS *Ada DX* mentioned in chapter 3.2 has been considered within a study by Ronicke et al. The study focused on the detection of rare diseases. Although the system is still a research prototype, correct diagnostic suggestions were displayed by the system in most cases. These were often indicated at a very early stage of the disease. Despite the enormous potential for improvement, this system has a high ability to detect rare diseases at an early stage and thus improve patient care and accuracy of results (cf. Ronicke et al., 2019, p.11). Another study conducted by Benditz et al. (2019, p.4) shows a significant correlation between diagnoses, therapeutic recommendations, medication and the CDSS. The link between prescription of medications, and other therapeutic interventions and the CDSS is considered successful (cf. Benditz et al., 2019, p.4).

An aging population structure, the rise of comorbidities, and complex disease patterns reinforces the need for modernized health care. The treatment of chronic diseases often goes hand in hand with multi-medication and a variety of concurrent interventions (cf. Sim et al., 2017, p.1). CDSSs enable physicians to maintain an overview and are able to indicate drug intolerances or incompatibilities between different drugs or serious drug interactions (cf. Greenes, 2014b, p.90). Various studies show an improvement in patient outcomes and savings in the cost of care. The Clinical Decision Support Systems can alert physicians to dangerous side-effects of pharmaceuticals and help them decide on possible diagnostic and treatment options. Immediate warnings can reduce or avoid serious complications. The possibilities offered by the CDSSs have a direct influence on the quality of care and also on the costs of care (cf. Berner/La Lande, 2007, p.9). In addition, Nanji et al. (2014, p.490) reported a significant improvement in patient safety and quality of care through CDSSs. Furthermore, it was found that medication was taken by the patients according to the instructions more frequently (increased medication compliance) (cf. Nanji et al., 2014, p.490).

4.3 Treatment Area

Decision Support Systems are proven in many industries, including the medical sector. CDSSs have the potential to advance evidence-based standardization to improve patient outcomes and treatment performance. This is particularly effective when the CDSS is integrated over the entire patient care process. However, CDSSs are only able to give patient-specific reminders and warnings if they function on the basis of an EHR (cf. Pawloski et al., 2019, p.331). A systematic review by Pawloski et al. (2019, p.334) identifies an increase in the use of guidelines through the use of CDSSs. Furthermore, the studies seem to indicate that these systems promote potentially meaningful improvements in patient care (cf. Pawloski et al., 2019, p.334).

According to Greenes (2014b, p.91), CDSSs are able to protect physicians from treatment errors and provide an overview of necessary measures, changes, and follow-up examinations at any time. In cooperation with EHR, a CDSS can automatically fill out various documentation tasks to ultimately save physicians time. The growth in the documentation, chronic diseases, regulatory compliance, and patients needing care is constantly putting more pressure on physicians (cf. Greenes, 2014b, p.91). CDSSs also improve the efficiency and quality of health care, and facilitates access to medical data. In addition, the authors Pawloski et al. (2019, p.331) see a cost savings potential in CDSSs.

5 Discussion

Given the results and the subsequent discussion, it is important to note that this paper was written under various restrictions. The search for literature was confined to the databases of the University of Bayreuth, PubMed, and Google Scholar. The literature was selected on the basis of the abstracts, since not every source could be checked within the specified processing time. For this reason, technical insights are reduced to a minimum. Nonetheless, the underlying literature provides a comprehensive overview and enables the research questions to be answered.

With an increase in digitalization and its possibilities, different medical data from various sources can be combined. However, difficulties may arise in the precise definition of terms. When data is transferred to a CDSS from different data sources, a clear definition of terms must be established beforehand (Tiwari et al., 2019, p.993). Moreover, there are problems with the transfer of analogue health records to the EHR. In this case, various values may be missing that the CDSS cannot include in the analysis. The authors Tiwari et al. (2019, p.994) mention that missing or incorrectly entered values falsify the results and thus the analysis of CDSSs. Nevertheless, if applied correctly, CDSSs can cause effective changes in healthcare. These changes can lead to positive developments towards patient safety and improvements in the quality of care (cf. Berner/La Lande, 2007, p.3). IT systems cannot replace a critical professional opinion, according to Zwack (2018, p.4). However, Zwack (2018, p.4) sees an opportunity to reduce the number of multiple examinations or other medically non-indication examinations. Furthermore, guidelines can be strongly integrated into the medical decision-making process (cf. Zwack, 2018, p.4). However, Miller and Geissbuhler (2007, p.101) explicitly mention that CDSSs should not be used as a substitute for all diagnostic options. The authors describe that the use of these systems only serves as a supplement. In a systematic review by Pawloski et al. (2019, pp.333) CDSS improve the measures of the caring processes. Furthermore, CDSSs that are implemented in the clinical path tend to show positive results (cf. Pawloski et al., 2019, p.334). Unfortunately, CDSSs are often not accepted by clinical experts due to a limited basis for argumentation foundations and intuitive explanatory approaches. Albeit, IT experts are able to make suggestions of the computer-based system more similar to human thinking. This leads to an increased acceptance of CDSSs by physicians (cf. Ehtesham et al., 2019, n. p.).

According to Wagholikar et al. (2013, p.750), there is limited evidence of the impact on clinical outcomes. Moreover, the potentially positive effects of CDSSs may not always be realized if systems are not used or incorrectly implemented (cf. Wagholikar, 2013, p.750). In order to critically examine the effectiveness of CDSSs in the future, cost-effectiveness should be investigated in depth in future studies (cf. Pawloski, 2019, p.331). The authors Pawloski et al. (2019, p.332) view large amounts of clinical data as a limitation during the implementation, and as well as the existence of large deficits with the availability of CDSSs. In addition, Benditz et al. (2019, p.4) outlines the idea of establishing CDSSs in waiting areas of emergency rooms and practices. With this application, patients in emergency situations could be prioritized or divided into the outpatient or inpatient sector by a first triage. Beyond that, the authors hope that CDSSs could take on a supervisory role in the field of public health (cf. Benditz et al., 2019, p.4).

6 Conclusion

The aim of this paper is to explore the influence of Decision Support Systems on the decision-making of physicians and the quality of care. In previous studies, the effectiveness of CDSSs on patient care was investigated. In particular, the quality of care and the outcome for the patients were analyzed. However, effective cost savings have not yet been sufficiently analyzed. Although several authors believe that CDSSs have a high potential for cost savings, this has not yet been fully proven because the possible role of CDSSs in public health in the future and the potential for improvement have not yet been comprehensively investigated. Positive effects on the quality of care and the management of therapeutic measures have been proven. However, the impact on clinical outcomes has not been adequately investigated. With the foundation of EHR Clinical Decision Support Systems can link patient-specific data with other information from medical databases. As mentioned above, CDSSs can directly influence a physician's treatment decision. In this context it should be emphasized that CDSSs can solely effectively influence a physician's treatment decisions effectively *if* they can access personal health data.

Moreover, many potential positive effects of CDSSs cannot be realized if the systems are not used or implemented incorrectly. Henceforth, some enhancements are necessary to increase the acceptance of CDSSs. Nevertheless, it can be concluded that a Clinical Decision Support System has enormous potential for improvement in the diagnosis and treatment process. In addition, the decision-making process for the physicians and the quality of care and outcomes for the patient are enhanced. Once physicians accept the CDSS as a support system and not as a threat that may replace physicians, the use of these systems can be optimized and outcomes can be maximized. The possibility of rapid access to current medical knowledge and the possibility of fast communication between physicians can hold the potential for simplified interdisciplinary cooperation. Even though CDSSs are primarily established in the inpatient sector, the opportunities offered by CDSSs promise a significant improvement in the entire health sector, in including the outpatient sector.

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Drug-Drug Interactions and Correct Prescriptions of Medications – Digital Solutions to Improve Drug Therapy and Patient's Safety

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Polypharmacy, the simultaneous use of several drugs by one individual, is an increasing phenomenon. Polypharmacy is especially present in the elderly population, since the elderly can suffer from several chronic diseases and co-morbidities, where they are forced to take many medicines at the same time. This may cause harm due to potential drug-drug interactions and potential medication errors arising. Digital solutions have the potential to improve drug therapy and strengthen patient safety. Furthermore, they offer concrete opportunities to reduce health care costs. This study aims to identify such digital solutions and analyzes them towards their effect on patient relevant outcomes and economic parameters. Evidence has shown that electronic prescriptions can reduce adverse drug reactions, reduce medication errors, and improve patients' adherence. Furthermore, it can decrease costs due to the reduction of adverse drug events. Clinical decision support systems showed improvements in process of care outcomes and medication errors. The findings with regards to cost-effectiveness are mixed. These systems aim to reduce drug-related harm. However, every new development bears new risk potential. Challenges arise by using such systems in clinical practice. Therefore, it is necessary to make professionals aware of the new challenges and develop these systems to ensure reliability.

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1 The Potential of Digital Solutions

Healthcare professionals and policies are always searching for better and safer ways to deliver services. Medicines are a key component of healthcare and can do a lot of good, but errors and wrong prescription can cause harm with serious consequences for patients. Polypharmacy, the simultaneously use of several drugs by one individual, is an increasing phenomenon, especially among the elderly population (Morin et al., 2018, pp.289ff). Polypharmacy may harm a patient for several reasons including inappropriate medications, medication nonadherence, and adverse drug reactions (Sharma et al., 2016, p.347).

In a 2015 study, Charlesworth et al. investigated the time trend in prescribing medicine from 1988 to 2010 in the United States (US). They focused on adults aged 65 and older and found out that prescription medication increased dramatically among this population. From 1988 to 2010, the median number of drugs used by the elderly doubled from 2 to 4, whereas the use of more than 5 medications has tripled (Charlesworth et al., 2015, pp.991ff). The year 2030 constitutes a turning point in United States' demographics. By 2030, there will be more people aged 65 and older than children in the United States (United States Census Bureau, 2018). Digitization in healthcare has the potential to reduce inefficiencies, improve access, reduce costs, and increase quality. Furthermore, it offers concrete opportunities to improve patient safety (Center for Devices and Radiology Health, 2019).

The aim of this paper is to examine digital solutions to improve drug therapy. Thereby, two research questions will be addressed. Firstly, which impact do these systems have on patient relevant parameters? Secondly, how do they affect economic parameters? Section 2 focuses on definitions and the theoretical background. The methodology is consequently presented in section 3. Following section 3, the main analysis displays the digital solutions which will be analyzed regarding their distribution in the market, their impact on patient-relevant parameters, and economic parameters. After a discussion of the main results, the paper ends with a conclusion with forecasted developments.

2 Terminology and Theoretical Background

2.1 Classification of Errors and Digital Solutions for Improvement

Since the terminology regarding errors in the use and prescribing of medication typically causes confusion, the following chapter will define the relevant key terms.

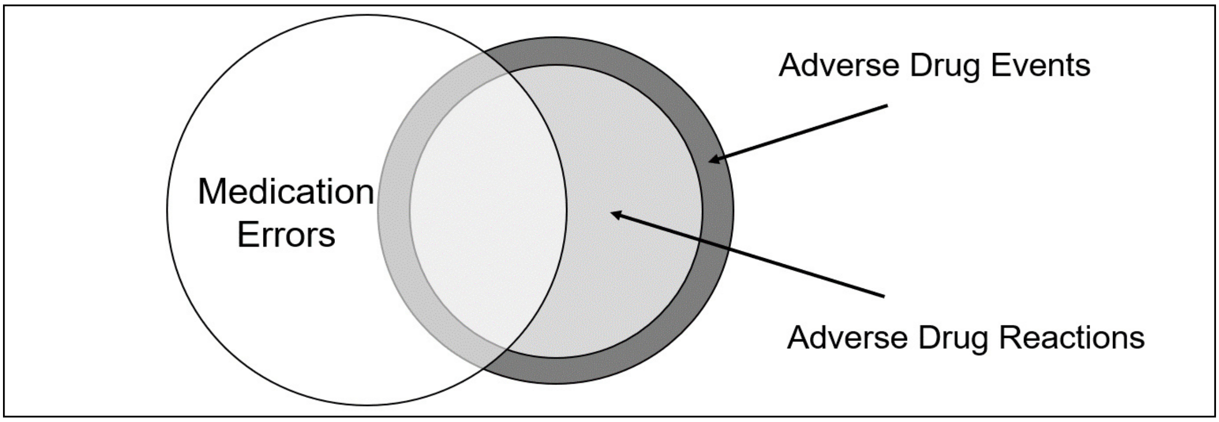
Medication errors

The FDA defines a medication error (ME) as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of a healthcare provider, patient, or consumer" (Center for Drug Evaluation and Research, 2018). Medication errors can occur during prescribing, transcribing, dispensing, administering, adhering, and monitoring medicines (National Coordination Coordinating Council for Medication Error Reporting and Prevention, 2014). In the US approximately 1.5 million people are affected and about 140,000 people die from ME each year (Marasinghe, 2015, p.1).

Adverse drug event and adverse drug reaction

Adverse drug events (ADE) and adverse drug reaction (ADR) are not interchangeable terms, and both terms must be differentiated from side effects. An ADE is “an injury resulting from medical intervention related to a drug” (Kohn, Corrigan and Donaldson, 2000, p.33). This comprises ME, ADR, overdoses and allergic reactions (Office of Disease Prevention and Health Promotion, 2019). A preventable ADE is an injury which is associated to a medication error. A potential ADE is a medication error which potentially may cause harm, but harm does not occur (Kane-Gill et al., 2016, p.206). About 2 million people are affected by ADE every year in inpatient settings, and hospital stays are prolonged by 1.7 to 4.6 days. In outpatient settings ADE lead to 3.5 million physician office visits and account for about 1 million emergency department visits (Office of Disease Prevention and Health Promotion, 2019). An ADR is causally linked to the drug and causes harm during normal use and doses of the drug. An ADR to a drug is, defined by the World Health Organization, a “response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function” (World Health Organization, 2002). Approximately 95% of ADR are predictable and an estimated proportion of 28% is preventable (Marasinghe, 2015, p.1). The connection between ME, ADR, and ADE is illustrated by Figure 1.

Figure 1: Connection between Medication errors, ADE, and ADR



Source: Own presentation based on Nebeker, Barach and Samone 2004, p.798.

Drug interaction

Anytime a person takes more than one medicine simultaneously, there is a risk of drug interaction (DI). The term can relate to drug-food/beverage, drug-disease, and drug-drug interaction. In this paper, DI will always refer to a drug-drug interaction. A DI arises when a drug changes the effect and/or toxicity by prior or concomitant use of another drug. The effect can be positive towards a higher efficacy, but it may also result in negative outcomes like decreased efficacy, toxicity, or idiosyncrasy. No matter which direction, the effects are unpredictable and undesirable in pharmacotherapy (Alvim et al., 2015, p.354). A pharmacodynamic interaction occurs when two drugs lead to additive or antagonistic pharmacological effects towards efficacy or adverse events. If one drug affects absorption, distribution, metabolism, or excretion of another drug, it is called a pharmacokinetic interaction (Tannenbaum and Sheehan, 2014, p.534). Among hospitalized patients, about 65% suffer from one or more DI, and 41% to 70% are discharged with drugs which potentially may interact (Helmons et al., 2015, p.764).

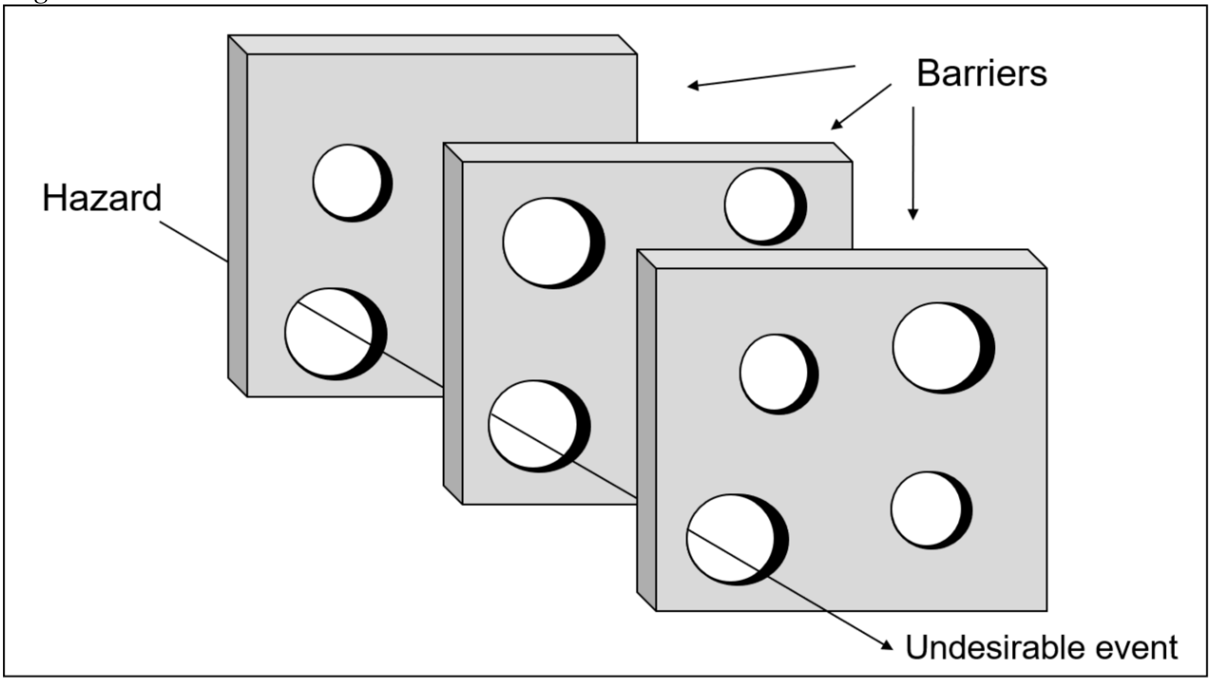
Digital Solutions

To understand how digital solutions can reduce errors, it is important to understand what digital solutions are. Electronic health covers a wide range of several applications which combine health, living, and society with digital technologies. Information and communication technologies are used to reduce inefficiencies, improve access, increase quality, reduce costs, and personalize medicine for patients (Centers for Devices and Radiological Health, 2019). The broad scope of digital health solutions includes software and hardware technology, standalone, or integrated. It ranges from "telemedicine, electronic health records, clinical decision support systems, mobile health, computerized physician order entry, electronic prescribing systems and web-based health services" (Fadahunsi et al., 2019, p.1).

2.2 Reason's Model of Accident Causation

When analyzing medical errors and patient safety incidents, Jason Reason's Swiss Cheese Model has become the leading paradigm that has been highly adopted by patient safety professionals. The causation of accidents by the metaphor of a 'Swiss Cheese' is explained below (Perneger, 2005, p. 71).

Figure 2: The Swiss Cheese Model



Source: Own presentation based on Perneger 2005, p. 72.

In a complex system, adverse events are prevented by several barriers. In the model above, the slices of cheese represent the separate barriers. Each barrier has several holes like the ones in Swiss cheese. In the case of barrier failure, which can be of human or technical nature or depending on procedures and administrative controls, a hazard can result in an undesirable event (Reason, 2000, p.769). The existence of a hole in a slice does not automatically cause damage. It is the succession of various unfavorable circumstances. When by chance, all holes align, the hazard can reach the patient and can cause harm (Perneger, 2005, p.72). There are two reasons for holes aligning: active failure and latent conditions. Active failure refers to unsafe acts by people acting on the interface between individuals and the system. They have a direct impact towards the defense of a system. A latent failure comes into force by wrong decisions of higher management. It may be that their negative consequences are not obvious immediately, but they can create long-lasting weaknesses in the defense of a system as well (Reason, 2000, p.769).

3 Digital Solutions

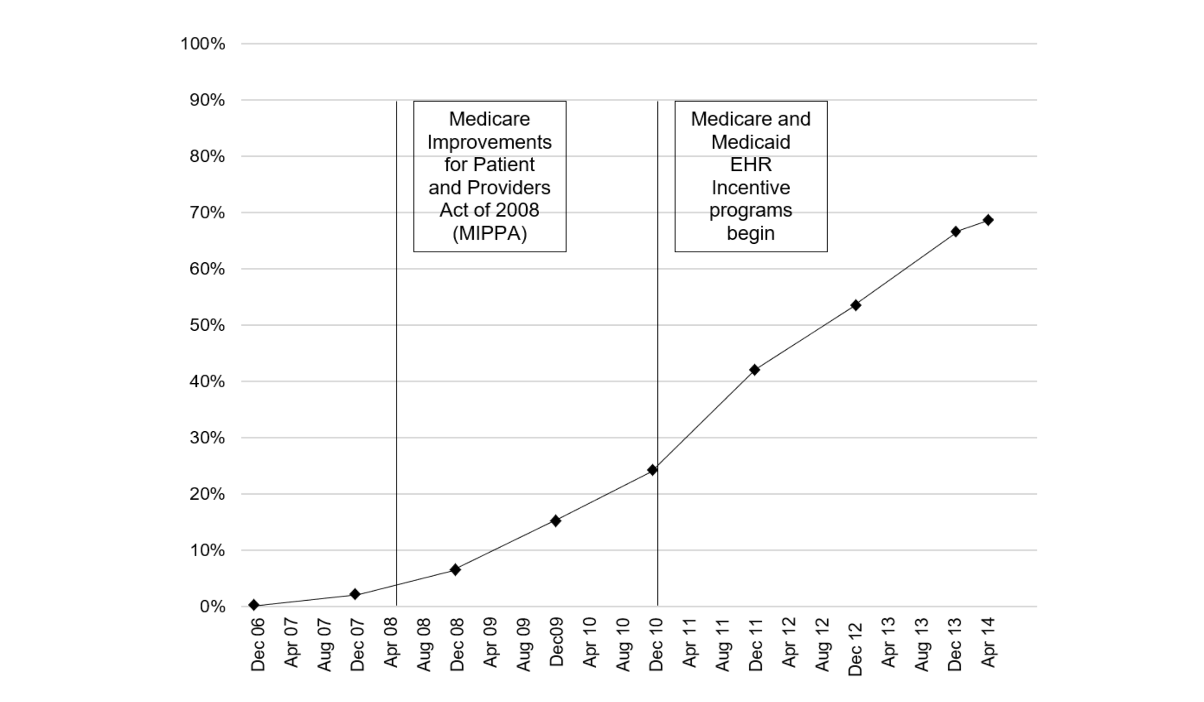
3.1 E-Prescribing

Prescribing describes the process where a medical practitioner authorizes the use of medication or treatment. A prescription provides instructions in which way, (how often, and in what doses) the treatment should be used (The Health Foundation, 2012, p.4). The number of prescriptions dispensed in the US increased from 3.95 billion in 2009 to 4.45 billion in 2016 (Statista, 2019). The hand-written prescription of medicines and remedies has been the traditional way for physicians to order a medication therapy and for pharmacists in distributing medicines (Samadbeik et al., 2017, p.3). ME may occur at any stage in the drug use process, but prescription errors are the most common type in the US (Donyai et al., 2008, p.231). E-Prescribing, also known as electronic prescribing, computerized physician order entry (CPOE), and ERx is the computer-based electronic process of a medical prescription. It can be used as a stand-alone solution, but it can also be integrated in an electronic health record. With a rising number of prescriptions in the US and the disadvantages of the hand-written process, ERx has the potential to improve drug therapy (Engelbert et al., 2014, p.202).

3.1.1 Distribution

The Medicare Modernization Act enacted in 2003 included provisions to introduce electronic prescription within the US and was a key towards the movement towards electronic prescriptions. Although the use of electronic prescribing was optional to physicians and pharmacists, Medicare Part D plans were required to support the introduction. In 2005, the Centers for Medicare and Medicaid Services (CMS) first published standards for e-prescription and then launched the so called 'eRx Incentive Program' in 2009 (Centers for Medicare & Medicaid Services, 2014b). This program was designed to encourage electronic prescribing by eligible professionals, including a combination of incentive payments and incentive adjustments. The year 2013 was the last year to earn eRx incentive payments. The last year to incur incentive adjustments was 2014. After the program ended, electronic prescribing continued with meaningful use (Centers for Medicare & Medicaid Services, 2018). In October 2015, CMS released the meaningful use stage 3 final rule. According to this rule, from 2015 to 2017, more than 60 percent of all permissible prescriptions had to be permitted electronically (Costello and Mash, 2015).

Figure 3: Physicians using E-Prescribing



Source: Own presentation based on The Office of the National Coordinator for Health Information Technology, 2014.

Figure 3 shows the trend of physicians using e-prescribing from 2006 to 2014; it illustrates the growth of eRx used by physicians. There was an increase after the Medicare Improvements for Patient and Providers Act (MIPPA) was passed, also known as eRx Incentive. The Medicare and Medicaid EHR Incentive Program – known as Meaningful Use – was another important policy to promote the use of eRx. As shown by the figure, 70% of physicians used the electronic form of prescription in April 2014 (Department for Health and Human Services, 2014). Surescripts, an information technology company that markets an e-prescription solution, published a report and found that 77% of all prescriptions in 2017 were delivered electronically. In total, there have been 1.74 billion e-prescriptons in 2017 in the US. This represents a 26% increase compared to the previous year (Surescrips, 2017, pp.4f).

3.1.2 Impact of E-Prescription on Patient-Relevant Outcomes

In a Delphi study, the main stakeholders involved in the e-prescribing process were asked to give a rank-order towards its positive and negative aspects. Patients named fewer ME and fewer adverse drug events, improved patient safety, convenience, fewer errors in prescription, increased efficiency, and lower cost options as the main benefits. For clinicians, availability of patient medication history was the most considerable effect, followed by time savings, fewer ME, and fewer prescription errors (DeMuro et al., 2017, p.72). Patients' safety can be improved due to better prescription legibility, decreased time to prescribe, and dispense medication (Porterfield, Engelbert and Coustasse, 2014, p.1). In a systematic review by Nuckols et al., the effectiveness of CPOE at reducing preventable ADE was assessed in a hospital-related setting. According to preventable drug events, the use of CPOE showed half as many ADE compared to paper-based prescriptions. The investigation towards ME demonstrated similar results, as medication errors were half as common in CPOE (Nuckols et al., 2014, p.62). ERx can further increase adherence; patients are adherent towards drugs when they take their medication in a timely manner and at doses prescribed by a health care provider (Iuga and McGuire, 2014, p.35). Adamson, assistant professor in the Department of Dermatology at the University of North Carolina in Chapel Hill, investigated if there is a link between patients' adherence and the method of prescribing. The investigation of nearly 2,500 probands showed that people are more likely to fill and pick up medication if they are prescribed electronically. The reduction of primary nonadherence was 47% if the medication was prescribed electronically (Adamson, Suarez and Gorman, 2017, pp.49ff). One declaration approach mentioned by the authors for this phenomenon are costs. As patients must pay per prescription, a higher number of prescriptions leads to a lower compliance. The need for multiple medications can result in a financial burden, which leads to lower medication compliance, as patients take not all the medication prescribed to reduce their costs (Adamson, Suarez and Gorman, 2017, p. 53f). Most of the studies focused on hospitals, however, most of the total prescriptions occur in the outpatient setting where less control towards patient safety is given. Hence, more prescription errors are expected to arise in the ambulatory setting. Eslami et al., focused their systematic review on the effect of outpatient CPOD, which showed mixed findings. Four studies assessed the effect of CPOE on safety but could not determine a significant correlation towards ADE. Only one study found a significant decrease in ME (Eslami, Abu-Hanna and Keizer, 2007, p.401).

3.1.3 Impact of E-Prescription on Economic Outcomes

ME may increase costs due to hospitalization, longer hospital stays, or additional services and investigations. The annual costs associated with ADR in the US are estimated to be 30.1 billion dollars (Sultana, Cutroneo and Trifiró, 2013, pp.76f). Most savings occur to a reduction of ADE as less visits to primary care physicians and emergency departments are necessary. Sultana et al. estimated that a hospitalization caused by ADE costs about $9,000, whereas a visit to an emergency room costs $427 and utilization of a doctor's service $111 (Sultana, Cutroneo and Trifiró, 2013, p.76). In a systematic review, Marques et al. evaluated the costs of ADR. Non hospitalized patients which evolved an ADR leading to a hospitalization generated total direct health care costs amounting from €702.21 up to €7,318.14 per patient, with a peak of €40,273.08 in the pediatric population. Hospitalized patients with an ADE during their hospital stay caused total direct health care costs of €943.40 to €7,192.36 per patient (Batel Marques et al., 2016, pp.421f).

3.2 Clinical Decision Support Systems

A Clinical Decision Support System (CDSS) is defined as a health information technology system to enhance health-related decisions. It assists physicians by classifying a patient's health status, making a diagnosis, or choosing an adequate therapy and medication. Clinical cases are linked to health observations with clinical knowledge to support clinicians by making decisions (Jia et al., 2016, p.2). The support can include information about general clinical knowledge, instructions, processed patient data, or a mix of all. It further provides user-specific information which can be intelligently filtered (Middleton, Sittig and Wright, 2016, p.103). Patient characteristics are matched with a computerized knowledge database, and then a software algorithm generates patient-specific assessments and recommendations (Moon and Galea, 2016, p.2). It can exist as a stand-alone system or can be integrated in an e-prescription system. CDSS must fulfill five criteria: they must provide the right information, to the right people, through the right channels, in the right intervention formats, at the right point in the workflow (Centers for Medicare & Medicaid Services, 2014, p.2).

3.2.1 Distribution

The enactment of the Health Information Technology for Economic and Clinical Health Act (HITECH) Act was a milestone towards the adoption of health information technology (HIT) in the US. Under the HITECH Act, meaningful use of electronic health records (EHR) was set as one of the overall national goals in the US. In order to ensure fast adoption, CMS granted eligible professionals and hospitals an incentive payment. If the hospitals could prove that they are engaged in adopting, implementing or upgrading EHRs, they were awarded the financial incentive payment (Centers for Disease Control and Prevention, 2017). Stage 2 of meaningful use committed eligible providers to implement five clinical decision support interventions. These interventions needed to relate to at least four clinical quality measures, supporting a relevant point of patient care. They further had to integrate some drug-drug and drug- allergy checks (Centers for Medicare & Medicaid Services, 2014). The acceptance of CDS interventions among professionals has grown. In 2013, almost 73% of eligible providers had implemented enough CDS interventions to meet the meaningful use criteria (HealthITSecurity, 2017). Towards a survey from 2015, 94.1% of hospitals in the US adopted an EHR. Further, this report stated that 80.9% had a CPOE system with clinical decision support (Kane-Gill et al., 2016, p.205).

3.2.2 Impact of CDSS on Patient Relevant Outcomes

Computerized alerts, reminders for professionals and patients, clinical guidelines, or condition-specific order sets may improve drug therapy. Furthermore, patient summaries, documentation templates, diagnostic support, or context-relevant information can be part of CDSS (Centers for Medicare & Medicaid Services, 2014, p.2). Jia et al. investigated the effects of CDSS on medication safety. The examination included the effect on endpoint outcomes (bleeding, ADE, hospitalization) and process of care outcomes which include medication error (dose and prescription), adherence, and intermediate outcomes. The authors found that ME and process of care outcomes were mostly improved by CDSS using alerts or medication reminders. In addition, the study emphasized that prescribing is improved by CDSS due to a reduction in inappropriate medication and monitoring long-term situations and medicines. The measurement of patients' outcomes included mixed findings. They determined that outcomes such as deaths, hospitalization, or bleeding complications that are not positive correlated with CDSS are more influenced by other factors. Their overall evaluation shows that CDSS has a positive influence on reducing ME, but the evidence towards patient outcomes is not sufficient (Jia et al., 2016, pp.4ff). Kane-Gill et al. published a review about CDSS for preventing drug related events. One study included in their review investigated the detection of ME by patients with acute kidney injury through CDSS and found that inappropriate drug doses can be reduced by CDS alerts in 17 out of 19 studies. Another study showed that in an eighteen month period, 631 of 731 recognized ADE were detected according to the usage of automated triggers. If there was potential for an ADE, medications would be stopped, they would be replaced by another drug, or an antidote would be prescribed (Kane-Gill et al., 2016, pp.206ff). Ali et al. evaluated the effectiveness of EMR/EHR-powered CDSS towards the quality of treatment of type II diabetes by analyzing eight randomized controlled trials. The authors used the glycated hemoglobin (HbA1b), low density lipid cholesterol (LDL-C), and blood pressure as specific indicators to measure process-related and clinical outcomes in diabetes. HbA1b was significantly improved by CDSS. Firstly, an improvement in the number of tests per patient could be proved; secondly, the documentation improved which likely positively affects the process of care. Furthermore, they found significant declines in the HbA1b levels. Due to LDL-C, there was no significant improvement found. Two studies mentioned none to slight effects from electronic reminders affecting the annual LDL-C test, but one study showed a relevant increase. Towards the clinical outcome, there was no significant improvement in the LDL-C level found. The number of blood pressure measurements completed was slightly improved in one study and showed a significant increasement in another study. Furthermore, the lack of documentation was corrected in 7.9% of the intervention group. All studies found a slight to statistically significant improvement in the systolic and diastolic blood pressure. Altogether, the study from Ali et al. found significant improvements in the quality of care indicators and weak to modest results towards the clinical outcomes of diabetes II due to CDSS (Ali et al., 2016, pp.92ff).

3.2.3 Impact of CDSS on Economic Parameters

Jacob et al. investigated the costs and economic benefits of CDSS in the prevention of cardiovascular disease. The annual costs of cardiovascular disease were estimated by the American Heart Association to be $193.1 billion and approximately $123 billion in productivity losses. A major part of these costs could be prevented due to CDSS by reducing the specific risk factors. The review integrated a health system and a societal perspective. A registry-based CDSS generates implementation costs per practice of $9,511 in a small, $20,649 in a medium, and $75,964 in a large size practice. EHR-based annual implementation costs per practice were estimated to be $6,056 in a small-sized practice and $35,201 in a medium-sized practice. They further found out that healthcare costs (e.g. inpatient and outpatient costs, costs for labs, emergency room, or drugs) dropped by -$35 per patient and year due to eight studies which included at least three cost indicators. At last, they assessed the cost-benefit and cost-effectiveness of CDSS. The economic benefit compared to the intervention costs were 0.42:1 (12 months) and 2.1:1 (24 months) in one study. Two other studies found rates of 0.55:1 in EHR-based and 2.3:1 in registry based. According to cost per QALY saved, two studies estimated CDSS to be cost effective at savings from $49,000 and $16,500, and one study concluded these interventions as not cost-effective at $143,000 (Jacob et al., 2017, pp.2ff).

4 Discussion

This essay provides an overview of electronic prescription and clinical decision support systems as digital solutions to improve drug therapy. There are mixed findings about their impact on patient relevant outcomes and the effects on economic parameters. It was demonstrated that e-prescribing in particular can reduce medication errors and adverse drug events. Patient adherence can be improved, and cost savings can be achieved. If CDSS uses reminder or alerts, this could improve process of care outcomes. The impact on patient outcomes showed mixed results; it is possible that some improvements in outcomes like hospital length of stay, bleeding complications, or death are not only due to better management in drug therapy, but they are also correlated with other factors (Jia et al., 2016, p.13). Lavan et al. named several other factors when talking about ME; individual factors such as the prescriber's knowledge about drugs and multimorbidity or factors directly related to the patient such as the patients' sincerity towards their drug ingestion affect the safety in drug therapy as well. Further, work environment like enough time for prescribing medicines, and special task-related factors like clear explanations of their medications are important factors which may cause errors (Lavan, Gallagher and O'Mahony, 2016, pp.858ff).

Every new development bears new risk potential. A research article from David Lyell et al. investigated automation bias which is defined as "the tendency to use automated cues (such as CDS alerts) as a heuristic replacement for vigilant information seeking and processing" (Lyell et al., 2017, p.1) in e-prescription. The authors simulated a prescribing system where medical students prescribed medicines for different scenarios. The setting of the study was varied due to the quality of CDS (correct, incorrect, no CDS) and the complexity (low (1), low + interruption (2), high (3)) between conditions. The aim was to measure the failure to detect prescribing errors (omission) and the acceptance of false positive alerts (commission). Their analysis showed that compared to no CDS, correct CDS reduced omission errors by 38.3% (1), 46.6% (2) and 39.2% (3). On the other side, omission errors increased due to incorrect CDS by 33.3% (1), 24.5% (2) and 26.7% (3). To summarize, the authors found out that prescribing errors decreased towards correct CDS, prescribing errors increased by incorrect CDS, and the complexity and interruption of prescribing had no effect on automation bias (Lyell et al., 2017, pp.5ff). 5ff). This study gives a glimpse into the upcoming challenges with using CDSS. Such systems are not meant to replace professionals' decision; their intention is to support the process of decision making. It is still necessary and important to be vigilant because computer-based systems may also fail. CDSS has great potential, but physicians must be mindful of its risks as well. It is still the clinician who decides whether to prescribe a medication or not. CDSS should be seen as an independent control, not as a replacement of a physician's effort to control ME (Lyell et al., 2017, p.8).

Remaining challenges and barriers

A Delphi study asked prescribers about the negative aspects of electronic prescription. Most of the prescribers cited implementation costs and poor fit with the workflow, and training and software licensing fees the main challenges of eRx (DeMuro et al., 2017, p.73). Even though the e-prescription system offers a lot of benefits, implementing and integrating it into the workflow is still challenging. According to Porterfield et al., the implementation costs of an eRx system total up to $42,332 with additive costs of $17,725 per year (Porterfield, Engelbert and Coustasse, 2014, p.4). Furthermore, there are inconsistencies within this system. Some eRx-technologies are stand alone, whereas others are integrated in electronic health records (EHR). However, there is still heterogeneity in existing systems (Hahn and Lovett, 2014, p.21).

This essay is subjected to some limitations. The first limitation arises from the design of this study. A literature review has the disadvantage of time lags. Publications that were published in 2016 for example, refer to data from 2012 and older. This may lead to a distortion of the study results, as data could have changed due to the fast pace of healthcare. Furthermore, only literature in English or German were used in this work. Finally, the quality of included studies was not assessed. Studies were selected by the previous named inclusion criteria. If studies met these criteria, they were not further evaluated by using criteria like AMSTAR or PRISMA.

5 Conclusion

The analysis shows that digital solution can significantly improve patient relevant outcomes and reduce health care costs. Politics has recognized the various benefits of these technologies and has made a great effort to put digital health solutions into practice. Electronic prescription seems to be distributed among the US, and CDSS is integrated within various workflows. In order to realize its full potential, these systems must be developed to provide increased reliability. A better understanding is needed to make training professionals aware of the new challenges arising. The new challenge arising is “to maximize the benefits of CDS while minimizing the risk of over-reliance” (Lyell et al., 2017, p.37). Furthermore, there is still more evidence needed for the effectiveness of these systems in different settings. It is problematic to transfer study results, especially when generalizing them. Altogether, the potential of digital solutions to improve drug therapy is proven in some areas, but more research is necessary.

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Part 5: Digital Transformation – Effects and Outcomes

Assessing the Outcomes of the HITECH Act – A Service-Dominant Logic Perspective

Florian Kaiser and Dominik Seitz

The Health Information Technology for Economic and Clinical Health (HITECH) Act has set substantial financial incentives to foster the implementation of electronic health records (EHRs) in the U.S. healthcare system. These incentives contributed to an increase to 86% in the use of EHRs among office-based physicians and 95% among hospitals in 2017. In order to assess whether the broad adoption of EHRs had a valuable impact on medical and economic outcomes, this paper will evaluate the findings from the SDL perspective. Results show that widespread use of EHRs does not necessarily lead to improved medical and economic outcomes. Empirical evidence suggests that effects range from negative to positive and significantly differ between medical service providers. Reasons for the variety of the findings may result in a gap between the value propositions of EHR manufacturers (higher quality, lower costs) and the actual increase in value after implementation. Strategies to improve the value achieved may include strategic planning for the implementation of EHRs and sufficient training of staff working with EHRs to digitalize and not purely digitize existing processes.

Contents

1 Digitization or Digitalization in the U.S. Healthcare System

Over the past decade, the U.S. healthcare system faced a comprehensive nationwide initiative to foster diffusion and use of electronic health records (EHRs). Under the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009, medical service providers that adopted EHRs and were able to prove that they met federally defined meaningful usage criteria were eligible to receive financial incentives. The HITECH Act was motivated by a broad consensus in research and policy that the implementation and use of EHRs would lead to significant improvements in hospital performance (Blumenthal, 2010). Objectives to meet when introducing EHRs included instant access to patient records, reminders to avoid medication errors, decision support for clinicians, and enhanced sharing of information across providers. According to Adler-Milstein et. al., EHRs should ultimately lead to better and more efficient care (Adler-Milstein, Scott and Jha, 2014; Atasoy, Greenwood and McCullough, 2019). However, the aforementioned effects and various facets of EHRs can only become reality when accompanied by a substantial change in the provision of healthcare. In other words, the implementation of EHRs should not focus on reproducing the same procedures and processes as before but just in digital form (digitization), but rather adapt existing processes to bolster and relieve the day-to-day work of clinicians by using the full potential of digital technologies (digitalization) (Steinhubl and Topol, 2015).

The aim of this paper is to analyze whether the implementation of EHRs has initiated digitalization in health care and whether only digitization has taken place without profound adaptation of the technological possibilities. For this purpose, the paper will investigate the empirical evidence both for medical and economic effects that may be associated with the introduction of EHRs through the HITECH Act from a service-dominant logic (SDL) point of view.

The structure of the paper is as follows: Section 2 defines the core ideas of SDL and proposes an adaptation of the concept to healthcare settings. Section 3 assesses the effects of the implementation of EHRs in the U.S. healthcare system based on existing empirical evidence. Section 4 discusses the results, suggests possible solutions for future implementations of EHRs, and responds to methodological limitations. Section 5 ends with a conclusion and summary of the paper.

2 Health Care from a Service Dominant Logic Point of View

2.1 The Concept of Service Dominant Logic

Service-dominant logic can be understood as a lens or a metatheoretical framework, that offers a new perspective, where service is the fundamental basis of economic exchange (Vargo and Lusch, 2008). Elements of such a service-based understanding can be traced back to Bastiat in 1848. However, Vargo und Lusch were the first to publish this idea as a comprehensive framework in 2004 in the Journal of Marketing (Vargo and Lusch, 2004). Since then, the concept has been continuously refined and has also been applied to other branches (Lusch and Vargo, 2006, 2018; Vargo and Lusch, 2008, 2016, 2017). In particular, since the article by McColl-Kennedy et al. on value cocreation practice styles from 2012, the concept has also been applied in the health care sector and is

becoming progressively more relevant (Joiner and Lusch, 2016; McColl-Kennedy *et al.*, 2012).
SDL can be distinguished from the predominantly applied goods-dominant logic (GDL) in management theory. In order to clarify this distinction, Vargo and Lusch have established an SDL specific lexicon. Besides almost using the same terms in SDL and GDL, the meanings are nuanced (Lusch and Vargo, 2018). Accordingly, service is referred to as “the process of using one’s resources for the benefit of another actor” (Lusch and Vargo, 2018, p. 4). “When goods are involved they are service distribution mechanisms or service appliances” (Joiner and Lusch, 2016, p. 26). Besides a pure linguistic distinction, this theory is also accompanied by a modified understanding of different terms. This shift in the mindset is represented by the five Axioms of SDL (Vargo and Lusch, 2017):

- Axiom 1: Service is the fundamental basis of exchange
- Axiom 2: Value is co-created by multiple actors, always including the beneficiary
- Axiom 3: All social and economic actors are resource integrators
- Axiom 4: Value is always uniquely and phenomenologically determined by the beneficiary
- Axiom 5: Value co-creation is coordinated through actor-generated institutions and institutional arrangements

Important aspects of the five axioms consider the co-creation of value. McColl-Kennedy and Cheung analyze and comprise existing definitions and define value co-creation as “the integration of resources from a range of sources by multiple actors, always involving the customer, to realize benefit in use for the beneficiaries involved in a given context” (McColl-Kennedy and Cheung, 2018, p. 70). The creation and assessment of value will be elaborated on within the health care context.

2.2 Service-Dominant Logic in Healthcare

Through the integration of resources such as knowledge and skills, health care providers and consumers “cocreate value using a definition of value, which far transcends that reflected by concepts, including patient engagement and patient activation, and measurements such as life expectancy, mortality in infancy or from treatable conditions, vaccination rates, and more” (Joiner and Lusch, 2016, p. 26). Thus, this definition of value differs significantly from Porters understanding of value in healthcare[1] (Porter, 2010). Given the definition of Joiner and Lusch, solely delivering medical services by physicians does not equal the value of a service. Instead Joiner and Lusch argue that it is valuable to engage the patient throughout the process. An important first step is to determine what value for the individual consumer looks like. As the second step, health care providers should present alternative decisions to the consumer, which could be

[1] Porter defines value as *"...health outcomes achieved per dollar spent "*. The outcomes, the numerator of the value equation, are condition-dependent and multidimensional by nature. For each medical condition, not a single result captures the results of care. Patient needs therefore determine the rate of success. The complexity of medicine means that competing outcomes (e.g. short-term safety versus long-term functionality) often have to be weighed against each other. The results for each

formulated as value propositions (Joiner and Lusch, 2016). Examples for value from a service-dominant logic view can be based on enabling positive or relieving negative experiences or activities. These may include not having to drive to the physician's office or being able to perform a certain type of sport (Joiner and Lusch, 2016).
The co-creation of value between consumers and health care providers can be facilitated by digital solutions like online health information or electronic health records. However, Joiner and Lusch explicitly mention that "information generated and/or transmitted is not intrinsically value producing, either for the consumer or the provider" (Joiner and Lusch, 2016, p. 30). Following this logic, the extent to which EHR have contributed to positive effects in the U. S. health care system will be examined further.
One further important aspect of a service-dominant logic view of the health care system is the service ecosystem that is an "relatively self-contained, self-adjusting system of resource-integrating actors that are connected by shared institutional logics and mutual value creation through service exchange" (Lusch and Vargo, 2014, p. 24). Hence, multiple actors like family, friends, physicians, caregivers, and other informal actors are involved in the process of value cocreation.
In order to acknowledge SDL as a metatheoretical framework, institutions and institutional arrangements will serve as midrange theory. North defines institutions as "humanly devised constraints that shape human interaction" (North, 1990, p. 3). Thus, institutions coordinate behaviors in service ecosystems and thus reduce the uncertainty of human interaction (Vargo and Lusch, 2016).

Figure 1: Regulative, normative, and cognitive pillars of institutions

	Regulative	**Normative**	**Cognitive**
Indicators	Rules, laws, contracts, conventions	Norms, values, expectations, standards	Beliefs, opinions, ideas, categories, typifications, schema
Basis of compliance	Expedience	Social obligation	Taken-for-grantedness, shared understanding
Basis of order	Regulative orders	Binding expectations	Constitutive schema
Basis of legitimacy	Legally sanctioned	Morally governed	Comprehensible, recognizable, culturally supported

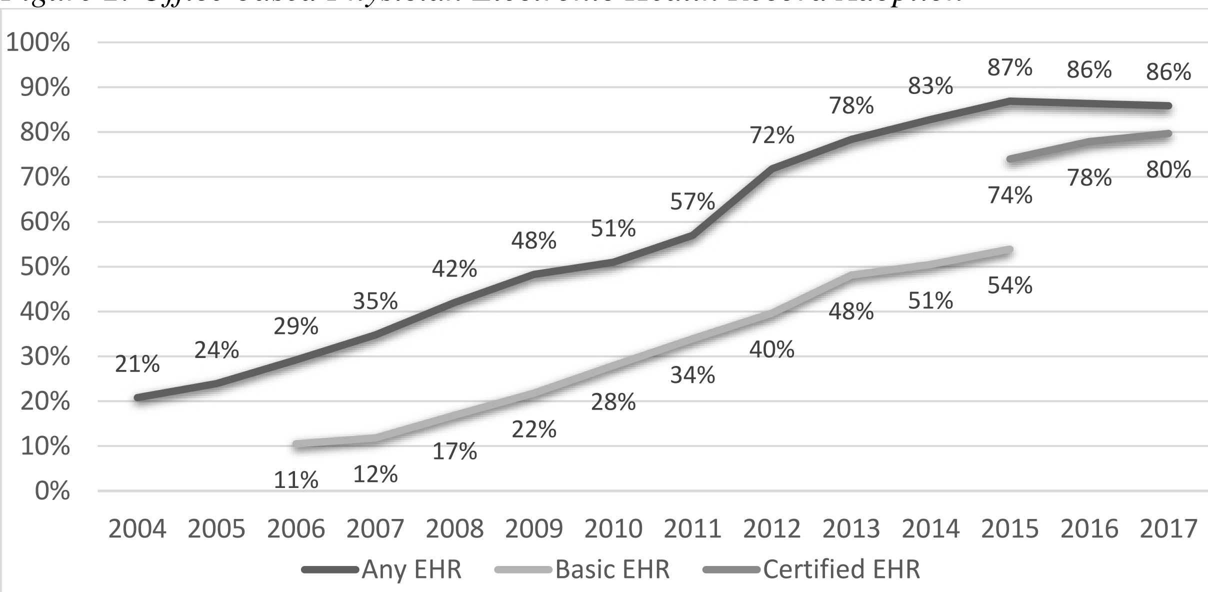
Source: Own presentation based on Scott, 2014, p. 60.

Following Scott, institutions comprise regulative, normative and cultural-cognitive pillars. The regulative pillar consists of formal rules and laws such as the HITECH Act. To avoid the negative consequences associated with regulative institutions, behavior of actors is mainly driven by self-interest. The normative pillar consists of norms and values. Based on internal commitment and social expectations, actors typically adhere to normative elements of institutions. One example of this in the context of healthcare is the expectations of patients to gain online access to their data. The cognitive pillar consists of beliefs that are shaped by the actors' perception of their environment (Scott, 2014). In an economic sense, institutions impact the effectiveness and the efficiency of resource integration because the predictable behavior reduces the costs of coordination and optimizes resource integration and value cocreation (Kleinaltenkamp, 2018). However, the different institutions may not be homogenous or aligned. The different manifestations of the three pillars individually determine the value of a resource for the respective actor (Kleinaltenkamp, 2018). The following section will describe the fundamentals of digital health care in the United States to subsequently assess the effects of the HITECH Act.

2.3 Digital Health Care in the U.S.

Electronic Health Records have the potential to improve the decision-making of health care professionals to improve patient outcomes and overcome the fragmented structure of health care systems (Blumenthal and Tavenner, 2010; Joiner and Lusch, 2016). According to the ONC, EHRs are broadly defined as "a digital version of a patient`s paper chart" (The Office of the National Coordinator for Health Information Technology, 2019b, p. 1). In order to harness the potential of EHRs, the HITECH Act was passed in 2009, which significantly promoted the adoption rate in the US. The federal government set up incentive payments consisting of $27 billion over a period of ten years (Blumenthal and Tavenner, 2010). This led to an increase in the use of EHRs by office-based physicians from 48% in 2009 to 86% in 2017 as shown in Figure 2.

Figure 2: Office-based Physician Electronic Health Record Adoption



Source: Own presentation based on The Office of the National Coordinator for Health Information Technology, 2019a.

The adoption of certified health IT in hospitals is as high as 95% in 2017, ranging from 99% in large hospitals to 93% in small rural ones (The Office of the National Coordinator for Health Information Technology, 2018). However, the aim of the HITECH Act was not only broad adoption, but also the *meaningful use* of EHRs. To achieve meaningful use, a set of objectives was developed by the Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services (DHHS). (Blumenthal and Tavenner, 2010). These objectives were framed into three stages with increasing requirements. In April 2018, the concept of 'meaningful use' within the EHR Incentive Programs was replaced by the Promoting Interoperability Programs (PI). With this change, the requirements shifted towards interoperability and improved patient access to health information (Centers for Medicare & Medicaid Services, 2019).

From a service-dominant logic point of view electronic health records (EHR) are seen as goods that provide a service in order to get a job done (Joiner and Lusch, 2016). At a superordinate level, this job can be described as accelerating value-based health care at a more concrete level because there is a free flow of information between all relevant actors (The Office of the National Coordinator for Health Information Technology and The United States Department of Health and Human Services, 2019). Joiner and Lusch mention the importance of the individualized adaption of digital products to achieve the highest possible value. From an SDL perspective, companies can only offer value promises with EHRs. The value in day-today practice is individually defined by the customer and his or her specific use (integration of resources) of EHRs (Axiom 4). Through the broad adoption of EHRs, the potential to increase value is available in a vast majority of facilities. The extent to which this potential also contributes to value improvements in everyday care is discussed in the following chapter.

3 Effects of the HITECH Act

3.1 Economic Consequences

In order to encourage eligible hospitals to implement and use EHRs, the federal government provides financial incentives to help overcome part of the high implementation costs. Multiple studies have shown that this financial support plays an important role for EHR adoption; hospitals had on average a two to four-time higher annual adoption rate since the incentive programs' introduction in 2011 , compared to ineligible organizations (Adler-Milstein and Jha, 2017; Kruse *et al.*, 2016). Although 2018 hospitals received nearly $30 billion for the adoption and meaningful-use of EHRs, literature assumes that the program is efficient on the system level as the incentives cover only about 10 percent of the total adoption costs while moving a large share of nonadopters (Adler-Milstein, Scott and Jha, 2014; Atasoy, Greenwood and McCullough, 2019). However, more than half of the hospitals that adopted an EHR only use basic functions, such as compiling and maintaining medical records in electronic form. This leads to the question of how homogenously aligned regulative, normative, and cognitive institutions can be. It is important to explore if medical service providers implemented EHRs primarily for the financial incentives and avoid financial penalties and if the adoption of EHRs has led to improved performance of healthcare facilities (Adler-Milstein *et al.*, 2017; Appari, Eric Johnson and Anthony, 2013; Atasoy, Greenwood and McCullough, 2019).
Regarding the effects of EHRs on the efficiency and financial performance of hospitals, the empirical evidence draws a more ambiguous picture. A 2017 study by Adler-Milstein et al. of 191 US hospital cardiac units finds that EHRs can lead to lower payments (as proxy for resource-intensity) and length-of-stays. However, the extent of these effects depends greatly on how well and how deep the hospital management is able to integrate EHRs into clinical practice. Well-managed hospitals, for example, use EHR data to measure and monitor their performance to drive improvements, enable their employees to embrace the EHR's capabilities, and optimize patient communication. Organizations, on the other hand, that only adopted EHRs due to regulatory pressure and with no precise strategy, achieved hardly any efficiency improvements according to the study (Adler-Milstein *et al.*, 2017; Adler-Milstein, Scott and Jha, 2014). These results are consistent with the hypothesis mentioned in chapter 2.2, that EHRs can only offer

value promises, but the individual customer assesses the actual achieved value. In a more comprehensive study, Adler-Milstein and colleagues analyzed secondary data of around 2,500 U.S. hospitals. Like in the aforementioned study, it becomes apparent that one of the most important factors to achieve a positive economic effect through EHRs is the intensity of integration. Higher levels of EHR integration were associated with better process quality, expressed through process adherence measures. Likewise, Devaraj and colleagues find that efficiency improvements mostly result from improved patient flows. Despite this, the authors were not able to find a significant relationship between the level of EHR integration and efficiency, measured as total expenditures per adjusted patient day. They attribute this to two opposing causes: efficiency losses due to high expenditures on EHR adoption and efficiency gains due to sinking operational costs resulting from higher process efficiency. In the long term, however, the authors except that efficiency improvements through EHRs will occur (Adler-Milstein, Everson and Lee, 2015; Devaraj, Ow and Kohli, 2013).
Finally, there is another important question at both the system and hospital level: to what extent can hospitals use their EHRs to increase reimbursement through upcoding or via better documentation of comorbidities? A difference-in-difference analysis of Medicare billing data conducted by Adler-Milstein and Jha compared payment per discharge and patient acuity between EHR-adopters and nonadopters. The study failed to find evidence that hospitals are systematically using EHRs to generate more revenue. Billing to Medicare increased, but to only to a similar extent to the matched control group of non-adopters (Adler-Milstein and Jha, 2014). Gowrisankaran et al. also find that EHRs primarily improve billing accuracy rather than increase fraudulent billing (Gowrisankaran, Joiner and Lin, 2016). Furthermore, a study by Gadu et al. shows that health insurance companies increasingly have the ability to identify systematic upcoding, further preventing misuse (Ganju, Atasoy and Pavlou, 2016). From a payer's perspective, this rebuts the presumption that EHR adoption will increase the costs of hospital care. At the same time, however, this means that hospitals can only expect revenue increases from EHRs to a limited extent.

3.2 Medical Consequences

The improvement of medical quality is one of the EHR's most widely anticipated benefits. Of central importance are outcome measures with hard endpoints, like mortality or survival rates. Although these parameters do not correspond to those of SDL, the results are presented below, as there are no known publications on the values of SDL. Regarding the association between EHR adoption and the risk-adjusted 30-day-mortality for acute myocardial infarction (AMI), Adler-Milstein et al. find no strong evidence that that these systems have a positive effect on outcome (Adler-Milstein, Scott and Jha, 2014). In a later study, however, the authors were able to draw a more differentiated picture: hospitals that adopted EHRs due to regulatory pressure and only used the system's basic functions, achieved even worse performance for mortality rates compared to nonadopters. By contrast, a more intensive use of EHRs and the introduction of new features were beneficial, resulting in a 0.21-percentage-point reduction in AMI mortality rate per year and per used function (Lin, Jha and Adler-Milstein, 2018). A study conducted by Enriquez et al. arrives at similar results. They find that hospitals with 'fully-integrated' EHRs are associated with lower AMI mortality rates, less frequent heparin overdosing, and slightly higher adherence to guideline-recommended therapies for AMI compared to hospitals with no EHR (Enriquez *et al.*, 2015). These findings support the findings of the previous chapter, which highlights that pure adaptation by itself does not lead to performance advantages.

A study conducted by Appari and colleagues suggests that one possible explanation for the observed improvements in clinical outcomes is improved process quality through more intensive EHR usage. Hospitals with a sophisticated EHR that met the 2011 meaningful use criteria achieved an incremental 0.35 to 0.49 percentage-point increase in process quality compared to hospitals with basic EHRs for heart attack, heart failure, pneumonia, and surgical care infection. Maintaining high process quality and process adherence is widely regarded as in important determinant for outcome quality. However, the study also points that not all EHR implementations will result in additional gains in process quality. The transition to the extensive use of EHR's functions is especially associated with statistically significant decline in quality. The authors argue that changes at the highest level may take longer to achieve positive effects, due to the high complexity of the system and its functions (Appari, Eric Johnson and Anthony, 2013).

In addition, patient satisfaction is increasingly becoming a key element of patient care and an important dimension of overall health quality. Empirical evidence suggests that the use of EHRs can increase the satisfaction of patients. Kazley et al. as well as Adler-Milstein et al. note that the intensive use of EHRs systematically correlates with higher patient satisfaction, measured using hospital ratings and recommendation rates (Adler-Milstein, Everson and Lee, 2015; Kazley *et al.*, 2012). However, a study by Marmor et al. finds an inverse relationship between the degree of EHR use and patient satisfaction for internists and medicine sub specialists, as physicians can be distracted and focus less on patients. Therefore, in order to achieve higher patient satisfactions rates, added functionality in EHRs should not only be technically sophisticated, but also easy and intuitive to use (Marmor *et al.*, 2018).

3.3 Summary of Main Findings

The widespread use of EHRs does not necessarily lead to better medical and economic outcomes. Rather, the value resulting from the use of EHRs is individually defined by the degree of integration and the digitization strategy. Hence, the economic and medical effects range from negative to neutral or unclear to positive. Empirical evidence suggests that there is a gap between the value propositions of EHR manufacturers (higher quality, lower costs) and the actual increase in hospital value after implementation. According to the included studies, the major reason for this gap is not lacking functionality of these information systems, but insufficient adoption and usage (resource integration in words of SDL). Therefore, in order to reduce this gap, it is necessary to analyze and solve the difficulties that arise with the implementation of EHRs.

4 Discussion

4.1 Challenges and Possible Solutions for Future EHR-Implementations

One major challenge mentioned is the disruption of workflows due to the time and attention requirements associated with EHR use. Consistent with previous research, Read-Brown et al. find in a study among departmental ophthalmologists that the interaction with EHRs accounted for 27% of time during patient encounters. Furthermore, there seems to be wide variations in how and when physicians use EHRs: 30% completed more than half of their EHR entries directly after the consultation, while another large part only entered information after the end of the clinic session (Read-Brown *et al.*, 2017; Tai-Seale *et al.*, 2017). According to literature, two steps are necessary to address these problems. First, to increase usability and workflows, EHR manufacturers need to incorporate more user-centered design methods and standardize and harmonize input procedures among all clinical applications. The improvement process should take place in collaboration with the clinical staff. Second, appropriate and target-group-specific training programs need to be developed to realize the potential value increase that lies within EHRs. As the functionalities of EHRs are constantly changing, training must not only take place during product launch but should also include continuous training and support (Horsky and Ramelson, 2016; Martin and Sinsky, 2016; Zulman, Shah and Verghese, 2016).

Another possible challenge to EHR adoption is the resistance of its users to change. Gawande argues that this also relates to the increasing amount of user-time most EHR systems claim in their current state, as information input can take longer than before or must sometimes even be completed digitally and on paper. Physicians therefore might have less time available to interact with patients leading to the fear that this might affect the physician-patient relationship (Gawande, 2018). In this context, Steinhubl and Topol call for a shift from digitization to digitalization. This shift means that the implementation of EHRs should not focus on reproducing the same procedures and processes as before in digital form, but rather adapt the existing processes to bolster and relieve the day-to-day work of physicians by using the full potential of digital technologies. For example, instead of just storing patient data in digital form, EHRs can use methods of data analytics to provide evidence-based support for the physician's treatment decisions or simplify and automate patient monitoring. By improving treatment quality and maintaining physician's time to treat patients, it is expected that the acceptance of EHRs will increase, as it no longer acts as a halfway technology (Krittanawong *et al.*, 2017; Steinhubl and Topol, 2015).

Finally, EHR's functionality - and therefore its acceptance - is often limited if it is not possible to share data with other providers, payers, or even within the same healthcare system. Since the HITECH Act has not defined clear legal requirements for interoperability, most of the current EHRs are not able to exchange information with each other (Adler-Milstein and Jha, 2014; Gold and McLaughlin, 2016). Furthermore, some providers strategically withhold information to gain advantages over competitors or EHR manufactures design systems that are deliberately incompatible with other systems to lock in their customers. Other factors that reduce the willingness to adapt the system and insert data are security and privacy concerns, since news of data leaks incidence in

hospitals tends to increase rather than decrease (Edwards *et al.*, 2010; Wright *et al.*, 2010). Potential solutions to these problems lie mainly at policy level. In order to increase interoperability, the government and legislators need to define uniform data standards. One way to enforce these standards is to introduce subsidies for compliance and to change the reimbursement system to provide incentives for exchanging data, similar to the mechanism used to implement EHRs under the HITECH Act (Atasoy, Greenwood and McCullough, 2019).
The available results relate mainly to the inpatient sector, while results from the outpatient sector are scarce. This should be considered, as inpatient facilities are in general larger and have more resources than outpatient facilities. This is essential because valuable use of EHRs involves high implementation effort and is often more challenging to accomplish for smaller institutions (Adler-Milstein and Bates, 2010).

4.2 Methodological Limitations

This paper analyzed economic and medical effects of the HITECH Act in U.S. healthcare from a service-dominant logic perspective. Since this concept only entered health economics literature in 2012, it is difficult to identify results that are consistent with the value definition of SDL. Existing articles mainly focus on outcomes like costs, life expectancy, and survival rates, and are consistent with the value definition of Porter. Although patient reported data has recently been gaining more consideration – for example in the form of patient reported outcome measurements (PROMs) – the questions asked differ significantly from the propagated ideas of Vargo and Lusch. The two authors mention asking patients questions such as if they believe that they can apply the knowledge gained in hospital to everyday life or if they have a better understanding of how to prevent from getting sick (Joiner and Lusch, 2016). One possible solution for health care providers that is in line with SDL is to co-create discharge plans with the patient.
Yet, considering the five Axioms of SDL allows the ability to gain new insights in healthcare. We identified that the co-creation of value plays a central role to achieve positive outcomes using EHRs. Only if the users integrate their knowledge and skills will the potential of digital solutions be realized. Furthermore, institutions are inadequately addressed in existing healthcare literature (Vargo and Lusch, 2016). The paper also demonstrated pitfalls of misaligned institutions if regulative and normative institutions differ. This misalignment could be due to the rather aggressive and fast diffusion of EHRs in U.S. healthcare, where normative institutions change slower than regulative institutions in form of the HITECH Act with rapid changes and severe financial incentives respectively penalties (Mason *et al.*, 2017).

5 Conclusion

This paper aimed to analyze whether the implementation of EHRs through the HITECH Act has initiated digitalization in health care, or whether only digitization of existing structures has taken place without profound adaptation of the technological possibilities. It was assumed that comprehensive digitalization would lead to significant improvements in the value of care. From a service-dominant logic point of view, EHRs are goods that provide a service to get a job done. However, they only offer value promises. SDL assumes that the customer and his specific use of EHRs in day-to-day practice individually determines the actual value improvement through co-creation. Based on the analysis of empirical evidence, we find this assumption to be valid. Medical service providers that have fully adapted EHRs and its capabilities showed significant improvements in the quality and cost of care, whereas pure implementation hardly showed any improvements. We therefore argue that in order to achieve an increase in value through EHRs, it is necessary to focus on co-creation and co-destruction. In other words, providers need to completely rethink and reorganize their structures and processes to achieve improvements. Strategies to improve the value achieved may include strategic planning for the implementation of EHRs and sufficient training of staff working with EHRs to digitalize.

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Costs and Benefits of the Use of AI in Imaging Analysis in Radiology

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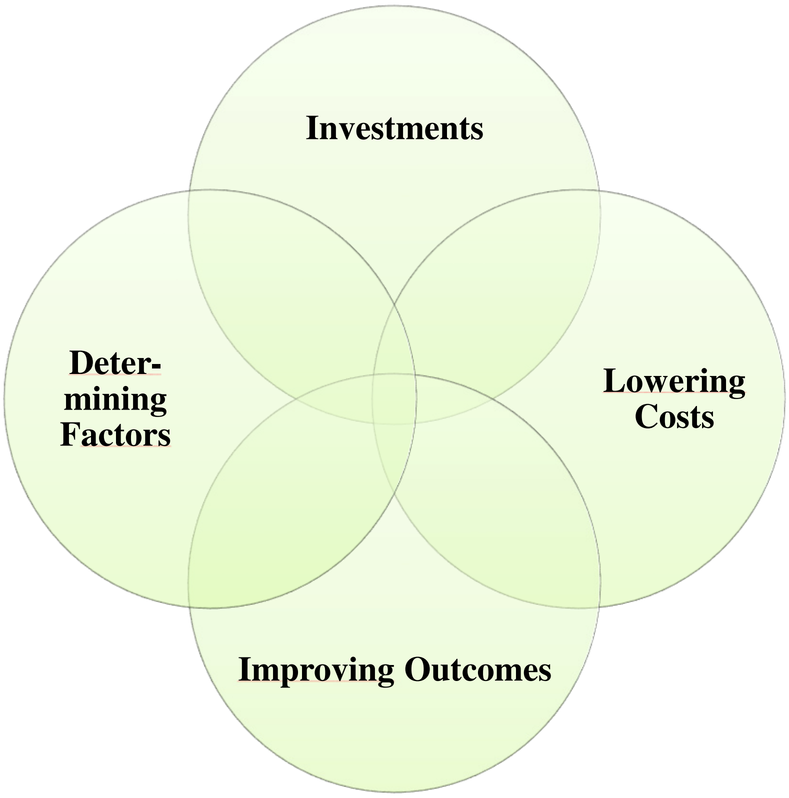
The importance of artificial intelligence (AI) has increased considerably in recent years in various fields of medicine. The application area of image analysis using AI has taken on a pioneering role in the field of radiology in particular. Value is the key to the successful establishment of a technology in the healthcare industry. The question is then, what value can AI achieve in imaging analysis for patients and service providers? This paper analyzes the potential of AI in imaging analysis to reduce health care costs and improve treatment outcomes. It considers associated investments and framework conditions which must be met in order to leverage its potential. The analysis will show that the added value of machine learning systems was controversial in the past. However, through the further development of computing power, availability of digitized medical data, and the developing industry's large investments, deep learning applications show great potential to change image analysis in radiology. The costs for the development and implementation of deep learning systems are offset by the potential savings through shortened reading times and a more efficient workflow. Deep learning also promises to increase the quality of patient care by increasing accuracy and reducing false positives. However, in order to be able to exploit the full potential of deep learning applications in medicine in the future, the framework conditions for development and implementation in the healthcare market must be improved and adapted to the fast-moving industry.

Contents

1 Introduction

The importance of artificial intelligence (AI) in the medical field has increased considerably in recent years. In radiology, image analysis applications using AI have assumed a pioneering role (ESR, 2019, p. 1). Today, the use of these systems is associated with many advantages for service providers and patients, although the technical prerequisites still have potential for development (Coiera, 2019, p. 1). The success of technology in medicine depends on the extent of added value in the delivery of care (Thrall, et al., 2018, p. 505). The use of AI in imaging analysis improves patient care and the radiologist's workflow to ensure greater effectiveness and efficiency in health care delivery (Hosny, et al., 2018, p. 501).
This paper will examine the potential of AI in imaging analysis to reduce health care costs and improve treatment outcomes. It will consider associated investments and framework conditions that need to be met to leverage its potential.

Figure 1: Areas of the Analysis



Source: Own presentation.

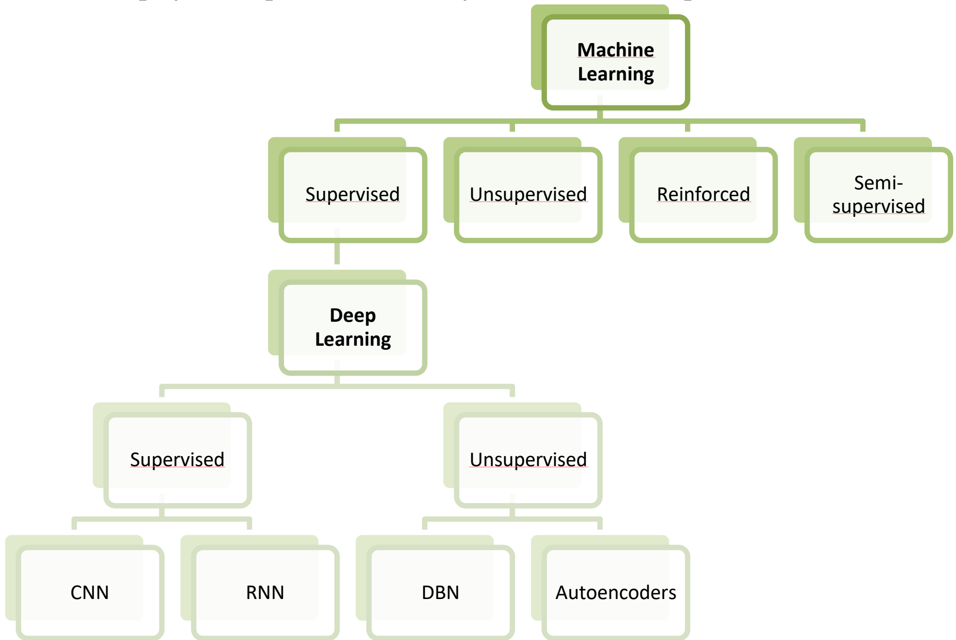
Chapter 2 summarizes current fields that utilize AI imaging analysis. Relevant terms such as AI, Deep Learning (DL) and Machine Learning (ML) are also explained and distinguished from each other for better understanding. The third chapter analyzes the costs and benefits of AI applications in imaging analysis based on selected criteria. The expenditures associated with the research and development and implementation of AI systems are analyzed. Consequently, it has been found that improved treatment quality leads to better results in diagnostics and increases in patient outcomes. The cost reduction potential analyses the extent to which technology contributes to improving the processes of analyzing imaging procedures and reducing treatment costs in connection with diagnostic findings. Considering the framework conditions, prerequisites for a

successful implementation of AI applications are determined and the realization of the benefits are examined. This paper concludes with a discussion of the findings and includes an outlook on future development opportunities and potential fields of application for AI in image interpretation.
Since the interests of different stakeholders must always be considered in the health care industry, the question of costs and benefits will always determine the perspectives of different players in the health care system – particularly the perspective of service providers and patients. However, due to the issue of delimitation of costs and benefits to individual stakeholders, the perspectives of other relevant groups (e.g. payers, industry, national health economy) must be considered.

2 AI in Imaging Analysis

Research in the field of artificial intelligence is surrounded by computer systems. Due to their 'intelligence', computer systems can compute problems and algorithms that are otherwise can only be solved by 'human intelligence' (Tang, et al., 2018, p. 122). The term AI covers several different technical applications and functionalities. AI is divided into Machine Learning (ML) and Deep Learning (DL) systems. ML refers to systems that can recognize patterns or correlations based on algorithms and associated data sets. In addition, they are capable of independently developing solution concepts (Hosny, et al., 2018, p. 501). Supervised and unsupervised learning are the two main categories of ML. Supervised learning means that the algorithm is trained with labeled data. Here the labeling process is often completed by radiologists. Unsupervised learning focuses on the understanding of data, which means that the algorithm should detect hidden structures and similarities between the data (Le, et al., 2019, p. 358). As shown in Figure 2, DL is a subcategory of the supervised ML. DL refers to the system being able to independently derive new links and improve its capabilities with the help of neural networks based on pre-learned content. The human does not actively intervene in the learning process of the system (Saba, et al., 2019, p. 15). The biggest difference between ML and DL is that rules, data, and algorithms for recognizing patterns and solution concepts must be designed and programmed by humans in advance (Hosny, et al., 2018, p. 501).

Figure 2: Simplified representation of the relationships between elements of AI



Source: Own presentation.

Medical specialties affected by AI are primarily those in which diagnostic imaging play a central role. The specialties include radiology, ophthalmology, pathology and dermatology (Hosny, et al., 2018, p. 500). Particularly in radiology, the application of such AI applications is very advanced and will therefore be the primary focus in paper. There are three core areas within image analysis that AI applications support in radiology: detection, characterization, and monitoring (Hosny, et al., 2018, p. 506). Detection is the discovery of pathological changes. Characterization includes segmentation, diagnosis, and the final classification of the discovered change. Monitoring observes and records the development of these changes over time (Hosny, et al., 2018, p. 506). Studies have already identified several clinical settings in which the use of AI is being researched. These include the discovery and characterization of breast, lung, colon and prostate cancer, brain tumors, changes in the liver (ESR, 2019, p. 3), and neurological disorders (e.g. Alzheimer disease). Meanwhile there are AI systems for every kind of imaging diagnostic (e.g. CT, ultrasound, etc.) that support image interpretation (Pesapane, et al., 2018, p. 746).

Computer-aided detection (CAD) has also been used since 1998. Although these systems belong to the category of AI applications, they still fall under the classic rule-based systems (Dreyer and Geis, 2017, p. 714). Classic CAD systems are often designed to be disease-specific and non-transferable (Hosny, et al., 2018, p. 502). Studies show a controversial benefit with regard to classic CAD systems. Both the accuracy and the benefit for the service provider failed to materialize (Hosny, et al., 2018, p. 502). Today, new applications that are established in medical practice are mainly developed based on DL algorithms (ESR, 2019, p. 2).

Convolutional neural networks (CNN) are the most common method in image analysis (Saba, et al., 2019, p. 15). In the context of characterization, a large number of tasks must be solved by AI, one task being segmentation. This means, for example, that diseased tissue has to be precisely delimited on the basis of the image. For context, this is a particularly relevant task when planning irradiation. CNN's first successes are also evident here (Hosny, et al., 2018, p. 503). Deep learning is also being used in diagnostics

- computer aided diagnostics (CADx) systems are based on deep learning and are already showing good results within diagnostics of breast cancer and lung nodules. Deep learning applications in the areas of staging and monitoring have been less researched. This is mainly due to the complexity and interaction of the many different features that need to be considered. There is still a need for research in these areas in the future (Hosny, et al., 2018, pp. 503–505).

3 Costs and Benefits

The systems introduced in the previous chapter will be analyzed with regard to their costs and benefits. Since costs and benefits cannot always be clearly distinguished among individual stakeholders in the use of digital applications in medicine, this chapter focuses on the perspectives of service providers and patients. The costs and benefits of artificial intelligence in imaging analysis will be identified and analyzed accounting for the (I) investments required, the potential for (II) cost reduction and (III) improvement in treatment quality, as well as the (IV) framework conditions required.

3.1 Investments

In order to promote and establish sustainable implementation of AI in image interpretation, different stakeholders need several types of investment in this development. Some of them are presented below.

3.1.1 Technological Infrastructure

The development and provision of the technological infrastructure for AI systems represents the largest expenditure. The developing providers and the service providers are the largest cost bearers (Thrall, et al., 2018, p. 507). The costs for the development of AI systems lie primarily with the developing companies (e.g. IBM) or the service providers who develop a system themselves. In addition to the development costs, they also bear the approval risks of their products in the health market by respective authorities, as well as the responsibility for the later usability in the daily care routine (Dreyer and Geis, 2017, p. 716). In the beginning of AI, the development of AI systems in image interpretation was very cost-intensive due to the limited computational power. However, algorithms from the developer's point of view can be seen cost-effective nowadays (Tang, et al., 2018, p. 123). Nevertheless, AI imagine analysis applications cannot be transferred from one service provider to another, which continues to drive up development costs (Coiera, 2019, p. 2). Due to individual patient profiles and differences in imaging modalities of each service provider, systems for different service providers need to be trained with different datasets in order to establish full functionality (Yasaka and Abe, 2018, p. 3). An example by Pickup et al. shows that a trained algorithm showed high performance on the patient profiles from the training data set, but lower performance when the model was used for patients from another hospital (Tang, et al., 2018, p. 124). These costs, on the developer side, are consequently passed on to the service providers contracting the development of these applications. Using AI in the daily care process prerequisites appropriate hardware and software (Guerriero, et al., 2011, p. 3). Considering the fast pace of development in the industry, it is important to ensure that systems are being updated in a timely manner. If, for example, an MRI requires an update or the scanner needs to be replaced, the resulting images deviate from those with which the algorithm was trained and works with daily. This may negatively affect image interpretation quality. For these cases, it is important to develop strategies to update the AI-system or to find cost-effective possibilities to make the algorithm easily work with the new scanner (Tang, et al., 2018, p. 125). However, there is no proof on frequency and cost-intensiveness of adjustments available. In addition, the future approval of modalities is only partially determined. Currently, AI applications are approved as software, which is likely why the market is expanding in this direction (Mayo and Leung, 2019, p. 2). Once this process has been established, it will lead to cost reductions for software-based products (Mayo and Leung, 2019, p. 2). In the future, it can be expected that the approval structures and requirements will establish themselves, but due to the rapid development steps of AI systems, uncertainties regarding approval will always remain, and the risk must continue to be accepted by the developers (Johner, 2019).

3.1.2 Data Sets

Another important and cost-intensive area mainly related to the training of AI algorithms is the availability of corresponding data sets. In order to train a system, large quantities of image material must be available (ESR, 2019, p. 5). The more differentiated a CNN is, the more data that is required for training. This follows the idea that greater diagnostic precision is linked to greater amounts of data used for training (ESR, 2019, p. 2). However, the availability of such data sets has been limited so far. The issue is further complicated by the fact that AI algorithms are not easily transferable between service providers, because they are influenced by the individual characteristics of each training set (Yasaka and Abe, 2018, p. 3). This could lead to incorrect results, for example in algorithms within patient groups of different ethnic groups (Pesapane, et al., 2018, p. 746). One approach in solving this issue could be to make large datasets publicly available. Systems could be trained comprehensively, and the precision of the systems would be independent of the individual patient structures of the service providers (Thrall, et al., 2018, p. 505). In addition to data availability, the quality of the available images needs to be considered as well. Images used for training purposes must be processed according to the requirements of the AI systems (Tang, et al., 2018, p. 126). These are increased costs for developers and service providers as well. Patients will likely pay with their data because a lack of data availability leads to an impasse in the system development stage (Coiera, 2019, p. 2). Throughout the course of this paper, the framework conditions that need to be met for the correct handling of patients' data and privacy will be explained in more detail.

3.2 Improving Outcomes

The use of AI bears many opportunities for quality improvements in radiology. Through the use of AI-based systems, the accuracy of the findings can be increased (Lee, et al., 2017, p. 571). Through image interpretation, many empirical findings on different diseases show the same or an increasing accuracy of the system when compared to radiologists. A study by Becker et al. showed a result of 0.81 for the area under the receiver operating curve (AUC), which was similar to the results of one of the three radiologists

(AUC=0.83) (Becker, et al., 2017, p. 434). Another Study by Rajpurkar et al. shows similar results for the accuracy for the detection of pneumonia with chest radiography (Rajpurkar, et al., 2017). The challenge from the 2017 Dialogue for Reverse Engineering Assessments (DREAM) spawned an algorithm which showed a ROC AUC of 0.87 in detection of breast cancer (Mayo and Leung, 2019, p. 2) . Results in lung cancer detection by Liang et al. show that CAD systems are able to detect 56-70% of lung lesions which are initially missed by radiologists (Liang, et al., 2016, pp. 282–284). AI systems are capable of compensating for some human error which may occur in the treatment of an individual (Giger, 2018, p. 513). According to Giger (2018), frequent reasons for error by a radiologist when making diagnoses are:

1. Large quantities of images in a short time
2. Fatigue/inattention
3. Poor quality of images
4. Disturbing factors (e.g. structure noise)
5. Complex disease stages

These errors could lead to false or delayed diagnoses, high false positive rates, high readmission rates, or unnecessary follow-up examinations, all which could have a great clinical impact (Fazal, et al., 2018, p. 246). By establishing AI-based systems in the radiologist's diagnostic process, these errors can be reduced, and the quality of care can be improved. The quality of current CAD systems (which work based on classical ML structures) is particularly dependent on the quality of the previously used data and the programming of the algorithm (Le, et al., 2019, p. 359). Therefore, different systems show different levels of accuracy. Various studies, particularly in studies with mammography screenings, have shown that systems have similar levels of accuracy as radiologists (Becker, et al., 2017, p. 438). Compared to normal double-reading, the use of CAD led to increased false-positives due to the sensitivity of the systems. For example, a study in the UK screening program shows a 0.5% higher recall-rate by same cancer detection-rate by using a CAD system versus the double-reading process (Gilbert, et al., 2008, pp. 1678–1679). Fazal et al. concludes that the false-positive findings by CAD are 1 in 2.2 examinations by mammography and 4.6 to 11 in chest CTs (Fazal, et al., 2018, p. 248). However, through the further development of CAD by DL, it is possible to reduce these false-positive findings. Therefore, it is possible to reduce the costs of unnecessary biopsies and the psychological burden for the patients (Lee, et al., 2017, p. 571; Fazal, et al., 2018, p. 248). The increasing accuracy in CAD also leads to a higher cancer detection rate, which has a positive effect on the early treatment of affected patients (Jung, et al., 2014, p. 169).

Another positive factor is the accelerated diagnosis of radiological images using AI. In time-critical situations, health care providers are supported when diagnostics tools are improved. Therefore, the patient receives a quick treatment and the worsening of the patient’s health condition is prevented (Mayo and Leung, 2019, p. 2). In addition, DL programs can improve training quality of service providers. As a result, patients can benefit from the support these systems provide in the care process (Yasaka and Abe, 2018, p. 2)

If the development of DL systems advances the future, further benefits for the care of the patients can arise. DL can, for example, be trained in the future to identify patients with urgent treatment needs (e.g. pneumothorax) more quickly, so that they receive the required therapy as quickly as possible (Taylor, Mielke and Mongan, 2018, p. 11). Deep learning can also be trained to recognize findings based on images that would require invasive surgery (e.g. biopsy). A study by Yasaka et al. shows that it is possible to stage a liver fibrosis by using a deep CNN with a value of the AUC ROC of 0.84, 0.84, and 0.85 for the stages F4, F3 and F2 of the New Inuyama classification system (Yasaka, et al., 2018, p. 151). This could lead to the prevention of invasive procedures and their associated complication risks, ultimately increasing patient safety (Yasaka and Abe, 2018, p. 2).

If imaging data can be linked with additional data in the future, the treatment of patients can be redesigned by so-called 'radiomics'. Radiomics describes the extraction of many features within image analysis, particularly characteristics, like size, shape, morphology, and kinetics of the tumor. The next step is the linking of these characteristics with other data points such as genomic data and outcomes data to make predictions about disease development (Giger, 2018, p. 514). In oncology, this method is already used to predict recurrence rates or the probability of survival (Hosny, et al., 2018, p. 501). The use of radiomics is an important step towards personalized medicine in the future.

3.3 Lowering Costs

The main question now is how the use of artificial intelligence in imaging interpretation can reduce treatment costs. In some diagnostic processes, the gold standard of diagnoses is 'double reading'. This involves two separate radiologists analyzing the same images and concluding with matching results. Double reading is common practice in the context of mammography screening. By using CADs in this step, it is possible to have the double diagnosis carried out by one physician and the CAD instead of two radiologists. This will save radiologist's time, reduce costs for diagnoses (Jung, et al., 2014, p. 8), and increase diagnostic capacity. A second cost reduction potential lies in the speed of the systems. In the US, an average of 260 million images are analyzed per day across all radiologists and imaging procedures. With the help of AI and small investments in technological equipment, a hospital would be able to process the same number of images in a single day (Saba, et al., 2019, p. 17). Additionally, AI systems can help the individual radiologist analyze images faster and decrease susceptibility to errors. If systems are sufficiently reliable, it is possible that the AI application could review the images first and radiologists would only have to re-examine critical cases (Mayo and Leung, 2019, p. 2). The costs in connection with false-positive diagnosis in mammography are estimated to 4 billion dollars per year. Decreasing false positives with the support of CAD, shows its enormous cost-reduction potential (Ong and Mandl, 2015, p. 581). CAD's support can lead to findings being produced more quickly and critical cases taken care of more quickly, reducing follow-up costs. In addition, increased case volumes could be treated with a constant or lower resource input (Jung, et al., 2014, p. 8). If deep learning systems evolve to having a negative predictive value of 100% (meaning they recognize a negative finding at 100% accuracy), there would be enormous time savings and thus cost reduction. In this case, radiologists would not have to re-examine the findings, but the negative findings could be verified solely by AI application (Mayo and Leung, 2019, p. 2). If these cost savings were to be passed on to health insurance companies and consequently to patients as part of the care delivery process, the entire healthcare system could benefit (D'Avolio, 2017).

3.4 Determining Factors

In order to advance the dissemination and further development of AI applications in image analysis, some basic conditions must be considered. These may impact advances positively or negatively.

3.4.1 Approval

A first important factor is the approval of AI systems for use in medical care. The Federal Drug Administration (FDA) is the responsible authority in the United States of America (USA) for the approval of medical devices and drugs for medical care. Approval hurdles generally play a major role when it comes to the dissemination of technological achievements in medicine. Since 2018, the FDA has classified AI-based CAD systems as medical device class II (Syed and Zoga, 2018, p. 543). In addition, the FDA published a draft for a new approval framework in April 2019. Among other things, it regulates how approvals are granted and how to handle product changes (FDA, 2019, p. 3). Such frameworks are important to make market approvals transparent for manufacturers and thus to improve market access for similar software systems in the future. Rapid approval options are advantageous for manufacturers, promote development, and offer service providers a broad spectrum of technical solutions (Pesapane, et al., 2018, p. 748).

3.4.2 Reimbursement

Another important factor when it comes to the nationwide establishment of AI-based systems in clinical care is reimbursement qualification (Ziemlewicz, et al., 2017, p. 1247). There are no studies in the existing literature on how the implementation of AI systems will affect today's compensation structures. However, there are some considerations as to what changes could take place in the remuneration of service providers. According to the current scheme, the fee for service principle is mainly applied in remuneration of radiologists, which means that they are remunerated individually for each service item. Medicare mammography screening services are reimbursed to radiologists in bundled payments (Mayo and Leung, 2019, p. 2). Both remuneration systems should, however, be reconsidered in view of the implementation of AI in imaging interpretation. Since AI support enables examining more images in a shorter amount of time, such remuneration models are no longer appropriate. The fee-for-service renumeration gives the incentive to review the most possible amount of cases per day. With the support of this technology, most of the review-process will be done by the machine and it will be possible to review thousands of pictures each day. These changes in health care provide a pathway towards value-based reimbursement. A value-based reimbursement model would ensure that radiologists are reimbursed according to the quality and accuracy of their diagnoses (Coiera, 2019, p. 2). In addition, adjusted remuneration structures have a positive effect on the spread of technological applications and innovation in medicine. A 2010 study by Fenton et al. shows the establishment of CAD increased from 4,8% in

2001 to 26,9% in 2003 with the introduction of Medicare coverage for CAD as part of mammography screening (Fenton, et al., 2010, pp. 987–988).

3.4.3 Data Availability

As explained earlier, huge amounts of test data are necessary in order to train deep learning structures in the medical field, especially for diagnostic purposes. However, this is not only important from the investment perspective, but also important because it requires certain conditions in the handling of medical data. In other training scenarios of algorithms, the availability and the usage of such test data is often unproblematic, as they are available in large databases like ImageNet. In medicine, however, there is not wide availability of test data (Savadjiev, et al., 2019, p. 1617). Radiological findings are very complex due to the number of pixels and different views. Furthermore, medical data is subject to strict data protection regulations. In order to further develop AI algorithms in radiological diagnostics in the future, special circumstances must be met to make radiological findings usable for training purposes. For this purpose, the formation of image sharing networks is suggested. These would improve the training process of AI algorithms significantly (Thrall, et al., 2018, p. 505).
In light of these challenges, it is also necessary to develop frameworks for legal, moral, and security aspects. During framework development, the highest accuracy standards must be applied. This includes the creation of legal regulations to clarify the responsibilities regarding wrong judgments and removing loop holes in current legislation. Doing so will increase patient safety and simultaneously offer the service provider transparency and assurance regarding potential liability concerns (Saba, et al., 2019, p. 18). Finally, clear regulations must be created to protect the privacy of patients and their data. These regulations should cover the use of data sets for training purposes as well (Tang, et al., 2018, p. 131).

4 Discussion

The discussion of costs and benefits illustrates the status quo and demonstrates future investment and development potentials. It is important to note that further development of computational power and GPUs and public initiatives (such as ImageNet 2012) have rapidly accelerated the development of AI (Saba, et al., 2019, p. 15). Nevertheless, further investments from various stakeholders will be necessary. Development efforts from radiologists, the developing industry, and broad interoperability between AI and existing systems (e.g. PACS) will promote AI in image interpretation and accelerate the spread of its benefits (Tang, et al., 2018, pp. 124–126).
The controversial discussion of AI's benefits to the field of radiology is expected to continue. There is controversy in the literature as to whether AI will replace or complement the profession of radiology (Coiera, 2019, p. 2). However, many believe that the technology will help to support the radiologist's workflow. Service providers can then be more present with patients and focus on more specialized tasks (Syed and Zoga, 2018, p. 543). Although AI-based systems will lead to better (or at least similar) results than their human counterparts, there will still be disruptive factors, such as changes in image quality, that require an assessment by radiologists (Saba, et al., 2019, p. 18). It is still unclear how the affected physicians will transform their role in the future of care and

receive the development of technologies (Lee, et al., 2017, p. 571). Another important factor is the improvement in traceability of AI-based decisions. For doctors to trust the decisions of an algorithm and consult them for their diagnosis, the decision paths of the systems must be transparent (Syed and Zoga, 2018, p. 543).

Frameworks for future use must be based on cooperation between service providers, industry, and regulatory institutions in order to avoid legal issues and patient privacy violations (Lee, et al., 2017, p. 580). Regulations must be developed, which promote the further development of DL in radiology, while at the same time safeguarding the personal rights and duties of all stakeholders. Agreeing on these regulations will likely be one of the greatest challenges in the future for the comprehensive implementation of AI in medical image interpretation.

5 Conclusion

The use of AI in image interpretation promises to be a great enrichment for service providers and patients in their care in the future. Today, AI-based systems support service providers in the care process and increase the quality of treatment. The investments in technological infrastructure and data sets will be offset by major cost reduction potentials. This means an increase in effectiveness and efficiency for the entire healthcare system in the future if systems are further developed in a targeted manner. To achieve the goals of increased effectiveness, efficiency, and cost savings, service providers and technology companies must closely work together. This will ensure that systems can be trained effectively with sufficient amounts of data while meeting the requirements of patient care. Additionally, a definitive regulatory framework must be established to ensure patient privacy and safety.

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Effects of EHR Implementation on Processes in Primary Care

Anna Giauque

The implementation of the electronic health record (EHR) is supposed to improve efficiency, quality, and safety of health care. While EHR systems are already integrated in almost every U.S. hospital, an area-wide use in primary care has not yet been achieved. With the passage of the HITECH Act in 2009, financial incentives were set to increase the adoption of EHR systems among health care providers. To participate in the financial incentive programs offered by Medicare and Medicaid, users must show 'meaningful use' of their EHR by meeting specific criteria. Since then, a significant increase in EHR adoption in primary care has been observed. In the US and many other countries, primary care providers (PCPs) are the first contact for patients if health issues occur. As the gatekeepers, primary care providers facilitate and coordinate care, therefore a strong relationship with patients are amongst their key functions. Based on the increased adoption of EHR systems, this paper assesses and analyses the effects of EHR implementation on processes within primary care. Opportunities and challenges with the EHRs will be addressed. Additionally, the adoption and diffusion process of EHRs based on Rogers 'diffusion of innovations' theory will be explained. The implementation of an EHR can strengthen communication within a team, with patients, other health care providers, and payers. It also improves care coordination, workflows, practice management, and the quality of primary care through better treatment. However, financial risks, lack of interoperability, technical aspects, and data security are significant obstacles of adoption. To further convey the adoption and diffusion of EHRs, these obstacles must be overcome.

Contents

1 Impact of EHR on Physician Practice

When looking at primary care, there are often many challenges (Bodenheimer & Pham, 2010, p. 799). Primary care physicians (PCPs) are confronted with too wide of a range of care. They are responsible for preventive care, chronic disease management, and acute care. Additionally, PCPs are the initial stop for patients when a condition arises. Over the years, the practice of medicine has risen in complexity, therefore accurately diagnosing and treating patients is becoming more difficult. These aspects often lead to PCPs suffering from lack of time.

Electronic health records (EHRs) were developed to address these challenges. However, in literature, there is an ongoing debate on abilities and barriers of EHR adoption in primary care (Linder et al., 2007, p. 1400). Do EHR systems lead to higher process quality? Are they sustainable solutions to improve the quality of care? Do they enhance delivery of guideline-adherent care or reduce medical errors? Is there a positive impact on the workflow?

The objective of this paper is to determine the effects of EHR implementations on primary care processes, with respect to medical, organizational and patient-related aspects. Furthermore, this paper will assess capabilities and challenges for EHR systems within primary care.

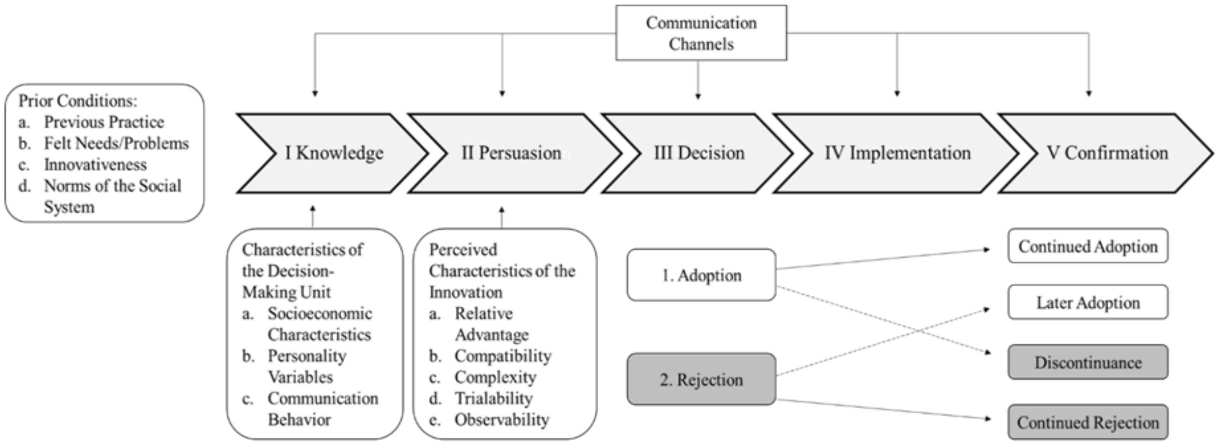
2 Primary Care and Electronic Health Records

2.1 Diffusion of Innovations

In this chapter, primary care will be looked at more closely, and specific features of EHRs will be explained. The theoretical framework of the paper will be outlined at the beginning of this chapter.

The theory of diffusion of innovations explains in which way, to what extent, and why new ideas and technologies spread (Rogers, 2003, p. 5). In 1962, Everett Rogers outlines this theory in his book *Diffusion of Innovations*. He defines diffusion as “the process by which an innovation is communicated over time to members of a social system via various channels” (Rogers, 2003, p. 11). According to his theory, four main elements of the diffusion process can be determined: the innovation itself, communication channels, time, and a social system. Therefore, the decision of whether an innovation is accepted or rejected is not a spontaneous reaction, but rather a social process that takes place over time and involves serial actions (Rogers, 2003, p. 28). Figure 1 shows the five stages within the innovation-decision process.

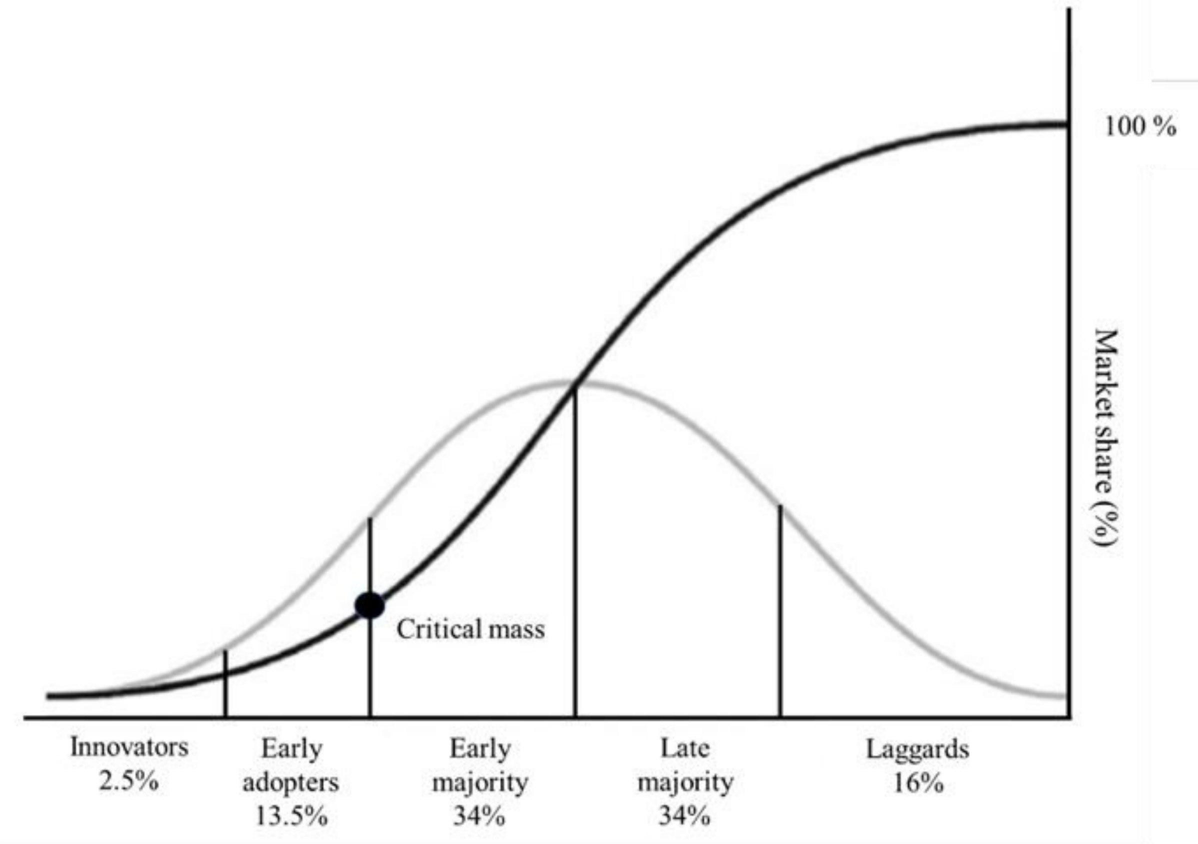
Figure 1: Model of five Stages in the Innovation Decision Process



Source: Own presentation based on Rogers, 2003, p. 170.

During the innovation-decision process, attempts are made to reduce uncertainty via communication channels or by testing a new idea. (Rogers, 2003, p. 170). The adoption-stage can only be reached if an innovation has adoption-relevant characteristics, such as high relative advantage, high compatibility, low complexity, high trialability, and high observability (Rogers, 2003, pp. 15-16, p. 229). In summary, the more of these characteristics an innovation encompasses, the faster it will be adopted over other innovations. Another aspect of the theory is how the innovation spreads within a social group (Rogers, 2003, pp. 22-24). Rogers defined five adopter categories which classify members of a social system based on level of innovation. The categories are delineated by "the degree to which an individual or other unit of adoption is relatively earlier in adopting new ideas than other members of a system" (Rogers, 2003, pp. 22-24). The two primary members of the social system are earlier adopters (innovators, early adopters, early majority) and later adopters (late majority, laggards). These groups differ in terms of socioeconomic status, communication behavior, and personal characteristics that positively relate to level of innovation (Rogers, 2003, p. 295). Innovators are the first to adopt new ideas and could be confronted with failure. Early adopters have a leadership role within the process: an innovation adopted by these innovators decreases uncertainty within a social system. Finally, it can be assumed that the adopter rate increases when the innovation reaches the point of *critical mass.* If an innovation is successfully adopted by the specific categories, it can ultimately reach 100% market share, as shown in Figure 2.

Figure 2: The Diffusion of Innovations – Adopter Categories based on Innovativeness



Source: Own presentation based on Rogers, 2003, p. 11; p. 112; p. 281.

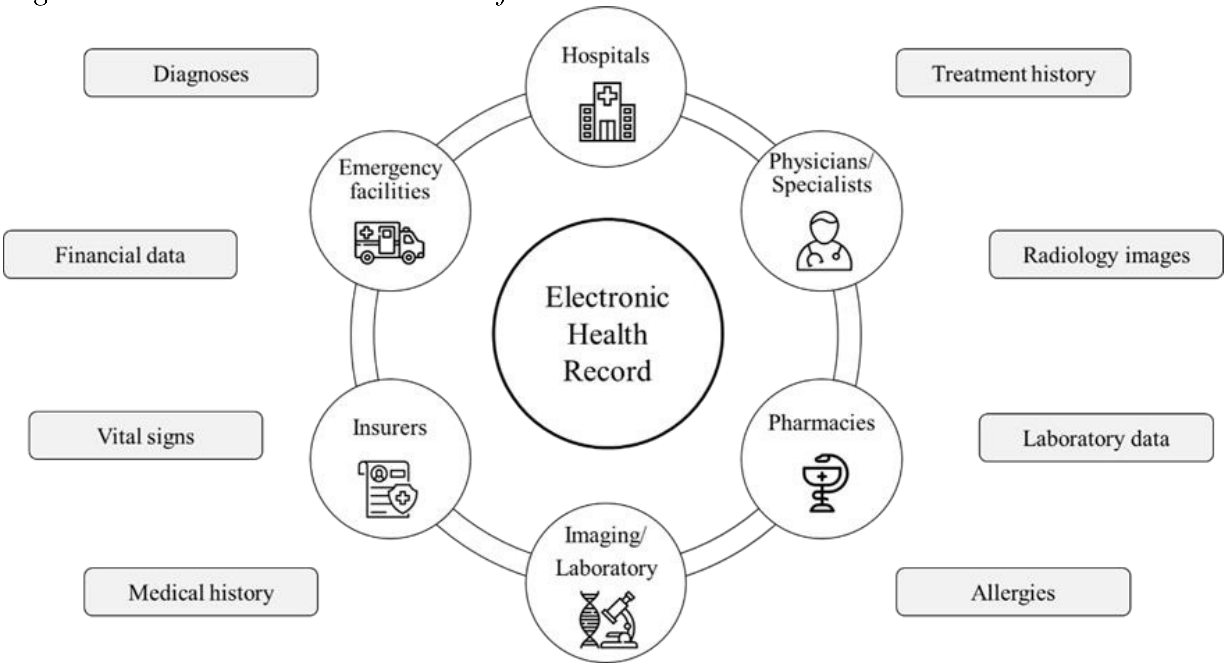
When applying Rogers` innovation-diffusion theory to analyze the effects of EHR adoption, the results are then compared to the stages of the innovation-decision process and the five innovation characteristics.

2.2 Definition and Functions of EHRs

Despite increasing digitization, there is still a large number of health care providers using paper-based records. Patient records are filled in by hand and passed on manually to other stakeholders (Garrido et al., 2005, pp. 1). Problems that arise with paper-based records include the availability of each record to only one person at a time, the inability to access them remotely, and the illegibility of notes due to poor handwriting (Bates et al., 2003, p. 3). On the contrary, EHRs are available at any time for any authorized user to access (ONC, 2018). Health data is recorded digitally and available in real-time.

The objective of an EHR system is to get a broader view on a patient's needs. Since EHRs are patient-centered, they accumulate patient specific information including a patient's medical history, diagnoses, allergies, and laboratory results. Through the use of EHR's, providers also have access to evidence-based tools which can support decision-making for the appropriate treatment. Additionally, EHR systems can positively influence provider workflow and processes through automation. EHR systems can also aid with financial and administrative functions. EHRs are designed to share data electronically with almost any stakeholder, including physicians, hospitals or pharmacies. Therefore, the main advantage of an EHR is that all patient data is recorded in a single digital record which is shared and managed by all authorized providers involved (Fig. 3).

Figure 3: Functions and Features of an Electronic Health Record



Source: Own presentation based on ONC, 2018.

In 2003, a committee of the Institute of Medicine (IOM) of the National Academies has identified the following eight key capabilities an EHR system supports: health information and data, results management, order/entry management, decision support, electronic communication and connectivity, patient support, administrative processes, and reporting and population health management (IOM, 2003, p. 5-11). EHR systems are used to support patient care delivery, manage care, and facilitate financial and administrative processes such as reimbursement or billing. In addition, EHR systems promote patient-empowerment due to the trend of patients getting more involved in managing their own health data. Additionally, EHRs are used to educate patients and support medical research. Ultimately, EHRs have been improving the efficiency of health care systems.

2.3 Primary Care

In many countries including the U.S., primary care providers are often the first contact for patients if they encounter any health issues (Hoon et al., 2017, p. 2). The principal specialties of primary care providers are comprised of the following: general practice, family practice, internal medicine, pediatrics, geriatrics, and obstetrics and gynecology (Americas Health Rankings, 2018). Note that nurse practitioners and physician assistants are included under primary care providers (Garrido et al., 2005, p. 3). The U.S. IOM Committee on the Future of Primary Care defines primary care as “the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community” (Donaldson et al., 1996, p. 31). This definition shows the many functions of primary care and highlights its multidimensionality, which gives it a high value among health systems. Because primary care providers are the gatekeepers and primary guidance in a health system, primary care providers end up facilitating long-term patient-physician-relationships.

3 Effects of EHR Use on Primary Care Processes in the U.S.

3.1 Background and Impact of EHRs

This chapter focuses on effects of EHR use in primary care. First, the background of EHR adoption will be discussed. Then, effects of the EHR on processes will be examined and evaluated. Finally, the benefits and barriers of EHR adoption will be assessed. There is evidence that EHRs have the potential to improve quality, safety and efficiency of health care (Makam et al., 2013, p. 2). EHR systems are integral in almost every U.S. hospital (Pedersen et al., 2017, p. 1338). In contrast, the adoption of EHR systems in outpatient facilities was slow up to 2009 (Hsio & Hing, 2014, p. 1). However, since 2009 there was a significant increase in adoption when the U.S. federal government authorized incentive payments to increase physician and facility adoption of EHR by investing $27 billion through the Health Information Technology for Economic and Clinical Health (HITECH) Act (Blumenthal & Tavenner, 2010, p. 501).

The Centers for Medicare and Medicaid Services (CMS) Incentive Programs are segmented in three stages with increasing requirements increasing at each level (CMS, 2010; CMS, 2012). Stage one includes data capture and sharing, stage two requires advanced clinical processes, and stage three entails improved patient outcomes. To qualify for incentive payments, EHR users must demonstrate that they are a 'meaningful use' certified EHR by meeting certain objectives (Jamoom et al., 2012, p. 1). In 2018, the CMS overhauled and renamed the program to 'Promoting Interoperability Program' (CMS, 2019).

The objectives of the meaningful use incentive programs were to improve the collaboration among health care providers and to provide patient-centric preventive care. The new program aims to strengthen interoperability, connectivity and patient access to health data. Beginning in 2019, all eligible professionals must use the latest certified electronic health record technology (CEHRT) edition from 2015 (2015 Edition) as set by the CMS and the Office of the National Coordinator for Health Information Technology (ONC) (HHS, 2015).

3.2 Opportunities of EHRs

EHR adoption resolves many of the challenges processes within primary care. The opportunities are discussed below:

Communication. As the gatekeepers within health systems and first point of contact on health issues, primary care providers are responsible for making a diagnosis and recommending further steps, such as referrals to specialists and hospitals. Hence, it is important that the communication between physicians and patients, and other health care providers is efficient (Murphy et al., 2012, p. 283). In addition, communication within the multidisciplinary team is important and EHR adoption has shown improved communication within a team (O'Malley et al., 2015, p. 429). This is due to universal access to patient data and mailing functions such as instant messaging or reminder functions

(Nemeth et al., 2008, p. 6). This supports delegating tasks and redefining team roles (Ranjan, 2018).

Patient-physician-interaction. Strengthening the communication between primary care providers and patients improves the doctor-patient relationship and can affect this interaction (Asan et al., 2014, p. 311). Communication features include patient-physician mailing, virtual consults, or telemedicine (Palen et al., 2012; Bashshur & Shannon, 2009). Especially in rural areas where fewer PCPs are located, these tools help patients stay connected with their providers and plan of care. Additionally, increased EHR use facilitates more effective telephone calls and contacts (Garrido et al., 2005, pp. 3-4). Appointments required by patients with minor health problems decrease since they can directly talk to a physician via phone call. Therefore, a PCP can directly treat a patient, since he has immediate access to patient data via the EHR system. Health needs can be identified earlier via an increased use of telemedicine, consistent observation of patients by PCPs, and use of an EHR system. This results in an overall decrease in the number of visits to a primary care physician's office. In addition, if a patient also has access to an EHR system, it can be used as a reminder for appointments and follow-up checks, resulting in fewer missed appointments (Nemeth et al., 2008, p. 6). Finally, the patient-physician relationship can be strengthened by using templates, either for medication plans or to write down diagnostic results. This enables more talking and face-to-face time with patients, since the PCP is already informed on the patient's current health status (O'Malley et al., 2015, p. 429). As EHRs become more patient-centered, patient-empowerment is promoted. As patients can access their health data, they may have a greater knowledge on their health and contact their PCP before a problem becomes too serious, which ultimately promotes preventive care (Ammenwerth et al., 2011, pp. 63-67). Finally, patient portals can increase patient empowerment because services like appointment scheduling, medication refill requests, and educational modules can be offered.

Accessibility. Since EHRs are digital, they can be accessed by a primary care provider at any time. This is especially beneficial for PCPs because they can immediately access health data if they are confronted with an acute condition. Furthermore, recorded diagnoses and laboratory results provided by an EHR can always be accessed directly (Evans, 2016, p. 51). Providers can choose between free text options or standardized templates to save time (Makam et al., 2013, p. 3). Increased accessibility also includes increased access to laboratory test results or radiology imaging results (Garrido et al., 2005, p. 4). As laboratory services are often a necessary part of a PCP visit, the visibility of former tests would decrease unnecessary procedures such as a repeated laboratory test.

Workflow and Practice Management. A PCPs workflow can be automated and streamlined through computer-assisted order sets and tests and practice management tools in order to increase visibility into daily responsibilities (Garrido, 2005, p. 2). Furthermore, documentation templates and easy searching options within EHR systems will accelerate processes. In addition, voice recognition tools specifically developed for medical use can replace manually recording diagnoses and clinical notes (Ramaiah, 2010, p. 22). In general, digital documentation counts as the key area to generate efficiencies (Newkirchen & Elsner, 2018, p. 4).

Billing. Transparency of costs and billing modules within EHR systems allow for easier facilitation with medical payments (Van, 2016) because EHRs can facilitate communication and billing with different payers. Additionally, automated diagnoses and billing code transcription within billing documentation reduce billing errors. Moreover, electronic eligibility verification saves time and resources and positively impacts revenues and claims management because patients are able to prequalify prior to receiving treatment (Ranjan, 2018).

Value-based Payment. EHR adoption rewards PCPs for high performance and health outcomes (Bardach et al., 2013, pp. 1056-57). This is due to financial incentives set by the CMS within the 'meaningful use' and interoperability programs of EHRs and the value-based programs within the ACA. Participating in value-based care impacts processes because providers are focused on delivering efficient care.

Coordination and Disease Management. As the number of chronically ill patients increases (Raghupathi & Raghupathi, 2018), their care management demands increase. As chronically ill patients are treated by multiple providers and have to track multiple drug prescriptions, they require a high level of care coordination. Therefore, PCPs serving as gatekeepers can support care coordination. Immediately available data, smoother flow of information, and mailings or virtual consultations all enhance individualized patient care. Additionally, patient portals promote patient's self-management of chronic conditions and the quality of care through process improvement (Kruse et al., 2015, p. 7).

Treatment, Medical Decision Making and Reduction in Medical Errors. Since all health data are recorded in an EHR, PCPs have a broad overview on an individual's health. This enables PCPs to focus on preventive care. Through meticulous documentation, adherence to preventative care guidelines can be tracked such as the completion of recommended and required vaccinations (Makam et al., 2013, p. 3). EHR systems can also strengthen medical guideline adherence and the reduction of drug-drug interactions. EHRs are able to look for any possible risk associated with prescribing a new medicine and directly inform the physician on potential conflicts (Ranjan, 2018). In addition, prescribing drugs digitally improves the accuracy of data and significantly helps prevent prescribing inappropriate medication to patients. One key feature of EHRs are medical decision support systems which assist PCPs in making an accurate diagnosis and help them find the proper treatment (Berner, 2006, p. 1167). As a result, a reduction in medical errors enhances health outcomes and the PCPs revenue. Furthermore, collecting medical data and physician-generated knowledge through EHR use helps to develop additional medical guidelines, evidence-based medicine, and best practices, which then can then lead to process improvements (Nemeth et al., 2008, p. 2).

3.3 Challenges of EHRs

Although the adoption of EHR systems is associated with many advantages and is of high value to primary care, there are a few obstacles that remain.

Financial. Costs associated with EHR system purchases, implementation, and maintenance are as the largest barrier to adoption (Newkirchen & Elsner, 2018, p. 5). The astronomical start-up costs and unintended costs are huge obstacles on implementation (Samantaray et al., 2011, pp. 354-357). The establishment of an exact overview on expenditures associated with EHR adoption such as costs for hardware, software licensing, Internet access, expenses on additional devices or infrastructure fees, and IT specialist or technical assistance fees seem to be important to PCPs and serve as a primary barrier. Hence, monetary incentives might be necessary to convince PCPs to consider adopting an EHR. Aside from the high initial expenditure, PCP are also unsure if EHRs result in significant savings when replacing paper-based records (Kakic, 2018). Thus, their concerns often might have a negative impact on their bottom line. This is due to the concern that patient volume is decreasing through digital solutions within EHRs, decreasing Medicare compensation, and increasing malpractice costs with respect to implementation of value-based payments (The Commonwealth Fund, 2005).

Interoperability. The second major obstacle is lacking interoperability between different EHR systems, as this negatively affects primary care processes if connectivity and data exchange cannot be ensured (Wang & Huang, 2012, p. 2255). Interoperability is the key to gathering patient information and health data in order to establish a single universally accessible database. EHRs are not always effortlessly available and accessible by mobile or other devices (Newkirchen & Elsner, 2018, pp. 2-5).

Technical. If EHR systems suffer from complexity, PCPs are unlikely to adopt them. Although there are already many EHR systems offered within the U.S. market, further development is still needed as systems are rising in complexity (Heimly et al., 2011, p. 361). EHRs often lead to long documentation time during appointments and after the end of a shift, which is a disadvantage (Newkirchen & Elsner, 2018, pp. 2-5). Inefficient use of templates due to poor design negatively affects primary care processes. In general, if an EHR system has technical limitations such as a lack of standards and functionalities or poor reliability, its adoption will be rejected. In addition, the success of adoption depends on know-how, motivation and skills of the PCP team (McAlearny et al., 2013, pp. 3-5). To profit from EHR use in process optimization, substantial IT expertise will be needed (Hummel & Evans, 2012, p. 7).

Data Privacy and Security. Legal aspects, such as data privacy and security are additional obstacles (Almulhem, 2011, p. 1). Patient health data is highly sensitive and as the number of digital health solutions increases, the need to ensure data security does as well (Newkirchen & Elsner, 2018, pp. 2-5). Data privacy and cybersecurity must be obtained as PCPs exchange this data with other stakeholders. The adoption of EHR systems will be greatly affected should their security be comprised (Almulhem, 2011, p. 9).

4 Discussion

Considering the previous analysis, it can be concluded that benefits of EHR system adoption outweigh the obstacles. EHRs can transform processes through more efficient flow of information within a digitally connected health care system. As health data is available for any user at any time, care becomes more transparent. Better care coordination, communication, workflows, and patient empowerment over time can result in process efficiencies, cost savings and improved health outcomes. In summary, the results show that EHR adoption in the long term optimizes processes in primary care (Wang & Huang, 2012, p. 2255). In order to ensure the success of EHR adoption, PCPs need enough time on selecting a vendor and appropriate support by experts (McAlearny et al., 2013, p. 3). The risk of selecting an inappropriate vendor could be reduced by setting standards and optimizing interoperability between different EHR systems (Bates et al., 2003, pp. 6-7). As a result, data security and cybersecurity considerations must be ensured. The integration of EHR systems in the routine workflow might be challenging at the beginning, but in the end, it reduces time spent on documentation and enables more face-to-face time with patients.

Using *Rogers* model on the innovation-decision process this highlights the complexity of the *Implementation*-stage. Before adoption, workflows must be analyzed as benefits shall be achieved (Deloitte, p. 7). This will often require the involvement of the whole care team (Nemeth et al., 2008, p. 6). Only if staff members have the necessary *Knowledge*, the decision process can start. Understanding and using EHRs right is inevitable as knowledge and skills of staff affect its success. Ensuring continuous support, such as individual trainings, impacts *Persuasion*. In addition, adoption-relevant characteristics, as a high advantage, high compatibility or low complexity must be complied in the *Persuasion*-stage. Although a high advantage is given through increase in efficiency of workflows and office visits, there still somehow remains complexity within EHR systems. This complexity could be reduced by developing standards and improving user interfaces (Heimly et al., 2011, p. 361). Developing standards and improving user interfaces can also promote interoperability.

To further promote the *Implementation*-stage, national strategies on advancing connectivity and interoperability as set by the ONC are critical on realizing long term efficiencies and enabling data exchange (ONC, 2019, p. 1; Bates et al., 2003, p. 7). Financial incentives, as proposed by the CMS, promote nationwide EHR use among PCPs (Pizziferri et al., 2005, p. 183). There is a correlation between financial incentives and EHR adoption and is obvious in a significant increase since 2009 (Hsiao & Hing, 2014, p. 1). The adoption and diffusion of EHRs in primary care has been an objective of the U.S. federal government since 2004 (Crosson et al., 2012, p. 221). Since then, a universal EHR system in the U.S. should have been implemented within ten years.

Through the HITECH Act in 2009, the Obama administration again began increasing EHR use through setting financial incentives for physicians and 'meaningfully use' EHRs. The slow adoption of EHRs between 2004 and 2009 can be explained by the fact that only *early adopters* were adopting EHR systems. In general, it is assumed that governmental regulations and processes result in the slow diffusion and complexity of EHR systems. As *critical mass* has passed since 2009, the adoption rate has steadily been increasing. Research shows that the diffusion of EHR systems in primary care will follow Rogers' *s-curve* for the diffusion of innovations. Although full coverage of EHR adoption has not yet been achieved, it can be assumed that full market share will be achieved due to digitalization.

5 Conclusion and Recommendation

This paper intends to evaluate the effects of EHR implementation on processes in primary care, and the analysis reflects that EHR systems positively impacts processes in primary care. Immediate availability and accessibility of health data and its exchange will enhance overall quality and efficiency of care. Communication with patients, other health care providers, and payers are being optimized through digital tools. Additionally, coordination of care can be enhanced among management of all diseases. As patient empowerment increases, telemedicine or virtual consults relieve physicians' workflow, which ultimately decreases the total number of office visits. Medical decision support systems enhance medical guideline-adherent therapy and help physicians in identifying the appropriate diagnoses and treatment. In addition, administrative processes such as billing are being facilitated through EHR adoption.

Despite the gains that EHR systems provide, several barriers exist among their implementation and use. These are financial obstacles to consider such as initial start-up costs and ongoing management costs. In addition, lack of interoperability discourages PCPs. Data security and protection must be obtained because health data are highly sensitive. Technical barriers to EHRs like complexity, lack of standardization, and poor technical expertise are additional obstacles to be considered. Since the EHR outreach and diffusion has been significantly increasing through financial incentives by the CMS, it is essential to further expand government programs to achieve nationwide participation in EHRs.

Finally, the implementation of EHRs in primary care has many positive impacts on processes in primary care. Some challenges such as data privacy, financial risks, and interoperability must be overcome to ultimately benefit PCPs. Since EHR adoption is inevitable, appropriate ways must be found to address these challenges. Thereby, government and vendors should proactively seek physician feedback to constantly optimize and improve on EHR systems. Moving to a unified EHR platform and developing standards to secure data exchange, is one way to potentially solve interoperability issues.

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Melina Ledeganck was born in 1993 in Düsseldorf. From 2014 to 2017 she completed her undergraduate program in Health Care Economics at the 'Hochschule RheinMain' University of Applied Sciences in Wiesbaden, graduating with a Bachelor of Science. In 2017, she started her residential master´s program in Health Economics and Management at the University of Bayreuth. While completing her academic programs, Melina has interned at a large statutory sickness fund, a consulting firm and a hospital. Since January she works as an intern at the Federal Joint Committee in Berlin. Melina´s main areas of interests include health policy and the digitalization in the health care sector.

Alexandra Lehmann

Alexandra Lehmann was born in 1996 in Bayreuth. She studied Health Economics and Management at the University of Bayreuth and graduated with Bachelor of Science in 2018. Her bachelor thesis focused on how the impact of mobile Health changes clinical care. Currently, she studies Health Economics and Management in the master´s program. She has gathered practical experience in the healthcare sector by completing several internships e.g. at SeniVita in the field of Quality Management. Since 2018 she is a working student at Siemens Healthineers and a treasurer of the AKGM, a student body for Health Economics and Management. Her main interests are digitization in the Health Care System, as well as the medical technology industry.

Marina Michelis

Marina Michelis was born in 1988 in Manschuk Mametowa, Kazakhstan. She moved to Germany in 1995. At the age of 17 she started an apprenticeship as a nurse at St. Marien – Hospital in Bonn and began working there in 2009. Meanwhile she graduated from Abendgymnasium Siegburg with a university – entrance diploma. In September 2015, she enrolled in the bachelor´s degree Health Economics and Management at the University of Bayreuth. In December 2018, she finished her bachelor´s degree and stayed for the master´s program Health Economics and Management. During her studies, she completed an internship in quality management at the teaching hospital Cologne. Marina is interested in hospital administration and management, the healthcare insurance area and eHealth.

Moritz Reinsch

Moritz Reinsch studied health economics and management (B.Sc. / M.Sc.) at the University of Bayreuth and the University of Michigan, USA. After completing his bachelor´s degree, he was responsible for the portfolio planning, market entry and business development of telehealth products. Now he is working as a consultant for Siemens Healthineers Value Partners and brings in a broad expertise in both strategy and process consulting for providers. Moritz is specialized in digitalization, project management and M&A projects. His research interests are in the field of digital transformation and the diffusion of innovations across health systems. You may find him on LinkedIn for follow – up discussions: goo.gl/q36nYF.

Verena Schiefelbein

Verena Schiefelbein, born in 1995 in Munich, is a second-year graduate student in Health Economics and Management at the University of Bayreuth. She graduated with Bachelor of Science in the same field in 2018. While doing her bachelor, Verena was an international student at the Unversitat Politècnica de València in Business Administration and interned at the Schön Klinik in Munich in the Controlling Department. During her master´s degree, Verena was a visiting scholar at the Gillings School of Public Health at the University of North Carolina in Chapel Hill and gained deeper insights into the American Healthcare System. Since 2016, Verena is a research assistant at the University of Bayreuth. She is especially interested in hospital management, consulting, and the comparison of different healthcare systems. Therefore, she wants to work abroad to focus on international health care systems and operations.

Lara Schmidt

Lara Schmidt, born in 1996, finished her A – levels in 2014. After that, she started her academic studies in Social – and Health Care Management at the University of Applied Sciences in Emden, graduating with Bachelor of Arts in 2018. During her bachelor studies Lara did an internship in the sector of corporate health management at one of the largest public health insurances in Germany. In 2017 she also took the chance to study abroad and spent one semester at the Institute of Technology in Tralee, Ireland. Currently she is enrolled in the master´s program in Health Economics and Management at the University of Bayreuth. Her main interests are digitization in the health care system and health policy challenges.

Theresa Schröder

Theresa Schröder was born in Berlin in 1996. After finishing her A – levels she studied Health Economics at the Fresenius University of Applied Sciences in Hamburg where she received her bachelor´s degree in 2017. Currently, Theresa is enrolled in the master´s program of Health Economics and Management at the University of Bayreuth. Through internships in the management department of a maximum care provider in Hamburg and in the health department of an European research institution, she has been able to gain deep insights into various health areas. She is particularly interested in the interface between outpatient and inpatient care, as well as process improvement within medical companies.

Dominik Seitz

Dominik Seitz studied Health Economics and Management at the University of Bayreuth. Since 2016, he has been working as a teaching and research assistant at the Chair of Healthcare Management and Health Services Research under the direction of Prof. Dr. Dr. Klaus Nagels. His research focuses on the digital transformation of outpatient care and its effects on physician-patient relationships. The focus of his teaching is on business models and health services research. Since 2018, he has also been working for medatixx GmbH & Co. KG, a major German manufacturer of practice management software.

Laura Trinkwalter

Laura Trinkwalter was born in 1994 in Lichtenfels (Germany) and completed her bachelor´s degree in Health Economics and Management at the University of Bayreuth in 2018. During her studies Laura gained practical experience in the healthcare sector by completing several internships. She was employed by Schoen Clinic, the largest family-run hospital group in Germany. To increase her knowledge in the German healthcare sector even further, Laura subsequently started her master´s program at the University of Bayreuth. After an internship in the Financial Accounting/ Controlling Department, she now writes her master´s thesis in cooperation with a specialized oncological hospital. Her main interest lies in hospital management and consulting.

Tina Zeilner

Tina Zeilner was born in 1994. She began studying Health Economics and Management in October 2015 and will complete her bachelor´s degree in April 2019. She is currently writing her bachelor thesis that focuses on cost effectiveness of bariatric surgery in adolescents. Afterwards, she intends to enter the subsequent master´s program in Bayreuth. In addition to her studies, she has gathered practical experience as an intern in the hospital sector at a hospital of the Sana Klinikum AG. Tina´s main areas of interest are health insurance as well as public health issues. Therefore, she is planning to do an internship at an insurance company to deepen her knowledge in this area.

Anna-Maria Zierenberg

Anna-Maria Zierenberg, born in 1990 in Berlin, studied Health Economics and Management at the University of Bayreuth and is currently pursuing her master´s degree. She has deepened her knowledge of economic sciences as a one-semester exchange student at the University of Economics – Varna, Bulgaria in 2016. Her attention to health care economics was attracted while doing a three – year traineeship as a social insurance clerk at the health insurance company Techniker Krankenkasse where she continued working while studying. Based on this, her main interests are now international health care and health insurance systems, as well as health service research.

Crossing Borders – Health Reform in the U.S.

This edited volume is a product of the undergraduate and graduate students from the University of Bayreuth who participated in a study tour to the U.S. to learn about the country's health reform efforts. Through writing about their experiences the students had a chance to reflect on the enormous amount of information they were exposed to during their time in the U.S. Students were free to choose a topic for their essay and to decide on the focus of their work. They all invested substantial amounts of time and effort to present their thoughts and reflections in a clear and informative manner. Nonetheless, this volume does not aim at presenting a comprehensive overview of the U.S. health care system. Rather, it gives an impression of what the students took away from ten extremely intensive days in the U.S. For the reader this volume offers the chance to get an up-to-date overview on a range of topics that shape current U.S. health policy.

PD Dr. Andreas Schmid is project manager at Oberender AG and senior lecturer for Health Economics and Management at the University of Bayreuth. He studied Health Care Management and Economics and was a Visiting Scholar at the Department of Health Policy and Management at the University of North Carolina at Chapel Hill. His research focus is on the coordination, collaboration and payment of health care providers.

Bruce Fried, PhD, is Associate Professor in the Department of Health Policy & Management in the Gillings School of Global Public Health at the University of North Carolina at Chapel Hill. His areas of interest include comparative health systems, the healthcare workforce, quality improvement in low-resource settings, and the impact of globalization on population health.

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