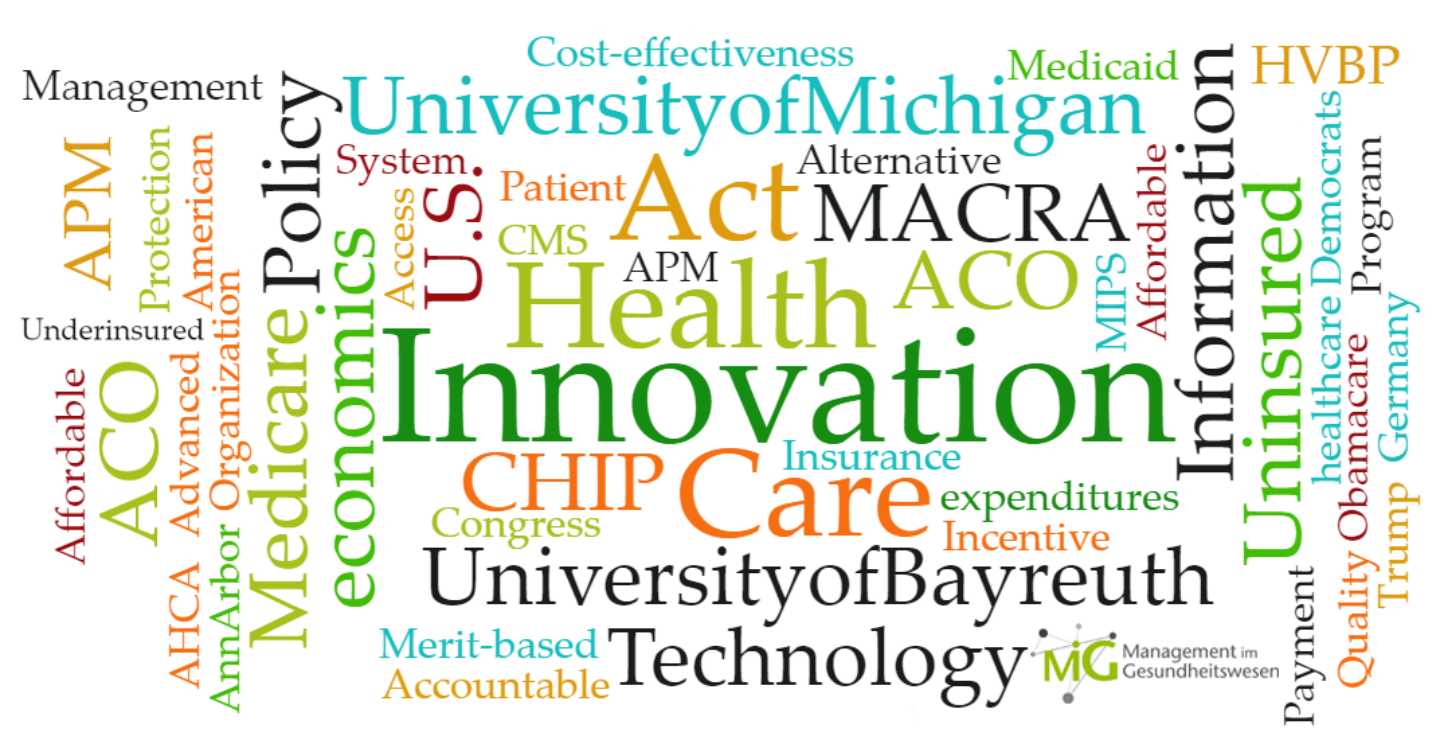

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Crossing Borders – Innovation in the U.S. Health Care System

Edited by

Andreas Schmid and Simone Singh

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Editorial
Crossing Borders - Innovation in the U.S. Health Care System

Simone Singh 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 an exchange program between the Health Economics and Management Program of the University of Bayreuth and the University of Michigan Department of Health Management and Policy. Since 2004, this collaboration has encouraged the exchange of thoughts and ideas between students and faculty from both sides of the Atlantic. During their most recent visit in the U.S. the group from Bayreuth encountered a health care system at a crucial crossroad.

The Affordable Care Act (ACA), the sweeping health care law passed in 2010, has had a tremendous impact on the delivery and financing of health care in the U.S. First and foremost, the ACA has expanded health insurance coverage to millions of previously uninsured Americans. A second important goal of the ACA has been to test and implement innovative ideas for improving care coordination and reducing the high cost of health care in the United States. These efforts have fostered the development of new and innovative payment systems, including bundled payments for episodes of care and value-based payment components, by both public and private health insurers. Health care providers are responding to this changing environment by designing innovative models for delivering care to their patients that simultaneously address the need to improve the quality of care while containing costs, such as Accountable Care Organizations (ACOs) and Patient-Center Medical Homes (PCMHs). The med-tech industry are adapting by developing new business models. At the same time, the future of the ACA is more uncertain than ever. The Trump administration has begun to take steps to repeal and replace the law but the details of a replacement bill have yet to be negotiated. Given the tremendous changes that U.S. health care system has been undergoing there is much to learn – for Americans and international visitors alike. In March 2017, 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 Michigan (UM), this excursion aimed to provide participants with a wide variety of opportunities to learn about health, health care, and health policymaking in the U.S. The tour started in Ann Arbor, where Bayreuth students and faculty had a chance to meet and interact with students and faculty in the Department of Health Management and Policy (HMP) at UM. During the first several days, HMP faculty took the time to provide the Bayreuth visitors with introductory overviews of the U.S. health care system to set the stage for

the many site visits, expert presentations, and group discussions that the group participated in during their time in the U.S. The tour then extended from Ann Arbor to Pittsburgh and Washington, DC.

During their time in the U.S. the Bayreuth group had a chance to meet and engage in discussions with many inspiring people including:

Bethany Lee-Lehner	Director of Patient Education and the Mardigian Wellness Center of the Frankel Cardiovascular Center, University of Michigan Health System
John Popovich	President and Chief Executive Officer, Henry Ford Hospital Detroit
Dave Fisher	Government Affairs and Policy, Siemens Healthineers
Denise Pike	Development Director, Community Health and Social Services (CHASS) Health Center
Elanor Kerr	Government Affairs and Policy, Siemens Healthineers
Elliott Attisha	Associate Medical Director, School-Based and Community Health Program, Henry Ford Health System
James Pitcavage	Strategic Program Director, Geisinger Health System
Jersey Liang	Professor of Health Management and Policy, Department of Health Management and Policy, University of Michigan
Jim Jordan	President & CEO of Pittsburgh Life Sciences Greenhouse, Distinguished Service Professor of Healthcare & Biotechnology Management and Sr. Director of Healthcare & Biotechnology Programs at Carnegie Mellon University
Joe Marks	Executive Director of the Center for Machine Learning and Health at CMU, Pittsburgh Health Data Alliance
Joneigh Khaldun	Executive Director and Health Officer, City of Detroit Health Department
Kimberlydawn Wisdom	Senior Vice President, Chief Wellness and Diversity Officer, Henry Ford Health System
Louisa Laidlaw	Administrative Fellow, Henry Ford Hospital and Health Network
Mark Esherick	Government Affairs and Policy, Siemens Healthineers
Mohsin Hashmi	Kaiser Permanente Center for Total Health
Noam Kimelman	Co-Owner, Fresh Corner Cafe
Pauline Do	Administrative Fellow, Henry Ford Hospital and Health Network
Peter Jacobson	Professor of Health Management and Policy, Department of Health Management and Policy, University of Michigan
Robert E. Moffit	Senior Fellow in The Heritage Foundation's Center for Health Policy Studies
Steve Phillips	Government Affairs, Johnson & Johnson
Terrisca Des Jardin	Administrative Director Physician Organization of Michigan ACO

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

Simone Singh
(University of Michigan at Ann Arbor)

Andreas Schmid
(University of Bayreuth)

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Generous financial support for the students who participated in this study tour was provided by Siemens Healthineers, AKGM e.V., International Office and Tuition Fee Commission of the University of Bayreuth and RWalumni. Your contributions ensured that no participant had to refrain from this excursion for financial reasons. Sincere thanks for the support!

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The study tour was organized by Prof. Dr. Andreas Schmid, Assistant Professor Health Management, University of Bayreuth (www.mig.uni-bayreuth.de) in close collaboration with Prof. Dr. Simone Singh, Assistant Professor, Department of Health Management and Policy, University of Michigan School of Public Health.

UNIVERSITÄT BAYREUTH

SCHOOL OF PUBLIC HEALTH HEALTH MANAGEMENT & POLICY UNIVERSITY OF MICHIGAN

MG Management im Gesundheitswesen

Part 1: The U.S. Health Care System at Crossroads

Introduction to the U.S. Health Care System

Meltem Sezer and Franziska Bauer

One of the key topics of political discussion in the U.S. these days is its healthcare system. Most recently, "repeal and replace" has been the pivotal issue of political debate. The urge to reform the Affordable Care Act comes not from its many accomplishments, such as reducing the uninsured rate, but from what still needs improving: healthcare costs and spending. In this context, the "Triple Aim" approach is the center of focus within the healthcare system and will be portrayed in this essay after giving a short overview of the U.S. healthcare system itself. The framework of the "Triple Aim" consists of goals aiming to improve the experience of care and health of the population at a lower per capita cost. Providers of the U.S. healthcare organizations are being paid by a hybrid structure with different insurance forms existing parallel to each other, resulting in an inefficient and extremely fragmented healthcare system. Like most other countries, there are both private and public insurers in the U.S., with payments coming from two main sources which will be explained in this essay. Political efforts play a big role in the American healthcare system. Health insurance marketplaces initiated by the Affordable Care Act come short of achieving managed competition where choice drives efficiency. High administrative costs also contribute to the current inefficiency of the American healthcare system, making it difficult to reach the Triple Aim. The goal of the Trump Administration to change regulations of the Affordable Care Act could not be reached either, letting the final structure and outcome of the U.S. healthcare system be unknown.

Contents

1 Introduction

Political debate over the U.S. healthcare system is a constant throughout the public space, media commentary, and the legislative bodies themselves. Most recently, "repeal and replace" has been the major topic of discussion, reignited by the transfer of governmental power from one party to another. The urge to reform the Affordable Care Act (ACA) comes not from its many accomplishments, such as reducing the uninsured rate, but from what still needs improving: healthcare cost and spending. The U.S. spent 17% of its gross domestic product (GDP) on healthcare in 2013, which correlates to twice the average of all Organization for Economic Cooperation and Development (OECD) countries (OECD, 2015). From 2015 to 2025, healthcare spending growth is projected to be an average of 5.8% or 1.3% faster than the growth in GDP, suggesting that by 2025 the U.S. will spend 20.1% of its GDP on healthcare (Keehan et al., 2016, p. 1,522). Despite the rising costs, the U.S. population faces poorer health outcomes than other high-income countries such as Germany or the UK. When it comes to infant mortality, the U.S. leads the ranking with 6 deaths per 1,000 live births, whereas in Germany (or the UK) 3.2 (or 3.9) infant deaths occur per 1,000 live births. In terms of life expectancy at age 60, the U.S. ranks last with 23.6 years compared to 24.1 years in the UK (Schneider et al., 2017, pp. 4-24). The aim of this essay is to give a short overview of the U.S. healthcare system, especially recent developments and new health insurance markets, to understand the reasons for the exorbitant cost Americans pay for inefficient healthcare and to argue whether the Triple Aim approach is observed in action.

2 Overview of the U.S. health care system

Compared to many of the other OECD countries, U.S. healthcare has no uniform, nationwide system. The U.S. hosts a hybrid payment structure with different insurance forms existing parallel to each other, resulting in an inefficient and extremely fragmented healthcare system (Schmid and Himmler, 2015, p.11). Additionally, no universal healthcare coverage is given in the U.S. As with most other countries, there are both private and public insurers in the U.S. healthcare system, with payments coming from two main sources:

- Public: Centers for Medicare and Medicaid Services (CMS)
- Private: State-Specific Nonprofit Blue Cross Blue Shield and Private Commercial Insurers

Insurance choice is influenced by a number of factors, including age, income, geography, employment status, and disability (Doonan and Katz, 2015, p. 747). Both private and public health insurance programs differ in regard to the benefits covered, financial sources, and payments to healthcare providers (De Lew et al., 1992, p. 151). Persons

without any health insurance can seek care from safety-net health systems that deliver essential services through inpatient, emergency, and ambulatory care. Core safety-net providers offer access to care regardless of a patient's ability to pay and have a patient population consisting mostly of uninsured or Medicaid patients in addition to patients who are ineligible for coverage under public programs. These individuals depend on subsidies and charity to bear the rising healthcare costs, which results in low operating margins at safety-net facilities (Chokshi et al., 2016, p. 1,790).

With the implementation of the ACA, the U.S. population was introduced to a new option for getting access to health insurance. However, this system is currently targeted to be repealed and replaced under the Trump Administration (Graves and Nikpay, 2017, pp. 297-304). The ACA health insurance marketplaces in place are accessible via websites and toll-free numbers enable insurance coverage independent of pre-existing conditions. The system provides consumers with choices, increasing competition between insurers which theoretically reduces cost, maximizes quality, and increases the number of insured persons (Doonan and Katz, 2015, pp. 749-752). Insurers can combine the small individual insurance market with the also small group insurance market into one risk pool, reducing payer risk and increasing the number of consumer choices (Doonan and Katz, 2015, pp. 749). For further analyzing of these marketplaces, see section 5 in this essay.

A new healthcare delivery concept initiated by the ACA is an Accountable Care Organization (ACO), a clinical care enterprise that influences provider financial risk by incentivizing improvements (Rosenbaum, 2011, pp. 875-876). An ACO can be defined as a healthcare delivery system with either a Medicare or private payer payment model as well as a network of providers responsible for the cost and quality of care for a defined groups of patients (Rosenbaum, 2011, p. 875). Inspired by private-sector examples of integrated health delivery system, such as Kaiser Permanente and Geisinger Health System, the goal of an ACO is to provide financial incentives for coordinated, deliberate use of adequate high quality care (Frakt and Mayes, 2012, p. 1,954). Section 4 in this volume provides a more detailed insight into this health care delivery form.

3 Triple Aim

When talking about goals in the healthcare system, a widespread term in the U.S. is the Triple Aim. The Triple Aim is a term originated by the Institute for Health Improvement (IHI) that it defines as, "A framework for optimizing health system performance," aiming to (1) improve the experience of care, (2) enhance the health of the population, and (3) reduce the per capita costs of healthcare. As independent goals, movement towards achieving one goal can affect the other two positively or negatively, making it essential that all three components are balanced in order to optimize the healthcare system. Pre-

conditions for reaching the three goals include the enrollment of an identified population, a commitment to universality for its members, and the existence of an organization (an integrator) that assumes responsibility for all three aims for that population.
In the U.S., the pursuit of the Triple Aim is facing a variety of obstacles which need to be overcome: supply-driven demand, physician-centric care, many new technologies that show limited impact on outcomes, little or no foreign competition to spur domestic change, and little appreciation of system knowledge among clinicians and organizations (leading them to sub-optimize the components of the system with which they are most familiar at the expense of the whole) (Berwick et al., 2008, p. 760). Similarly, the pursuit of the Triple Aim is also a question of political barriers since the effects of its vision includes disruption of the status quo in institutions, forms, habits, and income streams (Berwick et al., 2008, p. 768). Also absent, but necessary, is a focus on primary care and public health which must be developed (as a building block for high quality care) (Rice et al., 2014, p. 894).
One of the founders of the Triple Aim is Dr. Donald Berwick, who was recruited by former President Barack Obama in July 2010 to serve as the Administrator of the CMS. Berwick and his colleagues derived the Triple Aim strategy from IHI's leadership in measuring and improving the quality of care after having worked at IHI for decades. After Berwick left the Agency in 2011 (because of Senate Republicans refusing to confirm his nomination), the Triple Aim still remained a priority for CMS and the U.S. healthcare system (Fox and Grogan, 2017, pp. 32-33).

4 Providers in the U.S. Health Care System

4.1 Hospitals

Regarding providers of healthcare in the U.S., one can distinguish between primary providers (organizations providing health services) and secondary providers (organizations providing financial, educational or technological resources) (Janus, 2003, p. 120). This section will focus on the primary providers of the American healthcare system.
In 2017, more than 5,500 hospitals with about 900,000 beds were registered throughout the country (AHA, 2017a). Most of these are non-profit hospitals (Phelps, 2013, p. 214). With a total of 4,862, the majority of the hospitals are community hospitals, followed by 401 registered nonfederal psychiatric hospitals, 212 federal government hospitals, 79 nonfederal long-term care hospitals, and about 10 hospital units within institutions (such as prison hospitals) (AHA, 2017a). The community hospitals are nonfederal and provide mainly acute, short-term care. Often, they also function as academic medical centers where medical staff is trained (Folland et al., 2007, p. 294). Currently, 59% of the community hospitals are owned by non-government, non-profit institutions, 21% are owned

by profit seeking companies, and 20% are owned by state and local governments (AHA, 2017b).

Two classifications of medical treatment in hospitals can be distinguished: (1) inpatient care and (2) outpatient care. The first represents the more traditional case where patients stay in the hospital for more than one day, whereas the second represents a patient's intra-day treatment with no overnight stay included (Phelps, 2013, p. 233). In the past 30 years, the core function of hospitals has changed dramatically. Hospital utilization, lengths of stay, and surgeries have decreased considerably. Instead of the traditional inpatient treatment path, the number of outpatient medical procedures has increased (including outpatient clinics, emergency departments, outpatient surgeries, and other examples). Since 1975 outpatient visits have risen from 254,814 to 637,689 in 2005, which amounts to an inflation of about 165% (Phelps, 2013, p. 233).

4.2 Physicians

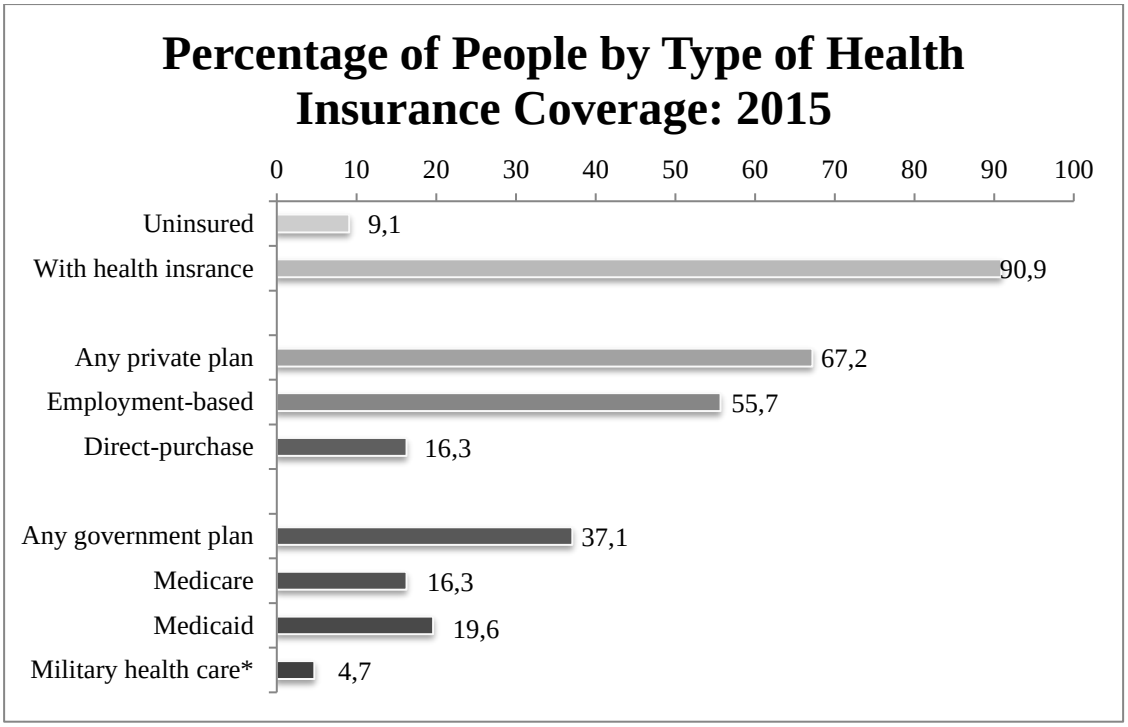
Several decades ago, the vast majority of physicians were in private practice and paid on a fee-for-service (FFS) basis. They could provide care to their patients in their offices and admit them to hospitals where they could personally serve them further (De Lew et al., 1992, p. 151). Nowadays, most physicians have negotiated third-party contracts with insurers and hospitals (Getzen, 2010, pp. 135-136). In 2010, the number of new doctors who started to work in hospitals exceeded the number of those who chose the work in a physician-firm for the first time in U.S. history (Ärztezeitung, 2012). In 2015, an AMA study found that nearly 57% of physicians worked in physician-firms (descending trend) and, in contrast, about 33% of the physicians worked directly for a hospital (ascending trend) (AMA, 2015).

In the U.S. healthcare system, a doctor in a hospital is not an employee, nor the owner of the hospital, since physicians function as independent economic entities (Janus, 2003, p. 123). Nevertheless, physicians in the U.S. often apply to the institutions in order to get access to hospital staff privileges and receive assignments for special procedures being practiced almost exclusively within hospitals. Yet physicians do not pay hospitals for the privilege of working there, rather the hospital functions as the doctor's "rent-free workshop" where the physicians get access to important resources (Folland et al., 2007, p. 296). It is another type of competition compared to other countries such as in Great Britain or Germany because in the U.S. the hospital does not hire physician, rather, it has to attract them. Evidently, without the service of a doctor, no hospital can provide medical treatment. However, because the two players do not directly exchange money, hospitals have to offer doctors other advantages to attract them, for example, by providing a high-tech environment, excellent nursing staff, and particular operating rooms and equipment. Hospitals aim to make themselves more attractive and ease the strain of medical practice while increasing profit (Phelps, 2013, pp. 239-240).

5 Health Insurance in the U.S.

In America, 28.5 million people remain uninsured, representing nearly 9% of the total population. For comparison, two thirds of the insured population is covered by private health insurance with the remainder covered under public insurance (Table 1) (Kaiser Commission on Medicaid and the Uninsured, 2016, p. 1).

Table 1: Percentage of People by Type of Health Insurance Coverage: 2015



Source: United States Census Bureau, 2016a.

A citizen has private coverage either through employment or direct purchase of coverage from a private company. Public insurance uses Tricare to cover those in military service and the Department of Veterans Affairs to cover military veterans[1]. The two pillars of public insurance are Medicare (primarily serving the elderly) and Medicaid (primarily serving poor persons). Medicare and Medicaid were both developed with the Social Security Act of 1965 and represent more than a third of national health spending today (Béland et al., 2016a, p. 92).

5.1 Public Health Insurance

Medicare is the predominant public insurance of the U.S. This national insurance program provides health insurance for people 65 years of age or older as well as for persons

1 The medical supply of the veterans, the military and their relatives is beyond the scope of this study. For more information look at Barnett and Vornovitsky, 2015, p. 1.

with disabilities, end-stage renal disease, and amyotrophic lateral sclerosis (CMS, 2014). With the original Social Security Act in 1965, Medicare consisted of two parts: Hospital Insurance (HI, which covers inpatient care, hospice care, and home health care) and supplementary medical insurance (SMI, which covers physician services, hospital outpatient care, and other services) (Jonas, 1998, p. 93).

2015 marked the 50th anniversary of signing the Medicare program into law. After 50 years of growth and development, 52 million Americans are covered by Medicare under one or many parts, most predominantly Parts A through D. All Medicare recipients have access to HI, also known as Part A, with all other parts coming at additional cost. Part B is for SMI, Part C is for Medicare Advantage plans, and Part D is for drug coverage. On average, Medicare Part A covers half of all expectant costs, forcing patients to cover remaining costs with supplemental Medicare insurance, separate insurance, or out-of-pocket spending (Cohzven et al., 2015, p. 15).

Medicaid is a welfare-based program that provides coverage for some health services to qualifying low-income people and those with disabilities (Cohen et al., 2015, p. 12). In 2014, 66 million people were covered by Medicaid, with applicants judged and placed in categories. Compared to Medicare, Medicaid covers a range of services that other government programs do not, including dental and long-term care coverage, but the program reimburses provider at a lower rate, thereby incentivizing providers to avoid Medicaid patients (Cohen et al., 2015, p. 14).

Medicaid functions as both federal and state-run initiative. The federal government creates general guidelines and mandates, while each state defines its own precise policy rules. The program is financed through federal, state, and municipal taxes with the federal government paying 50-80% of the total expenses for every state based on an agreed-upon-federal-state matching system. As a result, the financial health and stability of the program differs between states since Medicaid investments depend on the amount of federal funding received (Cohen et al., 2015, p. 14).

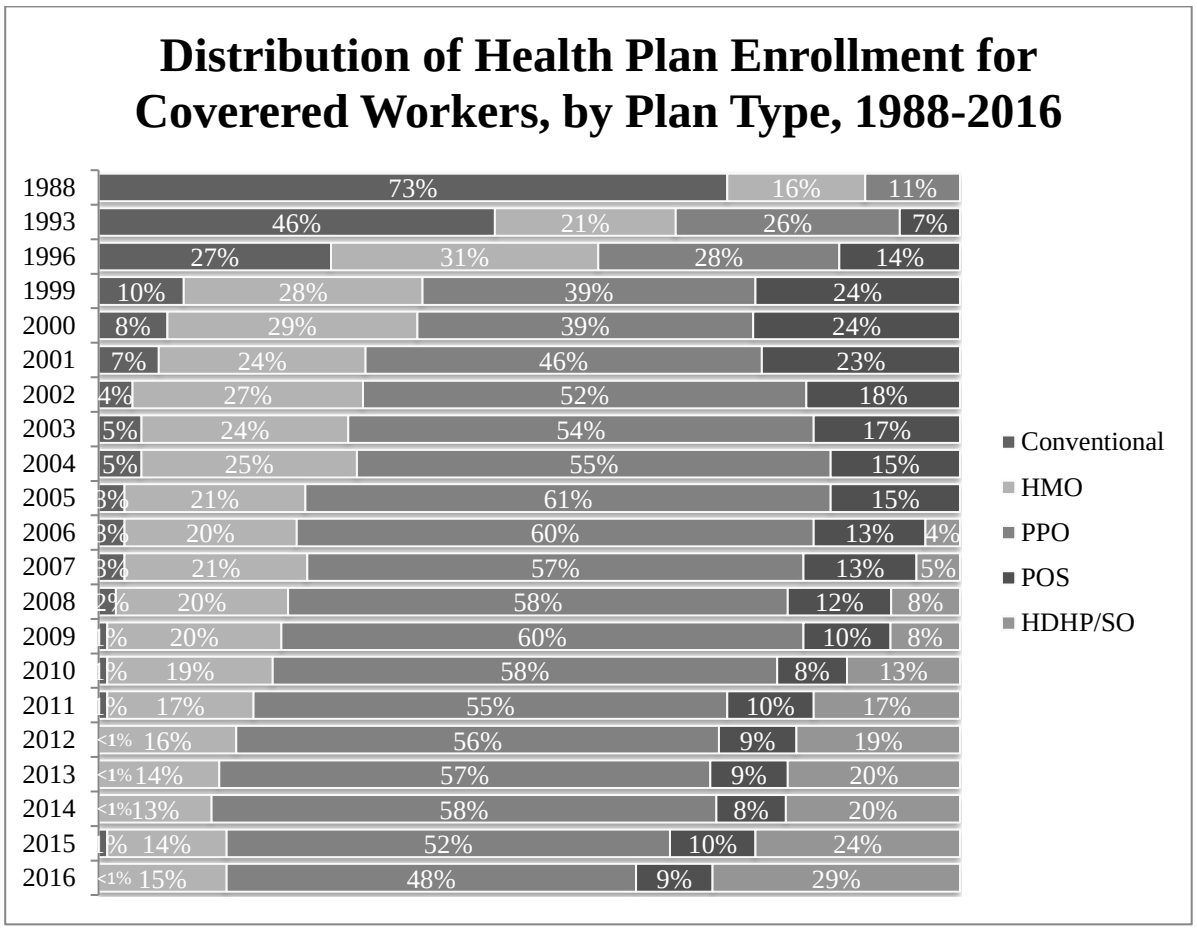
5.2 Private Health Insurance

In 2015, 67.2% of the American population had some kind of private health insurance coverage, with 55.7% of the population insured through employer-sponsored plans and the other 16.3% insured through direct purchase exchanges (Barnett and Vornovitsky, 2015, p. 1). The two biggest players in this sector are the 36 regional non-profit Blue Cross/Blue Shield organizations and large commercial for-profit companies (Blue Cross Blue Shield, 2017).

Private insurance coverage models have shifted over the last 30 years starting with the traditional FFS system chronologically trending towards the managed care or health maintenance organization (HMO) system, the preferred provider organization (PPO)

system, the points of service (POS) system, and the high deductible health plans (HDHPs, which are currently generating the most interest) (Table 2).

Table 1: Distribution of Health Plan Enrollment for Covered Workers, by Plan Type, 1988-2016



Source: Kaiser Family Foundation, 2016.

FFS is the easiest system to implement as it reimburses providers for every unit of care they offer, ensuring that they are fully compensated for their efforts. However, the system incentivizes providers to carry out the maximum volume of care without regard to its value, leading to high costs for the entire system while presenting limited value to its consumers.

In response, progressive provider organizations began the "Managed Care Movement" represented by the HMOs which became increasingly prevalent, even into today. The Managed Care Movement started in 1973 with the primary purpose of managing cost, quality, and access to health care. Additionally, it represents a spectrum of systems, which includes the previously mentioned private health insurance manifestations (HMOs, PPOs and POS plans) (Haubrock, 2000, p. 22).

To satisfy the movement toward managed care, the HMO Act was signed into law in 1973. Consequently managed care entities started participating in Medicare and Medicaid directly, controlling costs and clinically integrating healthcare delivery as early as the 1990s (Rosenbaum, 2011, pp. 875-876). Insurers began to influence healthcare delivery as many provider organizations created their own insurance platforms in order to reduce costs and maintain operating margins. However, a managed care backlash occurred in the late 1990s as operators of the HMOs deprived essential medical services to patients in order to maintain margins, inspiring distrust from patients (Schmid and Himmler, 2015, p.11). As a result, new forms of insurance coverage exist today that focus on the preferably full integration of coverage and care. The system pays providers less for the volume of treatment that they deliver compared to FFS, but offers providers the ability to recover those lost revenues through enhanced health promotion and care delivery for their patients. The system is capitated, meaning that the providers receive a fixed, covered budget through which all medical expenses must be paid. The advantage of this model is that the providers have the incentive to cost-effectively treat patients and save money by avoiding overtreatment in efforts to recover the unused part of the budget (Folland et al., 2007, pp. 242-243).

HMOs, on the other hand, restrict patient provider choice, requiring patients to stay within their network in an ambitious attempt to improve the value of care. Compared to the HMO model, the PPO model consists of groups of healthcare providers who have agreed with an insurance company or a third party administrator to provide care at a reduced rate to the insurer's or administrator's beneficiaries (Getzen, 2010, pp. 124-125). PPOs provide the most patient choice and have the highest beneficiary satisfaction rates in all categories besides cost, as such expansive selection often results in higher treatment costs. These organizations, due to their popularity among patients, currently represent 48% of all privately covered lives, the largest portion by far.

An attempt at an optimal system, the POS system, includes the positive aspects of HMO and PPO systems, such as the diminished costs, but inevitably carries some of the negative aspects as well, most significantly a diminished choice of providers for patients. Enrollees in a POS plan are requested to choose a primary care physician from within the plan's network, who acts as the patient's point of service. For care provided out of network, the insurer reduces provider compensation and raises patient out-of-pocket costs, encouraging both parties to stay within the network. In addition, the insurer performs all paperwork on behalf of the beneficiary for care provided in-network, whereas the patient handles those duties and the additional non-covered costs for care provided out-of-network (Health Coverage Guide, 2016).

In 2007, HDHPs with Savings Options were established on the private insurance marketplace. HDHPs are the only plans that allow an enrollee to contribute to health savings accounts into which they can deposit tax-exempt income to spend on future care tax-

free. These accounts are needed due to the plan's excessively high deductibles, which are more than $6,000 for an individual and $12,000 for a family. HDHPs only cover preventive care before the deductible is reached, meaning that the enrollee must pay for all not-preventive medical care out of pocket until the deductible is reached, after which point all care is covered based on the beneficiary's coinsurance rate. Fortunately, many HDHPs have complete coverage after the deductible, thereby covering catastrophes. These relatively new plans currently represent 29% of all privately insured patients, the second greatest portion of the sector (Health Insurance Resource Center, 2017).

5.3 The Problem of Uninsurance in the U.S.

In 2016, 29 million Americans, just under 10% of the population, had no health insurance for the entire calendar year. Although a significant number, it is a decrease of 13 million people since 2013 when the ACA took effect. The decrease is primarily the result of Medicaid expansion and private insurance enrollment through the exchanges. Being uninsured, especially in the U.S., is a major problem because it comes with many consequences: poorer health status, less healthcare access, less preventive care, delayed treatment for serious disease, poorer control of chronic diseases, and lower life expectancy (Kaiser Family Foundation, 2002). The majority of the uninsured are low-income adults and families that are either without access to or could not afford employer-sponsored coverage (Folland et al., 2007, p. 217). Additionally, some fall in the window between being too poor to afford private insurance but too rich to qualify for Medicaid, resulting in no coverage at all in the end. Illegal immigrants and those who do not legally qualify for insurance of any type in the country make up a small, but still significant, portion of the total uninsured population. Lastly, the prohibitively high cost of insurance causes some to risk paying out-of-pocket costs as opposed to risk-abating insurance, looking at it as a financial gain to go uninsured (Kaiser Commission on Medicaid and the Uninsured, 2016, p. 1).

6 Politics

6.1 Situation before the implementation of the ACA

Political measurements can lay the foundations for counteracting high rates of uninsurance. When President Barack Obama signed the ACA into law in March 2010, he fundamentally affected the future of healthcare in the U.S. Before the ACA, it was legal for insurance companies to practice Risk Rating in combination with Medical Underwriting. If insurers predicted higher costs for a person, they could look out for their own interests by lowering the number of these high-risk people they insured e.g. by denying them coverage (Doonan and Katz, 2015, p. 747). These tactics led to 47 million U.S. residents lacking insurance coverage before the ACA was implemented (Neuss, 2015,

p. 203). The uninsured had poor access to the services of private physicians, so these patients previously received care from safety-net providers such as federally qualified health centers, emergency rooms, and charity care. Although patients could buy insurance directly from insurers or through a state's high-risk pools, the high costs of both insurance and care itself made patient much more likely to skip seeking care altogether (Doonan and Katz, 2015, p. 747).

6.2 ACA

A major aim Barack Obama had during his presidency was to reform the fragmented U.S. healthcare system and move toward universal health insurance (Béland et al., 2016b, p. 42). In March 2010, he signed the ACA into law as the most significant health legislation since Medicare and Medicaid were established in 1965. Although it initiated much change, it had four main aspects which will be described in the following paragraphs.

First, the individual mandate requires all U.S. citizens and legal residents to either have insurance coverage that meets federally defined essential benefit standards of face a tax penalty. By requiring everyone to be covered, the pool of insured persons would be large enough for the cheaper, healthy individuals to cover the expenses for more costly, sick individuals (Béland et al. 2016b, p. 51).

Second, the employer mandate requires employers with more than 50 employees to either provide health benefits to full-time employees or face a steep financial penalty. By forcing employers to provide insurance to their employees, the number of insured persons increases (Kaiser Family Foundation, 2016b).

Third, the act expanded Medicaid coverage. As of now, 31 states have expanded Medicaid coverage in one way or another and received 90-100% of additional needed capital from the federal government (Béland et al., 2016a, p. 92). Not all states have chosen to expand coverage due to the Supreme Court decision *National Federation of Independent Business v. Sebelius* that ruled Medicaid expansion was a state right and therefore could not be forced upon states by a federal declaration.

Lastly, at a high, general level adolescents can stay on their parents' health insurance policies until age 26, caps on total insurance benefits and denial of coverage due to preexisting conditions have been eliminated, and the individual insurance marketplace exchanges have been established. The ACA also subsidizes insurance costs for low-income beneficiaries and requires all insurers to offer 10 essential health benefits, including maternity care and preventive services (Obamacare Facts, 2017).

However, as a partisan act, the ACA has received much criticism from the political right-wing supporters across the country. In 2013, during an episode of the NBC News, a Republican Representative stamped the ACA as, "The single worst piece of legislation that's been passed in modern times in this country." Nearly a year later, and for the

fiftieth time, the Republican-controlled House of Representatives voted to repeal or alter the ACA (Béland et al., 2016b, pp. 40-41).

6.3 Plans under the Trump Administration

On May 3, 2017, the House of Representatives passed the American Health Care Act (AHCA), which had the main purpose of repealing and replacing large fragments of the ACA. The bill was sent to the Senate for deliberation (Young, 2017). As explained above, the ACA requires individuals to gain health insurance and companies to offer it to their employees. The Republican bill was expected to repeal mandates that encouraged broader insurance coverage by imposing penalties. Such a step may have incited healthy people to stay uninsured, raising the prices for those who are older or sick. In order to limit unaffordability for those who need insurance, the Republican plan proposed a "continuous coverage incentive", charging residents in the individual market a 30% penalty for lapses in health insurance coverage (Park and Sanger-Katz, 2017). Federal funding animating Medicaid expansion (especially to cover low-income adults) would be reduced by capping it based on how much the state enrollees were living in was spending. After 2020, states that expanded Medicaid would receive less federal support, and those that did not undergo Medicaid expansion would be prohibited from doing so (Lee, 2017). Under the ACA, subsidies are tied to income and premiums, whereas the Republican bill would have provided U.S. residents with refundable tax credits to purchase health insurance, allotted mainly based on the age of the recipient. Some protections for those with pre-existing conditions would also be repealed: states could apply for waivers to allow insurers to offer slimmer policies, enabling them to charge higher premiums to those with chronic medical issues. Those states would then have to establish programs, such as high-risk pools, in order to protect insurers from patients causing high costs. Funds worth more than $130 billion would have been set up to finance and support high-risk pools and patients with pre-existing conditions (Lee, 2017). The provision in the ACA which lets children stay on their parents' insurance plans until the age of 26 would be one of the few pieces to not be repealed and replaced. However, this bill supported by the Trump Administration would have left 24 million fewer people insured by 2026 than under Obamacare (Lee, 2017).

On June 22, 2017, 13 Republican Senators drafted the Senate's substitute version of the AHCA, releasing the first discussion draft for an amendment to the bill (Ku et al., 2017, p. 2). However, this alternative was returned to the calendar on July 28, 2017 after the Senate rejected a third Republican amendment to repeal the ACA (Parlapiano et al., 2017). Since Donald Trump signed an executive order to change ACA regulations in the beginning of his time as President, it is presumable that the efforts to do so will continue in the future despite the fail of the AHCA (Amadeo, 2017).

7 Conclusion

All in all, the U.S. healthcare system is a fragmented complex that remains unclear in structure. Since the new AHCA has failed, it is unsure if future efforts will help to achieve the Triple Aim, but the U.S. healthcare system will likely face more problems if Congress is successful in repealing the major enhancements of the current system. Even after the passage of the ACA, the American healthcare system did not show any progress in terms of reduced costs. Expanded choice of insurance plans did not optimize quality of care at a lower cost. Large and small U.S. companies provided more insurance options for high deductible plans that have lower premiums, but higher out-of-pocket costs. As evidence indicates, these plans are more attractive to younger, healthier consumers, pushing older and sicker employees into conventional plans which raise their rates. High administrative costs also contribute to the inefficient healthcare system, making it difficult to reach the Triple Aim (Lave et al., 2011, pp. 139-144). To counteract higher costs, innovation centers were founded under the Medicare and Medicaid program as a result of the ACA. These centers are meant to establish measurable and lasting improvements in payment systems providers utilize. Ideally, payment should be linked to patient outcomes instead of merely services provided. However, the interests of the providers and those of patients differ strongly (Neuss, 2015, p. 2013). While the final structure and outcome of the U.S. healthcare system is unknown, these disagreements between providers, patients, insurers, and political parties will be instrumental in shaping the healthcare provided to Americans.

References

Amadeo, K. (2017), *Donald Trump on Health Care*, TheBalance [Online]. Available at: https://www.thebalance.com/how-could-trump-change-health-care-in-america-4111422 (Accessed August 08, 2017).

American Hospital Association (2017), *Fast Facts on US Hospitals*, American Hospital Association [Online]. Available at: http://www.aha.org/research/rc/stat-studies/fast-facts.shtml (Accessed July 31, 2017).

American Hospital Association (2017), *Number of U.S. Hospitals by Type (Total 5,564), FY2015*, American Hospital Association [Online]. Available at: http://www.aha.org/research/rc/stat-studies/pie%20chart%201%202017.pdf (Accessed April 16, 2017).

American Medical Association (2015), *AMA Study Finds Majority of Physicians Still Work in Small Practices*, American Medical Association [Online]. Available at: https://www.ama-assn.org/content/new-ama-study-reveals-majority-americas-physicians-still-work-small-practices (Accessed July 31, 2017).

Barnett, J. C. and Vornovitsky, M. S. (2016), *Health Insurance Coverage in the United States: 2015: Current Population Reports*, United States Census Bureau [Online]. Available at: https://www.census.gov/content/dam/Census/library/publications/2016/demo/p60-257.pdf (Accessed April 20, 2017).

Béland, D., Rocco, P. and Waddan, A. (2016), 'Medicaid Expansion: Take It or Leave It', in Béland, D., Rocco, P. and Waddan, A. (eds.) *Obamacare Wars*, University Press of Kansas, pp. 92–123.

Béland, D., Rocco, P. and Waddan, A. (2016), 'Uncertain Victory: The Political Context of Health Care Reform Implementation', in Béland, D., Rocco, P. and Waddan, A. (eds.) *Obamacare Wars*, University Press of Kansas, pp. 40–60.

Berwick, D. M., Nolan, T. W. and Whittington, J. (2008), 'The Triple Aim: Care, Health, and Cost', *Health Affairs*, vol. 27, no. 3, pp. 759–769.

Blue Cross Blue Shield (2017), *The Blue Cross Blue Shield System* [Online], Blue Cross Blue Shield. Available at: https://www.bcbs.com/about-us/blue-cross-blue-shield-system (Accessed July 29, 2017).

Centers for Medicare & Medicaid Services (2014), *Medicare Program – General Information* [Online], Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/Medicare/Medicare-General-Information/MedicareGenInfo/index.html (Accessed May 19, 2017).

Centers for Medicare & Medicaid Services (2015), *National Health Expenditures 2015 Highlights* [Online], Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/downloads/highlights.pdf (Accessed May 06, 2017).

Chokshi, D. A., Chang, J. E. and Wilson, R. M. (2016), 'Health Reform and the Changing Safety Net in the United States', *The New England Journal of Medicine*, vol. 375, no. 18, pp. 1790–1796.

Cohen, A. B., Colby, D. C., Wailoo, K. A. and Zelizer, J. E. (2015), 'Introduction – Medicare, Medicaid, and the Moral Test of Government', in Cohen, A. B., Colby, D. C., Wailoo, K. A. and Zelizer, J. E. (eds.) *Medicare and Medicaid at 50,* Oxford, Oxford University Press, pp. 11–20.

Doonan, M. and Katz, G. (2015), 'Choice in the American Healthcare System: Changing Dynamics under the Affordable Care Act', *Current Sociology*, vol. 63, no. 5, pp. 746–762.

Folland, S., Goodman, A. C. and Stano, M. (2007), *The Economics of Health and Health Care*, 5th edn, Upper Saddle River, Pearson Education Publishing Company.

Fox, D. M. and Grogan, C. M. (2017), 'Population Health during the Obama Administration: An Ambitious Strategy with an Uncertain Future', *American Journal of Public Health*, vol. 107, no. 1, pp. 32–34.

Frakt, A. B. and Mayes, R. (2012), 'Beyond Capitation: How New Payment Experiments Seek to Find the 'Sweet Spot' in Amount of Risk Providers and Payers Bear', *Health Affairs*, vol. 31, no. 9, pp. 1951–1958.

Getzen, T. E. (2010), *Health Economics and Financing*, 4th edn, Hoboken, John Wiley & Sons Publishing Company.

Graves, J. A. and Nikpay, S. S. (2017), 'The Changing Dynamics of US Health Insurance and Implications for the Future of the Affordable Care Act', *Health Affairs*, vol. 36, no. 2, pp. 297–305.

Haubrock, M., Hagmann, H. and Nerlinger, T. (2000), *Managed Care: Integrierte Versorgungsformen*, Bern, Hans Huber Publishing Company.

Health Coverage Guide (2016), *Point-Of-Service Plan* [Online], Health Coverage Guide. Available at: http://healthcoverageguide.org/reference-guide/coverage-types/point-of-service-plan-pos/ (Accessed May 05, 2017).

Health Insurance Resource Center (2017), *High-Deductible Health Plan* [Online], Health Insurance Resource Center. Available at: https://www.healthinsurance.org/glossary/high-deductible-health-plan/ (Accessed May 05, 2017).

Janus, K. (2003), *Managing Health Care in Private Organizations: Transaction Costs, Cooperation and Modes of Organization in the Value Chain*, Frankfurt am Main, Peter Lang Publishing Company.

Jonas, S. (1998), *An Introduction to the US Health Care System*, 4th edn, New York, Springer Publishing Company.

Kaiser Commission on Medicaid and the Uninsured (2016), *Key Facts about the Uninsured Population*, Kaiser Commission on Medicaid and the Uninsured [Online]. Available at: http://www.kff.org/uninsured/fact-sheet/key-facts-about-the-uninsured-population/ (Accessed May 22, 2017).

Kaiser Family Foundation (2002), *Sicker and Poorer: The Consequences of Being Uninsured*, Kaiser Family Foundation [Online]. Available at: http://www.kff.org/uninsured/report/sicker-and-poorer-the-consequences-of-being/ (Accessed August 01, 2017).

Kaiser Family Foundation (2016), *Distribution of Health Plan Enrollment for Covered Workers, by Plan Type, 1988-2016*, Kaiser Commission on Medicaid and the Uninsured [Online]. Available at: https://kaiserfamilyfoundation.files.wordpress.com/2016/09/8905-exhibit-5-11.png (Accessed August 02, 2017).

Kaiser Family Foundation (2016), *Trends in Employer-Sponsored Insurance Offer and Coverage Rates, 1999-2014*, Kaiser Family Foundation [Online]. Available at: http://kff.org/private-insurance/issue-brief/trends-in-employer-sponsored-insurance-offer-and-coverage-rates-1999-2014/ (Accessed May 22, 2017).

Keehan, S. P., Poisal, J. A., Cuckler, G. A., Sisko, A. M., Smith, S. D., Madison, A. J., Stone, D. A., Wolfe, C. J. and Lizonitz, J. M. (2016), 'National Health Expenditure Projections, 2015-25: Economy, Prices, and Aging Expected to Shape Spending and Enrollment', *Health Affairs*, vol. 35, no. 8, pp. 1522–1531.

Ku, L., Steinmetz, E., Brantley, E., Holla, K. and Bruen, B. K. (2017), *The Better Care Reconciliation Act: Economic and Employment Consequences for States*, The Commonwealth Fund [Online]. Available at: http://www.commonwealthfund.org/~/media/files/publications/issue-brief/2017/jul/ku_bcra_economic_effects_states.pdf (Access-ed August 02, 2017).

Lave, J. R., Men, A., Day, B. T., Wang, W. and Zhang, Y. (2011), 'Employee Choice of a High-Deductible Health Plan across Multiple Employers', *Health Services Research*, vol. 46, no. 1, pp. 138–154.

Lee, M. J. (2017), *House Republicans Pass Bill to Replace and Repeal Obamacare*, CNNpolitics [Online]. Available at: http://edition.cnn.com/2017/05/04/politics/health-care-vote/index.html (Accessed May 07, 2017).

Lew, N. de, Greenberg, G. and Kinchen, K. (1992), 'A Layman's Guide to the U.S. Health Care System', *Health Care Financing Review*, vol. 14, no. 1, pp. 151–169.

Neuss, M. F. (2015), 'Gesundheitsökonomie – USA: Deutliche Verbesserung der Gesundheitsversorgung', *Gesundheitsökonomie und Qualitätsmanagement*, vol. 20, no. 05, pp. 202–203.

Obamacare Facts (2017), *Affordable Care Act Facts*, Obamacare Facts [Online]. Available at: https://obamacarefacts.com/affordable-care-act-facts/ (Accessed May 22, 2017).

Organisation for Economic Cooperation and Development (2015), *Country Note: How Does Health Spending in the United States Compare?*, Organisation for Economic Cooperation and Development [Online]. Available at: https://www.oecd.org/unitedstates/Country-Note-UNITED%20STATES-OECD-Health-Statistics-2015.pdf (Accessed April 10, 2017).

Park, H. and Sanger-Katz, M. (2017), 'The Parts of Obamacare Republicans Will Keep, Change or Discard', *The New York Times*, 6 March [Online]. Available at: https://www.nytimes.com/interactive/2017/03/06/us/politics/republican-obamacare-replacement.html (Accessed April 22, 2017).

Parlapiano, A., Andrews, W., Lee, J. C. and Shorey, R. (2017), 'How Each Senator Voted on Obamacare Repeal Proposals', *The New York Times*, 28 July [Online]. Available at: https://www.nytimes.com/interactive/2017/07/25/us/politics/senate-votes-repeal-obamacare.html?mcubz=3 (Accessed August 02, 2017).

Phelps, C. E. (2013), *Health Economics*, 5th edn, Upper Saddle River, Pearson Education Publishing Company.

Pieper, C. (2012), 'Das Leiden der US-Ärzte', *Ärzte Zeitung*, 26 July [Online]. Available at: https://www.aerztezeitung.de/politik_gesellschaft/gesundheitspolitik_international/article/818735/leiden-us-aerzte.html (Accessed July 29, 2017).

Rice, T., Unruh, L. Y., Rosenau, P., Barnes, A. J., Saltman, R. B. and van Ginneken, E. (2014), 'Challenges Facing the United States of America in Implementing Universal Coverage', *Bulletin of the World Health Organization*, vol. 92, no. 12, pp. 894–902.

Rosenbaum, S. (2011), 'Law and the Public's Health', *Public Health Reports*, vol. 126, no. 1, pp. 875–878.

Sadeghi, S., Barzi, A., Mikhail, O. and Shabot, M. M. (2012), *Integrating Quality and Strategy in Health Care Organizations*, Burlington, Brown.

Schmid, A. and Himmler, S. (2015), *Netzwerkmedizin: Impulse für Deutschland aus den USA*, Stiftung Münch.

Schneider, E. C., Sarnak, D. O., Squires, D., Shah, A. and Doty, M. M. (2017), *Mirror, Mirror 2017: International Comparison Reflects Flaws and Opportunities for Better U.S. Health Care*, The Commonwealth Fund [Online]. Available at: http://www.commonwealthfund.org/interactives/2017/july/mirror-mirror/assets/Schneider_mirror_mirror_2017.pdf (Accessed July 31, 2017).

United States Census Bureau (2016), *Percentage of People by Type of Health Insurance Coverage: 2015*, United States Census Bureau [Online]. Available at: https://pbs.twimg.com/media/CsPXLP0VYAM1g8Y.jpg (Accessed July 01, 2017).

Young, J. (2017), 'This is What's in the Health Care Bill House Republicans Just Passed', *The Huffington Post*, 4 May [Online]. Available at: http://www.huffingtonpost.com/entry/this-is-whats-in-the-health-care-bill-republicans-just-passed_us_590b75b3e4b0e7021e95a5a8 (Accessed July 28, 2017).

Repeal, Replace, Reform – Current Issues in U.S. Health Politics

Laurenz Waider

With the election of Donald Trump as President of the United States, the start of a new chapter of uncertainty in health policy has begun. The Trump administration aimed to repeal the Affordable Care Act (ACA) and replace it with the American Health Care Act (AHCA). In March 2017, the AHCA was withdrawn before being voted on. However, it was passed by the House of Representatives with changes in May 2017. Based on this development, this essay analyzes and reviews the ACA and the AHCA on (1) access, (2) affordability, (3) quality of care and individual health, as well as (4) costs giving an overview about the ACA, the AHCA and their effects. This paper shows the ACA increased insurance coverage by 20 million Americans. However, Americans still face issues in affording healthcare due to high deductible plans while the American healthcare system is confronted with rising costs in the future. The AHCA would be cutting costs in the federal budget by an estimated $935 billion, but approximately 24 million Americans would lose their health insurance. Under the AHCA, costs for individual plans for Americans above the age of 50 as well as the actual out-of-pocket expenses for Americans would increase. Instead of improving shortcomings of the ACA, the AHCA would exacerbate these by increasing the uninsured rate and out-of-pocket expenses. Although being passed by the house, the bill was not passed by the Senate. At this point, it remains unclear how future political reforms will look like.

Contents

1 Introduction

On November 8, 2016, the Republican candidate Donald Trump won the presidential election and the Republican party retained the majority in the House of Representatives and the Senate (Wilensky, 2017, p. 21). As the presidential leadership of the United States of America (US) changes, health policy is likely to change as well (Obama, 2017, p. 297). With the triumph of Donald Trump and the Republicans, the start of a new chapter of uncertainty in health policy in the US has begun (Oberlander, 2017a, p. 1). During the election campaign Donald Trump repeatedly pledged to "repeal and replace" the Affordable Care Act (ACA), a healthcare policy enacted by his predecessor Barack Obama (Butler, 2017, p. 244). On March 6, the first proposal to replace the ACA, the American Health Care Act (AHCA), was released by the Trump administration drawing much criticism, even from Republicans (Steinhauer, 2017). Less than three weeks later, the bill was withdrawn from consideration before it was even voted on in the House of Representatives (Oberlander, 2017c, p. 1,497). After this, the bill was slightly changed by the GOP leadership and the administration, leading to its passing by the House on May 4 (Flegenheimer, 2017). However, the bill failed a Senate vote afterwards (Parlapiano et al., 2017).

Based on these current developments in American health policy, this essay will provide a broad overview and analyze the ACA and the AHCA on the basis of (1) access, (2) affordability, (3) quality of care and individual health, as well as (4) costs. Key elements and the effects of the ACA and AHCA will be discussed in the following sections. Based on the results of the analysis, a conclusion will be drawn from the most important findings.

2 Methods and Areas of the Analysis

Figure 1: The areas of the analysis

Source: Own representation.

In previous analyses of the ACA, criteria including access, affordability, quality of care/health, and costs were applied (Geyman, 2015, p. 209). Within the category of access, the effects of the ACA and AHCA in terms of insurance coverage is reviewed. The affordability category assesses the ability of people being able to pay for healthcare services under the bill. Within the quality of care and individual health section incremental quality and health improvements under the reform are reviewed. In the category of costs, budgetary effects of the bills are considered.
Within this paper, both bills, the ACA and the AHCA, their performance, and their effects will be assessed and hypothetically forecasted in the mentioned categories. For the AHCA, it can be stated, that an assessment of the quality of care or the influence on the overall health of individuals or the population cannot be evaluated at this time. For the other areas, a review of the literature was performed in the databases and search engines Web of Science, Science direct, J-Stor and Google Scholar. Abstracts of relevant articles were screened and then selected for the analysis.

3 The Affordable Care Act

3.1 General Approach

After a controversial political debate, the Affordable Care Act (ACA) was signed into law by President Barack Obama on March 23, 2010 (French et al., 2016, p. 1,735). The ACA has struck out as the most significant change to the US healthcare system since the enactment of Medicare and Medicaid in 1965. The intention of the bill was to address the three main challenges in US healthcare: access to healthcare, costs of healthcare and the delivery of healthcare services (Blumenthal, Abrams and Nuzum, 2015, p. 2,451). In 2010 elements of the law went into effect immediately but the major part of the law became effective in 2014. The following bullet points show the overall approach of the ACA to improve healthcare in the US (Kaiser Family Foundation, 2017a):

- Most US citizens and legal residents are required to have health insurance
    - People without coverage usually must pay a tax penalty
    - A tax penalty is imposed on employers with 50 or more employees that do not offer health insurance meeting government standards is imposed
    - Young adults are eligible to stay on parent's plan until the age of 26
    - Insurance companies are not allowed to neither neglect patients nor charge them higher premiums due to pre-existing conditions
- Implementation of state based health insurance exchanges
- Provision of refundable premium tax credits
- New insurance market regulations

- Insurance coverage for ten essential health benefits and no-cost preventive benefits
- Expansion of Medicaid eligibility to 138 percent of the federal poverty level as an option for states
- Extension of the funding for the Children's Health Insurance Program to 2015
- Enhancement of preventive benefits in Medicare and closing of the doughnut holeReduction of Medicare spending
- Establishment of an independent Payment Advisory Board and the Center for Medicare and Medicaid Innovation

3.2 Access

The ACA has succeeded in increasing insurance coverage. Since the enactment of the ACA in 2010, 20 million Americans obtained health insurance coverage by February 2016 (Uberoi, Finegold and Gee, 2016, p. 1). This has been the largest decline of the uninsured rate since the introduction of Medicare and Medicaid in 1965 (Obama, 2016, p. 527). The largest reductions were recorded in the uninsured rate among low-income individuals, people of color, as well as young adults (Kaiser Family Foundation, 2016, p. 6). Coverage has mainly increased by the expansion of Medicaid and operation of health insurance exchanges. Americans with annual incomes between 138 and 400 percent of the federal poverty became eligible for federal subsidies to be able to afford insurance coverage (Geymann, 2015, p. 210). Further, consumer protection became more important with the introduction of the ACA. Insurers are not allowed to deny patients with pre-existing conditions anymore (Blumenthal and Collins, 2014, p. 276). Furthermore, 7.8 million young adults aged 19 to 26 gained coverage by enrolling in the parents' plan. Most of them would not have been eligible without the enactment of the ACA (Blumenthal and Collins, 2014, p. 275).

However, even if the ACA was not repealed by the current Trump administration, 27 million Americans would remain uninsured in 2025. Within this uninsured group, less than one third would be undocumented immigrants and approximately 56 percent would be people who opted out. The remaining 10 percent would be people suffering from poverty in states that did not expand Medicaid (Hellander, 2015, p. 707). The US Supreme Court ruled in 2012 that states may choose to expand or not expand Medicaid. Although the federal government would pay 100 percent of the expansion initially, gradually phasing down to 90 percent in 2020, only 26 states decided to expand Medicaid. This caused 4.8 million people still being uninsured and is known as the Medicaid gap (Geymann, 2015, p. 211). In terms of access, it can be concluded that overall insurance coverage in the United States increased by 20 million. However, the healthcare system is still not close to achieving universal coverage for the US population as 27 million citizens still remain uninsured.

3.3 Affordability

As the previous part shows, the ACA increased the number of Americans with insurance coverage. But the affordability of healthcare also relies on factors like costs, prices, the value of insurance coverage, the household's income levels and other living expenses (Geymann, 2015, p. 213). An eleven-country survey published in 2016 found Americans are far more likely to go without healthcare because of high cost than in other countries (Osborn et al., 2016, p. 2,327). According to the survey, US adults were the most likely to report financial barriers to healthcare services. In 2016, 33 percent of Americans went without the recommended care, did not see a doctor when they were sick or failed to pick up a prescription because they could not afford it (Osborn et al., 2016, p. 2,328). The percentage decreased from 37 percent in 2013 by 4 percent over 3 years. However, in countries like Germany or Great Britain only 7 percent of the population experienced such problems (Osborn et al., 2016, p. 2,329). Furthermore, in October 2014 an Associated Press poll found stated one quarter of insured Americans feel insecure about their ability to pay for healthcare bills (Geymann, 2015, p. 213).

According to the Commonwealth Fund's measure of underinsurance, people are underinsured if the deductible is 5 percent or more of the total household income (Collins et al., 2014, p. 2). The share of employer-sponsored health plans having a deductible increased from 55 percent in 2006 to 80 percent in 2014. The average deductible of $1,217 more than doubled compared to the deductible of $584 in 2006 (Collins et al., 2014, p.1). A survey of the Commonwealth Fund in 2014 found that 13 percent of privately insured adults have a deductible which is 5 percent or more of their household's income (Collins et al., 2014, p. 3). In this survey, 43 percent of privately insured adults with a deductible plan claimed that their deductible caused them financial troubles or it was impossible to afford (Collins et al., 2014, p. 4). About 20 percent of the ACA enrollees are covered by Bronze plans, with an actuarial value of 60 percent. Enrollees in bronze plans face an average deductible of $5,331 for an individual per year. Some of these plans even require that the full amount of the deductible must be paid before any drugs get covered by the insurance (Hellander, 2015, p. 708). The assessment of affordability reveals that although more people gained insurance coverage by the ACA, the affordability of healthcare is still relatively low compared to other industrial countries.

3.4 Quality of Care and Health of Individuals

The intention of the ACA was to increase the access to care, enable the provision of preventive services without cost sharing, make payment changes attempting to encourage quality of care, establish accountable care organizations (ACOs), and expand the use of electronic-health records (EHR) and establish the Patient Centered Outcomes Research Institute (PCORI) (Geymann, 2015, p. 214). After the enactment of the ACA, the

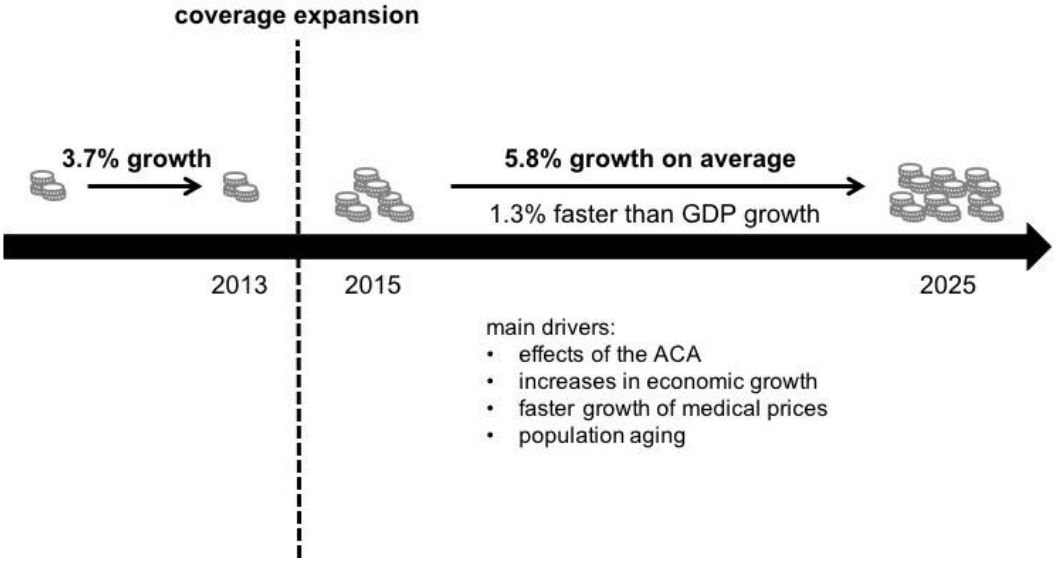
USA had some improvements in quality of care (Obama, 2016, p. 528). The rate of hospital acquired infections decreased by 17 percent from 145 per 1,000 discharges in 2010 to 121 per 1,000 discharges in 2014 (Agency for Healthcare Research and Quality, 2015, p. 1). Considering research on the relationship between hospital-acquired illnesses and mortality, the Agency for Healthcare Research and Quality estimated that the decline of hospital acquired conditions led to a prevention of cumulative 87,000 deaths over four years (Agency for Healthcare Research and Quality, 2015, p. 4). However, the policies initiated by the ACA might not be the only reason for this decline (Agency for Healthcare Research and Quality, 2015, p. 6). In addition to lower rates of hospital acquired infections, the readmission rate within 30 days after discharge of Medicare patients declined from 19.1 percent in 2010 to 17.8 percent during 2015 as well (Obama, 2016, pp. 528-529).

The expansion of insurance coverage may have positively influenced the health of Americans at some point as well. Given the results of the 2008 Oregon Health Insurance Experiment, a randomized controlled trial of Medicaid expansion, Medicaid expansion and insurance coverage is valuable for an improvement in health status but may not be as valuable as hoped due to a fragmented and inefficient system (Skinner and Chandra, 2016, p. 497) Newly insured individuals used more primary and hospital care than individuals without insurance and even received more preventive services as well. Furthermore, individuals had a better self-reported physically and mental health in addition to being less likely to suffer from medical debts and bankruptcy (Finkelstein et al., 2012, p. 1,057). However, there are limitations of increasing insurance coverage to improve population health, as hypertension and diabetes control did not change in comparison to the control group (Taubman et al. 2014, p. 263).

A true improvement in the health of individuals cannot be concluded at this point. There is no high-quality data, which demonstrates clearly a substantial improvement in health outcomes directly related to the ACA. The health outcomes above, hospital acquired infections and readmission rate more likely reflect process measures of care. Improving the health of an individual or an entire population takes much more time than the period since the ACA was enacted. Thus, the effects of the ACA on individual or population health cannot be quantified at this point (Bauchner, 2016, p. 492). Furthermore, social determinants of health, as a much more influencing factor for health than healthcare itself, must be considered here as well (Lantz, Lichtenstein and Pollack, 2007, p. 1,253).

3.5 Costs

Figure 2: Growth of costs



Source: own representation.

The implementation of the ACA has been less expensive than expected. This has helped lower federal deficits. The Congressional Budget Office estimates that in terms of overall costs of the ACA, the insurance coverage provisions from 2015 to 2019 have decreased 29 percent from 2010 estimate of $716 billion to $506 billion estimate in 2015. This decrease is caused by favorable factors like a low healthcare inflation but also factors like the Medicaid expansion in some states and the low number of enrollments in the exchanges (Emanuel, 2016, p. 1,331).

Overall, the healthcare system of the United States is the most expensive healthcare system in the world. In 2014 healthcare spending composed 17.1 percent of the US GDP compared to 12.3 percent for the OECD average (World Bank, 2017). From 2015 to 2025 health spending is estimated to grow by 5.8 percent on average. This rate would be 1.3 percent faster than the growth of the gross domestic product (GDP) and would represent 25 percent of the US total economy by 2025. The main drivers of the national health spending are expected to be the effects of the ACA (healthcare spending and insurance coverage beginning in 2014), increases in economic growth, faster growth of medical costs and population aging (Keehan et al., 2016, p. 1,522).

However, before 2014 and in the first years after the ACA was passed, the bill was supposed to help keep healthcare inflation modest. An analysis conducted by the Robert Wood Johnson Foundation-Urban Institute found that national health expenditures are expected to be $2.6 trillion (11 percent) lower from 2014 through 2019 than projected before the ACA was enacted (McMorrow and Holahan, 2016, p. 10). The five years between 2009 and 2013 had historically low growth of healthcare cost of 3.7 percent

(Martin et al., 2016, p. 150). Unfortunately, the expansion of high deductible health plans, which discourage the use of healthcare services, might be attributable to the low level of inflation as well (Emanuel, 2016, p. 1,331). Besides that, some analysts attribute this low healthcare inflation to a slow economic growth due to the economic recession (Blumenthal, Stremikis and Cutler, 2013, p. 2,551). A significant share of cost savings also derived from ACA measures slowing down the growth of reimbursement rates in Medicare (Center for Healthcare Research & Transformation, 2014, p. 2). A list of selected payment reform policies and initiatives of the ACA is shown below (Table 2.1).

Table 1: Selected payment reform initiatives

Policy/Initiative	Description	Project Cost Savings Over Ten Years
Disproportionate Share Hospital Payments	Reduction of Medicare & Medicaid disproportionate share hospital (DSH) funding as more patients gain insurance coverage	$36 billion
Hospital-Acquired Conditions	Reduction of Medicare payments by 1 percent for hospitals with relatively high rates of hospital-acquired conditions	$1.5 billion
Hospital Readmission Reduction Program	Issues penalties of up to 3 percent of payment to hospitals with relatively high preventable hospital readmissions among patients with defined conditions	$7 billion
Market Basket Updates	Reduction of rate of reimbursement growth through changes to providers' annual market basket updates and inclusion of productivity adjustments into such updates	$160 billion
Medicare Durable Medical Equipment	Expands competitive bidding for durable medical equipment from 70 to 91 areas; requires that all payment rates are subject to competitive bidding or that rates are adjusted using the competitively bid rates	$1 billion
Prescription Drug Rebates	Increases minimum Medicaid drug rebate amount and expands scope of drugs covered by the rebate requirement; expands rebate requirement to drugs provided through Medicaid managed care organizations	$38 billion

Source: Own representation based on Center for Healthcare Research & Transformation, 2014, p. 2.

4 The American Health Care Act

4.1 General Approach

The AHCA is the plan of the current Trump administration and the Republicans to repeal and replace Obamacare. Less than three weeks after the first introduction of the bill, it was withdrawn from consideration by GOP leadership and the Trump administration before it was voted on in the House of Representatives. Although Republicans hold a majority in the House of Representatives, it was very unlikely that this version of the bill would have been passed by the House (Oberlander, 2017c, p. 1,497). The Republican party was divided over the bill. For very conservative Republicans, such as the House Freedom Caucus, the bill was too much like the ACA and did not go far enough in deregulating healthcare markets and decreasing government spending. On the other hand, less conservative Republicans felt that the bill would go too far in eroding health insurance coverage (Andrews, Bloch and Park, 2017). Republican leadership finally changed some provisions of the AHCA to get the votes of the House Freedom Caucus. The bill was passed by the house on May 4 (Flegenheimer, 2017).

Although the AHCA aimed to originally repeal and replace the ACA, it actually proposes to retain important elements of it. Therefore, it would keep the ACA mostly intact (Oberlander, 2017b, p. 2). This similarity to the ACA is not surprising. A lot of Obamacare elements are quite popular in the American population. According to a Kaiser Family Foundation analysis, 90 percent of Democrats and 82 percent of Republicans have a favorable opinion of the provision allowing young adults on the parent's plan until the age of 26 (Kirzinger, Hamel and Rousseau, 2017). Furthermore, the ACA is a conservative reform model with ideas previously supported by Republicans. By fully repealing this bill, Republicans would have certainly renounced their own ideas in healthcare (Oberlander, 2017b, p. 2). According to the AHCA proposal, insurers are still not allowed to neglect patients with pre-existing conditions. However, a loophole for insurance companies is created within this bill. If a person does not continually have insurance for two months, insurers can charge an additional 30 percent premium surcharge when the individual seeks insurance. In the reworked bill of the AHCA, which has passed the house in May, more state options to waive provisions were enacted. States could waive retained essential health benefit requirements as well as the prohibition on health status rating for individual market applicants, who have not maintained continuous coverage (Kaiser Family Foundation, 2017b). Besides those alterations, young adults until the age of 26 are still allowed to stay under their parents' coverage (Stark, 2017, p.1). The overall approach of the AHCA including the amendments as of March 20, 2017 includes the following major elements (Kaiser Family Foundation, 2017b; Stark, 2017, pp. 2-3):

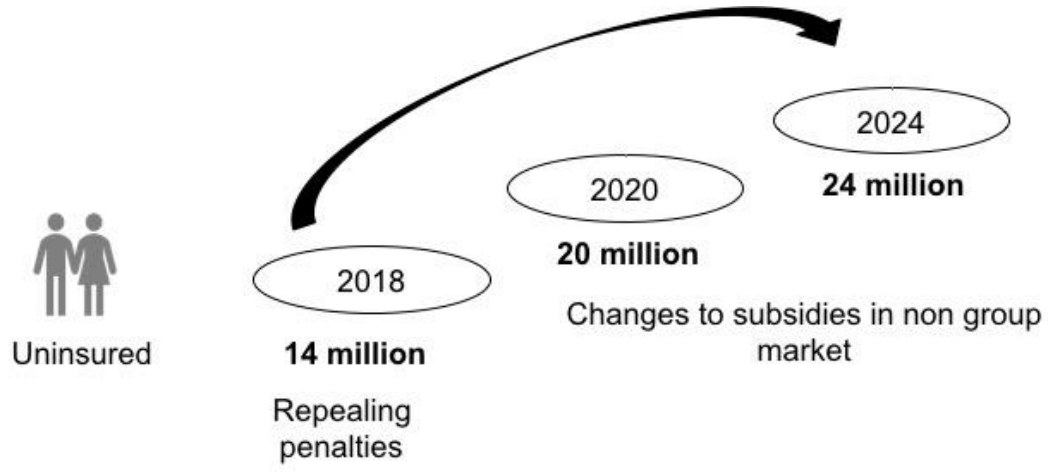
Table 2: Major elements of the AHCA

Major elements of the AHCA
Individual and employer insurance
- Repeal of individual and employer mandate immediately, standards for health plan actuarial values in 2020 and premium and cost sharing subsidies in 2020 - Retain health insurance marketplaces and annual enrollment periods - Modification of community rating from 3:1 to 5:1 - Impose late enrollment penalty for people who do not have continuous coverage - Modification of ACA premium tax credits based on age instead of income o Credit starts at $2,000 for 18-year-olds and gradually increases to $4,000 as people age. $14,000 is the maximum for a family o People, who purchase catastrophic health insurances without the current ACA benefits mandates, can receive tax credits o Expansion of health savings accounts (HSA) by increasing tax free contributions ▪ to $6,550 per year for individuals ▪ to $13,000 per year for families
Medicaid
- Conversion of federal Medicaid funding to a per capita allocation - Limit growth beginning in 2020 by using 2016 as a base year - State option to receive block grant for non-expansion adults and children or non-expansion adults only - Implement state option requiring employment/work as a condition of eligibility for nondisabled, nonelderly, non-pregnant Medicaid adults
Funding of States
- Establishment of State Innovation Grants o Over the next nine years, states would receive $130 billion federal funding and additional funding of $8 billion over 5 years for states that elect community rating waivers o States could use the money for financial help to high-risk individuals, promote access to preventive services, provide cost-sharing subsidies and other purposes (in states that do not successfully apply for grants, money is used for reinsurance) - Repeal of funding for Prevention and Public Health o Cancelation of any unobligated funds at the end of fiscal year 2018 o Provision of supplemental funding for community health centers of $422 million for fiscal year 2017
Other
- Repeal of Medicare high income tax increase and other ACA revenue provisions - Prohibition of federal Medicaid funding for Planned Parenthood clinics

Source: Own representation based on Kaiser Family Foundation, 2017 and Stark, 2017.

4.2 Access

Figure 3: Estimated development of uninsured population



Source: Own representation based on CBO, 2017, p. 2.

The CBO and the Joint Committee on Taxation (JCT) estimate that the number of uninsured would increase under the AHCA by 14 million in 2018. Repealing the penalties associated with the individual mandates would be the main reason for this increase, because many people chose to be enrolled just to avoid the penalty under the ACA. In 2020, the number of uninsured people would be expected to rise further to 21 million and in 2026 to 24 million. This increase in the number of uninsured people would be caused by changes to subsidies for insurance purchased in the non-group market and changes to the Medicaid program within the AHCA (CBO, 2017, p. 2).

Another important factor for access to insurance and healthcare is also the premium. Coverage will presumably drop, if insurance premiums increase (Chernew, Cutler and Seliger Keenan, 2005, p. 1,021). According to estimations of the CBO and JCT, premiums for single policy holders in the non-group market would increase by 15 to 20 percent in 2018 and 2019 under the AHCA because of the elimination of the mandate penalties. Because of the elimination, fewer healthy Americans would sign up for health insurance plans. Therefore, insurance companies would have higher risk pools and premiums would likely rise (CBO, 2017, p. 3). In 2020, premiums would be decreasing due to several factors, such as grants to states from the Patient and State Stability Fund, the elimination of a minimum actuarial value (see Affordability) and a younger mix of enrollees. In 2026, the average premium would be approximately 10 percent lower than under the ACA. In the long term, the AHCA would reduce average premiums. However, premiums would differ among different age groups, because insurers would be allowed to charge five times more for older enrollees than for younger under the new bill (CBO, 2017, p. 3).

4.3 Affordability

In general, the AHCA proposal is distinguishing itself from the current ACA legislation by giving more money to wealthier people through tax cuts and decreasing government support for the low-income population to afford health insurance (Oberlander, 2017b, p. 2). The tax credit under the AHCA for a 21-year-old with an income at 175 percent of the federal poverty level in 2026 would be $950 less than under the ACA (CBO, 2017, p. 16). In terms of affordability, that will result in a growing group of people not being able to afford health insurance and healthcare. In addition to that, the AHCA would make changes to the actuarial value requirements. An actuarial value is the percentage of total cost for covered benefits that the insurance plan pays (Kaiser Family Foundation, 2011). Under the current ACA legislation, the non-group and small group markets must have actuarial values of at least 60 percent. In 2020, the AHCA would allow plans to have an actuarial value below 60 percent. Although these plans would still be required to cover the ten categories of essential health benefits, the underinsurance would grow with the repeal of this requirement (CBO, 2017, p. 14). People would tend to buy plans with low premiums and therefore, they would only have limited financial coverage of benefits along with high deductibles. When they need healthcare it might be less affordable than it used to be under the ACA.

4.4 Costs

According to estimations of the CBO and the JCT, the enactment of the AHCA would reduce federal deficits by $935 billion over the 2017 - 2026 period (see Table 2.3). However, other provisions, mostly reduced tax revenues, would increase the deficits by $599 billion resulting overall in a reduction of approximately $337 billion (CBO, 2017, p. 6). Within these reductions, reductions from outlays in Medicaid and the elimination of the ACA's subsidies for the non-group health insurance would account for the largest savings (CBO, 2017, p. 1). However, by cutting the Medicaid expansion, the number of uninsured Americans will increase. Because Medicare makes an additional payment to facilities giving care to uninsured patients, Medicare spending would be expected to increase by $43 billion over the 2018-2026 period (CBO, 2017, p. 19). The estimated budgetary effects are displayed in the table below.

Table 3: Cost reducing and offsetting elements

Cost reducing elements		Offsetting cost elements	
Reduction in federal outlay for Medicaid	$880 billion	Costs for the new tax credit	$361 billion
Savings mostly from the elimination of ACA's subsidies for nongroup health insurance	$673 billion	Reduction in revenues from eliminating the penalties for uninsured	$210 billion
Savings mostly associated with shifts in the mix of taxable and nontaxable compensation	$70 billion	New Patient and State Stability Fund grant program	$80 billion
Savings from repeal of tax credit for certain small employers providing health insurance to their employees	$6 billion	Increased Medicare spending for uninsured patients	$43 billion
$1,629 billion		$694 billion	
= $935 billion deficit reduction			
- $599 billion increase from other provisions			
= $337 billion deficit reduction overall			

Source: Own representation based on CBO, 2017, pp. 6-7.

Another analysis of the Robert Wood foundation estimated the reduction in federal Medicaid spending to be $841 billion. This estimate is lower than the estimate by the CBO, which assumed that many states would cut Medicaid enrollment (Holahan et al., 2017, p. 2). However, concluding the budgetary point of view, the AHCA would certainly reduce the federal deficit and cut governmental costs in healthcare.

5 Discussion

After analyzing both bills in terms of performance and projections in the areas access, affordability, quality of care/individual health and costs, the differences and the effects caused by the ACA and AHCA become more obvious.

Access

In terms of access it becomes clear, that the two bills follow a completely opposite approach. Since the ACA's aim is to reduce the uninsured population by having an individual mandate and expanding Medicaid, the AHCA would emphasize the aspect of freedom of choice as well as reducing costs and premiums. Therefore, the AHCA would repeal the mandate and change the Medicaid funding into a block grant leading to individuals being unable to enroll in Medicaid if the block grant is used up. As shown in the previous section of the AHCA the projected increase of 26 million uninsured people by

2026 would more than repeal the efforts the ACA made in providing more Americans insurance coverage. However, it is questionable if the AHCA is actually proposing real freedom of choice to the American population. The vulnerable and poor population, due to their financial situation, is very limited in their freedom of choice and therefore the proposition of freedom is irrelevant here. Furthermore, individual choices are often limited due to restrictions of employers, insurers, doctors or pharmaceutical companies (Partanen, 2017).

Affordability

The analysis in terms of affordability of the ACA showed that although Americans have health insurance coverage, they are still facing challenges to afford healthcare due to high deductible plans under the ACA. By allowing insurance to have actuarial values below 60 percent (CBO, 2017, p. 14), the AHCA would decrease insurance premiums. However, insurance benefits would decrease and out-of-pocket costs for individuals would increase at the same time. Furthermore, the AHCA would have substantially raised costs of individual plans for older Americans (Oberlander, 2017c, p. 1,498). Another analysis from the Kaiser Family Foundation showed that 6.3 million people with pre-existing conditions would be at risk for higher premiums under the AHCA because they had a gap in insurance coverage of 63 days or more (Kaiser Family Foundation, 2017c). While proposing deep cuts in financial help for low-income Americans for buying health insurance, the AHCA is giving higher-income Americans and the healthcare industry large tax cuts (Oberlander, 2017c, p. 1,498). In terms of affordability, the AHCA is therefore not improving conditions for lower-income people at all and health insurance in the US can rather be considered as a protection against catastrophic circumstances for them.

Quality of Care/ Indivdiual Health

After the ACA was enacted, improvements in the rate of readmission of Medicare patients as well as the hospital-acquired diseases could be demonstrated. In terms of individual health there is no reliable data suggesting an improvement at this time. However, given the study about the Medicaid expansion experiment mentioned in section 0, it is likely that somehow population health has improved by expanding Medicaid coverage. Looking at the AHCA, possible effects cannot be stated at this point. However, according to the results of the study, the AHCA which would increase the number of uninsured, potentially worsening population health.

Costs

The most popular part of the ACA, which brings the US closer to universal coverage is the most expensive, too (Herzlinger, Richman, and Boxer, 2017, E1). With the major

insurance expansion in 2014, the growth in healthcare spending accelerated and is expected to be faster than the GDP growth by 1.3 percent (Keehan et al., 2016, p. 1,522). Costs are found to be one of the major challenges for US healthcare in the future. The AHCA is addressing this issue and is estimated to reduce the federal deficit by $935 million (CBO, 2017, p. 6). However, this reduction would be mainly achieved by cutting costs in the Medicaid program and eliminating the ACA subsidies. This comes at a high price to lower-income Americans and is throwing the US back to pre-ACA times in terms of coverage and access to care.

6 Conclusion

This paper aimed to compare the ACA and the AHCA and review their effects in the areas of access, affordability, quality of care and health of individuals as well as costs and to give the reader a broad overview and a comparison of these two health care bills. As the analysis showed, the ACA increased insurance coverage by 20 million Americans and therefore it represents a historic step in making health insurance a right in the US. However, the analysis also showed that Americans still face issues in affording healthcare due to high deductible plans while the American healthcare system is confronted with rising costs in the future.

The effort of the Republican party to repeal and replace the ACA was a failure at first. Only a few weeks after the AHCA was introduced, the bill was withdrawn from consideration by the Trump administration and the House GOP leadership without holding a vote in the House of Representatives. However, after the bill was changed in favor to the Freedom Caucus movement, it was passed by the House of Representatives in May 2017. The review showed that while the AHCA would be cutting costs in the federal budget by an estimated $935 billion, approximately 24 million Americans would be likely to lose their health insurance. Under the AHCA costs for individual plans for Americans above the age of 50 as well as the actual out-of-pocket expenses for Americans would increase. It becomes obvious that the AHCA would not improve the shortcomings of the ACA, instead it would worsen these.

Since the AHCA did not pass the Senate, the direction of future legislation is unclear, the results on American healthcare will be profound and either take the US healthcare system back into pre-ACA times or align with a movement towards universal health insurance coverage and healthcare.

References

Agency for Healthcare Research and Quality (2015), *Saving Lives and Saving Money: Hospital-Acquired Conditions Update: Interim Data from National Efforts to Make Care Safer, 2010-2014,* Agency for Healthcare Research and Quality [Online]. Available at: https://www.ahrq.gov/sites/default/files/publications/files/interimhacrate2014_2.pdf (Accessed April 24, 2017).

Andrews, W., Bloch Matthew and Park, H. (2017), 'Who Stopped the Republican Health Bill?', *The New York Times*, 24 March [Online]. Available at: https://www.nytimes.com/interactive/2017/03/24/us/politics/republicans-opposed-health-care-bill.html (Accessed April 24, 2017).

Bauchner, H. (2016), 'The Affordable Care Act and the Future of US Health Care', *JAMA*, vol. 316, no. 5, pp. 492–493.

Blumberg, L. J., Buettgens, M. and Holahan, J. (2017), *Who Gains and Who Loses under the American Health Care Act,* Health Policy Institute, Urban Institute [Online]. Available at: https://www.urban.org/research/publication/who-gains-and-who-loses-under-american-health-care-act (Accessed April 12, 2017).

Blumenthal, D., Abrams, M. and Nuzum, R. (2015), 'The Affordable Care Act at 5 Years', *The New England Journal of Medicine*, vol. 372, no. 25, pp. 2451–2458.

Blumenthal, D. and Collins, S. R. (2014), 'Health Coverage under the Affordable Care Act - A Progress Report', *The New England Journal of Medicine*, vol. 371, no. 3, pp. 275–281.

Blumenthal, D., Stremikis, K. and Cutler, D. (2013), 'Health Care Spending- A Giant Slain or Sleeping?', *The New England Journal of Medicine*, vol. 369, no. 26, pp. 2551–2557.

Butler, S. M. (2017), 'Repeal and Replace Obamacare: What Could it Mean?', *JAMA*, vol. 317, no. 3, pp. 244–245.

Chernew, M., Cutler, D. M. and Seliger Keenan, P. (2005), 'Increasing Health Insurance Costs and the Decline in Insurance Coverage', *HSR: Health Services Research*, vol. 40, no. 4, pp. 1021–1039.

Collins, S. R., Rasmussen, P. W., Doty, M. M. and Beutel, S. (2014), 'Too High a Price: Out-of-Pocket Health Care Costs in the United States: Findings from the Commonwealth Fund Health Care Affordability Tracking Survey, September-October 2014', *The Commonwealth Fund*, vol. 29, pp. 1–11 [Online]. Available at: http://www.commonwealthfund.org/~/media/files/publications/issue-brief/2014/nov/1784_collins_too_high_a_price_out_of_pocket_tb_v2.pdf (Accessed April 12, 2017).

Congressional Budget Office (2017), *Congressional Budget Office Cost Estimate American Health Care Act,* Congressional Budget Office [Online]. Available at: https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/americanhealthcareact.pdf (Accessed April 12, 2017).

Emanuel, E. J. (2016), 'How Well is the Affordable Care Act Doing?: Reasons for Optimism', *JAMA*, vol. 315, no. 13, pp. 1331–1332.

Finkelstein, A., Taubman, S., Wright, B., Bernstein, M., Gruber, J., Newhouse, J. P., Allen, H. and Baicker, K. (2012), 'The Oregon Health Insurance Experiment: Evidence from the First Year', *The Quarterly Journal of Economics*, vol. 127, no. 3, pp. 1057–1106.

Flegenheimer, M. (2017), 'The Next Step for the Republican Health Care Bill: A Skeptical Senate', *The New York Times*, 4 May [Online]. Available at: https://www.nytimes.com/2017/05/04/us/politics/senate-health-care-bill.html (Accessed May 10, 2017).

French, M. T., Homer, J., Gumus, G. and Hickling, L. (2016), 'Key Provisions of the Patient Protection and Affordable Care Act (ACA): A Systematic Review and Presentation of Early Research Findings', *HRS: Health Services Research*, vol. 51, no. 5, pp. 1735–1771.

Geyman, J. P. (2015), 'A Five-Year Assessment of the Affordable Care Act: Market Forces Still Trump the Common Good in U.S. Health Care', *International Journal of Health Services*, vol. 45, no. 2, pp. 209–225.

Hellander, I. (2015), 'The U.S. Health Care Crisis Five Years after Passage of the Affordable Care Act: A Data Snapshot', *International Journal of Health Services*, vol. 45, no. 4, pp. 706–728.

Herzlinger, R. E., Richman, B. D. and Boxer, R. J. (2017), 'Achieving Universal Coverage without Turning to a Single Payer: Lessons From 3 Other Countries', *JAMA*, vol. 317, no. 14, pp. 1409–1410 [Online]. Available at: http://jamanetwork.com/pdfaccess.ashx?url=/data/journals/jama/0 (Accessed April 24, 2017).

Holahan, J., Buettgens, M., Pan, C. and Blumberg, L. J. (2017), *The Impact of Per Capita Caps on Federal and State Medicaid Spending,* Robert Wood Johnson Foundation [Online]. Available at: http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2017/rwjf436077 (Accessed April 24, 2017).

Kaiser Family Foundation (2011), *What the Actuarial Values in the Affordable Care Act Mean,* Kaiser Family Foundation [Online]. Available at: https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8177.pdf (Accessed May 14, 2017).

Kaiser Family Foundation (2016), *The Uninsured: A Primer: Key Facts about Health Insurance and the Uninsured in the Era of Health Reform,* Kaiser Family Foundation [Online]. Available at: http://files.kff.org/attachment/Report-The-Uninsured-A%20Primer-Key-Facts-about-Health-Insurance-and-the-Unisured-in-America-in-the-Era-of-Health-Reform (Accessed April 24, 2017).

Kaiser Family Foundation (2017), *Analysis: 6.3 million People with Pre-Existing Conditions Would be at Risk for Higher Premiums under the House's Health Bill,* Kaiser Family Foundation [Online]. Available at: http://kff.org/health-reform/press-release/analysis-6-3-million-people-with-pre-existing-conditions-would-be-at-risk-for-higher-premiums-under-the-houses-health-bill/ (Accessed May 25, 2017).

Kaiser Family Foundation (2017), *Summary of the Affordable Care Act,* Kaiser Family Foundation [Online]. Available at: http://files.kff.org/attachment/Summary-of-the-Affordable-Care-Act (Accessed April 24, 2017).

Kaiser Family Foundation (2017), *Summary of the American Health Care Act,* Kaiser Family Foundation [Online]. Available at: http://files.kff.org/attachment/Proposals-to-Replace-the-Affordable-Care-Act-Summary-of-the-American-Health-Care-Act (Accessed April 24, 2017).

Keehan, S. P., Poisal, J. A., Cuckler, G. A., Sisko, A. M., Smith, S. D., Madison, A. J., Stone, D. A., Wolfe, C. J. and Lizonitz, J. M. (2016), 'National Health Expenditure Projections, 2015-25: Economy, Prices, and Aging Expected to Shape Spending and Enrollment', *Health Affairs*, vol. 35, no. 8, pp. 1522–1531.

Kirzinger, A., Hamel, L., Clark, C. and Rousseau, D. (2017), 'US Public Opinion on Health Care Reform 2017', *JAMA*, vol. 317, no. 15, p. 1516 [Online]. Available at: http://jamanetwork.com/journals/jama/fullarticle/2614802 (Accessed February 28, 2017).

Lantz, P. M., Lichtenstein, R. L. and Pollack, H. A. (2007), 'Health Policy Approaches to Population Health: The Limits of Medicalization', *Health Affairs*, vol. 26, no. 5, pp. 1253–1257.

Lausch, K., Shigekawa, E., Stroumsa Daphna and Tabak, R. E. (2014), *Cost Containment in the Affordable Care Act: An Overview of Policies and Savings*, Center for Healthcare Research & Transformation [Online]. Available at: http://www.chrt.org/publication/cost-containment-affordable-care-act-overview-policies-savings/ (Accessed October 03, 2017).

Martin, A. B., Hartman, M., Benson, J. and Catlin, A. (2016), 'National Health Spending in 2014: Faster Growth Driven by Coverage Expansion and Prescription Drug Spending', *Health Affairs*, vol. 35, no. 1, pp. 150–160.

McMorrow, S. and Holahan, J. (2016), *The Widespread Slowdown in Health Spending Growth Implications for Future Spending Projections and the Cost of the Affordable Care Act – An Update,* Robert Wood Johnson Foundation [Online]. Available at: https://www.urban.org/sites/default/files/publication/81636/2000824-The%20Widespread-Slowdown-in-Health-Spending-Growth-Implications-for-Future-Spending-Projections-and-the-Cost-of-the-Affordable-Care-Act-an-Update.pdf (Accessed April 24, 2017).

Obama, B. (2016), 'United States Health Care Reform: Progress to Date and Next Steps', *JAMA*, vol. 316, no. 5, pp. 525–532.

Obama, B. H. (2017), 'Repealing the ACA without a Replacement: The Risks to American Health Care', *The New England Journal of Medicine*, vol. 376, no. 4, pp. 297–299.

Oberlander, J. (2017), 'The Art of Repeal: Republicans' Health Care Reform Muddle', *The New England Journal of Medicine*, vol. 376, no. 16, pp. 1497–1499.

Oberlander, J. (2017), 'The End of Obamacare', *The New England Journal of Medicine*, vol. 376, no. 1, pp. 1–3.

Oberlander, J. (2017), 'The Mirage of Reform: Republicans' Struggle to Dismantle Obamacare', *The New England Journal of Medicine*, vol. 376, no. 15, e32(1)-e32(3).

Osborn, R., Squires, D., Doty, M. M., Sarnak, D. O. and Schneider, E. C. (2016), 'In New Survey of Eleven Countries, US Adults Still Struggle with Access to and Affordability of Health Care', *Health Affairs*, vol. 35, no. 12, pp. 2327–2336.

Parlapiano, A., Andrews, W., Lee, J. C. and Shorey, R. (2017), 'How Each Senator Voted on Obamacare Repeal Proposals', *The New York Times*, 28 July [Online]. Available at: https://www.nytimes.com/interactive/2017/07/25/us/politics/senate-votes-repeal-obamacare.html?mcubz=0 (Accessed August 31, 2017).

Partanen, A. (2017), 'The Fake Freedom of American Health Care', *The New York Times*, 18 March [Online]. Available at: https://www.nytimes.com/2017/03/18/opinion/the-fake-freedom-of-american-health-care.html (Accessed May 10, 2017).

Skinner, J. and Chandra, A. (2016), 'The Past and Future of the Affordable Care Act', *JAMA*, vol. 316, no. 5, pp. 497–499.

Stark, R. (2017), *Overview of the Proposed American Health Care Act,* Washington Policy Center [Online]. Available at: http://www.washingtonpolicy.org/library/doclib/Stark-LM-ACHA-Overview-3-16-17.pdf (Accessed April 12, 2017).

Steinhauer, J. (2017), 'G.O.P. Health Bill Faces Revolt from Conservative Forces', *The New York Times*, 2017 [Online]. Available at: https://www.nytimes.com/2017/03/07/us/politics/affordable-care-act-obama-care-health.html?rref=collection%2Fsectioncollection%2Fhealth&action=click&contentCollection=health&region=rank&module=package&version=highlights&contentPlacement=1&pgtype=sectionfront&_r=0 (Accessed April 24, 2017).

Taubman, S. L., Allen, H. L., Wright, B. J., Baicker, K. and Finkelstein, A. N. (2014), 'Medicaid Increases Emergency Department Use: Evidence from Oregon's Health Insurance Experiment', *Science*, vol. 343, no. 6168, pp. 263–268.

The World Bank (2017), *Health Expenditure, Total (% of GDP)* [Online], The World Bank. Available at: http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS?locations=US-OE (Accessed April 30, 2017).

Uberoi, N., Finegold, K. and Gee, E. (2016), *Health Insurance Coverage and the Affordable Care Act, 2010-2016*, Department of Health & Human Services USA [Online]. Available at: https://aspe.hhs.gov/system/files/pdf/187551/ACA2010-2016.pdf (Accessed April 24, 2017).

Wilensky, G. R. (2017), 'The Future of the ACA and Health Care Policy in the United States', *JAMA*, vol. 317, no. 1, pp. 21–22.

(Why) Did the Health Insurance Marketplaces Fail?

Antonia Rollwage

In 2010, the ACA was signed into law and required states to establish and operate health insurance marketplaces for individuals without access to governmental payment programs or employer sponsored health insurance. Currently, the media is flooded with increasing premiums and health insurance companies leaving the marketplace. This paper aims to analyze the performance of the marketplace in terms of (1) enrollment, (2) risk pooling, (3) navigation, (4) financial performance and (5) affordability. The analysis showed initial technological problems inhibited a smooth launch of the marketplaces and led to skewed risk pools. Enrollment numbers are mediocre, reaching only 20 percent of the market's target population. Individuals lacking health literacy face a challenging market environment, leading to a significant number of enrollees who do not know their exact insurance plan coverage and cost-sharing requirements. In the first two years, the financial performance of the insurance market was poor, but as more data on enrollees was obtained and used for premium calculations the performance of insurance companies slowly started to improve. Despite the positive trend, insurers decided to leave the marketplace. However, to offer profitability and maintain insurer participation, a continuing stabilization of the market is needed. Individuals and families, especially, report trouble in affording care, financial insecurities, and postponement of care. The establishment of the marketplaces helped to increase insurance coverage, but also introduced new challenges hindering the marketplace to reach its full potential. Interventions are needed for the marketplace to become more successful.

Contents

1 Introduction

In March 2010, President Obama signed the Patient Protection and Affordable Care Act (PPACA), also referred to as Affordable Care Act (ACA) into law (Lammert, 2017, p. 66). The ACA required the establishment of health insurance marketplaces, where individuals without access to governmental payment programs and employer sponsored health insurance can access information and buy health plans subject to common rules regarding coverage, pricing, funding and subsidies (Kaiser Family Foundation, 2010, p. 1). According to a Gallup survey in 2013, 22 percent of the Americans named the ACA as the greatest achievement of the Obama administration. Unfortunately, the law was not implemented as smoothly as expected. Four years later in 2017, 36 percent of the population named the ACA (also called "Obamacare") "the biggest mistake": Major problems occurred during implementation, partially some with long-term consequences (Brady, 2015, p. 649; Lammert, 2017, p. 66).

Seven years after passing the ACA, health reform is on the agenda again. Currently, the US media is flooded with news about health reform including failures of Obamacare and reform plans of the new administration. Major topics of conflict include the increasing prices of premiums, health insurers leaving the marketplace, and, consequently, less health insurance options for consumers (Murphy, 2017). Aetna, the third-largest health insurer in the US, just announced it will be leaving the marketplaces in all states due to a loss of USD 450 million in 2016 and the future uncertainty about the exchanges in 2018 (Goldstein, 2017).

This paper aims to evaluate the performance of the health insurance marketplaces under the ACA to assess whether the establishment of the marketplaces was successful or failed. After an introduction of the marketplace, the performance by the means of (1) enrollment, (2) risk pooling, (3) navigation, (4) financial performance, and (5) affordability ill be examined. Based on the analysis, the paper discusses the major challenges the marketplace faces and concludes with key findings.

2 The Health Insurance Marketplace

The ACA

The ACA introduced several changes to the American health care landscape. It (1) mandates that all individuals need to have health insurance coverage by 2014, (2) requires employers with 50 or more full time employees to provide health insurance coverage meeting defined minimum requirements, (3) requires states to establish insurance marketplaces as a place where individuals and small employers can buy health insurance and (4) requires states to expand their Medicaid program to individuals under the age of 65 with an income up to 133 percent of the Federal Poverty Level (FPL) (Brady, 2015, pp. 631-633).

The Marketplace

The health insurance marketplace, also known as the *exchange* or *non-group market*, was established by the ACA to provide a platform on state-level where individuals and small businesses without access to governmental insurance programs or employer-sponsored health insurance can compare and purchase health insurance plans starting on October 1, 2013. All health insurance plans offered must meet federal and state coverage requirements regarding coverage minimums or price regulations. The marketplace also offers help connecting individuals and families to financial assistance by allowing consumers to access tax credits or obtain coverage through governmental payment programs. Despite these requirements, flexibility was given to the states to allow a variety of substantially different marketplace designs (Kaiser Family Foundation, 2010, pp. 1-4; Robert Wood Johnson Foundation, 2013, p. 1).

The marketplaces can be run by state governments, the federal government (by default if the state government defers its responsibility to the federal level), or a combination of both known as *state partnership exchange* (Robert Wood Johnson Foundation, 2013, p. 1). The responsibilities for implementation of the marketplaces included core functions such as (1) eligibility and enrollment, (2) plan management, (3) consumer assistance (4), outreach and education, and (5) fiscal management (Kaiser Family Foundation, 2010, p. 2).

Funding

To promote the establishment of marketplaces by states, the federal government provided appropriations and more than four billion USD in grants for marketplace planning and facilitation (Robert Wood Johnson Foundation, 2013, p. 2; Hellander, 2015, p. 720). States were able to choose between operating two separate marketplaces for individuals and small businesses or combining both target groups into one marketplace. It was also possible to create multistate/regional marketplaces or several marketplaces within one state to account for regional differences as long as the marketplace operated for a specific region (Health Policy Brief, 2013, p. 2; Kaiser Family Foundation, 2010, p. 1).

Governmental funding for the establishment of the marketplaces was only provided for the duration of one year starting in January 2014. Afterwards, marketplaces needed to prove that they are self-sustaining. In 2015, many of the state-run marketplaces ran at deficit and still relied on leftover funding. To achieve self-sustainability, the marketplaces could charge user fees to participating health insurance companies or pursue other alternatives to generate funding (Kaiser Family Foundation, 2010, p. 1; Hellander, 2015, p. 720).

Eligibility and Coverage

Individuals, including U.S. citizens and legal immigrants, qualify for the marketplaces if they are not eligible for governmental payment programs and have no access to employer-sponsored health insurance. Health plans are *not allowed to discriminate* against individuals on the grounds of age, disability, or expected length of life. Previously, these aspects were considered in the design of benefit packages or reimbursement schemes to benefit health insurers. (Kaiser Family Foundation, 2010, pp. 1, 3).

According to the ACA, all health insurance plans offered must cover at least the *essential health benefits:*

- Ambulatory patient services
- Chronic disease management
- Emergency services
- Hospitalization
- Laboratory services
- Maternity and newborn care
- Mental health benefits and substance abuse disorder services
- Pediatric services including oral and vision care
- Prescription drugs
- Preventive and wellness services
- Rehabilitative and habilitative services and devices

Further, states can require additional benefits be covered by plans (Kaiser Family Foundation, 2010, p. 3). In practice, more than half of the health plans purchased on the marketplace use higher standards than required by the law (Collins and Garber, 2013, p. 1). To make the comparison of different plans easier, all insurance plans are offered with four coverage levels depending on how much the insurer pays:

- *Bronze:* Benefits equal 60 percent of the actuarial value
- *Silver:* Benefits equal 70 percent of the actuarial value
- *Gold:* Benefits equal 80 percent of the actuarial value
- *Platinum:* Benefits equal 90 percent of the actuarial value

All insurances must offer at least one silver and one gold plan on each marketplace where the insurance operates (Kaiser Family Foundation, 2010, p. 3).

3 Challenges and Problems

3.1 Enrollment

Before the launch date of the marketplace, one of the immediate challenges for all 50 states was ensuring that all eligible individuals could enroll in a timely manner and that recipients of subsidies de facto enroll in health plans (Collins and Garber, 2013, p. 1). However, one of the biggest difficulties the ACA has faced was the initial rollout of the federal website *healthcare.gov*, which was dysfunctional for several weeks due to failures affecting the consumer's interface as well as the back-end of the website. In advance, enrollees were promised that buying health insurance coverage would be as easy as shopping on Amazon.com, a website many Americans were familiar with. Based on the 30,000 simultaneous users at the launch of the marketplace, government officials expected the typical website traffic to be between 50,000 and 60,000 simultaneous visitors. The actual number of 250,000 simultaneous users exceeded these planned numbers, though, and lead to several glitches, error messages, and long waits. During this timeframe, the sign up option for health insurance had even been rendered unusable. In the first few days, the website was visited more than eight million times (Brady, 2015, p. 638).

Although technological problems were resolved by making additional servers available and updating the software, critics of the Obama administration still disapproved and sentiment that the federal government was not competent enough to administer the marketplaces remained (Hall, 2014, pp. 1,036-1,037; Brady, 2015, p. 639). Thousands of Americans discovered that the website made mistakes by denying coverage, enrolling individuals in the wrong insurance program, and incorrectly calculating their subsidies. To address these problems, more than 20,000 Americans filed appeals with the government, a process that was complicated by a non-existent complaint system for the marketplaces. Until the technological challenges were resolved, some enrollees had to pay more or were left without coverage at all (Brady, 2015, p. 639). Nevertheless, more than twelve million individuals were enrolled through the marketplace by 2017. Comparing this number to potential marketplace population, enrollees only make up to 40 percent of the target population (Kaiser Family Foundation, 2016; Kaiser Family Foundation, 2017a).

3.2 Risk Pooling

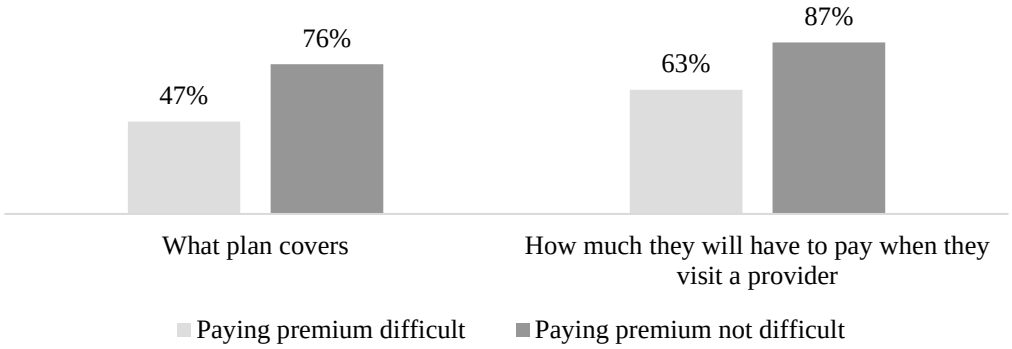
The more severe concern, however, was that the complicated enrollment affected the type of enrolling individuals. Sick and older people were more motivated to fight their way through the marketplace to get coverage for preexisting conditions, leading to unbalanced risk pools (Hall, 2014, pp. 1,038-1,039). There were also concerns about spillover effects into the subsequent year (Hall, 2014, p. 1,054). For the marketplace to work

successfully, individuals of all types – healthy and sick, young and old – must sign up to ensure a balanced risk pool. Although the marketplace is not a system offering universal health care, the system works in the same way: The healthy and young use less resources than they pay into the system, offsetting the cost of the old and sick. Because of the non-discrimination requirement in the ACA, health insurance companies cannot turn down sick or older individuals. Further, the insurer is not allowed to discriminate by age when setting premiums, making health insurers reliant on young people to sign up to cover the expenses of older, sicker individuals. If expenses cannot be covered, it could lead to a *death spiral:* Insurance companies being forced to increase premiums, making health insurance for *low-risk individuals* too expensive and leaving the marketplace more attractive. The remaining group is then more expensive than the calculated premium, leading to another premium increase and people leaving the insurance pool until the market eventually collapses. Therefore, the penalty for individuals without insurance coverage is essential to force young people to enroll and balance the risk pools (Brady, 2015, p. 639). The penalty was gradually increased from USD 95 in 2014, where only 27 percent of the enrollees were between the ages 18 and 34, to USD 695 or 2.5 percent of household income in 2016 (whichever is greater) (Brady, 2015, pp. 641-642).

3.3 Navigation

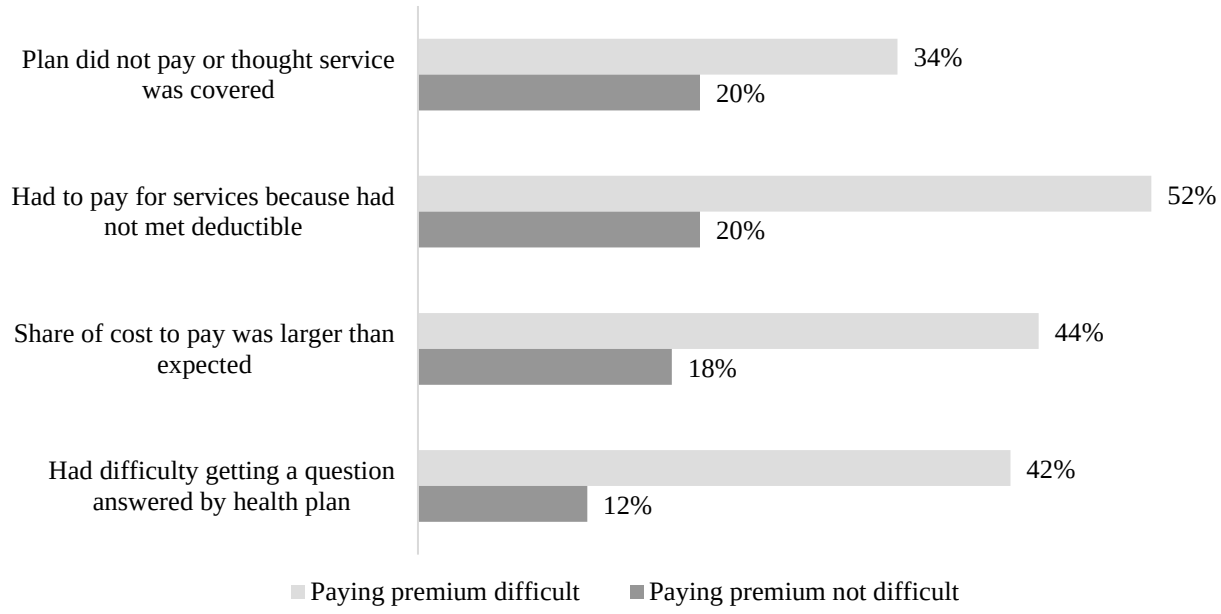
Looking at problems consumers face with their health plans, there is growing evidence that a lack of health literacy makes navigation on the marketplace more challenging. Health illiterate individuals do not fully understand the coverage and cost-sharing provisions of their health plans. Enrollees who report problems affording health care are reported to have lower levels of health literacy and were more likely to not understand what their health plans covered (see Figure 1). The group reporting “paying premium was difficult” was also not more likely to be uninsured before the ACA was introduced. This suggests the complexity of the available health plans leads to great confusion, especially for those experiencing trouble affording their coverage (see Figure 2) (Tolbert and Young, pp. 5-6).

Figure 1: Understanding of health insurance among nonelderly adults with marketplace coverage, by affordability of premium



Source: Author's own presentation, data from Tolbert and Young, 2016, p.1.

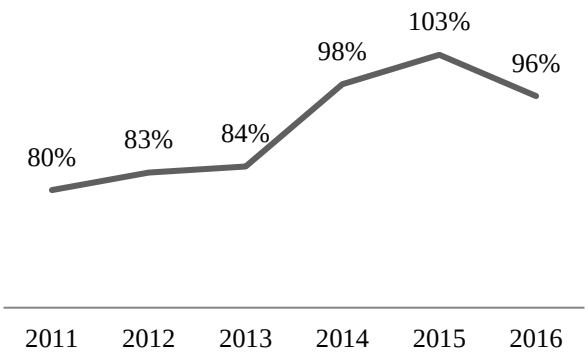
Figure 2: Problems with health plans among nonelderly adults with marketplace coverage, by affordability of premium



Source: Author's own presentation, data from Tolbert and Young, 2016, p.1.

3.4 Financial Performance

Figure 3: Average medical loss ratio by year



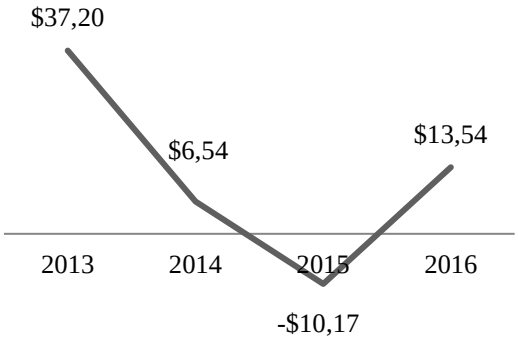
Source: Author's own presentation, data from Cox, Levitt and Claxton, 2017.

An analysis by the Kaiser Family Foundation found that the performance of key insurers operating on the marketplaces declined after opening the marketplaces but had stabilized in 2016. The study included two indicators for financial performance: the *average medical loss ratio* (the share of health premium paid out as claims) and the *average gross margin per member per month*. Since implementation of the ACA, the insurers remained profitable at all times, although performance worsened as changes accompanying the ACA came into effect in 2014 and 2015. Medical loss ratios should usually not exceed 85-90 percent for an organization to remain profitable. Nevertheless, after the ACA became effective the average medical loss ratio grew past this percentage and even up to 103 percent (see Figure 3). In 2014, the transition of the insurance market came with several changes and insurance companies had little experience in pricing the plans for the new population. On average, insurers set the premiums too low and they were not able to cover the cost of the plans. This mispricing was likely due to a smaller share of young and healthy enrollees than initially expected. Other factors, including competitors who strategically underpriced their plans and the retention of ACA non-compliant plans, increased the mispricing effect. In 2015, claims still outgrew premiums leading to an increase of medical loss ratios to an average of 103 percent. During the same year, premiums remained stable due to an ongoing lack of information and pricing knowledge on behalf of insurers, and ongoing competition for issuing the lowest-cost plan (Cox, Levitt and Claxton, 2017).

In addition to higher medical loss ratios, average gross margins per member fell with the transition to the marketplace from USD 37.20 in 2013 to USD -10.17 in 2015 (see Figure 4). Although gross margins are a great indicator of performance, a positive margin does not automatically translate into a higher profitability since they do not take

administrative expenses into account. Despite the medical loss ratio decreasing per individual, the total premium income is higher compared to pre-ACA conditions due to a higher total number of enrollees (Cox, Levitt and Claxton, 2017).

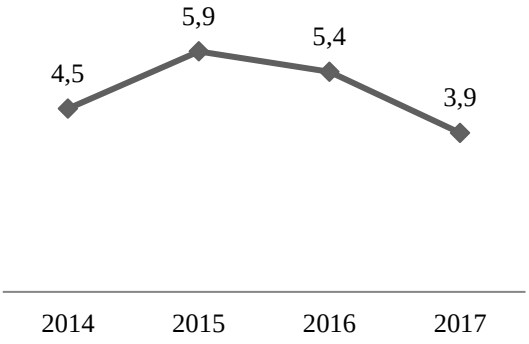
Figure 4: Average gross margins per member per month



Source: Author's own presentation, data from Cox, Levitt and Claxton, 2017.

In 2016, the third operating year of the marketplace, insurance companies were finally able to analyze more meaningful data to set more reasonable premium rates. For the first time, the premiums grew faster than cost claims leading to decreasing market loss ratios. Medical loss ratios fell by 7 percent to 96 percent but remained higher than the 2013 level of 80 percent. If insurers want to return to pre-ACA margins, the conditions still need to improve to include steady marketplace enrollment with premium increases and no substantial increase in claims. For the ACA's success it is essential that the marketplace remains stable and maintains the willingness of insurers to participate on the marketplace. Insurers will only be interested if long-term profitability is not at risk (Cox, Levitt and Claxton, 2017; Kaiser Family Foundation, 2017b).

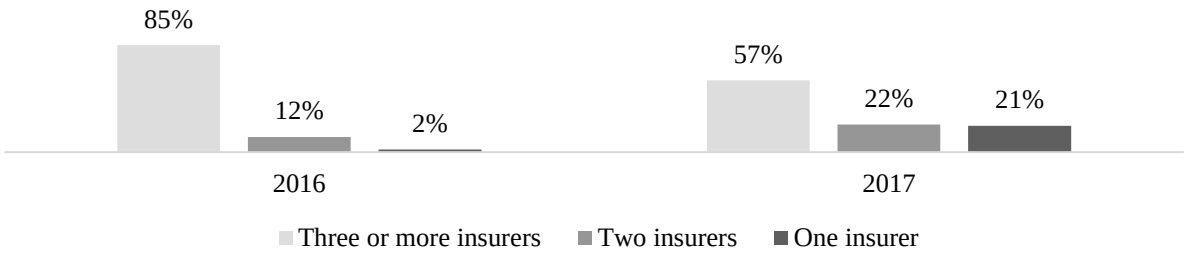
Figure 5: Average number of insurers participating on the marketplace



Source: Author's own presentation, data from Cox, Long, Semanskee, et al., 2016.

Due to the retained losses of insurance plans operating on the marketplace, health insurance companies like UnitedHealth and Aetna announced their decision to leave some local markets or the ACA marketplace completely. In 2017, the average number of insurers participating on the marketplace will be 3.9 (see Figure 5), ranging from one insurer in five states and 15 insurers in Wisconsin. Per state, the number of available health insurers is decreasing with 21 percent of states having only one health insurer in 2017 compared to 2 percent of states having only one available insurer in 2016 (see Figure 6) (Cox, Long, Semanskee et al., 2016). On a county level, those numbers look more alarming: The number of counties with just one marketplace insurer is likely to increase from 225 counties in 2016 to 974 in 2017 due to the exit of UnitedHealth, which was formerly the second largest insurer in rural areas (Cox and Semanskee, 2016).

Figure 6: Insurer participation and choice of enrollees

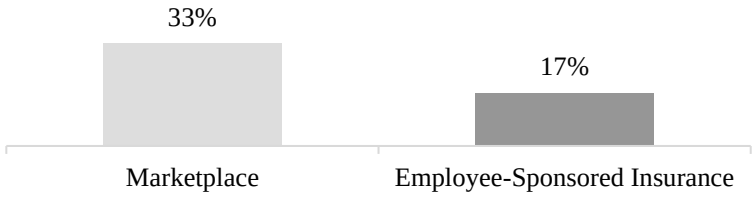


Source: Author's own presentation, data from Cox, Long, Semanskee, et al., 2016.

3.5 Affordability

Although subsidies are available to lower costs of private health insurance plans for individuals, 25 percent of the population have trouble affording premiums, deductibles and out-of-pocket costs when they receive health care services. Focusing on premiums only, a third of the marketplace enrollees find affording their premium *somewhat difficult* or *very difficult* compared to 17 percent of enrollees in an employer-sponsored health insurance (see Figure 7). These findings are consistent with other reports indicating that 36 percent of marketplace enrollees with a deductible are dissatisfied compared to 17 percent of employer-sponsored insurance enrollees (Tolbert and Young, 2016, p. 1).

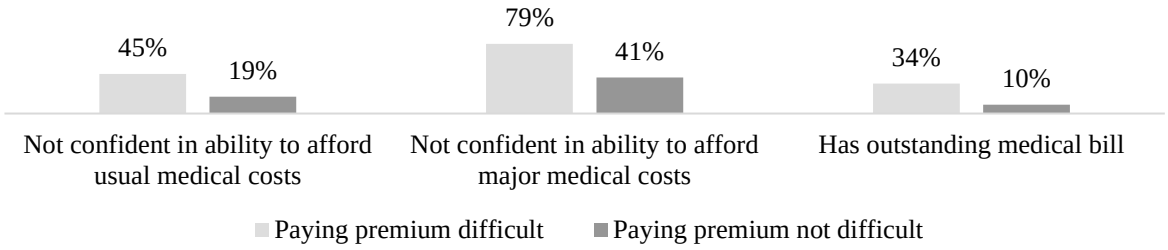
Figure 7: Difficulty affording health insurance premiums among nonelderly adults, by insurance coverage



Source: Author's own presentation, data from Tolbert and Young, 2016, p. 1.

Comparing both population groups, with and without difficulties in affording coverage, both groups shared similar characteristics regarding income, age, and health status. The only difference is the group with difficulties was more likely to have dependent children (49 percent versus 16 percent) (Tolbert and Young, 2016, p. 2). Available subsidies for health insurance are based on the family's income rather than on a percentage of the health plan's cost. Thus, families do not pay more for coverage than childless individuals because they chose a family plan. Rather, families face higher household expenses due to additional cost for housing, food, or education which can stress the family budget, especially for lower income families. This can lead to trade-offs between paying for health insurance or household essentials (Tolbert and Young, 2016, pp. 2-3).
Individuals with having trouble paying their premiums were also more likely to feel financially insecure than the population without trouble. Further, the insecurity over medical cost was not fully eased for the insured population with trouble affording their premiums, including usual and major medical cost. Medical debt was a major cause for personal bankruptcies (see Figure 8) (Tolbert and Young, pp. 3-4).

Figure 8: Financial insecurity over medical costs among nonelderly adults[2] with marketplace coverage, by affordability of coverage



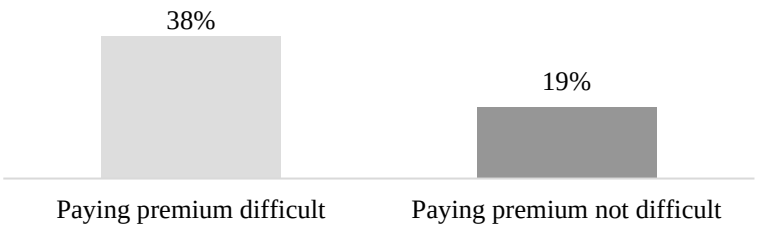
Source: Author's own presentation, data from Tolbert and Young, 2016, p. 3.

People facing difficulties in paying for health care were also more likely to use health services and to have higher unmet health needs than those without difficulties in paying

[2] Includes adults aged 19-64.

for care (38 percent versus 19 percent). For families with already strained budgets, accessing care put another burden on families perceiving their insurance coverage as unaffordable (see Figure 9). Worryingly, individuals facing challenges in affording their premiums were also more likely to postpone care and cost was often mentioned as a factor (Tolbert and Young, 2016, pp. 4-5).

Figure 9: Unmet needs for care among nonelderly adults with marketplace coverage, by affordability of premium



Source: Author's own presentation, data from Tolbert and Young, 2016, p 4.

The initial premiums were based on the actuarial assumptions regarding age and health status mix of an unknown population (Hall, 2014, p. 1039). Due to the previously mentioned substantial losses of health insurances participating in the marketplace and the phasing out of the ACA's reinsurance program, insurance companies started to increase premiums. For the second-lowest priced silver plan, which serves as the benchmark plan for financial assistance, the premium for a 40-year-old non-smoker ranges from USD 299 in Cleveland, Ohio, to USD 904 in Anchorage, Alaska, before tax credits are taken into account. The largest increases in premiums were recognized in Phoenix, Arizona, with up to a 145 percent increase from USD 207 to USD 507 (Kaiser Family Foundation, 2016). The increase in premiums was one major issue publicly debated with critics and defenders citing negative and positive aspects of a system with subsidies: younger, healthier people pay more for their insurance than older, sicker population pays (Hall, 2014, pp. 1044-1045). On average, insurers participating on the marketplace raised premiums substantially by 22 percent from 2016 to 2017 (Cox, Levitt and Claxton, 2017). On the contrary, the premium projections of the Congressional Budget Office of the year 2009 show a different picture: The average nationwide premium for the benchmark plan for the year 2016 was USD 5,200 a year compared to an actual USD 4,583 or 12 percent lower than originally projected. Even if premiums rise by nine percent in 2017, the average premium still remains below the cost projections of the Congressional Budget Office. Potential explanations are intense competition, underpricing, and a slowdown in healthcare cost suggesting some reason for optimism (Levitt, Cox and Claxton, 2016).

4 Discussion

After analyzing the marketplace in the areas of enrollment, risk pooling, navigation, financial performance and affordability the reasons for the failure of the marketplace become more evident.

Enrollment
Although the initial failure of the website *healthcare.gov* affected enrolling individuals, the problems have been resolved and the government has likely learned from its mistakes. More than twelve million individuals are enrolled in a marketplace plan as of 2017. Nevertheless, the share of the actual enrollees in relation to the marketplace potential was unfortunately only 40 percent in 2016, leading to a mediocre performance of the marketplace which was far from reaching its full potential.

Risk Pooling
The automatic risk selection process which happened due to the failure of the website is the more severe problem because the risk pool was not as balanced as needed. Having more old and sick people in the risk pool risks starting the *death spiral*, which poses a substantial risk to health insurances due to repeated premium increases and individuals leaving the marketplace. Eventually, healthy individuals weigh the costs and benefits of paying for health insurance coverage versus paying the fine. The government should set incentives to ensure that as many people as possible enroll on the marketplace so the risk pools are large enough and balance the number of high- and low-risk individuals. This is essential to stabilize the market and make operations profitable for participating health insurance companies.

Navigation
A lack of health literacy makes it harder for individuals to understand their coverage and the cost-sharing provision they receive. Individuals who report having trouble affording their premium were especially more likely to lack health literacy and not understand their health plans. Also, this population was less likely to know what they must pay in case they see a provider. This suggests the marketplace and its website *healthcare.gov* confuses individuals so that coverage and cost of health plans are not fully understood. *Healthcare.gov* offers many plans with various cost-sharing options so that comparing plans is not a simple task even for educated people. Since being covered by health insurance is not enough to improve health outcomes, the marketplace should improve its efforts to assist customers by presenting information as clearly as possible.

Financial Performance
Due to an initial lack of knowledge of the future marketplace population and a lack of pricing skills, the financial performance of health insurers declined after entering the

marketplace. The average medical loss ratio, typically not higher than 85 percent, increased with a spike at 103 percent in 2015. A similar negative development could be seen with the average gross margins per member per month which declined to a low of a negative gross margin of -10.17 USD in 2015. After insurance companies gained more data and improved their pricing schemes, the average medical loss ratio started to decline and the average medical gross margin started to rise. To return to pre-ACA conditions in the perspective of health insurers, the positive trend needs to continue. Therefore, the stabilization of the marketplace is essential to maintain the participation of insurers.

Despite the fact that the marketplace enrollees only make up a small part of the business insurers receive, the first insurance companies which decided to leave the marketplace decreased the choice of the consumer considerably. 21 percent of states have only one insurer left on the marketplace; bearing in mind that low competition is not beneficial for individuals in terms of price and quality, this number is alarming.

Affordability

Due to incorrect initial premium projections, the financial performance of insurers declined. As insurers were able to recalculate premiums in the second year of the exchange, premiums increased significantly. From 2016 to 2017, premiums were again increased by an average of 22 percent, making this a major topic of critique in the media. Considering the premium projections of the CBO, the premium increase is put in a different perspective: The 2016 premium was lower than projected in 2009, deflating the arguments of critics.

The goal of health insurance is to make health care services affordable to the general population. Despite the substantial increase in the number of individuals with health insurance coverage, a third of the marketplace enrollees still face challenges in affording their insurance premiums, deductibles and out-of-pocket costs. This puts an especially large burden on families with children who have higher household expenditures in general, leading to families weighing their choices of paying for health insurance or household essentials because health care seems unaffordable. Further, enrollees who have trouble paying their premiums also felt more financially insecure and were more likely to have unmet health needs than the individuals without difficulty. Troublingly, individuals having issues affording care were also more likely to postpone care, likely due to cost. Although the *Affordable* Care Act was meant to increase access to care and make health services more affordable, many enrollees still struggle in paying for their care and perceive healthcare as still unaffordable. Since premiums increased rather than decreased, financial assistance programs might be a starting point to lift the financial burden.

5 Conclusion

This paper aimed to evaluate the performance of the marketplace in terms of (1) enrollment, (2) risk pooling, (3) navigation, (4) financial performance, and (5) affordability to give a broad overview of the current challenges enrollees and insurers face. As the analysis showed, the initial problems of the marketplace such as technological challenges are resolved, but the marketplace still suffers from the aftermath in terms of a skewed risk pool composed of higher-risk individuals than intended. Since the outreach has been mediocre after 3 years of operation, it is essential to increase the enrollment rate to stabilize the market. Penalizing individuals without health insurance in a reasonable way is key for building up a balanced risk pool. Additionally, the navigation of the marketplace is complex. Achieving a balanced risk pool requires more assistance and a simpler presentation of information to assist individuals lacking health literacy so they can fully understand the coverage provisions and cost sharing requirements of marketplace plans. The initial financial performance of insurers operating on the market place was poor and reached the lowest point in 2015. Due to additional data used for price calculations, the financial situation of insurers has steadily improved and the market is stabilizing again. Nonetheless, the first insurers deciding to leave the marketplace in some or all states did so because of significant losses in 2016. Premiums increased again to make marketplace operations for insurance companies more profitable, but these higher rates also increased the financial burden on individuals. A third of marketplace enrollees, especially families with strained budgets, reported trouble in affording their insurance premiums, deductibles or out-of-pocket costs. Unfortunately, this leads to individuals suffering from financial insecurity and deciding to postpone care. Increasing the budget of financial assistance program could be one way to lift the financial burden off of individuals and making sure that everyone can afford to receive care.

Finally, the establishment of the marketplace was an approach which helped many people gain insurance coverage and did not fail entirely. Unfortunately, the implementation of the ACA has not happened as smooth as expected. Some challenges which occurred were only temporary – like the failure of website – but other problems still persist and hinder the marketplace. These issues prevent the marketplace from reaching its full potential and explain why its implementation was not successful. By examining the reasons for the failure of the marketplace, potential solutions have also come to light and may lead to future success of the marketplace.

References

Brady, J. (2015), 'The Affordable Care Act: Creating Headaches instead of Healing Them', *University of Louisville Law Review*, no. 53, pp. 627–650.

Collins, S. R. and Garber, T. (2013), 'State Health Insurance Exchanges: Progress and Challenges', *The Hastings Center Report*, vol. 43, no. 1, p. 1.

Cox, C., Levitt, L. and Claxton, G. (2017), *Insurer Financial Performance in the Early Years of the Affordable Care Act,* Kaiser Family Foundation [Online]. Available at: http://kff.org/private-insurance/issue-brief/insurer-financial-performance-in-the-early-years-of-the-affordable-care-act/ (Accessed May 27, 2017).

Cox, C., Long, M., Semanskee, A., Kamal, R., Claxton, G. and Levitt, L. (2016), *2017 Premium Changes and Insurer Participation in the Affordable Care Act's Health Insurance Marketplaces*, Kaiser Family Foundation [Online]. Available at: http://kff.org/health-reform/issue-brief/2017-premium-changes-and-insurer-participation-in-the-affordable-care-acts-health-insurance-marketplaces/ (Accessed May 28, 2017).

Cox, C. and Semanskee, A. (2016), *Preliminary Data on Insurer Exits and Entrants in 2017 Affordable Care Act Marketplaces,* Kaiser Family Foundation [Online]. Available at: http://kff.org/health-reform/issue-brief/preliminary-data-on-insurer-exits-and-entrants-in-2017-affordable-care-act-marketplaces/ (Accessed May 27, 2017).

Goldstein, A. (2017), 'Aetna Exiting All ACA Insurance Marketplaces in 2018', *The Washington Post,* 10 May [Online]. Available at: https://www.washingtonpost.com/national/health-science/aetna-exiting-all-aca-insurance-marketplaces-in-2018/2017/05/10/9dedbeea-35d4-11e7-b373-418f6849a004_story.html (Accessed May 31, 2017).

Hall, M. A. (2014), 'Evaluating the Affordable Care Act: The Eye of the Beholder', *Houston Law Review*, no. 51, pp. 1029–1056.

Hellander, I. (2015), 'The U.S. Health Care Crisis Five Years after Passage of the Affordable Care Act: A Data Snapshot', *International Journal of Health Services: Planning, Administration, Evaluation*, vol. 45, no. 4, pp. 706–728.

Housten, A. J., Furtado, K., Kaphingst, K. A., Kebodeaux, C., McBride, T., Cusanno, B. and Politi, M. C. (2016), 'Stakeholders' Perceptions of Ways to Support Decisions about Health Insurance Marketplace Enrollment', *BMC Health Services Research*, vol. 16, no. 1, pp. 634–644.

Kaiser Family Foundation (2010), *Explaining Health Care Reform: Questions about Health Insurance Exchanges,* Kaiser Family Foundation [Online]. Available at: http://kff.org/health-costs/issue-brief/explaining-health-care-reform-questions-about-health-2 (Accessed May 21, 2017).

Kaiser Family Foundation (2016), *Marketplace Enrollment as a Share of the Potential Marketplace Population,* Kaiser Family Foundation [Online]. Available at: http://kff.org/health-reform/state-indicator/marketplace-enrollment-as-a-share-of-the-potential-marketplace-population-2015/?currentTimeframe=0&sortMod-el=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (Accessed June 02, 2017).

Kaiser Family Foundation (2017), *Analysis: Insurer Financial Indicators Show Signs of Stabilizing after Transition to ACA Marketplaces,* Kaiser Family Foundation [Online]. Available at: http://kff.org/private-insurance/press-release/analysis-insurer-financial-indicators-show-signs-of-stabilizing-after-transition-to-aca-marketplaces/ (Accessed May 27, 2017).

Kaiser Family Foundation (2017), *Total Marketplace Enrollment,* Kaiser Family Foundation [Online]. Available at: http://kff.org/health-reform/state-indicator/total-marketplace-enrollment/?currentTimeframe=0&-sortModel=%7B%22colId%22:%22 Location%22,%22sort%22:%22asc%22%7D (Accessed June 01, 2017).

Lammert, C. (2017), 'Ein historischer Erfolg: Obama und die Reform des Gesundheitssystems', *Zeitschrift für Außen- und Sicherheitspolitik,* vol. 10, Suppl 2, pp. 65–80.

Levitt, L., Cox, C. and Claxton, G. (2016), *How ACA Marketplace Premiums Measure Up to Expectations,* Kaiser Family Foundation [Online]. Available at: http://kff.org/health-reform/perspective/how-aca-marketplace-premiums-measure-up-to-expectations/ (Accessed May 27, 2017).

Murphy, T. (2017), 'Insurers Continue to Hike Prices, Abandon ACA Markets', *The Washington Post*, 25 May [Online]. Available at: https://www.washingtonpost.com/national/health-science/insurers-continue-to-hike-prices-abandon-aca-markets/2017/05/25/daf9564e-4157-11e7-b29f-f40ffced2-ddb_story.html?utm_term=.a1395bff345b (Accessed May 31, 2017).

Robert Wood Johnson Foundation (2013), 'Health Insurance Exchange and State Decisions', *Health Affairs - Health Policy Brief.*

Tolbert, J. and Young, K. (2016), *Paying for Health Coverage: The Challenge of Affording Health Insurance among Marketplace Enrollees,* Kaiser Family Foundation [Online]. Available at: http://files.kff.org/attachment/issue-brief-paying-for-health-coverage-the-challenge-of-affording-health-insurance-among-marketplace-enrollees (Accessed May 24, 2017).

Part 2: Innovation in Health Care Delivery

Accountable Care Organizations

Franziska Distler

In the historically fragmented U.S. health care system, care has been delivered by multiple providers with little or no coordination, raising issues with access, cost, and quality. Under the Affordable Care Act (ACA), the Centers for Medicare and Medicaid Services (CMS) is guiding several experimental programs in health care payment and delivery. A fundamental element of this reform is the development of Accountable Care Organizations (ACOs), which offer providers financial rewards if they can reduce Medicare cost expansions and ensure quality standards. Alternative payment models are not only in the center of current U.S. government efforts, but have also gained international attention. Due to their heightened importance, this essay provides a general overview of ACOs based on a theoretical analysis of the existing body of literature. Evaluation of cost reduction and quality improvement of early ACOs show promise but also unintended incentives for providers through the benchmarking methodology. Enacting the Final Medicare Shared Savings Rule in 2016, the government is making continuous efforts to reset providers' incentives to strengthen their satisfaction and maintain ACO participation.

Contents

1 Healthcare Delivery in America: Shift from Volume to Value

The American government is making a great effort to change payment models for healthcare delivery. The shift from current fee-for-service (FFS) payments to alternative payment models aims to provide not only better care for patients but also lower costs (CMS, 2016a, p. 1). Turning away from incentivizing providers to increase the volume of services, the government strives to tie payments to quality and value. Improving healthcare delivery, Accountable Care Organizations (ACOs) have a strong impact on making this shift. Through this model, a set group of providers are held contractually accountable to payers for the cost and quality of the care they provide for a specific population (Cimasi, 2013, p. 1).

The aim of this essay is to provide a general overview of ACOs in America. After explaining the formation process of accountable care in the 1970s, this paper focusses on basic structures of ACOs, like important definitions, compensation information, and participating players. The Status Quo in Section 4 contains how ACOs are spread around the United States and how they performed so far. For a better understanding of current benchmarking challenges, Section 5 points out unintended incentives, resulting inefficiencies, and the government's response. It is followed by a conclusion with forecasted developments.

2 Accountable Care: From Managed Care to ACO

While ACOs have only recently become popular in the American healthcare industry, the concept of *accountable care* is found in the origin of the managed care movement. The Health Maintenance Organization Act of 1973 provided prepaid group practice plans as an alternative to America's traditional fee-for-service system. The act authorized $375 million for the development of Health Maintenance Organizations (HMOs), which are "prepaid health plan model[s] that use provider networks with a system of primary care gatekeepers and capitated provider reimbursement incentivizing decreases in utilization and increases in the efficiency of care for HMO members" (Cimasi, 2013, p. 5). Reducing the separation between medical service provision and compensation, capitation succeeded in controlling healthcare costs in a variety of settings, leading not only to an expansion of managed care in the private sector but in the public as well (Lagoe et al., 2005, pp. 5-6). The managed care approach flourished all over the United States and reached its high point in the mid-1990s. Employers widely accepted these less costly HMOs, leading to the enrollment of around 65 million Americans in these plans in 1996 (Cimasi, 2013, p. 5; Lagoe et al., 2005, pp. 7-8). While managed care performed well in reducing costs, individual providers opposed non-physician control over the medical profession and resisted changes in reimbursement models. Parts of the

cost-reduction were also due to physicians underproviding services for fear of surpassing their spending thresholds (Cimasi, 2013, p. 5). As a result, patient dissatisfaction rose as they saw both their access to care restricted and a decline of medical quality (Blendon et al., 1998, pp. 80, 83). This so called *managed-care backlash* describes a dramatic drop of the approach in the late 1990s (Enthoven, 2005, p. 101). History clearly indicates that integrated organizations have great potential to reduce costs, but ensuring quality and patient's acceptance is essential for these plans to remain viable. Currently, most states have laws ensuring wider public choice and access for still-existing managed care plans (Cimasi, 2013, p. 6).

McClellan et al. (2010) describe the American health system as "neither effective nor sustainable" (McClellan et al., 2010, p. 982), characterized by high medical expenditures, overuse, and fragmentation. Compared to all 34 OECD countries, America not only spends the greatest share of its gross domestic product on healthcare but also shows the greatest relative growth in health expenditures (OECD, 2017). In 2011, almost all Medicare spending was FFS payments, creating strong financial incentives for physicians to increase the volume of services they delivered with little incentives to ensure value or quality of care (Meyer, 2011, p. 1,228). Against this background, there is great interest across the United States in improving health care delivery, performance, and payment mechanisms.

Required by the Affordable Care Act, the Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health & Human Services (HHS), established the *Medicare Shared Savings Program* in 2012. Using Medicare, the nearly universal coverage program for older adults, the program aims to provide better care for patients, achieve better health for communities, and lower costs through improvements in healthcare delivery (Barnes et al., 2014, p. 1 and CMS, 2016a, p. 1). In 2015, for the first time in history of the Medicare program, HHS set explicit goals for alternative payment models. Turning away from FFS payments, it is targeting to tie 85% of all Medicare payments to quality or value by the end of 2018 (HHS, 2015). In addition to this self-commitment, the statement signals healthcare providers to get involved in alternative payment models, such as bundled payment. In March 2016, HHS announced that they reached the interim goal of tying 30% of Medicare payments to quality ahead of schedule. ACOs, which experienced a boom through the MSSP, represent about three quarters of this success, allowing health care providers to better coordinate care for Medicare patients (HHS, 2016).

3 Basic Structures of Accountable Care Organizations

3.1 Definition and Objectives

CMS defines ACOs as "groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high-quality care to their Medicare patients" (CMS, 2017a). If providers can slow the growth of patient healthcare costs, for example by reducing unnecessary services, while ensuring good quality of care, they will receive financial rewards. Contrary to the fragmented care that often results from FFS payments, ACO providers are striving to deliver seamless, high-quality care for Medicare beneficiaries across different care settings (CMS, 2016a, p. 2).
Known as the Three-Part Aim (originally called Triple Aim), proponents believe that ACOs will deliver better quality and outcomes, improved patient experience, and lowered per capita costs (Berwick et al., 2008, p. 760 and IHI, 2007, p. 2). While ACO-like models have been implemented in the private sector for years, ACOs for Medicare patients were established nationwide with the Affordable Care Act in 2010 (Auerbach et al., 2013, p. 1,781). Intended to shift the delivery of health services from an emphasis on volume to an emphasis on value, ACOs constitute an innovative model in America (Hofler and Ortiz, 2016, p. 1).

3.2 Variations in Medicare-ACO Models

While ACOs administered by CMS receive the most attention, the numerous commercial ACOs are more flexible in individual contract agreements as they are only subject to ordinary legislation. The coexistence of various kinds of ACOs creates an ideal environment of learning and improvement (Schulte et al., 2017, pp. 373-374). The following provides an overview of different types of Medicare ACOs. Besides the regular program, CMS is constantly developing and testing different models with a smaller number of participants to expand their knowledge for future ACO development.
With 480 ACOs, the permanent *Medicare Shared Saving Program (MSSP)* is the most popular model administered by CMS. An ACO must apply and meet certain criteria to participate, requiring a service population of at least 5,000 Medicare FFS patients and participation for at least three years. ACOs can either chose a one-sided risk model, where they may receive shared savings but are not liable for shared losses, or the more ambitious two-sided model, where they may receive a greater portion of shared savings but also share losses (CMS, 2016a, p. 4).
The *Advance Payment ACO Model* ran from 2012 to 2015 and was mainly designed for physician-based and rural providers. It supported them with upfront and monthly payments instead of retrospective shared savings, providing the startup capital necessary to grow infrastructure and finance staff for care coordination (CMS, 2017b). Maintaining the idea of pre-paid shared savings, the *ACO Investment Model* started in 2015. Building

on knowledge gained through Advanced Payment ACOs, it aims to encourage ACOs to take on greater financial risk and to set up new ACOs, especially in underserved areas. The more advanced *Pioneer ACO Model* only addressed providers with previous experience in coordinating care and managing the appropriate infrastructure. Running until 2016, Pioneer ACOs took on higher levels of shared savings and risks than any other ACOs in the MSSP and were designed to test innovative ways of compensating and regulation (CMS, 2017f). For example, they derived most of their clinical service revenues from value-based payments of private insurers, with some ACOs converting parts of their FFS reimbursements into a monthly population-based payment (Pham et al., 2014, p. 1,636). Even with experienced leadership, this ACO model turned out to be very challenging. While only 8 of the initial 32 Pioneer ACOs remained in the fifth and final performance year, most switched to the less ambitious and lower risk MSSP. Growing from these experiences, CMS announced the *Next Generation ACO Model* at the end of 2016, providing 44 organizations with the opportunity to take high levels of financial risks and rewards. The model provides better predictability of financial targets through refined benchmarking and tools to support patient engagement and care (CMS, 2017e). Finally, the *Comprehensive ESRD Care Model* strives to improve care for beneficiaries with End-Stage Renal Disease (ESRD). As this disease is causing complex health needs and requires multiple provider visits, the model aims to create incentives for improved patient-centered and coordinated care as well as reduce medical costs associated with this condition (CMS, 2017d).

3.3 Healthcare Providers

Any Medicare-enrolled provider or supplier is free to join an ACO. The collaboration can be composed of a range of healthcare organizations such as hospitals, independent practice associations, multi-specialty medical collaborations and groups of doctors or other providers (Goldsmith, 2011, p. 33). The Medicare ACO programs do not specify a set composition of providers that must be included, requiring only a minimum service population of Medicare beneficiaries (Colla et al., 2016, p. 432).

3.4 Compensation via Benchmarking

Healthcare providers participating in Medicare ACOs receive regular remuneration for covered Medicare services through the FFS system. Additionally, ACO annual performance is measured against an individual benchmark calculated by CMS that indicates whether the ACO generated savings or losses for the Medicare program. The benchmark is an estimation of "what the total Medicare Fee-For-Service […] expenditures for assigned ACO beneficiaries would otherwise have been in the absence of the ACO" and is updated every year (CMS, 2016a, p. 4). Following the idea of value-based payments, a combination of efficiency and quality is needed for reward (McCellan et al., 2014, p.

1,509). Therefore, only "ACOs that meet or exceed a minimum savings rate (MSR), satisfy minimum quality performance standards, and otherwise maintain their eligibility to participate in the Shared Savings Program are eligible to receive a portion of the savings they generate" (CMS, 2017a, p. 3). The CMS quality measurements are classified in four, equally weighted domains: patient experience, care coordination/patient safety, preventive health, and at-risk population. Over the three-year implementation period, CMS payments shift from ACOs simply reporting these measures to the entities bearing risk for meeting performance targets (MedPac, 2016, p. 3).

3.5 Patient's Assignment

Unlike HMOs and managed care programs, ACOs do not limit patients in their choice of healthcare provider. Beneficiaries are freely able to choose any Medicare-enrolled provider regardless of their participation in an ACO (MedPac, 2016, p. 1). However, if an attributed patient chooses a provider outside of the ACO, the ACO remains responsible for the costs. This incentivize physicians to provide patients with exceptional care in order to maximize ACO retention (MedPac, 2016, p. 1). From a patient's perspective, coordinated care and quality improvements are intended to lead to less paperwork and fewer repeated medical tests due to electronic health record utilization (Barnes et al., 2014, p. 2).

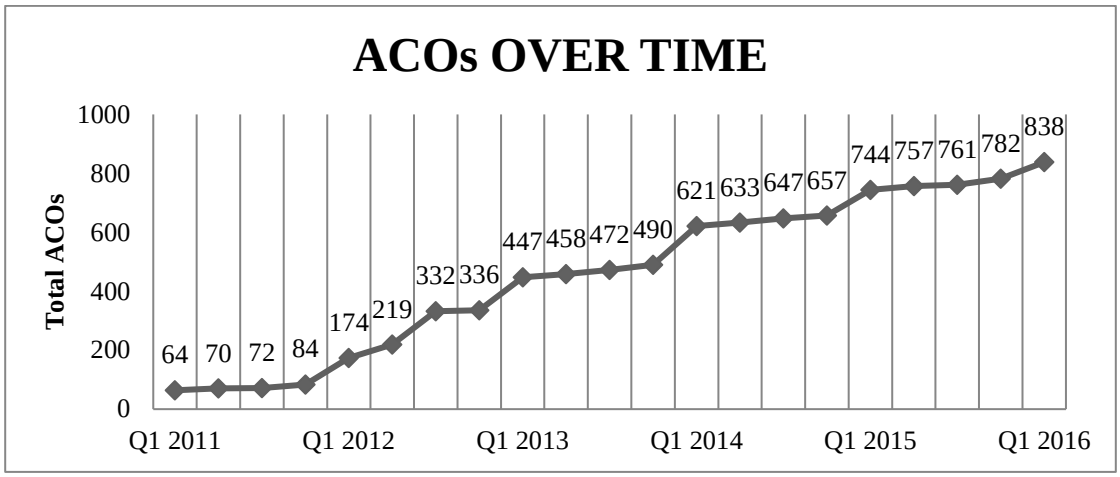
Nevertheless, CMS has to assign beneficiaries to an ACO since the yearly performance-measurement is based on a defined patient population. In most cases, the assignment is made retrospectively at the end of each year based on the population served during that period. For advanced two-sided models, a prospective method uses data from one year to assign patients to the ACO for the following year (CMS, 2016a, p. 6). Generally, prospective methods avoid problems of free-riding and resource expenditure on patients who are not attributed to the ACO, while retrospective methods ensure a larger overlap of the assigned and the treated populations (Lewis et al., 2014, p. 592).

4 Status Quo – ACOs in America

4.1 Number of ACOs

The consulting company Leavitt Partners estimates a total of 838 public and private ACOs in January 2016, showing a significant increase in previous years as shown in Figure 1. With an estimated 28.3 million people, ACOs are covering 8.9% of the American population (Muhlestein and McClellan, 2016).

Figure 1: ACOs Over Time



Adapted from: Muhlenstein and McClellan, 2016.

More than 600 ACOs are managed by CMS. Currently they register 480 MSSP ACOs, 45 Investment Model ACOs, 37 Comprehensive ESRD Care Model ACOs and 44 Next Generation Model ACOs. Still, contracts of private payers usually cover lager numbers: The 17.2 million lives covered by private payer ACOs dwarfs the 11.1 million covered by MSSP ACOs in 2016 (Muhlestein and McClellan, 2016).

4.2 Composition of Healthcare Providers

More than half of ACOs include a hospital, which generally provides more capital, advanced data sharing, and better engagements of providers across the care continuum (Colla et al., 2016, p. 437). Additionally, hospital care influences several ACO quality measures, such as readmission rates and medication reconciliation. Still, findings indicate that "ACOs with a hospital do not report significant differences in their capabilities, compared to their counterparts without a hospital" (Colla et al., 2016, p. 437). Hospitals might not be able to fully commit to reducing spending as they typically own many players of the health care provider team, such as laboratory services, rehab facilities etc. Targeting savings within the ACO might thereby reduce the revenue of their own holdings (Brennan, 2016). The fact that physician-led and integrated (physician-hospital partnerships) ACOs are more likely to achieve shared savings, supports this assumption (Muhlestein et al., 2016). Besides fewer bureaucratic layers, physicians might be able to negotiate better prices for external services and can generate savings by reducing emergency department and hospital admissions, which lower revenue for hospitals (Finnegan, 2017). Contrary to previous concerns that hospitals dominate ACO leadership because of their managerial strengths and resources, physicians have a major impact, leading 51% of ACOs alone and 33% jointly with hospitals (Colla et al., 2014, p. 694).

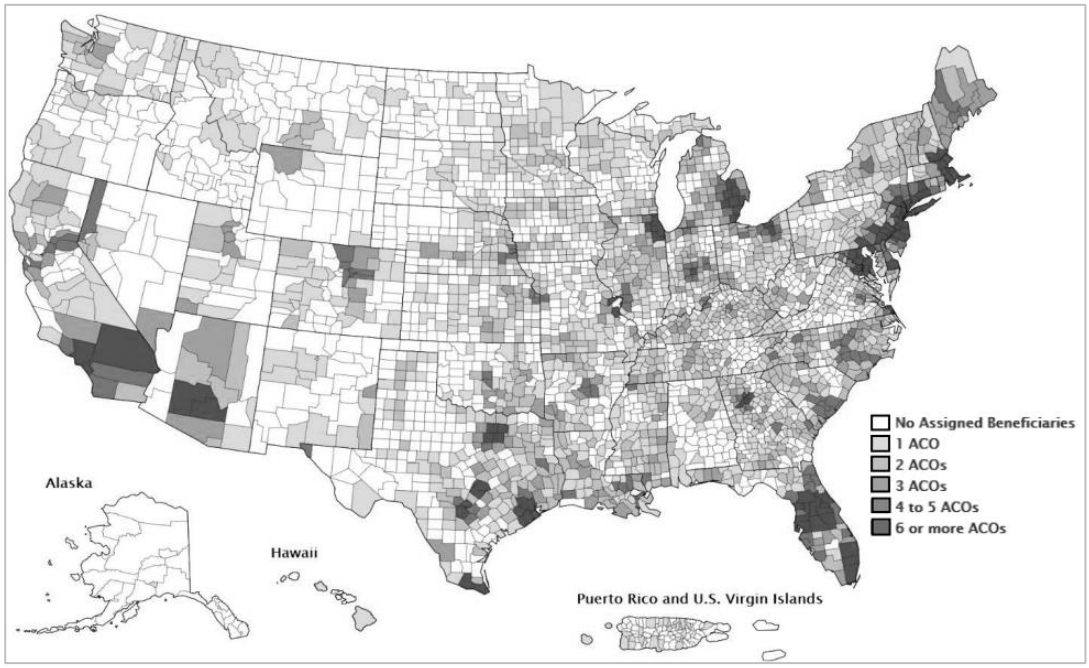
According to the 2015 Medicare report, the best-performing ACOs are not only physician-led but also older and smaller. Older ACOs are at an advantage since they have had more time to improve their health care delivery models and their internal structures. In pursuit of finding the best service provision model, smaller ACOs also succeed by adapting to changes quickly (Brennan, 2016). The smallest ACOs with about 5,600 patients generated savings of $114.70 per beneficiary while the largest ACOs with about 46,600 patients generated losses of $23.93 per capita (Muhlestein et al., 2016). Even if CMS was taking great efforts to encourage the creation of large, consolidated health systems to increase efficiency and functional integration in the past, the 2015 results suggest that it might be more important to emphasize the performance of smaller ACOs (Muhlestein et al., 2016).

4.3 Geographical Distribution

A key marker of where ACOs are forming is pre-existing provider integrations such as hospital systems and large groups of primary care physicians (Auerbach et al., 2013, pp. 1,786-1,787). As shown in Figure 4.2, most MSSP ACOs are located in metro areas like Atlanta, Chicago, Dallas, New York, Philadelphia and San Francisco, with 62% of ACOs found in high population density areas and only 12% in low population density areas (CMS, 2017c).

Interestingly, MSSP ACOs are not preferentially located in areas with high per capita Medicare spending or a high percentage of the area's Medicare population (CMS, 2017c). Even if it seems intuitive that high spending indicates unnecessary care and a great potential of future cost reduction, Auerbach et al. (2013) found out that a lack of key infrastructure and limited ability to integrate care characterize these regions. This might decrease strategic options for ACOs and therefore make these areas less preferred locations.

Figure 2: MSSP ACO Assigned Beneficiary Population by ACO by Country



Source: CMS, 2017c.

4.4 Prerequisites and Performance

Through today's expanding knowledge of healthcare costs, growing opportunities in big data, and experience in collaborating with other health care providers, ACOs have a higher likelihood to succeed compared to the managed care approaches of the 1990s. Patient freedom to use ACO services and select a provider independently reduces mistrust and dissatisfaction in the population (Emanuel, 2012, pp. 2,263-2,264). Expanded physician governance increases acceptance, as physicians prefer an ACO model that permits a greater level of independence and self-governance (Cimasi, 2013, p. 6). Additionally, providers do not have to take on as much financial risk as those in HMOs, which carried up to 100% of the risk, and can now use electronic health records to integrate care (Barnes et al., 2014, pp. 5-6). In the following, performance results of Medicare ACOs are focused because they are subject to a mandatory and independent evaluation through CMS. As there are no such regulations in private sector, results of commercial ACOs might be published incompletely or biased (Schulte et al., 2017, pp. 539-540).

According to CMS, Medicare ACOs generated more than $466 million savings in 2015 and a total of $1.29 billion from 2012 to 2015. Even if more ACOs received shared savings than in previous years, the number remains less than one third of all ACOs. To share in savings, ACOs not only have to satisfy minimum quality performance standards but also meet the MSR. While 8 of all 12 Pioneer ACOs generated savings, only six had sufficient savings to receive a portion of them (CMS, 2016c). Looking at individual

results, many ACOs missed their benchmarks by millions of dollars. An analysis by Introcaso and Berger (2015) revealed that the $341 million in shared savings in 2014 were highly concentrated among the 86 most successful ACOs.
Generally, high-risk ACOs remain unpopular. In January 2017, the clear majority of 438 MSSP ACOs (91%) are participating in the one-sided model while 9% has chosen the two-sided model (CMS, 2017c). Summarizing the financial results of MSSP ACOs in 2015, more ACOs saved rather than lost relative to their benchmarks. While Medicare saved $429 million, it paid out $646 million in shared savings to MSSP ACOs. The net program losses of $216 million are due to the high proportion of one-sided ACO models that receive shared savings but are not liable for losses (MedPac, 2016, p. 4). CMS uses pilot ACOs to evaluate how incentives can increase ACO enrollment and convince providers to take higher risks. Organizations identify lack of capital, absence of integrated IT systems, and deficiency of evidence-based treatment protocol data as the obstacles in forming ACOs (AMN Healthcare, 2011). Additionally, according to Hofler and Ortiz (2016), joining an ACO can raise costs for primary care providers up to 10%, meaning higher costs per patient visit during the first several years. Implementing essential ACO infrastructure, such as an electronic health record system and hiring the necessary administrative staff, can be very costly.
CMS describes a constant increase in the quality of services, reporting that ACOs improved on 84% of the quality measures. Significantly, all 12 Pioneer ACOs improved their scores from 2012 to 2015 by over 21 percentage points (CMS, 2016c). While CMS results suggest great success in Medicare ACOs, they only cover a small share of the American healthcare market and the results have a relatively small sample size. Even if a final evaluation about ACO success cannot be made at this point, the rising number of ACOs indicates widespread organizational faith in the program and significant saving potential.

5 Challenge Benchmarking: Unintended Incentives and CMS Response

The ACO benchmarking system was strongly criticized in years past. At the start of MSSP, every ACO can choose between the one- or two-sided risk model for its first three-year period (see Chapter 3.2). For that time, CMS sets a spending target for the ACO to receive shared savings. The benchmark is a weighted average of the healthcare costs for the attributed patients over the last three years, including annual adjustments for patient characteristics and anticipated growth in Medicare FFS expenditures (Harvey et al., 2014, p. 123). Assuming that more recent spending is more predictive of current ACO expenditures, the most recent year receives the highest weight. For example, for an ACO that started in 2016 spending for patients served in 2015 received a weight of 0.6 while spending in 2014 and 2013 received weights of 0.3 and 0.1, respectively (Douven et al., 2015, p.143).

CMS uses the same method to recalculate the benchmark at the start of each new three-year contract term. This process implies that ACOs which still show high Medicare expenditures at the end of the first term will receive a higher benchmark and hold greater potential to generate savings in the second term. Similarly, ACOs that generated significant savings in the first term receive tightened benchmarks in the second. In order to receive shared savings, these well-performing organizations do not only have to maintain previous expenditure levels but also achieve additional cost reductions. This creates hardship on ACOs in this position, with fewer safe and effective saving opportunities remaining for an ACO to take in upcoming terms. By "placing an ACO in a race against itself" (Harvey et al., 2014, p. 122) and penalizing previous cost reductions with lower benchmarks for the next period instead of rewarding, the MSSP creates unintended incentives (Douven et al., 2015, pp. 143-144). Instead of reducing unnecessary medical services, ACOs may be constrained to increase spending, especially shortly before new benchmark calculations, to receive a better benchmark for the future. One estimate suggests that "for every dollar increase in spending in the last year before an ACO starts a new three-year contract, the ACO will get back between $1.48 and $1.90 during the contract period" (Douven et al., 2015, p. 143). This turns out to be profitable for ACOs but describes the opposite of the original target to reduce Medicare expenditures (Douven et al., 2015, pp. 143, 146).

In June 2016, CMS announced the *Final Medicare Shared Savings Program Rule* in order to "continue broad-based program participation and improve program function and transparency" (CMS, 2016b). In effect, CMS modified the process for resetting benchmarks for the second and subsequent agreement periods, beginning in 2017. Instead of using national Medicare spending data, CMS will now use regional spending growth trends to update ACO benchmarks while removing the adjustment that accounts for the savings generated in the period shortly before the new agreement. Because regional spending is determined by all providers in the area, this change limits the link between ACO performance and future benchmarks (Rose et al., 2016, p. 441). The rebased historical benchmark will now reflect ACO efficiency in relation to other regional providers (CMS, 2016b).

Although very promising, the use of regional data and the resulting convergence in benchmarks between ACOs with spending above and below local average FFS spending could cause less-well-performing ACOs to leave the program, as the new spending target falls below their reach (Rose et al., 2016, p. 441). To avoid this circumstance, CMS also announced a phased-in approach for ACOs with higher-than-average regional spending that applies a lower weight to the benchmark's regional adjustment component in the beginning (CMS, 2016b).

Oppositely, with the new benchmark reflecting the average of high- and low-spending providers in the area, Rose et al. (2016) highlight, that well-performing ACOs with below-baseline spending may not be incentivized to further improve their performance. Recognizing that a shift to a two-sided model promises the greatest savings to these organizations, CMS provided the opportunity for one-sided ACOs to extend their initial benchmark contract for an additional year before the shift to the two-sided model (CMS, 2016b). Future evaluations will show if the adapted benchmark methodology can reach its goals of both strengthening provider satisfaction and increasing ACO participation rates.

6 ACOs - Opportunities and Limitations

Auerbach et al. (2013) describe ACOs as "the heart of the government's efforts to transform healthcare delivery in the United States to a more coordinated, high-quality and efficient system" (Auerbach, 2013, p. 1,786) and underline that the cooperation and continued growth alongside private-sector ACOs has the potential to change the orientation of care systems in America. Trying to avoid circumstances which caused the managed care backlash, ACOs differ in several aspects from HMOs. Voluntary participation, less financial risk, more advanced outcome measurements, and knowledge of care management increases provider acceptance while more coordinated and better quality care attracts and retains patients. Nevertheless, ACOs might also face serious problems, as they gradually take on greater financial risk that could negatively affect the quality of care through rationing, denial of care, or ACO organizational instability. Additionally, consolidation of providers could lead to expanded market power and monopolization, resulting in higher prices (Barnes et al., 2014, pp. 5-6). To prevent future setbacks, CMS strives to improve the position of ACOs through policies such as adapting the benchmarking methodology to accommodate variably performing organizations.

Even as the number of ACOs increases and innovative ACO models raise international awareness of alternative payment models, Barnes et al. (2014) underline the limited impact of ACOs on health expenditures. They may lower costs marginally, but overall, expenditures will remain high unless the demand for acute medical care and the price of care decrease. Thus, socio-economic factors like food supply, unemployment and environment have to be simultaneously targeted as the origin of medical demand (Barnes et al., 2014, p. 7).

References

AMN Healthcare (2011), *Accountable Care Organization Survey: Healthcare Facility Challenges and Participation in ACOs,* AMN Healthcare.

Auerbach, D. I., Liu, H., Hussey, P. S., Lau, C. and Mehrotra, A. (2013), 'Accountable Care Organization Formation is Associated with Integrated Systems but Not High Medical Spending', *Health Affairs,* vol. 32, no. 10, pp. 1781–1788.

Barnes, A. J., Unruh, L., Chukmaitov, A. and van Ginneken, E. (2014), 'Accountable Care Organizations in the USA: Types, Developments and Challenges', *Health Policy,* vol. 118, no. 1, pp. 1–7.

Berwick, D. M., Nolan, T. W. and Whittington, J. (2008), 'The Triple Aim: Care, Health, and Cost', *Health Affairs,* vol. 27, no. 3, pp. 759–769.

Blendon, R. J., Brodie, M., Benson, J. M., Altman, D. E., Levitt, L., Hoff, T. and Hugick, L. (1998), 'Understanding the Managed Care Backlash', *Health Affairs,* vol. 17, no. 4, pp. 79–91.

Brennan, D. (2016), *Physician-Led ACOs Outperform Hospital-Led Peers,* Truthin-HealthCare [Online]. Available at: http://www.truthinhealthcare.org/physician-led-acos-outperform-hospital-led-peers/ (Accessed June 30, 2017).

Centers for Medicare & Medicaid Services (2016), *Accountable Care Organizations: What Providers Need to Know,* Centers for Medicare & Medicaid Services [Online]. Available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/sharedsavingsprogram/downloads/aco_providers_factsheet_icn907406.pdf (Accessed April 27, 2017).

Centers for Medicare & Medicaid Services (2016), *Final Medicare Shared Savings Program Rule (CMS-1644-F),* Centers for Medicare & Medicaid Services [Online]. Available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-06-06.html (Accessed May 03, 2017).

Centers for Medicare & Medicaid Services (2016), *Medicare Accountable Care Organizations 2015 Performance Year Quality and Financial Results,* Centers for Medicare & Medicaid Services [Online]. Available at: https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2016-fact-sheets-items/2016-08-25.html (Accessed April 27, 2017).

Centers for Medicare & Medicaid Services (2017), *Accountable Care Organizations (ACO),* Centers for Medicare & Medicaid Services [Online]. Available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/aco/ (Accessed May 05, 2017).

Centers for Medicare & Medicaid Services (2017), *Advance Payment ACO Model*, Centers for Medicare & Medicaid Services [Online]. Available at: https://innovation.cms.gov/initiatives/Advance-Payment-ACO-Model/ (Accessed May 03, 2017).

Centers for Medicare & Medicaid Services (2017), *All Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs)*, Centers for Medicare & Medicaid Services [Online]. Available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/sharedsavingsprogram/downloads/all-starts-mssp-aco.pdf (Accessed April 27, 2017).

Centers for Medicare & Medicaid Services (2017), *Comprehensive ESRD Care Model*, Centers for Medicare & Medicaid Services [Online]. Available at: https://innovation.cms.gov/initiatives/comprehensive-esrd-care/ (Accessed April 28, 2017).

Centers for Medicare & Medicaid Services (2017), *Next Generation ACO Model*, Centers for Medicare & Medicaid Services [Online]. Available at: https://innovation.cms.gov/initiatives/Next-Generation-ACO-Model/ (Accessed April 27, 2017).

Centers for Medicare & Medicaid Services (2017), *Pioneer ACO Model Frequently Asked Questions*, Centers for Medicare & Medicaid Services [Online]. Available at: https://innovation.cms.gov/initiatives/Pioneer-ACO-Model/Pioneer-ACO-FAQs.html (Accessed April 27, 2017).

Cimasi, R. J. (2013), *Accountable Care Organizations: Value Metrics and Capital Formation*, Boca Raton, CRC Press.

Colla, C. H., Lewis, V. A., Shortell, S. M. and Fisher, E. S. (2014), 'First National Survey of ACOs Finds that Physicians Are Playing Strong Leadership and Ownership Roles', *Health Affairs*, vol. 33, no. 6, pp. 964–971.

Colla, C. H., Lewis, V. A., Tierney, E. and Muhlestein, D. B. (2016), 'Hospitals Participating in ACOs Tend to be Large and Urban, Allowing Access to Capital and Data', *Health Affairs*, vol. 35, no. 3, pp. 431–439.

Douven, R., McGuire, T. G. and McWilliams, J. M. (2015), 'Avoiding Unintended Incentives in ACO Payment Models', *Health Affairs*, vol. 34, no. 1, pp. 143–149.

Emanuel, E. J. (2012), 'Why Accountable Care Organizations Are Not 1990s Managed Care Redux', *Journal of the American Medical Association*, vol. 307, no. 21, pp. 2263–2264.

Enthoven, A. C. (2005), 'The U.S. Experience with Managed Care and Managed Competition', *Conference Series*, vol. 50, no. 6, pp. 97–117.

Finnegan, J. (2017), *3 Ways Physician-Led ACOs Outperform Hospital-Led Organizations*, FierceHealthcare [Online]. Available at: http://www.fiercehealthcare.com/healthcare/three-advantages-physician-led-acos (Accessed June 30, 2017).

Goldsmith, J. (2011), 'Accountable Care Organizations: The Case for Flexible Partnerships Between Health Plans and Providers', *Health Affairs*, vol. 30, no. 1, pp. 32–40.

Harvey, H. B., Gowda, V., Gazelle, G. S. and Pandharipande, P. V. (2014), 'The Ephemeral ACO: An Unintended Consequence of the Medicare Shared Savings Program', *Journal of the American College of Radiology*, vol. 11, no. 2, pp. 121–124.

HHS (2015), *Better, Smarter, Healthier: In historic Announcement, HHS Sets Clear Goals and Timeline for Shifting Medicare Reimbursements from Volume to Value*, HHS [Online]. Available at: https://wayback.archive-it.org/3926/20170127185400/https://www.hhs.gov/about/news/2015/01/26/better-smarter-healthier-in-historic-announcement-hhs-sets-clear-goals-and-timeline-for-shifting-medicare-reimbursements-from-volume-to-value.html (Accessed May 01, 2017).

HHS (2016), *HHS Reaches Goal of Tying 30 Percent of Medicare Payments to Quality Ahead of Schedule*, HHS [Online]. Available at: https://mountsinaihealth.me/file/2016/05/HHS-reaches-goal-of-tying-30-percent-of-Medicare-payment-to-quality-ahead-of-schedule.pdf (Accessed May 01, 2017).

Hofler, R. A. and Ortiz, J. (2016), 'Costs of Accountable Care Organization Participation for Primary Care Providers: Early Stage Results', *BMC Health Services Research*, vol. 315, no. 16, pp. 1–8.

IHI (2007), *Technical Brief: Best Health Care Results for Populations (A Three-Part Aim)*, IHI [Online]. Available at: http://www.commonwealthfund.org/usr_doc/best_healthcare_results_3part.pdf (Accessed April 25, 2017).

Introcaso, D. and Berger, G. (2015), *MSSP Year Two: Medicare ACOs Show Muted Success*, HealthAffairsBlog [Online]. Available at: http://healthaffairs.org/blog/2015/09/24/mssp-year-two-medicare-acos-show-muted-success/ (Accessed April 27, 2017).

Lagoe, R., Aspling, D. L. and Westert, G. P. (2005), 'Current and Future Developments in Managed Care in the United States and Implications for Europe', *Health Research Policy and Systems*, vol. 3, no. 4, pp. 4–15.

Lewis, V. A., McClurg, A. B., Smith, J., Fisher, E. S. and Bynum, J. P. W. (2014), 'Attributing Patients to Accountable Care Organizations: Performance Year Approach Aligns Stakeholders' Interests', *Health Affairs*, vol. 32, no. 3, pp. 587–595.

McClellan, M., Kent, J., Beales, S. J., Cohen, S. L. A., Macdonnell, M., Thoumi, A., Abdulmalik, M. and Darzi, A. (2014), 'Accountable Care around the World: A Framework to Guide Reform Strategies', *Health Affairs*, vol. 33, no. 9, pp. 1507–1515.

McClellan, M., McKethan, A. N., Lewis, J. L., Roski, J. and Fisher, E. S. (2010), 'A National Strategy to Put Accountable Care into Practice', *Health Affairs*, vol. 29, no. 5, pp. 982–990.

MedPac (2016), *Accountable Care Organization Payment Systems,* MedPac [Online]. Available at: http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_16_aco_final.pdf?sfvrsn=0 (Accessed May 05, 2017).

Meyer, H. (2011), 'Accountable Care Organization Prototypes: Winners and Losers?', *Health Affairs*, vol. 30, no. 7, pp. 1227–1231.

Muhlestein, D. B. and McClellan, M. (2016), *Accountable Care Organizations in 2016: Private and Public-Sector Growth and Dispersion,* HealthAffairsBlog [Online]. Available at: http://healthaffairs.org/blog/2016/04/21/accountable-care-organizations-in-2016-private-and-public-sector-growth-and-dispersion/ (Accessed April 27, 2017).

Muhlestein, D. B., Saunders, R. and McClellan, M. (2016), *Medicare Accountable Care Organization Results for 2015: The Journey to Better Quality and Lower Costs Continues,* HealthAffairsBlog [Online]. Available at: http://healthaffairs.org/blog/2016/09/09/medicare-accountable-care-organization-results-for-2015-the-journey-to-better-quality-and-lower-costs-continues/ (Accessed June 30, 2017).

OECD (2017), *Health Expenditure and Financing* [Online], OECD. Available at: http://stats.oecd.org/Index.aspx?DataSetCode=SHA (Accessed May 05, 2017).

Pham, H. H., Cohen, M. and Conway, P. H. (2014), 'The Pioneer Accountable Care Organization Model: Improving Quality and Lowering Costs', *JAMA,* vol. 312, no. 16, pp. 1635–1636.

Rose, S., Zaslavsky, A. M. and McWilliams, J. M. (2016), 'Variation in Accountable Care Organization Spending and Sensitivity to Risk Adjustment: Implications for Benchmarking', *Health Affairs,* vol. 35, no. 3, pp. 440–448.

Schulte, T., Pimperl, A., Hildebrandt, H. and Bohnet-Joschko, S. (2017), 'USA: Accountable Care Organizations als neue Form der Kooperation mit Verantwortungsübernahme', in Brandhorst, A., Hildebrandt, H. and Luthe, E.-W. (eds.) *Kooperation und Integration – das unvollendete Projekt des Gesundheitssystems,* Wiesbaden, Springer Fachmedien Wiesbaden, pp. 535–552.

Patient-Centered Medical Homes

Catharina Harms and Iris Ruckdäschel

The Patient-Centered Medical Home (PCMH) is an interdisciplinary institution designed to secure and stabilize the primary care of the population. This form of care is characterized by a high degree of cooperation between individual specialist disciplines, the involvement of all participants (patient, relatives and nurses) and the constant clarification of the course of treatment. Especially in the US, which is characterized by its vastness and large rural areas, this model could improve medical care and facilitate access for people living there. However, it is necessary to generate and implement standards, particularly for the evaluation and implementation of these facilities, in order to demonstrate comparability of the performance achieved.

Contents

1 Introduction

Frustration with the U.S. health care system is on the rise, and therefore, a variety of critiques exist including the rise of out-of pocket costs and the lack of accessible health care. One major problem is the lack of implementation of a primary care system and the resulting overuse of emergency departments, as well as the decline in the numbers of primary care physicians (Phillips and Bazemore, 2010, p. 807; Berry and Mirabito, 2010, p. 157). Rural areas, especially, have significant problems with providing primary care (Ewing and Hinkley, 2013, p. 1). These issues require that new paths should be chosen which would encourage delivery system innovations (Berry and Mirabito, 2010, p. 158). One important and possible innovation is "patient-centered medical homes" (PCMH), which promise to reinforce the primary care system. The origin of the concept of a "medical home" was in 1967 (Klein, Laugesen and Liu, 2013, p. S82; Braddock et al., 2013, p. 141). Medical homes were designed as a coordinated-care model for children and a number of specialty pediatric clinics to manage patients with complex medical problems. These medical homes, re-imagined as the PCMH, entered the discussion on American health care because of some problems with primary care in the 2000s. One core component of this model is the formation of a primary care basis to improve the value of healthcare and reduce health care spending (Stange et al., 2010, p. 601; Klein, Laugesen and Liu, 2013, p. S82). These principles could be a real solution for the problems of primary care provision in rural areas.

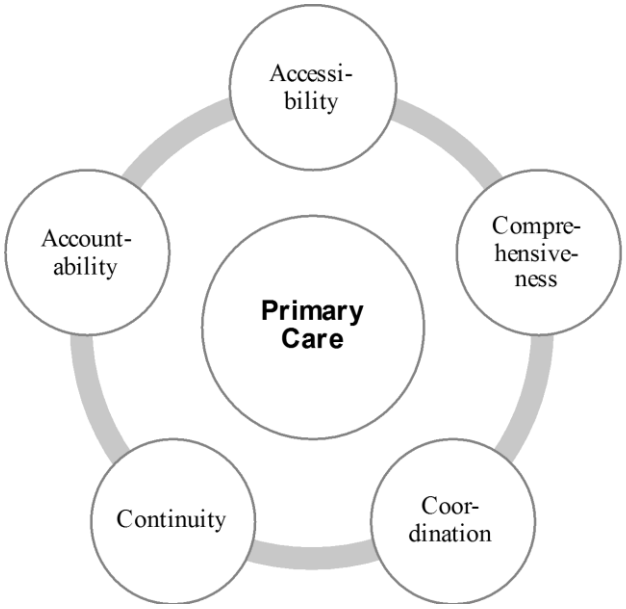
This essay aims to assess the strengths and challenges the of PCMH as an innovative approach to primary care of rural areas. In the first section, an overview of primary care in general and primary care in rural areas is presented, followed by the theoretical framework of PCMH and their strengths and challenges. Finally, a critical evaluation of the suitability of the PCMH as an innovative approach to primary care of rural areas is provided.

2 Primary Care and Rural Areas in the United States

2.1 Primary Care in the United States

The U.S Institute of Medicine (IOM) defines primary care as the provision of integrated, accessible health care services (Donaldson et al., 1996, p. 2). Additionally, primary care providers should be the first access point of the health care system (Berry and Mirabito, 2010, p. 158; Stange, 2009, p. 201). Primary care is a crucial factor for an effective and efficient health care system. Through primary care, a large majority of personal health care needs should be addressed and a sustained partnership between physician and patient should be established (Donaldson et al., 1996, p. 2). In order to reach these aims, five core attributes of primary care, as shown in Figure 5.1, are to set: accessibility, comprehensiveness, coordination, continuity and accountability (IOM, 1978, p. 16).

Figure 1: Five core attributes of primary care



Source: Own figure, based on IOM, 1978, p. 16.

Access to needs-based primary care services can maintain and improve health care, which is characterized by lower rates of illness and premature death (Starfield, Shi and Macinko, 2005, p. 457; Ewing and Hinkley, 2013, p. 1). Moreover, countries which have implemented an advanced primary care system achieve lower health care costs, enhanced outcomes and greater satisfaction overall. Population health in the U.S. federal states with improved primary care services is better than in those without (Macinko, Starfield and Shi, 2007, p. 123; Starfield and Shi, 2002, p. 213). However, due to various reasons, there is a lack of implementation of a primary care-centered health care system in the United States, and as a result, when scoring the availability and use of primary care, the U.S. has very low ratings (Sandy et al., 2009, p. 1,136, p. 1,140; Bates, 2010, p. 998).

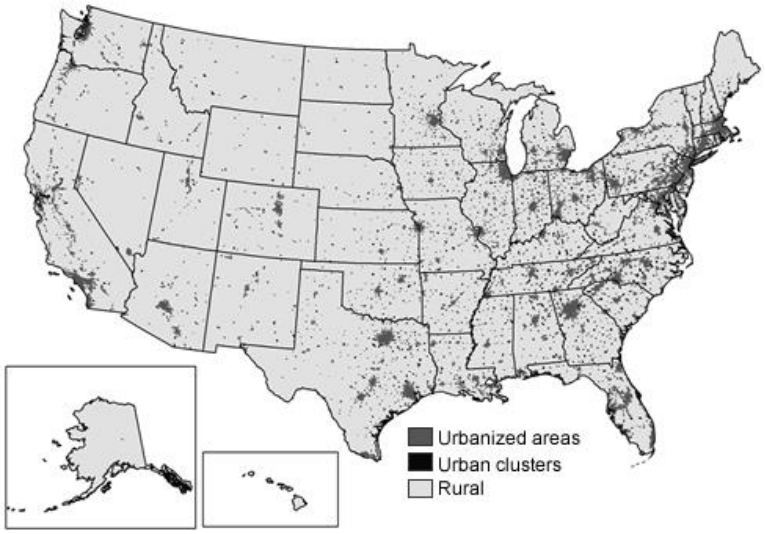
The reasons for the poorly developed primary care system in the U.S. are multi-layered and are based on political, economic, policy and institutional factors. One reason is the lack of national policies regarding the proportion of generalists versus specialists, which leads to a dominance of hospitals, especially of teaching hospitals and their focus on specialist care. More important is the failure of public policy to prevent the disintegration of primary care (Sandy et al., 2009, p. 1,140). Due to the focus on specialist care, the number of primary care physicians is declining, which in turn hampers the efforts to meet the current demand. Additionally, the high fragmentation of the health care system and the regular use of the emergency room as an access point to primary care complicate the implementation. Another issue and a source of dissatisfaction lies in the long waiting times for primary care, which can vary significantly from just a few days to a few months

(Berry and Mirabito, 2010, pp. 157-158). However, there are plenty of reasons for optimism due to the growing recognition of the importance of primary care (Sandy et al., 2009, p. 1140). The high costs of U.S. health care system may be reduced by a well-developed primary care system (Berry and Mirabito, 2010, p. 157; Reid et al., 2009, p. e71).

2.2 Rural Areas

First of all, it is essential to define the term "rural areas" due to the stark differences which distinguish rural and urban areas in the U.S. (USDA, 2017b). The different regions can be defined on the basis of administrative, land-use, as well as economic indicators. Therefore the results vary considerably in terms of socio-economic factors and well-being (Cromartie and Bucholtz, 2008). The U.S. Census Bureau defines rural areas as those areas that are outside of urban areas and urban clusters. The definition of urban areas is based on the population density and other measures of dense development (Ratcliffe et al., 2016, pp. 1-2). According to the National Rural Health Association (NRHA) approximately 20 percent of U.S. citizens live in rural areas (though due to the different definitions, the percentage can vary from 17 to 19 percent) (NRHA, n.D.; Cromartie and Bucholtz, 2008). The following figure illustrates the distribution of rural and urban areas.

Figure 2: U.S. Census Bureau's urban and rural areas, 2010



Source: USDA, 2017b; U.S. Census Bureau, 2015.

Generally, rural areas face specific and distressing obstacles: high poverty rates, less-educated inhabitants, increased numbers of uninsured people, effects of the demographic shift such as the increasing elderly rural population, as well as the additional rise in demand for primary care as an impact of the Affordable Care Act (NRHA, n.D.;

Ewing and Hinkley, 2013, pp. 1-2; Bates, 2010, p. 998; USDA, 2017a). Consequently, the health of rural populations and their health-specific issues are significantly different from those in urban areas. When measuring health, the results show a health disadvantage for the rural population, especially in terms of the premature mortality rate (before 75 years) is higher (Eberhardt and Pamuk, 2004, p. 1,682).

When looking to the obstacles of primary care, rural areas have a lower primary care physician ratio with 39.8 physicians per 100,000 inhabitants than urban areas (53.3 physicians per 100,000) (Hing and Hsiao, 2014, p. 4). Due to this uneven distribution, there is concern about the health care of the population in rural areas. Moreover, the lack of accessible and efficient primary care in rural areas can be explained by the large geographical areas which have to be served by physicians. Rural health care is therefore characterized by long travel times and the partial deficit in hospitals and other health care facilities (Ewing and Hinkley, 2013, p. 1; RHIhub, 2017). A further impact is the aging rural physician workforce due to a demographic shift. As a consequence, approximately 28 percent of the primary care physicians in rural areas are going to retire during the next few years (Fordyce, Doescher and Skillman, 2013, p. 6).

Meeting the current demand for primary care is a significant issue which will continue to worsen in the near future, and the availability of primary care is a growing concern (Ewing and Hinkley, 2013, p. 1).

In conclusion, primary care services will face several obstacles, especially with respect to the availability of accessible and efficient primary care in rural America and the recent demographic trends. As a result, several states of the United States have tried to reinforce the role of non-physician providers in the supply of primary care (Ewing and Hinkley, 2013, p. 1). In the development of new approaches, the Rural Policy Research Institute Health Panel defined five core attributes similar to the key components of primary care that should be considered: affordability, accessibility, high quality of care, community focus and patient-centeredness as well as patient engagement (Mueller et al., 2016, p. 3).

3 The Patient-Centered Medical Home

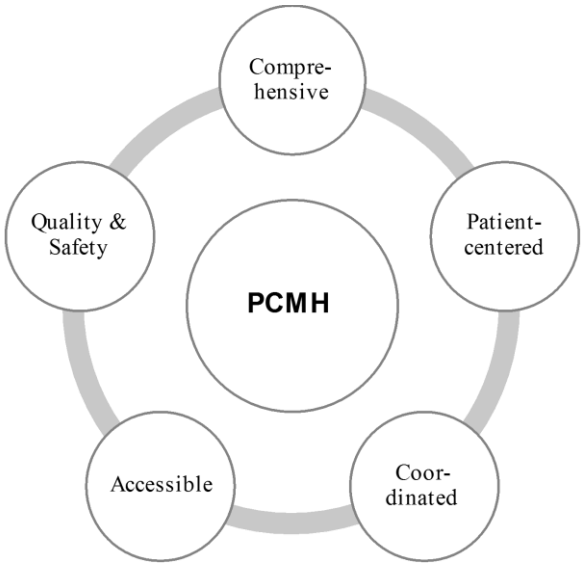
3.1 Definition of the Model

The PCMH was developed as an alternative primary care model with the aim of cost reduction, improved supplier coordination and higher quality of care, resulting in better health outcomes (Klein, Laugesen and Liu, 2013, p. S82). It is an attempt to reinvigorate the delivery of outpatient healthcare and is one of the keystones of a national health care reform (Braddock et al., 2013, p. 141). A medical home is not simply a place, but a concept which delivers the core functions of primary care (AHRQ, n.D.). Moreover, medical homes provide the opportunity to have a personal physician who coordinates

each step of treatment and serves as a liaison for comprehensive care (Starfield and Shi, 2004, p. 1,495). This structure removes the doctor from the traditional role as a gatekeeper.

A further important distinction of medical homes, which enables the proactive and patient-oriented design of patient panels, is the formation of interdisciplinary teams with the support of health information technology (Klein, Laugesen and Liu, 2013, p. S83). The PCMH, specifically, is a team-based model which is integrated into the community. A further aim is to optimize the basic attributes of the primary care system, which should encourage new ideas about the provision of primary care and changes to the health system (Stange et al., 2010, p. 602). The five key attributes of the PCMH, as shown in Figure 5.3, are based on the five key attributes of primary care and will be explained in detail in the following section (AHRQ, n.D.).

Figure 3: Five core attributes of PCMH



Source: Own figure, based on AHRQ, n.D.

1) Comprehensive Care

The core attribute *Comprehensive Care* is defined as the care of a large majority of physical and mental conditions both acute and chronic, as well as a focus on prevention and wellness. This demands a cooperation of the different suppliers of care. In other words, this means building a team-based care system, which includes medical providers, pharmacists, behavioral health providers and other care coordinators. Because of the different case complexities, different interdisciplinary levels and, consequently, different teams are required. These teams can be settled in clinics or operate as virtual teams, thereby connecting patients and providers in the community (AHRQ, n.D.; Maragakis and O'Donohue, 2015, p. 4).

2) Patient-centered Orientation

Health care in a PCMH is marked by patient-oriented performance and a relationship-based system. Consequently, it is not only the patient with his or her unique condition who is at the center of interest, but also his or her informal background, culture, values and personal situation, which should be understood and respected. His or her family is also involved so that they can assist in the treatment process and the management of care (AHRQ, n.D.; Maragakis and O'Donohue, 2015, p. 4).

3) Coordinated Care

The PCMH coordinates and contains all necessary elements of comprehensive health care, including specialty care, hospital, home health care, and community of service and supports. The importance of *Coordinated Care* emerges from the need for a smooth process when patients are discharged from the hospital. Furthermore, open and clear communication between the patients, their family, the medical home, and members of the broader care team is an outstanding characteristic of medical homes (AHRQ, n.D.).

4) Accessible Service

A further goal of the PCMH is to shorten waiting times for urgent cases. Therefore, the PCMH offers increased in-person hours, a 24-hour service via telephone or electronic access to medical staff, as well as other alternative communication methods such as e-mail. The medical home practice focuses on the individual preferences of their patients regarding method of access (AHRQ, n.D.).

5) Quality and Safety

The last attribute of the PCMH involves the use of evidence-based practices and clinical decision-support devices to accompany treatment, since quality and quality improvement are of particular concern. In order to support decision-making with patients and families, technologies such as electronic health records are used. In this way, performance can be measured and, if necessary, improvements can be made. In addition, patient satisfaction plays an important role. Quality and safety data, along with improvement activities, are subsequently published, which is a good indicator of a system-level commitment to quality (AHRQ, n.D.; Maragakis and O'Donohue, 2015, p. 6).

3.2 Strengths of Patient-Centered Medical Homes

The implementation of PCMHs can change the primary care system fundamentally, and therefore change the role and the processes of patients and physicians (Cassidy, 2010,

p. 5). When the aims of the PCMH model are considered, several strengths can be identified such as quality of care, patients' experience, cost of care and professional working experience (Maragakis and O'Donohue, 2015, p. 11). However, not every setting can qualify as a PCMH. Six program standards developed by the National Committee for Quality Assurance must be met to achieve PCMH recognition, as shown in Figure 5.4.

Figure 4: PCMH Content and Scoring

PCMH Content and Scoring
(6 standards and 27 elements)

1. Enhance Access and Continuity	Pts	4. Plan and Manage Care	Pts
		A. Identify Patients for Care Management	4.0
A. *Patient-Centered Appointment Access	**4.5**	**B. *Care Planning and Self-Care Support**	**4.0**
B. 24/7 Access to Clinical Advice	3.5	C. Medication Management	4.0
C. Electronic Access	2.0	D. Use Electronic Prescribing	3.0
		E. Support Self-Care and Shared Decision Making	5.0
2. Team-Based Care	**Pts**	**5. Track and Coordinate Care**	**Pts**
A. Continuity	3.0		
B. Medical Home Responsibilities	2.5	A. Test Tracking and Follow-Up	6.0
C. Culturally and Linguistically Appropriate Services (CLAS)	2.5	**B. *Referral Tracking and Follow-Up**	**6.0**
		C. Coordinate Care Transitions	6.0
D. *The Practice Team	**4.0**		
3. Population Health Management	**Pts**	**6. Measure and Improve Performance**	**Pts**
		A. Measure Clinical Quality Performance	3.0
A. Patient Information	3.0	B. Measure Resource Use and Care Coordination	3.0
B. Clinical Data	4.0	C. Measure Patient/Family Experience	4.0
C. Comprehensive Health Assessment	4.0	**D. *Implement Continuous Quality Improvement**	**4.0**
D. *Use Data for Population Management	**5.0**	E. Demonstrate Continuous Quality Improvement	3.0
E. Implement Evidence-Based Decision-Support	4.0	F. Report Performance	3.0
		G. Use Certified EHR Technology	0
Scoring Levels:	Level 1: 35-59 points Level 2: 60-84 points Level 3: 85-100 points	***must pass elements** Pts = points	

Source: Own figure, based on NCQA, 2014a, p. 3.

In order to maintain the performance of PCMH, three different levels of PCMH status are defined. These standards target the key aspects of primary care. The respective settings can obtain points based on the number of factors that the provider fulfills. Quality and performance are constantly monitored (Maragakis and O'Donohue, 2015, pp. 8-9). It is a method to increase standardization and to help PCMHs develop a good reputation. The more elements that are fulfilled by the PCMH, the higher becomes the point value. The point value determines the classification in the scoring level, and the PCMH then gets the certification. By this system the standardization, and therefore the certification, of such facilities should be easier and clearer (NCQA, 2014b, p. 21).

A positive change in the working environment of physicians is the smaller number of patients to be treated, which reduces the scope of work and leads to a reduction in the risk of burnout (Cassidy, 2010, p. 5; Reid et al., 2009, p. e76). A further goal of the PCMH is to improve the patient experience, the obtainment of which has been shown in multiple studies (Maragakis and O'Donohue, 2015, p. 12). A better patient experience

resulted in significant improvement in doctor-patient interaction and access to care (Reid et al., 2009, p. e75). While some studies showed no significant change or no change in multiple aspects, it can be generally assumed that due to their interdisciplinary nature, the well-trained teams will enhance the organization and coordination of the treatment path as well as patient satisfaction through a high level of information exchange (Solimeo, Stewart and Rosenthal, 2016, pp. 378/379; Hoff, Weller and DePuccio, 2012, p. 637; Jaen et al., 2010, p. S57; Zutshi et al., 2014, p. 48).

The term *quality of care* can be split in this context into the factors processes of care, health outcomes and mortality. Both the procedures in the care processes, as well as health outcomes can improve (Reid et al., 2010, p. e77; Grumbach, Bodenheimer and Grundy, 2009, p. 1; Zutshi et al., 2014, p. 48). However, the effects on mortality do not have statistically significant results (Maragakis and O'Donohue, 2015, p. 12). Another important issue is that in primary care, patients with chronic diseases such as diabetes, cardiovascular problems, asthma and hypertension are predominant, and they often need time-intensive care and regular check-ups. With the conversion and integration of PCMHs, an improvement of care and health outcomes for these patients may be reached. Moreover, multi-morbid middle-aged patients can be treated more effectively due to the interdisciplinary nature of PCMHs (Hornberger and Freeman, 2015, pp. 46-47). It is precisely these chronically ill patients, who require more help with the correct treatment of their illnesses and advice on preventative behavior, who stand to benefit most from the PCMH model. In addition, the interdisciplinary nature of PCMHs can lead to a reduction of redundant services while increasing preventive services (Hoff et al., 2012, p. 622). A further quality enhancing factor of the PCMH is evidence-based medicine, which is supported by the core attributes (Rogers, 2008, p. 370).

PCMH can achieve a reduction in health expenditures through increased use of primary care, and thus, a reduction in emergency and specialty care (Maragakis and O'Donohue, 2015, p. 12). With regard to the use of emergency service, in some studies positive effects were shown with the PCMH model. However, the actual objective of effective cost reduction could not be clearly demonstrated in the investigation (Zutshi et al., 2014, p. 48).

In principle, the PCMH model can be presented as an efficient model for the US health system. Significant cost savings could be generated and preventive activities expanded and strengthened. Patients and their families are involved in the entire treatment process and are always kept up-to-date (Klein, Laugesen and Liu, 2013, p. S89).

3.3 Challenges of Patient-Centered Medical Homes

There are, however, some limitations and gaps in the system. Well-organized practices are faced with the problems of underfunding – PCMH are introduced within the scope of the Medicaid care (Klein et al., 2013, p. S84) – and underemployment. There is still

a need for further development in the implementation of the model and the efficient use of existing resources in order to ultimately achieve top performance (Klein, Laugesen and Liu, 2013, p. S89). Another problem may be rejection of this model by the primary care workforce, as well as a fear of change. Moreover, the PCMH is still in its early stages, and therefore unintended consequences cannot be foreseen. The lack of resources such as money and time can block the implementation of changes to the health care system (Hoff, Weller and DePuccio, 2012, p. 641; Rogers, 2008, p. 372). Because of the partially negative relationship with the term "medical home," this system was a source of confusion for some patients. To reduce this misunderstanding, a new terminology has been considered: advanced basic care. However, the organization of health care for young and healthy people is made more difficult since it would not represent a cost-effective model for them. A proposal for a more effective solution would be the cooperation of PCMH with other integrated care models (Cassidy, 2010, p. 5).

Due to the large number of payment models that underpinned the PCMH, a series of debates were raised to decide which model is the best (Berenson et al., 2016, pp. 2-3). When looking at the supply side more closely, some payment methods limit personal contact between the service providers and the patient, which could solve the problem with time, but in turn, counteracts the PCMH principle of promoting communication. On the demand side, the patient is encouraged to visit medical homes for care. A moderate cost participation and value-oriented insurance design promote a more cost-efficient processing of the available services. Through management approaches, care providers and payers are given the authority to monitor and manage patient care (Berenson et al., 2016, p. 7). This model, including the key attributes of PCMHs, should help to reduce the administrative costs. Because of the high number of health insurance providers and their different methods of reimbursement and individual contracts, the PCMH should be responsible for the standardization, centralization and coordination of work of providing care to reduce the level of complexity and optimize the medical care for all people (Martin et al. 2004, p. S12, Neumann, 2014, pp. 37/38).

The individual PCMH models differ in their structure, culture as well as existing resources, and are independent in the design of their interdisciplinary teams. Unfortunately, no uniform standards are currently being followed and a direct comparison of performance is hampered. Therefore, a balance between standardization and innovation is needed. If the objectives of uniformity, and the implementation of a standardized model as well and multi-regional acceptance are to be met, the PCMH should be further developed through more rigorous evaluations (Klein, Laugesen and Liu, 2013, p. S87).

4 Discussion and Conclusion

Considering the previous analysis, it can be concluded that the fundamental pillars of the PCMH model take into account the core attributes of primary care. The PCMH represents a comprehensive, patient-centered, coordinated and accessible primary care model. However, patient-centeredness and the community play a greater role within the PCMH as can be seen from the core attributes (see 3.1). The PCMH is a successful innovation, and therefore is an important part of health care reform. Optimizing the PCMH model could fundamentally change the status of primary care in the health care process and can help to enhance the degraded position of primary care (Bates, 2010, p. 998).

Although, as shown above, the PCMH has many strengths and innovative approaches, it could be an overrated approach due to the fundamental political, economic and social barriers in the health care system (Sandy et al., 2009, p. 1,141). The implementation of PCMH models could be hampered by the different structures of the individual states of the U.S. and the differing values both within and across these states. A further obstacle for realization could be a lack of uniform electronic health record systems, especially of rural regions (Bates and Bitton, 2010, p. 619). In addition, a necessary infrastructure for PCMH should be implemented at the respective providers' locations in order to utilize the potential of the model (Klein, 2009, p. 128). This, in turn, requires a high level of commitment from providers and patients. The latter must proactively participate in managing their health, which could lead to difficulties in patient adherence, especially among those with low socioeconomic status. Consequently, these obstacles and the high costs could lead to incomplete implementation, especially in rural areas, and a full integration is necessary for comprehensive improvements. Furthermore, the high fragmentation of the American health care system poses a problem that is unlikely to be solved by merely further developing a new system (Sandy et al., 2009, p. 1,140). New systems also require a sufficiently high number of patients to implement them, and due to the very low partial patient volume, adverse effects on reliability, validity and utility may be a problem (Moscovice, Johnson and Burstin, 2017, p. 259). Additionally, especially in rural areas, the dwindling workforce of primary care physicians is an obstacle which cannot be solved simply by the implementation of another system. This workforces need to have special skills for their new role as care integrators and also support the changes to the system (Mueller et al., 2016, p. 4). This may be a special problem among the elderly health care workforce in rural areas.

However, the PCMH has many promising features to address the long-time national challenge of health care workforce shortage (Collins, 2016, p. 99). Especially in rural areas, the urgency to find solutions for maintaining an adequate primary health care workforce has risen (Collins, 2016, p. 99). With the opportunity to change the image of

primary care through the PCMH, the profession of primary care physician could be re-invigorated with the interdisciplinary approach and the increased involvement of health technologies. Even if the popularity of becoming a primary care physician changes with the PCMH model, there may be further steps needed to attract more students to rural areas. One solution may be to intensify the recruitment of students from these rural communities to complete their education and community-based residency training. During this training, the students could be placed into underserved areas (Carolina GME Advisory Group, 2014, pp. 12/13). Another approach to increase the number of students working in rural areas is the loan repayment programs of different states (Carolina GME Advisory Group, 2014, p. 32). As a result of these and other efforts, more medical students may decide to become primary care physicians, which in turn could solve the problem of declining numbers of physicians, and ease the demand-supply situation within rural areas. In conjunction with the PCMH these approaches could reduce the workforce shortage.

A further problem of primary care, especially in rural areas, that the PCMH may solve is the inadequate payment provided to primary care physicians. The income gap between specialist and primary care physician is steadily rising, leading many graduates to frequently avoid primary care careers (Berenson and Rich, 2010, p. 613; Bodenheimer, 2006, p. 862) because a significant decisive factor for the choice of a specialty is the chance to earn money (Carolina GME Advisory Group, 2014, pp. 31/32). Due to the integral payment reform feature of the PCMH, the number of students who are interested in this profession could rise (Berenson and Rich, 2010, p. 613). This new payment model would be especially beneficial in rural regions with a workforce shortage. For example, this model could address the considerable increase in the number of working hours and the long travel distances in rural areas. There are already some rural physician grant programs that use an enhanced reimbursement as a retention strategy for physicians leading primary care teams in rural areas. This represents an ongoing incentive to work in rural areas as a primary care physician (Carolina GME Advisory Group, 2014, pp. 31/32). With payment reform and efforts to enhance the attractiveness of working in rural areas, the PCMH could help ensure better primary care provision in rural areas.

The PCMH is an interdisciplinary approach and increases the involvement of health care technologies, and can therefore help to improve the coverage of extensive areas, and in particular, of the elderly. Through the increased use of telemedicine, the coordination with specialty care providers can be eased in rural areas. The rural primary care physicians could benefit from the advanced practice of urban specialty doctors in case of a complex indication areas, and the patients can achieve better and faster treatment (Carolina GME Advisory Group, 2014, p. 35). The travel times for the physicians may even be partly reduced. In addition, the high involvement of family members and the high

level of information exchange among all participating parties could improve health status and patient adherence, particularly in rural regions where the elderly people are often dependent on family support and sometimes live a long distance from the nearest hospital. The PCMH provides a highly coordinated and patient-centered model with high dependency.

The PCMH is already implemented in approximately twenty-one states. The PCMH model of Arkansas was designed as a flexible model, which can adapt to variations in the efficiency of primary care processes (Müller et al., 2016, p. 9). With this model and a benefit system linked to provider participation, the primary care and the health of rural populations was reinforced by overcoming a number of hurdles. The implementation of a PCMH model in Alaska brought a recorded reduction in the use of the emergency room, which in turn reduced costs (Driscoll et al., 2013, p. S48). The implementation of a PCMH model by the Veterans Health Administration also resulted in an improvement in the primary care system, including an increase in telephone and electronic encounters, as well as an improvement in post-hospitalization follow-up (Rosland et al., 2013, p. e263).

Finally, the PCMH's core attributes represent the key components of an effective rural health system, and community and patient-centeredness play a great role within both rural health systems and PCMH. Additionally, the approach of the PCMH both at the micro (processes) and macro (society) perspective offers a comprehensive concept that could solve the problems particularly of rural areas. These are indicators that the PCMH can be an innovative approach for changing the U.S. rural health system.

To conclude, the PCMH is a promising and innovative care concept in primary care in general, and especially for primary care in rural areas. However, additional studies are needed to further refine the efficacy of the model and adapt it to the appropriate needs so that the triple aim of health care (better quality, improving experience, reducing cost,) can be achieved sustainably (Zutshi et al., 2014, p. 1, p. 56).

References

AHRQ (n.d.), *Defining the PCMH* [Online], AHRQ. Available at: https://pcmh.ahrq.gov/page/defining-pcmh (Accessed April 12, 2017).

Bates, D. W. (2010), 'Primary Care and the US health Care System: What Needs to Change?', *Journal of General Internal Medicine*, vol. 25, no. 10, pp. 998–999.

Bates, D. W. and Bitton, A. (2010), 'The Future of Health Information Technology in the Patient-Centered Medical Home', *Health Affairs*, vol. 29, no. 4, pp. 614–621.

Berenson, R. A., Delbanco, S. F., Murray, R. and Upadhyay, D. K. (2016), *The Patient-Centered Medical Home: Advanced Primary Care,* Urban Institute.

Berenson, R. A. and Rich, E. C. (2010), 'US Approaches to Physician Payment: The Deconstruction of Primary Care', *Journal of General Internal Medicine*, vol. 25, no. 6, pp. 613–618.

Berry, L. L. and Mirabito, A. M. (2010), 'Innovative Healthcare Delivery', *Business Horizons*, vol. 53, no. 2, pp. 157–169.

Bodenheimer, T. (2006), 'Primary Care - Will it Survive?', *The New England Journal of Medicine*, vol. 355, no. 9, pp. 861–864.

Bodenheimer, T. and Pham, H. H. (2010), 'Primary Care: Current Problems and Proposed Solutions', *Health Affairs*, vol. 29, no. 5, pp. 799–805.

Braddock, C. H., Snyder, L., Neubauer, R. L. and Fischer, G. S. (2013), 'The Patient-Centered Medical Home: An Ethical Analysis of Principles and Practice', *Journal of General Internal Medicine*, vol. 28, no. 1, pp. 141–146.

Carolina GME Advisory Group (2014), *Leveraging Graduate Medical Education to Increase Primary Care and Rural Physician Capacity in South Carolina,* Carolina GME Advisory Group [Online]. Available at: www.nationalahec.org/pdfs/gme_advisory_group_report.pdf (Accessed August 29, 2017).

Cassidy, A. (2010), 'Patient-Centered Medical Homes', *Health Affairs - Health Policy Brief*, pp. 1–6.

Collins, C. (2016), 'Challenges of Recruitment and Retention in Rural Areas', *North Carolina Medical Journal*, vol. 77, no. 2, pp. 99–101.

Cromartie, J. and Bucholtz, S. (2008), *Defining the 'Rural' in Rural America,* United States Department of Agriculture Economic Research Service (USDA) Amber Waves [Online]. Available at: https://www.ers.usda.gov/amber-waves/2008/june/defining-the-rural-in-rural-america/ (Accessed April 19, 2017).

Donaldson, M. S., Yordy, K. D., Lohr, K. N. and Vanselow, N. A., eds. (1996), *Primary Care: America's Health in a New Era*, Washington DC, National Academies Press.

Driscoll, D. L., Hiratsuka, V., Johnston, J. M., Norman, S., Reilly, K. M., Shaw, J., Smith, J., Szafran, Q. N. and Dillard, D. (2013), 'Process and Outcomes of Patient-Centered Medical Care with Alaska Native People at Southcentral Foundation', *The Annals of Family Medicine*, vol. 11, Suppl 1, 41-49.

Eberhardt, M. S. and Pamuk, E. R. (2004), 'The Importance of Place of Residence: Examining Health in Rural and Nonrural Areas', *American Journal of Public Health*, vol. 94, no. 10, pp. 1682–1686.

Ewing, J. and Hinkley, K. N. (2013), *Meeting the Primary Care Needs of Rural America: Examining the Role of Non-Physician Providers*, National Conference of State Legislatures [Online]. Available at: http://www.ncsl.org/documents/health/RuralBrief313.pdf (Accessed October 03, 2017).

Fordyce, Meredith A., Doescher, Mark P. and Skillman, S. M. (2013), *The Aging of the Rural Generalist Physician Workforce: Will Some Locations Be More Affected than Others?*, WWAMI Rural Health Research Center.

Golden, W., Thompson, J. W., Olson, S., Hill, R., Fendrick, A. M., Mathis, C. and Chernew, M. (2014), *Patient-Centered Medical Homes in Arkansas*, Health Affairs Blog [Online]. Available at: http://healthaffairs.org/blog/2014/05/20/patient-centered-medical-homes-in-arkansas/ (Accessed April 29, 2017).

Grumbach, K., Bodenheimer, T. and Grundy, P. (2009), *The Outcomes of Implementing Patient-Centered Medical Home Interventions: A Review of the Evidence on Quality, Access and Costs from Recent Prospective Evaluation Studies*, Patient-Centered Primary Care Collaborative.

Hing, E. and Hsiao, C.-J. (2014), *State Variability in Supply of Office-Based Primary Care Providers: United States, 2012*, Centers for Disease Control and Prevention.

Hoff, T., Weller, W. and DePuccio, M. (2012), 'The Patient-Centered Medical Home: A Review of Recent Research', *Medical Care Research and Review*, vol. 69, no. 6, pp. 619–644.

Hornberger, J. and Freeman, D. (2015), 'Blending Behaviorists into the Patient-Centered Medical Home', in O'Donohue, W. and Maragakis, A. (eds.) *Integrated Primary and Behavioral Care* [Online], Cham, Springer International Publishing, pp. 39–59. Available at: http://link.springer.com/10.1007/978-3-319-19036-5_3 (Accessed April 24, 2017).

Institute of Medicine (IOM) (1978), *A Manpower Policy for Primary Health Care: Report of a Study*, National Academy of Science.

Jaén, C. R., Ferrer, R. L., Miller, W. L., Palmer, R. F., Wood, R., Davila, M., Stewart, E. E., Crabtree, B. F., Nutting, P. A. and Stange, K. C. (2010), 'Patient Outcomes at 26 Months in the Patient-Centered Medical Home National Demonstration Project', *The Annals of Family Medicine*, vol. 8, Suppl 1, 57-67.

Klein, D. B., Laugesen, M. J. and Liu, N. (2013), 'The Patient-Centered Medical Home: A Future Standard for American Health Care?', *Public Administration Review,* vol. 73, Suppl 1, 82-92.

Klein, M. A. (2009), 'The Integrated Patient-Centered Medical Home: Tools for Transforming Our Healthcare Delivery System', *American Health & Drug Benefits,* vol. 2, no. 3, p. 128.

Macinko, J., Starfield, B. and Shi, L. (2007), 'Quantifying the Health Benefits of Primary Care Physician Supply in the United States', *International Journal of Health Services,* vol. 37, no. 1, pp. 111–126.

Maragakis, A. and O'Donohue, W. (2015), 'Patient-Centered Medical Homes: The Promise and the Research Agenda', in O'Donohue, W. and Maragakis, A. (eds.) *Integrated Primary and Behavioral Care,* Cham, Springer International Publishing, pp. 3–16.

Martin, J. C. (2004), 'The Future of Family Medicine: A Collaborative Project of the Family Medicine Community', *The Annals of Family Medicine,* vol. 2, Suppl 1, 3-32.

Moscovice, I., Johnson, K. and Burstin, H. (2017), 'Performance Measurement in Rural Communities: The Low-Volume, Large Measurement Challenge', *Joint Commission Journal on Quality and Patient Safety,* vol. 43, no. 5, pp. 259–262.

Mueller, K. J., Alfero, C., Coburn, A. F., Lundblad, J. P., MacKinney, M. A. C., McBride, T. D. and Weigel, P. (2016), *Medicaid Payment and Delivery System Reform: Challenges and Opportunities for Rural Health Systems,* Rural Policy Research Institute.

NCQA (2014), *Patient-Centered Medical Home (PCMH) 2014 – Part 2: Standards 4-6,* NCQA [Online]. Available at: https://www.ncqa.org/Portals/0/Programs/Recognition/RPtraining/PCMH%202014%20Intro.%20Training%20Slides%20Part%201%20-%20Standards%201-3%20-%2011.26.pdf (Accessed August 29, 2017).

NCQA (2014), *Standards and Guidelines for NCQA's Patient-Centered Medical Home (PCMH) 2014,* NCQA [Online]. Available at: http://www.acofp.org/acofpimis/Acofporg/Apps/2014_PCMH_Finals/Tools/1_PCMH_Recognition_2014_Front_Matter.pdf (Accessed August 29, 2017).

Neumann, K., Gierling, P. and Dietzel, J. (2014), *Gute Praxis in der ambulanten Versorgung – Anregungen für Deutschland auf Basis internationaler Beispiele,* IGES Institut.

NRHA (n.d.), *About Rural Health Care* [Online], NRHA. Available at: https://www.ruralhealthweb.org/about-nrha/about-rural-health-care (Accessed October 03, 2017).

Phillips, R. L. and Bazemore, A. W. (2010), 'Primary Care and Why it Matters for U.S. health System Reform', *Health Affairs,* vol. 29, no. 5, pp. 806–810.

Ratcliffe, M., Burd, C., Holder, K. and Fields, A. (2016), *Defining Rural at the U.S. Census Bureau: American Community Survey and Geography Brief*, U.S. Census Bureau.

Reid, R. J., Coleman, K., Johnson, E. A., Fishman, P. A., Hsu, C., Soman, M. P., Trescott, C. E., Erikson, M. and Larson, E. B. (2010), 'The Group Health Medical Home at Year Two: Cost Savings, Higher Patient Satisfaction, and Less Burnout for Providers', *Health Affairs*, vol. 29, no. 5, pp. 835–843.

Reid, R. J., Fishman, P. A., Yu, O., Ross, T. R., Tufano, J. T., Soman, M. P. and Larson, E. B. (2009), 'Patient-Centered Medical Home Demonstration: A Prospective, Quasi-Experimental, Before and After Evaluation', *The American Journal of Managed Care*, vol. 15, no. 9, 71-87.

RHIhub (2017), *Rural Mental Health* [Online]. Available at: https://www.ruralhealthinfo.org/topics/mental-health (Accessed April 22, 2017).

Rogers, J. C. (2008), 'The Patient-Centered Medical Home Movement - Promise and Peril for Family Medicine', *Journal of the American Board of Family Medicine*, vol. 21, no. 5, pp. 370–374.

Rosland, A.-M., Nelson, K., Sun, H., Dolan, E. D., Maynard, C., Bryson, C., Stark, R., Shear, J. M., Kerr, E., Fihn, S. D. and Schectman, G. (2013), 'The Patient-Centered Medical Home in the Veterans Health Administration', *The American Journal of Managed Care*, vol. 19, no. 7, 263-272.

Sandy, L. G., Bodenheimer, T., Pawlson, L. G. and Starfield, B. (2009), 'The Political Economy of U.S. Primary Care', *Health Affairs*, vol. 28, no. 4, pp. 1136–1145.

Solimeo, S. L., Stewart, G. L. and Rosenthal, G. E. (2016), 'The Critical Role of Clerks in the Patient-Centered Medical Home', *The Annals of Family Medicine*, vol. 14, no. 4, pp. 377–379.

Stange, K. C. (2009), 'The Generalist Approach', *The Annals of Family Medicine*, vol. 7, no. 3, pp. 198–203.

Stange, K. C., Nutting, P. A., Miller, W. L., Jaén, C. R., Crabtree, B. F., Flocke, S. A. and Gill, J. M. (2010), 'Defining and Measuring the Patient-Centered Medical Home', *Journal of General Internal Medicine*, vol. 25, no. 6, pp. 601–612.

Starfield, B. and Shi, L. (2002), 'Policy Relevant Determinants of Health: An International Perspective', *Health Policy*, vol. 60, no. 3, pp. 201–218.

Starfield, B. and Shi, L. (2004), 'The Medical Home, Access to Care, and Insurance: A Review of Evidence', *Pediatrics*, vol. 113, Suppl 4, pp. 1493–1498.

Starfield, B., Shi, L. and Macinko, J. (2005), 'Contribution of Primary Care to Health Systems and Health', *The Milbank Quarterly*, vol. 83, no. 3, pp. 457–502.

U.S. Census Bureau (2015), *2010 Census Urban Area Thematic Maps* [Online], U.S. Census Bureau. Available at: https://www.census.gov/geo/maps-data/maps/thematic_2010ua.html (Accessed April 27, 2017).

USDA (2017), *Poverty Overview: A Note About the Data Source,* USDA [Online]. Available at: https://www.ers.usda.gov/topics/rural-economy-population/rural-poverty-well-being/poverty-overview.aspx (Accessed April 22, 2017).

USDA (2017), *What is Rural?,* USDA [Online]. Available at: https://www.ers.usda.gov/topics/rural-economy-population/rural-classifications/what-is-rural.aspx (Accessed April 19, 2017).

Zutshi, A., Peikes, D., Smith, K., Genevro, J., Azur, M., Parchman, M. and Meyers, D. (2014), *The Medical Home: What Do We Know, What Do We Need to Know?: A Review of the Earliest Evidence on the Effectivness of the Patient-Centered Medical Home Model,* AHRQ.

The Geisinger Model

Patrick Walberer

Despite having one of the highest health expenditures internationally, the US health system for many years has only achieved average care outcomes. Additionally, the quality of care is not adequately considered in reimbursement processes. Insufficient individual access to medical care, fragmented care structures, as well as the still high number of uninsured Americans, represent great challenges across the nation. Geisinger Health System, an integrated healthcare delivery system located in Pennsylvania which has operated for more than 100 years, has set a goal to counter sprawling healthcare costs with innovative service, insurance, and remuneration structures. Therefore, Geisinger Health System relies in particular on innovations in information technology, which are based on an electronic health record system that spans all institutions. The approach and implementation of innovations as well as some directive innovations of the Geisinger Health System are examined in this essay. The value added for the patient as well as for Geisinger will also be discussed. Finally, prospects and limitations will be presented to evaluate if and how the innovative thinking of Geisinger Health System can be seen as a beacon for other US healthcare providers.

Contents

1 Status and Hurdles of Health Care Delivery in Rural US Regions

Historically, there exist various parallel healthcare and insurance systems in the United States of America (US) which operate as a "highly inefficient, … extremely fragmented whole" (Smith and Medalia, 2014). The insurance coverage of the US population, defined as access to medical care, is a very heterogeneous mixture of mainly private insurance as well as many state support programs, without a general insurance obligation. Fee-for-service reimbursement dominates the insurance market, but some plans reward good treatment and outcomes (Yuan et al., 2017, pp. 12-14). With costs of $9,403 per-capita in 2015, the US health care system ranks third most expensive in the world, while the treatment quality is only rated as average (World Bank, 2017). Constantly rising treatment costs as well as dissatisfaction of the patients with the care they are provided causes further problems for the health care system.

Usually, US healthcare structures consist of various spatially and organisationally separated outpatient medical practices, emergency services, and inpatient service providers. However, this organisation of care structures no longer corresponds to the demands and possibilities for patient care in the 21st century. Innovative care models are only very slow introduced into healthcare delivery. A well thought-out medical care restructuring including innovative supply components is urgently needed (Prince and Graf, 2015, p. 16).

All the problems previously mentioned resulted in a loss of value in the healthcare system and created the necessity for reorganisation and innovation. This leads to the following research question, which is to be answered within the scope of this paper:

> The aim of this essay is to examine if and how the Geisinger model can be seen as an example for innovative healthcare delivery in the US and describe what generalizable implications can be derived from it for other providers.

2 Classification of Legal Background, Basic Conditions, and Necessities

Access to medical care in the US depends on an individual’s insurance protection through an appropriate health plan. As described in the previous chapter1, health insurance in the US means any type of program that is designed to cover and pay for illness expenses. This includes privately purchased insurance and government funded insurance (Medicare) or social welfare program (Medicaid) (Shi and Singh, 2013, p.139; KFF, 2017; Torgan, 2013).

Fragmented, uncoordinated, and highly variable treatment procedures can be identified within this system. Fragmented healthcare structures often lead to safety risks as well as wasted resources, two main reasons for the low value of US healthcare, defined as the outcome depending on the cost of the input (Porter and Olmsted-Teisberg, 2006, p. 4).

Private health insurance companies, in particular, negotiate health plans with individual supply conditions and payment models with different service provider groups, creating a lot of bureaucracy and inefficiency (Chua, 2006, p. 4; Torgan, 2013).
Governmental reform measured previously proposed mostly focused on better access to care or cost control of healthcare. Thereby, both approaches ignored the basic problem of lower healthcare value for a long time (Porter and Olmsted-Teisberg, 2006, p. 4; Torgan, 2013). It is important to increase the value of healthcare and maximize the benefits of high healthcare expenditures. Productivity and efficiency gains, which are common in other industrial sectors, barely exist or are non-existent in the US healthcare sector (Paulus et al., 2008, p. 1,235). To increase the value of healthcare, a well-thought-out health care system strategy as well as the associated organisational capacity to change is needed. Sustainable healthcare value can only be created when the various stages of the care process are abolished, automated, delegated to appropriate but more cost-effective personnel, or otherwise made more efficient (Porter and Olmsted-Teisberg, 2006, pp. 4-6; Torgan, 2013).
Key components for an innovative change in care processes are:

- Consumers and patients who are actively directed to behaviour that alleviates illnesses or increases the patient-centred performance.
- Safer and more effective medicines or medical devices are used
- Physicians who provide faster, more appropriate and reliable patient-centred care
- Costs of the supply chains are systematically reduced and the value of healthcare increased

These changes offer the greatest sustainability within a supply system, in which the focus is on the creation of value and the output of innovation is measured and appropriately rewarded in the market (Porter and Teisberg, 2006, pp. 4-6; Paulus et al., 2008, pp. 1,235-1,236).
The US healthcare system is not just struggling with the existing lack of value; it also has geographical barriers. The geography and settlement structure can be characterized by a two-track development - various metropolises of millions and many sparsely populated rural regions. The organisation and assurance of an adequate supply structure, especially in rural areas, is often challenging. This is also the case for Pennsylvania, a state in the northeast of the USA with an area of about 120,000 km^2 and a population of 12,702,379. This corresponds to an average population of 106 inhabitants per km^2. The median age is 39.6 years, with an age cohort between 18 and 64 years comprising 62.3% of the population. The number of men and women are almost equal. The Geisinger Healthcare System (GHS), headquartered in Danville, Pennsylvania, is predominantly

active in Pennsylvania and is therefore subject to the issues in design of its care structure described above, especially since the system services rural regions.

3 Geisinger Healthcare System as an Innovator of Need-based Healthcare in the USA

3.1 Historical background, Ideas, and Development of the GHS

More than 100 years ago, in 1915, Abigail Geisinger founded her own hospital modelled on the Mayo Clinic in rural Pennsylvania and set a mission "to make it the best" (Paulus et al., 2008, p. 1,236). Today, this single hospital has developed into its own healthcare system consisting of around 30,000 employees, distributed into three hospitals and 110 network-clinics allocated over 45 counties in Pennsylvania (GHS, 2015, p. 17; Paulus, 2009, p. 123; O´Connell, 2016). The primary care physicians in the 45 mostly rural counties ensure the basic outpatient care of GHS patients in spoke facilities[1] and function as gatekeepers for the downstream and inpatient GHS care provider structures. In these downstream care settings, specialists treat patients who have been recommended to be seen by a specialist within three hospitals, which act as hubs[2] (McKinley et al., 2002, pp. 574-575).

The GHS works as a not-for-profit provider of care in Pennsylvania. The reason GHS places importance on offering innovative healthcare solutions is an established culture of reinvesting a large amount of their profit every year. In 2016, GHS spent 15% of their operating expenses on community support. This amount of community service is three times greater than the necessary amount to meet the standards of a charitable organisation in Pennsylvania. Compared to for-profit organisations, which focus on maximizing their revenue and potentially neglect the quality of care, the GHS mission is to develop a care model based on innovation and value to enhance the quality of care. Because of its clinical and financial success, the not-for-profit mission of GHS is a model for other healthcare organisations nationwide (GHS, 2017).

The GHS was initially an integrated healthcare delivery system[3] (IDS) and later developed into a HMO with central and north-eastern Pennsylvania as the main area of activity[4] (Paulus et al., 2008, pp. 1,236-1,237). As an HMO, the GHS offers four main types

[1] Spokes are to be understood as facilities for the provision of health services, which serve as the first point of contact in the treatment of patients (Porter and Olmsted-Teisberg, 2006, p.197; McKinley et al., 2002, pp. 574-575).

[2] Hubs are large and centralized health care provider facilities (Porter, Olmsted-Teisberg, 2006, p.197; McKinley et al., 2002, pp. 574-575).

[3] An IDS is a network of healthcare organisations where physicians network with or without hospitals (Evashwick and Meadors, 1994).

[4] A health maintenance organization (HMO) is a provider for health services as well as a medical insurance group that offers health plans (Kovner and Knickman, 2011, p.31).

of health plans: one for children, a plan for individuals and families, a plan specific to Medicare recipients, and separate plan for Medicaid recipients (Geisinger, 2017). In 2015, the Geisinger Health Plans (GHP) had 540,172 members, of which approximately 31% were on the Medicaid plan. A total of over 2,640,000 ambulatory patients were seen and over 213,000 patients were treated in the emergency room (GHS 2015). The referrals to GHS facilities are not limited to GHS doctors, but can also be made by doctors outside the GHS (Paulus et al., 2008, pp. 1,236-1,237). With a volume of 33% of the GHS total turnover, the proportion of treated GHP patients is significantly lower than non-GHP patient population (Paulus et al., 2008, p. 1,236). This figure demonstrates that recommendations for patients from outside providers are important to the success of GHS (Paulus et al., 2008, pp. 1,236-1,237).

The GHS can particularly be characterized by its strong affinity toward and focus on improving healthcare delivery. In order to design innovative insurance and reimbursement models, the GHS has always been ready to take risks, believing in the future success of the projects. Their conviction in high-value treatment quality is particularly clear since Geisinger started to offer a reimbursement of costs a few years ago to patients who were not satisfied with their treatment (Burke, 2017; Casale et al., 2007, pp. 613-623).

Geisinger´s decision to take part in the Medicaid managed care program required –especially for the rural areas of Pennsylvania – a suitable and cost-effective strategy for treatment options for patients living in these regions. This was the starting point of an innovative care model, for which e-visits and telemedicine based expert consultations were actively researched (Prince and Graf, 2015, p. 16). Geisinger's understanding of how healthcare is provided is subject to rapid change in treatment options, remuneration models, and communication technologies particularly influenced by demographic changes. Geisinger's strength as a participant in healthcare delivery is that it can effectively adapt to these trends and other conditions. To deliver healthcare that patients need most, GHS has tested various care models, focusing on innovations in the medical, insurance, and technological context. GHS has continually improved these models through adaptations and further developments over time. Furthermore, this positive and innovative image as a healthcare supplier can play a crucial role as a competitive parameter (Prince and Graf, 2015, p. 16; Housley, 2011).

3.2 Understanding the Systematic Implementation of Innovation at Geisinger

To understand GHS´s insight and passion for innovation, it is important to take a closer look at its historically justified guiding culture and principles. The development and implementation of innovation is a very labour intensive undertaking, according to Geisinger. Many other healthcare providers simply add innovative concepts to existing processes. For further development and implementation of GHS´s supply and financing

structures, it is essential to place this task in the hands of an inter-professional team. Such a team at GHS, especially in the case of large innovation projects, consists of GHS employees of different professions, for example clinicians, operators, controllers, payers, and, increasingly, also patients or customers. This team is expected to first assess changes in the patient care and disease spectrum, evaluate the required and available technologies, and examine existing insurance and reimbursement structures. Even though the team members all belong to the same healthcare system, each has their own viewpoint, motivation, and goals. In addition, the group is striving at the beginning of each innovation process for an answer to a simple yet rarely asked question: Which realistically viable care model[5] can most reliably deliver the highest value of health care? Subsequently, there is a continuous search for new options for insurance, reimbursement, and healthcare models to be added to the GHS. This ability to assess and respond adequately to the changes that underlie different inputs is a very important element for future success in GHS´s opinion (Prince and Graf, 2015, p. 16; Paulus et al., 2008, p. 1,237).

Prior to designing a new care model, a clinical business plan is developed that includes the expected outcomes based on the appropriate processes, outcome measurements, and management responsibilities for each implementation step. The development teams are supported by clinical evidence of existing workflows, analyses of financial reimbursement policies, and legal frameworks. To redesign specific supply and reimbursement models, Geisinger pays particular attention to the following four areas:

- Service providers with the greatest impact on the patient population or resource consumption
- Services with the greatest degree of unauthorized variations
- Models with evidence-based or consistently derived best-practice and easily accessible outcome measurements
- Healthcare services with the highest expected diversity in outcome performance

In addition, GHS managers are particularly focused on initiatives that are expected to have a noticeable effect on the healthcare system as soon as possible. Newly designed supply processes are linked directly to expected efficiency and quality goals. After completion of the new approach to clinical care, the reimbursement, incentive structures, and non-financial remuneration are negotiated between managers of the service provider units and GHP executives (Paulus et al., 2008, p. 1,238).

[5] In this context, the care model is defined as a step-by-step approach, personalized to provide preventive care as well as diagnoses, treatments, management, and involvement of ill patients resulting in increased value (Paulus et al., 2008, p. 1,237).

For the introductory stage of innovation projects GHS usually tries to address the "sweet spot", the one-third of the patients with a GHP for whom Geisinger is financially responsible as well as their primary medical service provider. These innovations are not kept from the other two-thirds of GHS´s patient group, but this approach makes it easier for Geisinger to measure the impact of the innovation on the medical as well as on the financial aspects of healthcare. Particularly in the case of new GHP reimbursement models, GHS service providers are given the opportunity to experiment extensively on whether new interventions have the potential to develop commercial market models for quality and value-based care. As a marketing aspect for any GHP, only patients with a GHP enjoy the privilege of being the first to benefit from such innovations (Paulus et al., 2008, p. 1,237; Stock et al., 2014, pp. 1,540-1,548).

To evaluate the innovative approaches and create measurement data for ongoing process improvements, Geisinger relies on scientifically recognized methodologies, which include continuous quality improvements, six-sigma, or lean restructuring. These methodologies examine the influence of the approaches on the healthcare supply and also show potential for further improvement for subsequent innovation efforts. This systematic approach to developing, introducing, and evaluating innovations at the same time allows GHS to create a culture of self-learning and draw conclusions from its own setbacks for future projects. To that end, the members of the innovation team build modular innovation components which can be utilized to further develop functions, technologies, or components of already successfully established healthcare supply models at every stage of development. Such reusable innovation model components, for example, consist of the use of human resources, hardware and software tools, technologies, or analysis instruments. In addition, this approach and the use of modular innovation components allows the GHS to design future supply models faster, creating an optimized and cost-effective process. (Paulus et al., 2008, p. 1,238). Previous experience associated with the GHS innovation culture shows that the failure rate of innovation projects has declined since the introduction of this procedure, and the share of expectations that have been reached or even surpassed has risen. This process of scientifically supervised and evaluated innovation is repeated over and over again, and thereby plays a decisive part in increasing the production of value in the healthcare system (Paulus et al., 2008, p. 1,238).

In 2013, the GHS launched a new business unit called Geisinger Ventures (GV), whose task is to improve the introduction and growth of new business areas as an extension of existing structures in healthcare. Up to now, GV has been supporting the implementation of different retail clinic[6] model projects in various organizational forms. These GHS

[6] Retail clinics or micro clinics are small primary care facilities, staffed by nurse practitioners or unmanned through use of telemedicine applications (Dunn, 2014).

retail clinics exists as a number of walk-in business model facilities, including in-store clinics, stand-alone retail clinic sites, and combined models with basic healthcare practices and emergency services at the same site. For each model, various benefits and challenges arose in terms of patient care, marketing, personnel composition, and clinical integration. However, this was effectively countered by GV through the ability to access various modular innovation components and the efforts to create innovative supply models which can be continually optimized (Prince and Graf, 2015, p. 16).

3.3 Milestone Innovation Examples from Geisinger Healthcare System

The following examples illustrate pioneering innovations of GHS.
In 1995, the platform for an electronic health record (EHR), which covered the complete array of outpatient services, was introduced. Today, all inpatient facilities have fully implemented integrated EHRs in place (Paulus et al., 2008, p. 1,237). The approach of the Geisinger-EHR is innovative in that physicians who are not part of the GHS, but are involved in the treatment process of a GHS patient, receive reading and writing authorization via a web portal. Even patients can access their own data via the web portal online, albeit to a limited extent. This gives patients direct access to their data and helps them to become partners within the care system. Providing patients digital tools within the EHR enables them to better manage their own care and improve the value of treatment given (Paulus et al., 2008, pp. 1,244-1,245). Geisinger has also aided in the implementation of integrated electronic systems and centralization of innovation and quality support in many freestanding medical practices and small independent hospitals. This approach divides the best practices of GHS into individual care process steps and integrates these steps into decision support and other tools that are designed to help deliver performance at the right place and at the right time (Paulus et al., 2008, pp. 1,244-1,245). GHS´s innovative and transparent culture of digital data workflows and the integrated EHR infrastructure within the healthcare system also enable a strategic analysis of long-term, comparable supply data. In addition, this digital data and workflow make it possible to provide most of the services with high value near to the patient, minimizing long trips for the patient to treatment hubs (Paulus et al., 2008, p. 1,237).
In 2007, Geisinger launched the community health initiative called MyCode. MyCode is a system-wide genomic biobanking program and a platform for value-based precise medicine. It links DNA-samples and EHR data for broad research use, particularly projects focused on learning more about DNA and patient outcomes. The DNA-samples are used to generate molecular data, including a comprehensive genotype and exome sequence data. Key elements for MyCode are the stable patient population, EHR infrastructure, and the integrated health system. MyCode is free for all GHS patients and is also open to primary care and emergency patients. More than 90,000 people now participate in MyCode, with an additional average enrolment rate of 4,000 people per month

and consent rate of about 85%. Compared to traditional clinical research approaches, the MyCode model is more flexible, faster and more cost-effective. Because the model is nearly unlimited in scale, it can be adapted across multiple platforms to create and use an even broader range of data with growing resources. MyCode and genomic medicine is seen to have the potential for disruptive innovation. Furthermore, the value of healthcare can be increased using this kind of precise medicine. Mycode underscores the importance of an EHR, because without the underlying EHR infrastructure this innovative model of healthcare is not able to work (Carey et al., 2016, pp. 906-913; Avellino et al., 2013, pp. 151-152; Faucett and Davis, 2016, pp. 33-35; Wade et al., 2014, pp. 112-116). The complete and integrated EHR at Geisinger enabled more than MyCode; it also paved the way for one of the latest innovations positively influencing healthcare delivery - the use of big data technologies in a clinical context (Cohen, 2017). Innovative, analytical big data technologies are already used successfully in many branches of industry worldwide. However, the breakthrough of this technology-based analysis methodology, which processes and systematically uses large, unstructured, and digitally collected data packages, is still largely absent in healthcare, despite the large amount of digital health data which are collected every day (Dedic and Stanier, 2017). The main obstacles to this breakthrough are data protection concerns, legal restrictions, as well as a lack of technical possibilities or internally available knowledge (Erskine et. al., 2016; Cohen, 2017). A basic prerequisite for the use of big data analysis at GHS was the complete conversion to electronic data collection, storage, and use in the form of an integrated EHR in 1996, as described at the beginning of this section. To structure the collected data and to make it strategically usable, a multi-stage innovation process within the EHR was needed, which required the definition of standards for all process steps. The lack of uniform standards and lack of compatibility of individual information systems are the biggest obstacles for most hospitals seeking to implement big data technologies.

In 2015, GHS introduced an IT system called Unified Data Architecture (UDA). The UDA can import the huge amounts of data into the data analysis and management systems already present at GHS. The synthesis of the data enables Geisinger to not only record the outcome parameters of their patients, but also evaluate them in a structured manner and derive conclusions or patterns from them. Furthermore, a correlation between the clinical care data and the genomic sequences of individual patients from MyCode can be established, as well as the visualization of health data on patient cohorts and care provider networks (Erskine et al., 2016; Cohen, 2017).

The data gathered and stored by GHS, for example from clinical department systems such as radiology, patient satisfaction surveys, and data from various health-related apps, enable Geisinger to create detailed long-term reports of their patients. However, Geisinger's Big Data usage strategy is not limited to the data collected individually in

its institutions. Rather, with the patient´s prior consent, Geisinger tries to incorporate health-related data from outside sources into the UDA. These include, for example, data from grocery shopping and loyalty programs from various traders, as well as smartphone and app data. The UDA offers each patient extra storage space and has designed software to ensure that the addition and storage of data is very easy. With the UDA, Geisinger pursues the goal of closing the gap between data, which are digitally collected and stored in many areas of life, but are not systematically and structurally linked to each other. This is a common challenge for conventional health data systems. Processing large amounts of data and importing them from a variety of sources is no longer a problem for GHS, making it a unique system (Erskine et al., 2016). At present, Geisinger has the largest big data application in health care with the UDA. (Erskine et al., 2016).

4 Geisinger Health System as a Beacon for Change in US Healthcare

Geisinger Healthcare System is an innovative microcosm in national healthcare which can serve as an example for other systems. Their willingness to continue ongoing development of healthcare delivery and insurance structures centred on the 21st century patient´s needs makes it an exceptionally innovative US healthcare provider system. Parts of Geisinger´s approaches for offering health-insurance plans as well as delivering healthcare are unique and influence decision-makers of other health plans and organizations (Paulus, 2009). Its health plans, reimbursement structures, and, especially, its focus on innovation and value-based treatments are a beacon for change in US healthcare. As described in the previous sections, two central ideas can be derived from Geisinger's experience in innovation to solve the initially described problems in US healthcare delivery and possibly effect national health policy (Robeznieks, 2015).

Develop and align incentives and reimbursement structures toward value for the patient to improve experience and generate financial success

Geisinger´s integrated health system is both a service provider system and an insurance provider. For its GHP patients, it can offer better incentive structures, as opposed to other traditional health care provider organisations. Because of its innovative care models and its financial success, it is easier for GHS to use monetary and non-monetary incentives to attract physicians. The ability to cross-subsidize unprofitable services is another advantage of the GHS. Even offering patients the right to reclaim payments for treatment if they are unsatisfied is an attractive marketing strategy (Paulus and Steele, 2008, pp. 1,243-1,244; Casale et al., 2007, pp. 613-620). Beside the innovative incentive and reimbursement structures, the digital-based business models are also important aspects of GHS´s pioneering role in healthcare delivery.

Digital-based business models and infrastructure are essential to create sustainable changes in healthcare provision:

The central element of nearly all GHS technological innovations is based on the integrated use of EHR and the associated digital data workflow infrastructure. This helps to automate care processes, overcome geographical barriers, involve patients more closely in the treatment process, and increase overall safety and healthcare value. Many of the current political discussions in the US suggest that EHRs can fundamentally change health care provision. According to the evidence gathered at Geisinger, there are indications that no fundamental change can be expected from the introduction of an her alone, but this can be the starting point of a long-term digital change, and thus fundamentally change way in which health services are provided. Nevertheless, there are some barriers, such as prohibitive implementation costs and low acceptance of EHR technology in some areas, as well as the need for stable patient populations. The local applicability and use of EHR technology can be difficult if these requirements are not met.
These lessons from GHS have the ability to guide other health organizations and insurance providers towards healthcare which is value-based and beneficial to patients as well as future innovation. Putting these ideas into action through US policy could dramatically change not only Medicare and Medicaid programs, but transform the entire health delivery system.

References

Avellino, S., Colonie, R. and Carey, D. (2013), 'PS2-7: Automated Ordering and Sample Collection to Leverage Electronic Medical Record Based Genetic Research: The Geisinger MyCode Project', *Clinical Medicine & Research*, vol. 11, no. 3, pp. 151–152.

Burke, G. F. (2017), *Geisinger´s Refund Promise: Where Things Stand After One Year*, NEJM Catalyst [Online]. Available at: http://catalyst.nejm.org/geisinger-refund-promise-one-year/ (Accessed May 20, 2017).

Carey, D. J., Fetterolf, S. N., Davis, D. F., Faucett, W. A., Lester-Kirchner, H., Mirshahi, U., Murray, M. F., Smelser, D. T., Gerhard, G. S. and Ledbetter, D. H. (2016), 'The Geisinger MyCode Community Health Initiative: An Electronic Health Record-Linked Biobank for Precision Medicine Research', *Genetics in Medicine*, vol. 18, no. 9, pp. 906–913.

Casale, A. S., Paulus, R. A., Selna, M. J., Doll, M. C., Bothe, A. E., McKinley, K. E., Berry, S. A., Davis, D. E., Gilfillan, R. J., Hamory, B. H. and Steele, G. D. (2007), '"ProvenCareSM": A Provider-Driven Pay-for-Performance Program for Acute Episodic Cardiac Surgical Care', *Annals of Surgery*, vol. 246, no. 4, pp. 613–623.

Chua, K. P. (2006), *Overview of the U.S. Health Care System*, American Medical Student Association [Online]. Available at: http://www.amsa.org/AMSA/Libraries/Committee_Docs/HealthCareSystemOverview.sflb.ashx (Accessed March 22, 2017).

Cohen, J. K. (2017), *Geisinger Health System Taps Stanson Health for Clinical Decision Support*, Becker´s Health it & Cio Review [Online]. Available at: http://www.beckershospitalreview.com/healthcare-information-technology/geisinger-health-system-taps-stanson-health-for-clinical-decision-support.html (Accessed April 30, 2017).

Dedić, N. and Stanier, C. (2017), 'Towards Differentiating Business Intelligence, Big Data, Data Analytics and Knowledge Discovery', in Piazolo, F., Geist, V., Brehm, L. and Schmidt, R. (eds.) *Innovations in Enterprise Information Systems Management and Engineering: 5th International Conference*, Cham, Springer International Publishing, pp. 114–122.

Dunn, L. (2014), *Are Micro Clinics the Future of Healthcare Delivery?*, Becker´s Hospital Review [Online]. Available at: http://www.beckershospitalreview.com/hospital-management-administration/are-micro-clinics-the-future-of-healthcare-delivery.html (Accessed May 30, 2017).

Erskine, A. R., Karunakaran, B., Slotkin, J. R. and Feinberg, D. T. (2016), *How Geisinger Health System Uses Big Data to Save Lives*, Harvard Business Review.

Evashwick, C. and Meadors, A. (1994), 'Defining Integrated Delivery Systems', *AHSR FHSR ANNU Meet Abstr. Book*, vol. 11, pp. 31–32.

Faucett, W. A. and Davis, F. D. (2016), 'How Geisinger Made the Case for an Institutional Duty to Return Genomic Results to Biobank Participants', *Applied & Translational Genomics*, vol. 8, pp. 33–35.

Geisinger (2017), *Pick the Right Plan* [Online], Geisinger Health Plan. Available at: https://www.geisinger.org/health-plan/plans (Accessed May 30, 2017).

GHS (2015), *2015 Annual Report: Enhancing the Patient Experience*, GHS [Online]. Available at: https://www.geisinger.org/-/media/OneGeisinger/Images/GHS/News%20and%20Media/Annual%20Reports/ar-2015.ashx?la=en (Accessed May 30, 2017).

GHS (2017), *Our Not for Profit Mission* [Online], GHS. Available at: https://www.geisinger.org/about-geisinger/in-our-community/our-not-for-profit-mission (Accessed May 30, 2017).

Housley, D. D. (2011), *Make it the Best: A History of Geisinger Health System 1912-2011*.

KFF (2017), *Health Insurance Coverage of the Total Population 2015,* Kaiser Family Foundation [Online]. Available at: http://kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (Accessed May 30, 2017).

Kovner, A. R. and Knickman, J., eds. (2011), *Jonas and Kovner's Health Care Delivery in the United States*, 11th edn, New York, Springer Publishing Company LLC.

McKinley, K. E., Bryan-Smith, L., Dosch, T. L., Hamory, B. H. and Fillipo, B. H. (2002), 'A Hub-and-Spoke Model of Care: Providing Specialty Care in Patients' Own Communities', *The Joint Commission Journal on Quality Improvement*, vol. 28, no. 10, 574–575.

O´Connell, J. (2016), *Geisinger Agrees to Purchase the Commonwealth Medical College*, The Citizens´ Voice [Online]. Available at: http://citizensvoice.com/news/geisinger-agrees-to-purchase-the-commonwealth-medical-college-1.2096559 (Accessed May 20, 2017).

Paulus, R. A. (2009), 'ProvenCare: Geisinger´s Model for Care Transformation through Innovative Clinical Initiatives and Value Creation', *American Health & Drug Benefits*, vol. 2, no. 3, pp. 122–127.

Paulus, R. A. and Steele, D. K. (2008), 'Continuous Innovation in Health Care: Implications of the Geisinger Experience', *Health Affairs*, vol. 27, no. 5, pp. 1235–1245.

Porter, M. E. and Olmsted-Teisberg, E. (2006), *Redefining Healthcare : Creating Value-Based Decision on Results*, Boston, Mass., Harvard Business School Press.

Prince, D. B. and Graf, T. (2015), 'Geisinger´s Retail Innovation Journey', *Frontiers of Health Services Management*, vol. 31, no. 3, pp. 16–31.

Robeznieks, A. (2015), *Geisinger´s Second Century of Innovation: Health System Spreading Best Practices Through New Company*, Modern Healthcare [Online]. Available at: http://www.modernhealthcare.com/article/20150214/MAGAZINE/302169982 (Accessed May 30, 2017).

Shi, L. and Singh, D. A. (2013), *Essentials of the U.S. Health Care System*, Burlington, Jones & Bartlett Learning.

Smith, J. C. and Medalia, C. (2014), *Health Insurance Coverage in The United States: 2013*, United States Census Bureau.

Stock, S., Pitcavage, J. M., Simic, D., Altin, S., Graf, C., Feng, W. and Graf, T. R. (2014), 'Chronic Care Model Strategies in the United States and Germany Deliver Patient-Centered, High-Quality Diabetes Care', *Health Affairs*, vol. 33, no. 9, pp. 1540–1548.

The World Bank (2017), *Health Expenditure per Capita (current US$)*. [Online], The World Bank. Available at: http://data.worldbank.org/indicator/SH.XPD.PCAP?contextual=default&end=2014&locations=US&start=1995&view=chart&year_high_desc=true (Accessed May 08, 2017).

Torgan, C. (2013), *Patient Outcomes Improved by Pay-For-Performance*, National Institutes of Health [Online]. Available at: https://www.nih.gov/news-events/nih-research-matters/patient-outcomes-improved-pay-performance (Accessed May 30, 2017).

Wade, J. E., Ledbetter, D. H. and Williams, M. S. (2014), 'Implementation of Genomic Medicine in a Health Care Delivery System: A value proposition?', *American Journal of Medical Genetics*, vol. 166, no. 1, pp. 112–116.

World Health Organization (2000), *World Health Organization Assesses the World´s Health Systems*, World Health Organization [Online]. Available at: http://www.who.int/whr/2000/media_centre/press_release/en/ (Accessed May 31, 2017).

Yuan, B., He, L., Meng, Q. and Jia, L. (2017), 'Payment Methods for Outpatient Care Facilities', *Cochrane Database of Systematic Reviews*, vol. 3, 1-14.

The UMHS Samuel and Jean Frankel Cardiovascular Center

Laura Veigl

The paper Illustrates potential benefits the University of Michigan Health System would gain with the implementation of a specialty hospital for cardiovascular care in an existing healthcare complex in Michigan. Through an introduction of some of the many business strategies of healthcare delivery in the American healthcare system, an overview of delivery within a specialized hospital is provided. Benefits of these various strategies are examined in the specific context of the University of Michigan Health System and the Samuel and Frankel Jean Cardiovascular Center. The Integrated Care Model of the Michigan Health Complex creates numerous benefits, including economy of scale and avoidance of double examination. Through the new construction of the Cardiovascular Center, the patient flow through the system could be improved. With a concentration on a business strategy of specialized care, they can enhance excellence in patient values and product differentiation through the focus on cardiovascular diseases.

Contents

1 Demand for new strategies at the hospital market in the United States

Porter and Teisberg (2006, p. 20) define the U.S. healthcare system as a "dangerous path, with a toxic combination of high costs, uneven quality, frequent errors and unlimited access to care". Evidently, the system faces a few challenges such as rising health care expenditures[1] (OECD, 2017b), an aging population[2] (OECD, 2017a) and increasing availability of technologies. The demographic change and the new technologies cause an increasing demand for healthcare services, and an increasing availability of tests and procedures (Denton, 2013, p. 183). As a result, providers need to improve the efficiency of the healthcare delivery systems, which would result in decreasing costs while improving access to care (Denton, 2013, p. 75). The challenges, economic trends and demographic changes in this system (Denton, 2013, p. 182) require health care provider to plan and coordinate health care resources (Denton, 2013, p. 75). The problems in healthcare delivery are primarily due to structural and managerial weaknesses (Porter and Teisberg, 2006, p. 149). Healthcare delivery is becoming increasingly challenging and complex for providers, who must incorporate stringent regulatory requirements, integrate new medical technologies and constantly improve services. This is further complicated by the lack of a proper strategy, direction or focus. Success or failure of the health system is in part attributed to the way patients receive care as well as how medicine is practiced. As a result, every organization has to develop a strategy in which kind of business it will operate, which services they want the offer and how they want to differentiate themselves from their competitors (Porter and Teisberg, 2006, pp. 149–151).

The paper will aim to answer the question of which structure of facility and which strategy of healthcare delivery an implementation of a specialty hospital in an integrated care system would provide additional benefits. This will be answered by highlighting a strategy of healthcare delivery on the business case and the delivery of high-end care at the Frankel Cardiovascular Center (CVC) in Michigan.

2 The concept of integrated care delivery

2.1 Building a business strategy in health-care delivery

The hospital market is one of the largest industries in the U.S. and operates in a unique institutional setting (Gaynor and Town, 2012, p. 524). Hospitals or health delivery providers need a clear strategy to compete and establish themselves in the hospital market (Porter and Teisberg, 2006, 151). One guiding point is to focus on increasing the value for the patients. The value[3], in this case, can only be understood at the level of

[1] e.g. 12,5 % of share of domestic product in 2000 to 16,9% in 2015
[2] e.g. 12,4% of population are 65 or older in 2000 to 14,9% in 2015
[3] Defined as „the health outcomes achieved per dollar of cost compared to peers" (Porter and Teisberg,

medical conditions,[4] including how well the medical condition is treated through all activities and specialists (Porter and Teisberg, 2006, p. 158). Therefore, the first step in building a strategy is to define the goal they want to achieve, for example "excellence in patient value". The patient value should include management of the strategic and operational choices, resulting in informed decisions for delivery of services. When providers can achieve good outcomes for patients, they can compete with hospitals that offer similar services. The choice which medical conditions for which they want to offer treatment should be guided by the questions of whether they can gain excellence in value and if they have the frameworks to provide appropriate services (Porter and Teisberg, 2006, p. 159ff.). With excellence and, hence, an improved reputation, more patients will come to the hospital, resulting in greater efficiency and higher margins. (Porter and Teisberg, 2006, p. 156) As a result, specialized providers will also have the facility and the space to act more profitable. When providing specialized care like cardiac care, they can gain high standards on value, have the ability to compete on results, can have generous reimbursement rate and also receive the benefit of focus (Porter and Teisberg, 2006, p. 162).

Furthermore, the competing hospital providers have to consider geographic and product differentiations (Lindrooth, 2008, p. 1). The hospital must know in which geographic area they serve and compete with patient care. The concentration on the geographical side should be on the national or even regional markets, due to its growth potential as well as possibility to form partnerships (Porter and Teisberg, 2006, 158 - 159). An important decision point for patients is the distance to the hospital, adding weight to the importance of the geographical aspect of service provision (Lindrooth, 2008, p. 21).

Another aspect is product differentiation in the healthcare market. The hospitals should concentrate on either clinical or non-clinical patient preferences. (Gaynor and Vogt, 2000, pp. 3–4). Healthcare providers have the potential to distinguish themselves through the quality of the services offered on the clinical or non-clinical level. An example for non-clinical preferences is offering patients private rooms with features of a four-star hotel. The hospital can also gain advantages compared to their competitors by offering specialized treatments that patients cannot get at their local hospital. Patients are often willing to travel a longer way to receive the specialized treatments. It can be concluded that both product differentiation and geographical focus are thus two underlying factors when developing an effective strategy (Lindrooth, 2008, pp. 21–22).

2006, p. 154)

[4] Includes "diseases, illnesses, injuries, and natural circumstance such as pregnancy" (Porter and Teisberg, 2006, p. 105)

2.2 The Approach of Integrated Care

A frequent challenge in the healthcare sector is to directly provide healthcare services more efficiently. As a result, new forms of institutional and contractual arrangements in the health care sector, like managed care, can arise. In this context, vertical integration, which takes various forms, can be a possibility for providers and insurers to be more efficient. (Douven et al., 2014, p. 345 f.). According to expert opinions, 20 percent of healthcare expenses can be saved with managed care programs. These programs affect patient orientation, efficiency, and quality of health care by using suitable organization forms and management principles. Providers utilize different combinations of organizational models and management instruments. One accepted type of managed care is the approach of integrated care (Amelung, 2014, Preface).

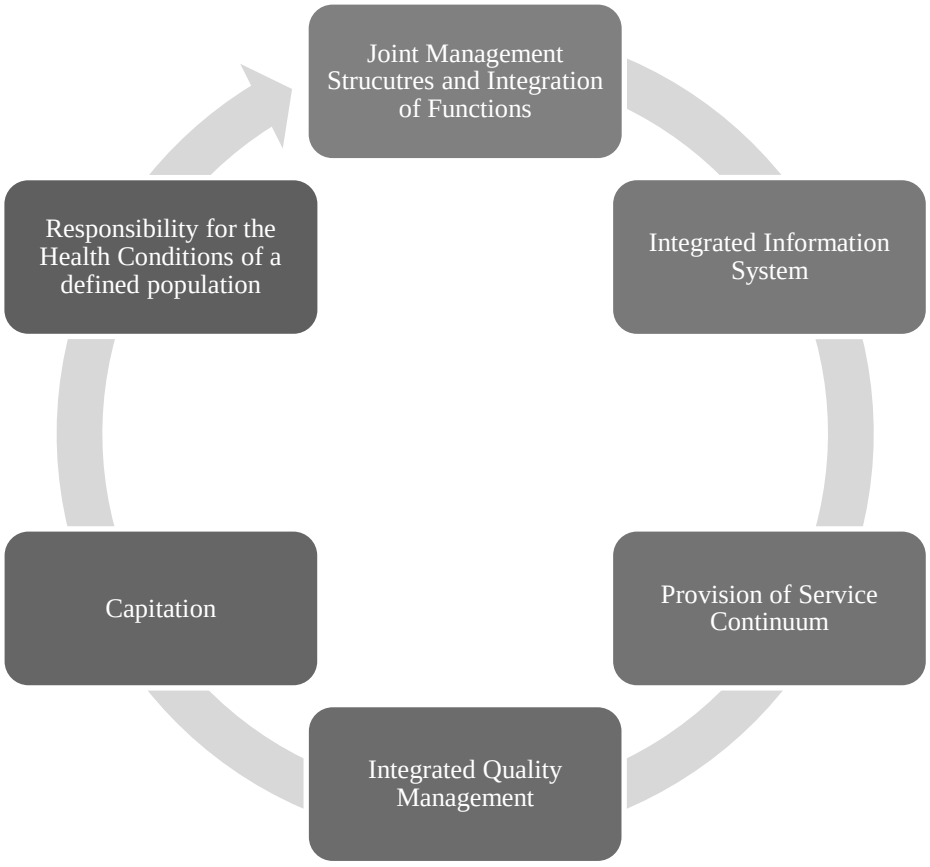
There are many different definitions of integration and integrated care (World Health Organization, 2016, p. 3). One definition is from Kodner and Speeuwenberg (2002, p. 2) and indicates the integration of various methods and models have "the goal to enhance the quality of care and quality of life, consumer satisfaction and system efficiency for patients with complex, long-term problems cutting across multiple services, providers, and settings. The result of such multipronged efforts to promote integration for the benefit of these special patient groups is called 'integrated care'." This definition points out the complex and inter-sectoral character of integrated care. (World Health Organization, 2016, p. 4) On principle, it is the combination of organizations and professionals with the goal to improve outcomes (Curry and Ham, 2010, p. 3).

There is, therefore, a distinction between different types of integration. In this context, the distinction is made between functional, organizational, service and clinical integration. Functional integration is designated to integrate non-clinical support and back-office functions, such as electronically organizing patient records. When different organizations formally join, by mergers or virtually with coordinated provider networks, it is called an organizational integration. The integration of different clinical services at the same organizational level as multidisciplinary professionals or teams is known as service integration. Clinical integration includes integrated care for patients in a single or coherent process within and across professions, for example, through the shared use of guidelines and protocols (Contandriopoulos and Denis, 2005 cited in Fulop et al., 2005, p. 4).

There is also a difference between horizontal and vertical integration. Horizontal integration describes the process of two or more organizations or service deliverer of care coming together at a similar level, for example, two or more acute hospitals. Vertical Integration, on the other hand, is the merger between two or more organizations or service delivering care at different levels, such as when an acute hospital and community health services come together (Curry and Ham, 2010, p. 4).

The goal of the integrated delivery system (IDS) is to have integrated care across all systems through the coordination of all health services by either providing the health services by itself or through purchase. The system has both the medical and financial responsibility for all services, and consequently, assumes an insurer function by transacting with large employers or by compensating with capitation (Amelung, 2014, p. 69).

Figure 1: Characteristic of Integrated Care



Source: Own presentation according to Amelung, 2014, p.70

The IDS has some important characteristics, shown in Figure 7.1, which lead to integrated care for the population. The first step is functional integration, which leads to a coordination of the management levels, and thus, of all non-medical services, like personnel department and financing. The next step is to implement an integrated information system, which is strategically relevant and a core function of an IDS. It allows access to all patient information and financial aspects concerning the whole system. (Amelung, 2014, p. 70) Providing a continuum of services across the system is also part of an IDS, which means that the care has to consists of three service components. These components include hospital services, clinical services as well as the possibility of an outpatient operation center or day clinic (Sanofi Aventis 2006 cited in Amelung, 2014, p.70). The IDS has the advantage of the concrete planning of necessary services

and hence the precise, internal management of service requirements (Amelung, 2014, p. 71). Planning the internal care processes leads to a reduction of overcapacity, shifts the supply stage to a more economically optimal point and tends to restructure important, expensive treatments to be more affordable (Witgert and Hess, 2012 citied in Amelung, 2014, p. 71). Further advantages of integrated care result from an increased economy of scale, because of the avoidance of double examination. Improved communication amongst health care professionals leads to optimized and more efficient health care services, and provides uniform standards like infrastructure (Amelung, 2014, p. 72).

2.3 Options for optimizing processes through an integrated system

The complexity and specialty of healthcare delivery require patients to go to different types of physicians in various settings. Furthermore, improving and advancing innovations tend to result in a larger quantity of tests and procedures. This contributes to the challenge of provide more quality care at lower costs to the patients (Denton, 2013, p. 183). One solution to improve patient satisfaction and achieve better outcomes more efficiently is to speed up the patient flow through the health systems (Arthur, 2011, p. 4) for just in time treatment and maximum utilization of available tests (Hall, 2013, p. 3). It is important to know how disruptions or delays in the patient flow develop, and what problems arise because of them. The patient's process through the healthcare system starts when a patient becomes ill and goes to see a physician; this process ends when the patient becomes healthy or gets discharged from the hospital. However, there are lots of steps between the starting point and the discharge. It is possible that there are problems in the patient flow, which result in delays of treatments, medical errors and poor outcomes (Arthur, 2011, p. 19). There are a few possibilities that cause delays in the delivery of healthcare. A lack of physical capacity, missing important informations like lab tests, bad planning for use of equipment (Denton, 2013, pp. 183–184) or space, as well as inadequate use of technologies (Hall, 2013, p. 72), are all possible reasons. There are a lot of approaches and strategies to improve the patient flow through the healthcare system. On the one hand, there are simple opportunities for eliminating waste and time like lowering the given time in the stages of the delivery process, cutting stages and unnecessary treatments, combining stages or reducing the time between the different stages (Denton, 2013, p. 184). On the other hand, a possibility to enhance the patient flow and the capacity is through the design of the healthcare delivery system. For that to occur, there is a need for essential design strategies that will promote contemporary capacity and flow management (Hall, 2013, p. 71). A strategy to improve the patient flow is depicted by Lean Management, which focuses on slim processes (Töpfer, 2009, p. 3). Concentrating on the value of the products or services (Gorecki and Pautsch, 2014, p. 1), this strategy reduces bottlenecks without adding resources. During the average hospital stay, 95% of the patients need to wait between several stages (Arthur, 2011, p.

21). With this in mind, one opportunity to reduce the time between the stages is with the design of the cell. A cell is an arrangement of workstations, machines, and equipment to improve the patient and product flow through the system with reducing costly transport, minimize delays, saving floor space and decreasing inventory. An example for cells is exam rooms in the Emergency Department, which are provided with all necessary resources and equipment, and process patients with a selection of similar products. In order to minimize lab and waiting times, they sometimes are offer CT-Scanner or MRI-machines as well (Arthur, 2011, pp. 40–41).

3 The case of the Frankel Cardiovascular Center at the University of Michigan Health System

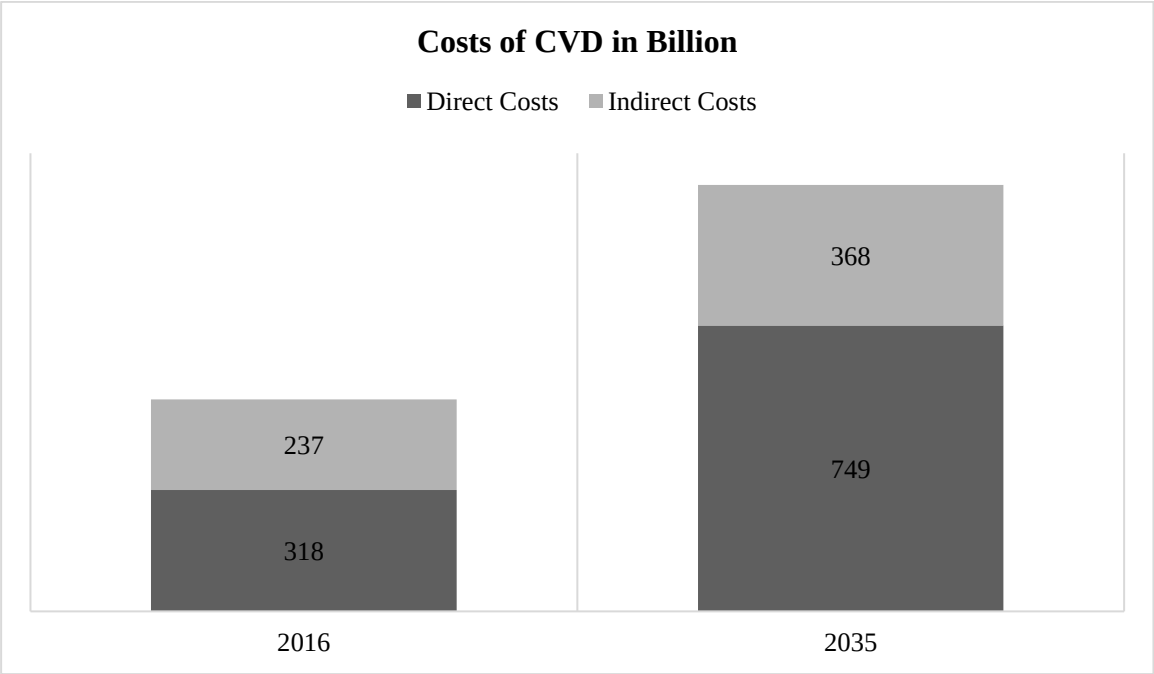
3.1 Cardiovascular diseases

Diseases of the heart and blood vessels, coronary or ischemic heart disease and hypertension etc. are included in the group of cardiovascular disease (CVD). Many of these problems and illnesses occur because of atherosclerosis (Tulchinsky and Varavikova, 2014, p. 257), which means that plaque builds up inside in the wall of the arteries. In the worst case, the plaque can result in a blood clot, which stops the blood flow and can lead to a heart attack or a stroke (The American Heart Association, 2014). All types of heart and cardiovascular diseases are treated in the CVC at Michigan.

In every country, heart disease is one of the leading causes of death. About 30 percent of global mortality is induced by heart diseases (Tulchinsky and Varavikova, 2014, p. 258). In the United States, heart disease is the number one cause of death for men and women (The American Heart Association, 2017b, p. 5). The number of heart-related deaths every year includes about 800,937 Americans. Statistically speaking, that means one in every three deaths is caused by heart disease (Mozaffarian et al., 2016, p. 185) The overall mortality rate of 2013 was 222,9 per 100 000 Americans (Mozaffarian et al., 2016, p. 41).

CVD is not only the most common disease in the U.S. population, but is also the most costly (The American Heart Association, 2017b, p. 5). Studies from the American Heart Association (AHA) show the continuing rise of the costs and economic pressure due to CVD (The American Heart Association, 2017a).

Figure 2: Costs of CVD



Source: Own presentation according to The American Heart Association, 2017, pp.5-6

The AHA released a study in February 2017 in order to forecast the future costs and prevalence of CVD. The study showed that CVD costs will continue to rise and will result in economic, as well as health-related problems for the United States finances and healthcare system. (The American Heart Association, 2017a). The costs are expected to climb from current 555 billion dollars with 102.7 million Americans affected, to 1.1 trillion dollars and 131.2 million Americans with CVD in 2035. Furthermore, the study demonstrates that the population from the age of 45 has a 50% risk of suffering from CVD. Past the age of 85, the chance of being affected by at least one sort of CVC increase to 90% (The American Heart Association, 2017b, pp. 5–6).

3.2 The Frankel Cardiovascular Center at the University of Michigan Health System

The University of Michigan Health System (UMHS) is a not-for-profit institution (The University of Michigan Health System, n.d.c), which means that they do not have shareholders who are entitled to their earned profits (Phelps, 2013, p. 214). The system's philosophy is to offer excellence in research, medical education and patient care (The University of Michigan Health System, 2015, p.1). Their vision is to form the future of healthcare with research and development, become a national leader in health care, and receive health care reform, biomedical innovation, and education. The system consists of three hospitals, the University of Michigan hospital, the C.S. Mott Children's Hospital and the Van Voigtlander Women's Hospital (The University of Michigan Health System, n.d.e). Additionally, the health system owns more than 40 health centers

and clinics throughout the state of Michigan along with the University of Michigan Medical and Nursing School (The University of Michigan Health System, 2015). A few specialized health centers and programs are included in this system like the Kellogg Eye Center and the Frankel Cardiovascular Center (The University of Michigan Health System, n.d.a). Besides offering medical services, the UMHS is also involved in research and community health. To further community health, the UMHS supports programs and services for a healthy community like "Ann Arbor on Wheels" and the "Bureau for seniors," services that patients and families can benefit from (The University of Michigan Health System, n.d.d)

The Cardiovascular Center of Michigan is a specialty hospital that can offer high-quality care at their facility along with the traditional University hospital (Schneller and Smeltzer, 2006, p. 159). There is a continuous growth in single specialty hospitals (Al-Amin et al., 2010, p. 294), which focus on specific treatments and procedures for patients (The United States General Accounting Office, 2003, p. 1). One pending question is how these specialty hospitals influence the costs or the quality of care (Barro et al., 2006, p. 703). They may have advantages like economies of scale, improved quality, decreasing costs from the aggregated volume and focus on patients with the same medical services (United States General Accounting Office, 2003, p. 1) and be more efficient than general hospitals (Kumar, 2010, p. 94). In terms of all specialized hospitals, the cardiac care section produces the greatest aggregated revenues (United States General Accounting Office, 2003, p. 10).

The cardiology and heart surgery at Michigan Medicine is nationally ranked 22nd by the U.S. News and World Reports amongst all cardiovascular-related hospitals (The U.S. News and World Report, 2016). Construction of the CVC was completed on June 11, 2007, and includes a 350,000 square foot multidisciplinary facility. The facility provides space for outpatient visits and tests, an inpatient unit, connecting walkways to university hospitals, outpatient clinics and specialized care for children. These elements show that the CVC is a central location for coordinated cardiovascular care. The building includes beds for surgical post procedures, vascular general/moderate care and rooms for cardiac procedures, cardiac and vascular surgery operations and endovascular procedure labs (The Samuel and Jean Frankel Cardiovascular Center, n.d.a). For the procedures and treatments, they work with the most advanced digital technology, such the 64- slice CT scanners, compounding CT, MRI systems and a PET -scanner (The Samuel and Jean Frankel Cardiovascular Center, n.d.h). There is a health information system installed in the whole building, including computers in the private and consultation rooms, as well as in the workstations at the moderate and intensive care unit. These computers provide access to all patients' information. This includes, for example, test and lab results, medications and information from the portable monitors, which measure the heart rate

and rhythm vital signs, oxygen level. For the patients and visitors, the CVC has private rooms (The Samuel and Jean Frankel Cardiovascular Center, n.d.i), an Atrium with tropical garden and flowers, an indoor and outdoor garden, quiet meditation rooms, a patient skill lab, a healthy heart café and a Mardigian Wellness Resource Center, where health-related questions can be answered (The Samuel and Jean Frankel Cardiovascular Center, n.d.c). Patients also have access to a Patient and Family-centered Programm (The Samuel and Jean Frankel Cardiovascular Center, n.d.e). The CVC provides a multidisciplinary medical team for heart and vascular care. There are specialist from different disciplines, such as cardiologists, cardiac and vascular surgeons, as well as stroke neurologists helping patients with cardiovascular diseases (The Samuel and Jean Frankel Cardiovascular Center, n.d.d).

4 Additional benefits of the Frankel Cardiovascular Center

4.1 Benefits through the business strategy

In this section, the CVC at Michigan will be analyzed in connection to the business strategies for health care provider mentioned in Section 2.1 and the Epidemiology of CVD in section 3.1 of this paper. The CVC belongs to the UMHS; it is a specialty hospital for CVD. Thus they have the possibilities to concentrate in a separate facility with more space for CVD to gain excellence in patient value and compete on results with the benefit of focus. They can thereby offer unique or rare treatments, which result in a better reputation and patients who will travel a longer way to receive that special treatment. The new building of the Cardiovascular Center offers a few non-clinical components, like the indoor and outdoor garden. The goal is to create a comfortable atmosphere for the patients and their families, resulting in increased patient satisfaction. Focusing on cardiovascular care has advantages, and since the prevalence of CVD is high, and they have the opportunity to incrase the number of patients in their facility. Besides that, cardiovascular care treats conditions with generous reimbursements from the insurance companies. However studies from AHA show the costs of cardiovascular diseases will continue to rise. Therefore, the UMHS aims to work more cost-effectively and save money, even within the specialization.

4.2 Benefits through the integrated system

The implementation of the CVC in one of the largest healthcare complexes in the world (The University of Michigan Health System, n.d.e) cause a couple forms of integrations and integrated care. Some contents of Section 2.2. will be revisited in this section, though will be focusing specifically on the CVC in Michigan. As previously mentioned in Figure 7.2, there are a few characteristics which lead to an integrated care system.

First, there is a functional integration of the CVC in the Michigan Medicine Health System, which integrates their nonmedical-services and management. An example of the functional integration are the electronic patient records, which are available throughout the whole system (The University of Michigan Health System, n.d.b). For that, the CVC implements computers at the examination rooms and the workstations in order to have a connection to all relevant patient's information. Thereby they accomplish an integrated information system. As a result, the CVC and the UMHS provide a continuum of services to their patients. There already is an outpatient clinic and diagnostic unit for cardiovascular care and the inpatient clinic at the CVC. They have the facilities to combine clinical and hospital services, along with an outpatient operation center in the Cardiovascular Center. With the connection to the C.S. Mott Children hospital and University Hospital, they can integrate a few more services (The Samuel and Jean Frankel Cardiovascular Center, n.d.g). There is a walkway to the C.S Mott Children's Hospital, where physicians have access to children suffering from heart diseases. Patients can also be transported across a sky bridge to the University Hospital (The Samuel and Jean Frankel Cardiovascular Center, n.d.h). At the CVC doctors and nurses from five different disciplines like cardiac surgery and vascular surgery work together (The Samuel and Jean Frankel Cardiovascular Center, n.d.g). Therefore, they have an improved communications, and as a result, they can offer optimized and more efficient health services and avoid double examinations, which lead to increased economy of scale.

4.3 Benefit through optimizing processes

Through the built up of new facility, the UMHS gained a couple of additional benefits for enhancing the patient flow. This paper will certainly only give a few possible examples of the strategies previously mentioned in Section 2.3. At the CVC doctors and nurses from five different disciplines including cardiac surgery and vascular surgery work together so that the patients can get coordinated care from several specialists, often all in one day. (The Samuel and Jean Frankel Cardiovascular Center, n.d.g) For instance, the patients don't have to go to different types of physicians of cardiac care in various settings (Denton, 2013, p. 183). As a result, it is likely they can reduce the stages or the labs between the stages in the delivery process (Denton, 2013), and consequently, decrease the waiting times. The facility also provides a 14 room- diagnostic area at the Diagnostic and Outpatient- Unit with, for example, a treadmill stress test, echocardiogram, ultrasound exams and a station for blood tests (The Samuel and Jean Frankel Cardiovascular Center, n.d.g). Just as CT-Scanners in the Cardiac Procedure Unit (The Samuel and Jean Frankel Cardiovascular Center, n.d.f) and in the surgery and intensive care level (The Samuel and Jean Frankel Cardiovascular Center, n.d.h). The advantages resulting from this are that they have immediate access to important information and therefore reducing waiting times and delays for important data and hence decreasing the time

between the stages. The workstations at the moderate care unit and the intensive care unit arranged between each pair of the room for the patients and implied computers with computerized records with all patient information. (The Samuel and Jean Frankel Cardiovascular Center, n.d.i) Moreover, a cupboard with all necessary items stands next to the doors. This cell design has provided the benefit of reducing ways for the staff, saving floor and consequently improve the patient and product flow.

5 Conclusion

In conclusion, there are a number of additional benefits the UMHS has gained through the construction of the Cardiovascular Center beside their University hospital and in their healthcare complex. At first, through the concentration on a business strategy of specialized care, they can gain benefits like excellence in patient values, product differentiation through the focus on cardiovascular diseases and by offering unique, special treatments. Additionally, they can achieve benefits through offering non-clinical components through new construction and offering a great atmosphere to the patient. Besides the benefit of a focus on cardiovascular diseases with the implementation of the center in a healthcare complex, there are a few benefits associated with establishing a form of an integrated delivery system. Benefits such as economies of scale and avoiding double examination can be a result of integration. Furthermore, some form of management instrument and strategies for optimizing processes could be achieved through the new design and infrastructure of the building. This leads to enhancing the patient flow through the Cardiovascular Center and thus through the University Michigan Health System. The assumed strategies mentioned in this paper are only a few of many business strategies in the complex American healthcare system. The goal was to provide an overview of some basic strategies of providing health care delivering in a health system with a specialized hospital. Besides the benefits, there are of course some negative components of specialty hospitals, such as cherry-picking patients (Porter and Teisberg, 2006, p. 162). However, mentioning all drawbacks would go beyond the scope of this research paper. The existing negative components of specialty hospitals in today's literature are often associated with for-profit specialty hospital. (Barro et al., 2006, p. 702) The specialty hospital in Michigan however, is a nonprofit institution belonging to University of Michigan Health System.

The University of Michigan Health Systems has a great opportunity to differentiate themselves from competitors in the cardiovascular field and gain some additional benefits. Furthermore, due to the research and development in their facility, they are able to further grow and provide the latest procedures and treatments to the patients, (The Samuel and Jean Frankel Cardiovascular Center, n.d.b). With that in mind, it is possible to imagine that in a few years the Cardiovascular Center could reach an even better spot than the 22nd, as ranked by the U.S. News and World Reports.

References

Al-Amin, M., Zinn, J., Rosko, M. D. and Aaronson, W. (2010), 'Specialty Hospital Market Proliferation: Strategic Implications for General Hospitals', *Health Care Management Review*, vol. 35, no. 4, pp. 294–300.

Amelung, V. E. (2014), *Healthcare Management: Managed Care Organisations and Instruments*, Heidelberg, Berlin, Springer Texts in Business and Economics.

Arthur, J. (2011), *Lean Six Sigma for Hospitals: Simple Steps to Fast, Affordable, Flawless Healthcare*, New York, McGraw-Hill.

Barro, J. R., Huckman, R. S. and Kessler, D. P. (2006), 'The Effects of Cardiac Specialty Hospitals on the Cost and Quality of Medical Care', *Journal of Health Economics*, vol. 25, no. 4, pp. 702–721.

Curry, N. and Ham, C. (2010), *Clinical and Service Integration*, London, The King's Fund.

Denton, B. T. (2013), *Handbook of Healthcare Operations Management: Methods & Applications*, New York, Springer Science+Business Media New York.

Douven, R., Katona, K. and Shestalova, V. (2014), 'Vertical Integration and Exclusive Behavior of Insurers and Hospitals', *Journal of Economics & Management Strategy*, vol. 23, no. 2, pp. 344–368.

Fulop, N., Mowlem, A. and Edwards, N. (2005), *Building Integrated Care: Lessons from the UK and Elsewhere*, The NHS Confederation.

Gaynor, M. and Town, R. (2012), *Competition in Health Care Markets*, 2nd edn, San Diego, Elservier Academic Press.

Gaynor, M. and Vogt, W. B. (2000), 'Antitrust and Competition in Health Care Markets', *Handbook of Health Economics*, vol. 1, no. 1, pp. 1405–1487.

Gorecki, P. and Pautsch, P. (2014), *Praxisbuch Lean Management: Der Weg zur operativen Excellence*, 2nd edn, München, Hanser.

Hall, R. W., ed. (2013), *Patient Flow: Reducing Delay in Healthcare Delivery*, 2nd edn, New York, Springer Science+Business Media New York.

Kodner, D. L. and Spreeuwenberg, C. (2002), 'Integrated Care: Meaning, Logic, Applications, and Implications: A Discussion Paper', *International Journal of Integrated Care*, vol. 2, pp. 1–6.

Kumar, S. (2010), 'Specialty Hospitals Emulating Focus Factories: A Case Study', *International Journal of Health Care Quality Assurance*, vol. 23, no. 1, pp. 94–109.

Lindrooth, R. C. (2008), 'Research on the Hospital Market: Recent Advances and Continuing Data needs', *Inquiry - J Health Care Organ Provision Finance*, vol. 45, pp. 19–29.

Mozaffarian, D., Benjamin, E. J., Go, A. S., Arnett, D. K., Blaha, M. J., Das, S. R., Ferranti, S. de, Després, J.-P., Fullerton, H. J., Howard, V. J., Huffman, M. D., Isasi, C. R., Jiménez, M. C., Judd, S. E., Kissela, B. M., Lichtman, J. H., Lisabeth, L. D., Liu, S., Mackey, R. H., Magid, D. J., McGuire, D. K., Mohler, E. R., Moy, C. S., Muntner, P., Mussolino, M. E., Nasir, K., Neumar, R. W., Nichol, G., Palaniappan, L., Pandey, D. K., Reeves, M. J., Rodriguez, C. J., Rosamond, W., Sorlie, P. D., Stein, J., Towfighi, A., Turan, T. N., Virani, S. S., Woo, D., Yeh, R. W. and Turner, M. B. (2016), 'Heart Disease and Stroke Statistics-2016 Update: A Report From the American Heart Association', *Circulation*, vol. 133, no. 4, pp. 338-360 [Online]. Available at: http://circ.ahajournals.org/content/133/4/e38.long (Accessed May 25, 2017).

OECD (2017), *Demographic References* [Online], OECD. Available at: http://stats.oecd.org/Index.aspx?DataSetCode=SHA (Accessed May 25, 2017).

OECD (2017), *Health Expenditures and Financing* [Online], OECD. Available at: http://stats.oecd.org/Index.aspx?DataSetCode=SHA (Accessed May 25, 2017).

Phelps, C. E. (2013), *Health Economics*, 5th edn, New Jersey, Pearson Education.

Porter, M. E. and Teisberg, E. O. (2006), *Redefining Health Care: Creating Value Based Competition on Results*, Harvard Business School Press.

Schneller, E. S. and Smeltzer, L. R. (2006), *Strategic Management of the Health Care Supply Chain*, San Francisco, Jossey-Bass.

The American Heart Association (2014), *What is Cardiovascular Disease?* [Online], The American Heart Association. Available at: http://www.heart.org/HEARTORG/Support/What-is-Cardiovascular-Disease_UCM_301852_Article.jsp (Accessed May 18, 2017).

The American Heart Association (2017), *Cardiovascular Disease Costs Will Exceed $1 Trillion by 2035, Warns the American Heart Association* [Online], The American Heart Association. Available at: http://newsroom.heart.org/news/cardiovascular-disease-costs-will-exceed-1-trillion-by-2035-warns-the-american-heart-association (Accessed May 29, 2017).

The American Heart Association (2017), *Cardiovascular Disease: A Costly Burden for America*, The American Heart Association [Online]. Available at: http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_491543.pdf (Accessed May 25, 2017).

The Samuel and Jean Frankel Cardiovascular Center (n.d.), *About Our building* [Online], The Samuel and Jean Frankel Cardiovascular Center. Available at: http://www.umcvc.org/about-our-building (Accessed May 18, 2017).

The Samuel and Jean Frankel Cardiovascular Center (n.d.), *About the Samuel & Jean Frankel Cardiovascular Center* [Online], The Samuel and Jean Frankel Cardiovascular Center. Available at: http://www.umcvc.org/about-samuel-jean-frankel-cardio vascular-center (Accessed May 18, 2017).

The Samuel and Jean Frankel Cardiovascular Center (n.d.), *Frankel Cardiovascular Tour* [Online], The Samuel and Jean Frankel Cardiovascular Center. Available at: http://www.umcvc.org/frankel-cardiovascular-center-tour (Accessed May 18, 2017).

The Samuel and Jean Frankel Cardiovascular Center (n.d.), *Meet Your Heart Care Team* [Online], The Samuel and Jean Frankel Cardiovascular Center. Available at: http:// www.umcvc.org/meet-your-heart-care-team (Accessed May 18, 2017).

The Samuel and Jean Frankel Cardiovascular Center (n.d.), *Patient and Family Centered Care Program* [Online], The Samuel and Jean Frankel Cardiovascular Center. Available at: http://www.umcvc.org/patient-and-family-centered-care-program (Accessed May 18, 2017).

The Samuel and Jean Frankel Cardiovascular Center (n.d.), *What's on CVC Level 2?* [Online], The Samuel and Jean Frankel Cardiovascular Center. Available at: https:// www.med.umich.edu/cvc/pdf/grand%20opening%20fact%20sheets/ CVC%20fl%202%20fact%20sheet.pdf (Accessed May 29, 2017).

The Samuel and Jean Frankel Cardiovascular Center (n.d.), *What's on CVC Level 3?* [Online], The Samuel and Jean Frankel Cardiovascular Center. Available at: https:// www.med.umich.edu/cvc/pdf/grand%20opening%20fact%20sheets/ CVC%20fl%203%20fact%20sheet.pdf (Accessed May 29, 2017).

The Samuel and Jean Frankel Cardiovascular Center (n.d.), *What's on CVC Level 4?* [Online], The Samuel and Jean Frankel Cardiovascular Center. Available at: https:// www.med.umich.edu/cvc/pdf/grand%20opening%20fact%20sheets/ CVC%20fl%204%20fact%20sheet.pdf (Accessed May 29, 2017).

The Samuel and Jean Frankel Cardiovascular Center (n.d.), *What's on CVC Level 5?* [Online], The Samuel and Jean Frankel Cardiovascular Center. Available at: https:// www.med.umich.edu/cvc/pdf/grand%20opening%20fact%20sheets/ CVC%20fl%205%20fact%20sheet.pdf (Accessed May 29, 2017).

The U.S. News and World Report (2016), *Cardiology & Heart Surgery Scorecard,* The U.S. News and World Report [Online]. Available at: http://health.usnews.com/best-hospitals/area/mi/university-of-michigan-hospitals-and-health-centers-6440110/cardiology-and-heart-surgery (Accessed May 18, 2017).

The University of Michigan Health System (n.d.), *Departments & Programs* [Online], The University of Michigan Health System. Available at: http://www.uofmhealth.org/ departments-programs (Accessed May 18, 2017).

The University of Michigan Health System (n.d.), *Great Lakes Health Connect* [Online], The University of Michigan Health System. Available at: http://www.uofmhealth.org/provider/great-lakes-health-connect (Accessed May 31, 2017).

The University of Michigan Health System (n.d.), *UMHS Partnerships & Affiliations* [Online], The University of Michigan Health System. Available at: http://www.uofmhealth.org/umhs-partnerships-affiliations (Accessed May 18, 2017).

The University of Michigan Health System (n.d.), *Welcome to Community Health Services* [Online], The University of Michigan Health System. Available at: http://www.med.umich.edu/chs/ (Accessed May 18, 2017).

The University of Michigan Health System (n.d.), *Welcome to Michigan Medicine* [Online], The University of Michigan Health System. Available at: http://www.uofmhealth.org/about (Accessed May 18, 2017).

The University of Michigan Health System (2015), *Leading our Future: Annual Report 2015*, The University of Michigan Health System [Online]. Available at: http://www.med.umich.edu/pdf/UMHS-2015-Annual-Report.pdf (Accessed May 18, 2017).

Töpfer, A. (2009), *Lean Six Sigma: Erfolgreiche Kombination von Lean Management, Six Sigma und Design for Six Sigma*, Berlin, Springer Science+Business Media New York.

Tulchinsky, T. H., Varavikova, E. and Bickford, J. D. (2014), *The New Public Health*, 4th edn, San Diego, Elservier Academic Press.

United States General Accounting Office (2003), *Specialty Hospitals:. Geographic Location, Services Provided, and Financial Performance*, United States General Accounting Office [Online]. Available at: http://www.gao.gov/new.items/d04167.pdf (Accessed May 28, 2017).

World Health Organization (2016), *Integrated Care Models:. An Overview*, World Health Organization [Online]. Available at: http://www.euro.who.int/__data/assets/pdf_file/0005/322475/Integrated-care-models-overview.pdf (Accessed May 29, 2017).

Part 3: Innovation in the Medical Technology Industry

The Impact of Payment Reform on Industry Strategy

Carolin Rupprecht

The following essay examines implications of new Centers for Medicare and Medicaid Services payment regulations, especially those stemming from the Medicare Access and CHIP Reauthorization Act (MACRA), which the medical technology industry faces in the health care market. Providers determine the coverage of medical devices within the constraints of Medicare's payment systems and therefore are affected by new payment regulations. MACRA aims to improve the quality of care, advance care information distribution, and reduce health care costs, which can only be achieved together through enhanced care coordination and collaboration between different stakeholders. For the medical technology industry, success means that the paradigm shift from volume to value needs to be accepted at all levels. Medical device creators must better recognize consumer needs and establish systems to measure, monitor, and improve patient-centered outcomes. Moreover, companies need to understand their contribution to the full cycle of care through expanded collaboration between different stakeholders and participation in risk-sharing. Collaboration is also needed regarding electronic health records to make patient documentation simple and standardized. The medical technology industry is not directly integrated in Medicare's payment reforms. As a result, it is their responsibility to demonstrate their value to patients, providers, and payers. In the long run, these different stakeholder needs must be integrated in the research and development of novel technologies.

Contents

1 Push Towards Value-Based Payment Systems

Without a commensurate gain in health outcomes, the United States spends more per capita on healthcare technology and care than European nations. Higher technology costs, larger volumes of certain procedures (e. g. hip and knee replacements), and a greater supply of doctors and hospitals contribute to higher US spending (Sorenson et al., 2013, p. 788). As a result, US payment regulations are undergoing considerable reform to lower spending.

In general, there is a push towards value-based payment schemes. The Patient Protection and Affordable Care Act of 2010 and the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 have played a leading role in this shift for Medicare. As the single largest healthcare payer in the US (MedPAC, 2016 c), p. 3), Medicare influences the payment schemes of private insurers. Using Medicare as a role model, these companies adjust their reimbursement rates and structures accordingly (Clemens, Gottlieb, 2013, p. 1).

Through its prospective payment system, Medicare regulates the cost and coverage of most medical devices. This means that within the constraints of fixed prospective payment, the provider determines the coverage. In this way, the coverage and payment decisions made on an individual basis determine revenues. Explicit coverage decisions are made locally (Sorenson et al., 2013, pp. 789, 790).

Consequently, the payment the Medical Technology Industry (MTI) receives is dependent on the providers who care for Medicare beneficiaries. This suggests that the MTI may also be affected when payment regulations for provider's change, but the effect on the MTI remains uncertain.

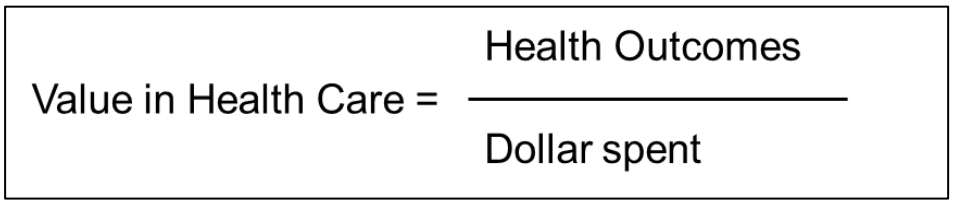
This essay analyses possible implications of recent Medicare payment regulations, especially MACRA, for the MTI and focuses on the inpatient sector through implantable medical devices, using hip and knee replacements as examples.

Although the future of MACRA is unclear, currently available literature and journal articles from different stakeholder perspectives provide a window into possible change. In this essay, an illustration of the shift from volume to value in healthcare will first lay the groundwork for understanding the theory of new payment regulations in the US healthcare system. Secondly, details surrounding the current situation of medical device payment will act as a starting point for the implications of Medicare policy changes. Thirdly, an exploration of political developments that influence Medicare payment, with a focus on MACRA, will provide an image of the present leading into the future. Lastly, the implications of new payment regulations on the MTI will demonstrate where the industry is headed in the coming years.

2 Definition of Value in Health Care

When discussing value in health care, the question "What is value in health care?" arises. This question will be addressed in the following section.
As a whole, value in healthcare is both largely misunderstood and unmeasured, as all stakeholders tend to have diverging goals (here and the following Porter, 2010, pp. 2,477-2,478). As a result, the first goal should be unifying healthcare stakeholders under one common goal: creating high value for patients. The following illustrates value in healthcare.

Figure 1: Value in Health Care



Source: Author according to Porter, 2010, p. 2477.

Value can be defined as health outcomes achieved per dollar spent. However, outcomes are multidimensional and, therefore, difficult to measure. Outcomes depend on the condition and no single outcome encompasses the total body of delivered care. Consequently, costs in the equation refer not to individual services but to the total costs of the full cycle of care. Altogether, to improve outcomes and reduce costs, there must be a push towards expanding measuring and reporting metrics combined with a robust method of comparison (Porter, 2010, pp. 2,477-2,478).

3 Current Payment Situation

Medicare uses a prospective payment system in the outpatient and inpatient hospital sectors. The base rate for each prospective payment system is modified to consider geographic differences in input prices and type of case or service. Payment rates are updated annually (MedPAC, 2016 a), p. 67). As mentioned in Section 1, coverage for and purchase of medical devices is made by providers considering the constraints of Medicare's payment system.
The decision to use a device is usually determined by the desires of the physician and the added value for the patient. Costs for medical devices like hip and knee implants account for approximately 30% to 80% of a hospital's reimbursement for the procedure. Similarly, physician preferences account for a large amount of hospitals' variable costs as they choose the devices while the hospital faces the financial burden. Along those same lines, a physician can reduce the total cost of care by choosing devices from a discounted contracted vendor, but they still have the option to prefer more expensive

options, thereby forcing hospitals to pay higher prices (Obremskey et al., 2012, pp. 1,054-1,055).
Additionally, setting prices for medical devices does not need to follow requirements. Depending on negotiations with group purchasing organizations, device costs for high volume items can both be discounted and set individually for each hospital. Consequently, to stay competitive, health systems are increasingly using the services of consulting firms to get insight into the prices paid by similar hospitals. However, even this avenue is flawed as hospitals only post prices listed rather than those negotiated with various payers, thereby creating a lack of price transparency (Robinson, 2008, p. 1,526). Through a fixed, less flexible prospective payment system, hospitals face higher costs associated with changes in technology and devices (Clyde et al., 2008, p. 1,632).
As a result, fragmentation and misalignment of information, incentives, and organizational capabilities between the hospital and physician are the main obstacles for value-based purchasing of medical devices (Robinson, 2008, p. 1,524).

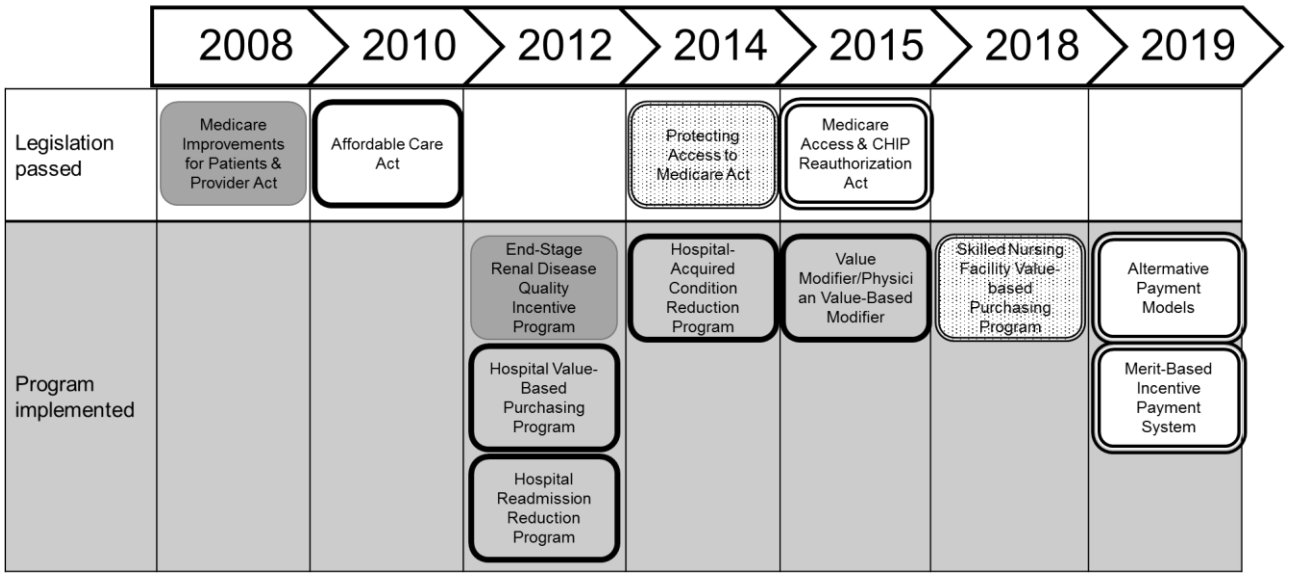
4 Payment Reforms

In this section, an overview of reforms within the past nine years is given first. Then the latest developments in value-based payment will be described. The most common inpatient surgery for Medicare beneficiaries is hip and knee replacement (CMS, 2017 b)). For this reason, hip and knee replacement play a key role for the Center for Medicare & Medicaid Services (CMS) and therefore will be used as example.

4.1 Overview of Reforms in Medicare

Figure 8.2 shows the legislation timeline between the years 2008 and 2019 along with associated value-based programs. Providers for Medicare recipients receive incentive payments through these value-based programs (CMS a), 2017).

Figure 2: Timeline for Value-Based Programs



Source: Author according to CMS a), 2017.

As shown, a variety of programs that introduce value into payment systems are being implemented or are intended to be established. However, since it takes several years to implement a program after the passage of legislation, considerable time and resources are required to ensure that the program is successfully carried out and evaluated. Under consideration and review for years before its recent passage, MACRA is the latest significant regulation that impacts payment reform.

4.2 Medicare Access and CHIP Reauthorization Act

Final regulations for MACRA were released in 2016 by CMS to repeal the sustainable growth rate formula and update the physician fee schedule. The act rewards the delivery of high-quality care with quality measurements incorporated into provider payments and the development of new policies to incentivize provider participation in alternative payment methods (APMs), including innovative episode payment models for joint care and shared savings program. The Quality Payment Program was created (Department of Health and Human Services, 2016, pp. 1-4) to reform Medicare Part B payments for more than 600,000 clinicians (specifically for physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetics) (CMS, 2016).

The Quality Payment Program consists of the Merit-based Incentive Payment System (MIPS) which combines three existing Medicare incentive programs: Physician Quality Reporting, Electronic Health Record Meaningful Use, and the Value-Based Payment Modifier (Quality Payment Program Service Center, 2017 a)). It also includes Advanced

APMs. These programs can apply to a specific clinical condition, an individual care episode, or a population (Quality Payment Program Service Center, 2017 b)).
In aggregate, the budget will stay neutral, but the bonuses and penalties of individual physicians will have a significant impact on payments at the individual level. Hence, there will be effects on the attractiveness of the APM and MIPS path (MedPAC, 2016 b), p. 30). If clinicians do not participate in the Quality Payment Program in the Transition year 2017, it will result in a negative 4% payment adjustment. Eligible clinicians are free on what and how they report. They can choose between submitting a minimum amount of data, reporting for 90-day period or full participation to avoid the negative payment adjustment (CMS, 2016).

Merit-based Incentive Payment System
The Merit-based Incentive Payment System (MIPS) determines whether physicians receive a bonus or penalty on their fee-for-fee-service payments through the quality of their performance (MedPAC, 2016 b), 29-30). To begin, physician performance in 2017 will adjust the payments for 2019, with the anticipated amount of data submitted for the transition year of 2017 resulting in neutral to modest positive changes with regards to performance (CMS, 2016). The law determines the measurement of performance on four components, outlined in Figure 8.3.

Figure 3: Performance Categories in 2017 for payment in 2019

Source: Author according to Quality Payment Program Service Center a) (2017); CMS (2016).

The four categories are weighed differently and different measures can be chosen by providers. Each of the categories is weighed differently, with quality making up 60%, improvement activities 15%, advancing care information 25%, and cost initially making

up 0% but increasing over time. Quality of performance is measured with six measures of the provider's choice out of a possible 300 and compared against benchmarks. For improvement activities, clinicians can choose from over 90 activities categorized in nine different areas, including care coordination and participation in an Advanced APM. Advancing care information provides more flexibility with two different sets of measurements for reporting based on Electronic Health Record Meaningful Use. Costs are not weighed in 2017 (CMS, 2016).

Existing measurements do not capture many important aspects of quality. Furthermore, differences in patient severity influence and conflict measurements as well. Using similar measures in the 2016 Value-based Payment Modifier, 96% of physician practices were scored "average costs." Since these measurements are used by smaller practices that often do not capture their discretionary service through well-developed episode definitions, average scores do little to promote change. This high percentage suggests that there is a risk of the same phenomena for MIPS measures, which could limit the usefulness of measurements to drive change toward a value-based care system (Clough, McClellan, 2016, p. 2,397).

Advanced Alternative Payment Models

Advanced APMs are APMs that hold the chance to earn a 5% incentive payment in 2019 for participation in 2017. Comprehensive ESRD Care, Comprehensive Primary Care Plus, Next Generation ACO Model, Shared Savings Program (Track 2), Shared Savings Program (Track 3), Oncology Care Model or Comprehensive Care for Joint Replacement Payment Model (CJR) are the seven Advanced APMs in 2017 (Quality Payment Service Center, 2017 b)). The concept these programs are based on is that bearing some financial risk for spending might contribute to limit spending growth (MedPAC, 2016 b), p. 33). In Advanced APM the participants share risk, not only for gains, but also for losses. However, CMS set the standard higher than many hoped for (Clough, McClellan, p. 2,397). In the following section information on the CJR are given.

Comprehensive Care for Joint Replacement Model

The CJR Model is classified as an Advanced APM (Quality Payment Service Center, 2017 b)).

The most common inpatient surgeries for Medicare beneficiaries are hip and knee replacements (here and for the following CMS, 2017 b)). Advanced APMs support better and more efficient patient care by using bundled payments and quality measurement systems for each episode of care. This improves the quality and coordination of care along the extended, post-acute care continuum.

In the program, participating hospitals are financially accountable for the quality and cost of a CJR care episode, including all related items and services paid under Medicare

A and B. The system aims to increase coordination among different stakeholders, including physicians and hospitals, while raising patient awareness of quality of care. The admission of a patient with certain Diagnosis Related Groups (DRGs) to a participant hospital is the beginning of the care episode and ends 90 days post-discharge. Actual spending for the episode is compared to target episode prices at the end of the performance year. Through DRG analysis and CMS' use of simple risk stratification methodology different target prices are set for patients with a hip fracture. Well-performing hospitals may receive additional payment whereas poor performers must repay Medicare for a certain share (CMS, 2017 b)).

5 Implications for the Medical Technology Industry

Medicare reforms are likely to change the entire health care system. Therefore, physicians and other providers need to understand the opportunities represented by MACRA to shape the future of payment and medical practice (Clough, McClellan, 2016, p. 2,397). The MTI needs to both to understand its significance and also their role in improving the outlook of healthcare.

5.1 Paradigm Shift: from Volume to Value

Marketing and sales activities of the MTI involve seeking preferred positions through discounts, rebates, and volume incentives. Meanwhile, suppliers behave as if their technologies are interchangeable and demonstrate little effort in justifying their value to certain patient groups. Competition happens through offering lower prices or incentives offered to physicians for using their technologies instead of demonstrating effective results (Porter, Teisenberg, 2006, p. 285). As a result, a major challenge is the shift from volume to value, which depends on results rather than inputs. Value is not measured by volume, but rather the outcomes achieved (Porter, 2010, p. 2,477).

Fortunately, physician medical education programs are beginning to place importance on the concept of value in healthcare. Topics including patient safety, quality improvement, team work, and health policy are becoming the third pillar of medical education after the basic and clinical sciences (Prina, 2017, p. 191). This goes along with the need for a strategy for health care organizations to thrive in a competitive marketplace (Porter, Lee, 2015, p. 1,684).

For the MTI, this means that all activities must be focused on value, requiring a paradigm shift from volume to value at all levels of a company. Furthermore, developments in the customer environment, like education programs and strategies for organizations, must be monitored and tackled with appropriate reactions. For example, creating a purchaser strategy together with a provider to solidify a market, establish a price, and create a performance feedback loop would better incorporate a member of the MTI into the strategy of a healthcare organization.

5.2 Demonstrating Value

A major challenge in determining the value of care is collecting effective data that objectively influences coverage and reimbursement decisions. Such data are generally not required for market approval (Sorenson et al., 2013, p. 792). More obtainable details on process measurement and improvement are poor substitutes for outcome and cost measurements. Similarly, providers tend to measure what is in their direct control and what is easily obtainable, e. g. providers measure what is billed (Porter, 2010, pp. 2,477-2,478). It is crucial to track patient-centered outcome measures and make results transparent to the organization and patients to demonstrate delivery of high-value health care (Shaikh, U; Roth, A., 2017, p. 1). With that, new kinds of data and analyses are required to better measure value and abundant, novel relationships must be formed with providers. The MTI must work alongside groups of providers to collect and analyze care cycle information, since such data has been shown to be difficult to obtain and interpret alone (Porter, Teisenberg, 2006, p. 291). Similarly, the training and skills of health professionals, especially surgeons using medical devices, have an enormous impact on the accuracy and effective use of these devices (Sorenson et al., 2013, p. 793). Surgeons must begin to work in networks and communicate to better coordinate care, guiding investigations of patient-centered outcomes and healthcare delivery systems that give the organization a competitive advantage (Rudnicki et al., 2015, p. 355).
For the MTI, the impact of a device on patient-centered outcomes must be measurable at both the individual and aggregate level to determine the efficacy of both devices and providers. This requires communication with providers and stakeholders, particularly surgeons using the devices and technology.

5.3 Creating a Holistic Perspective of Treating a Condition

When determining the total cost of an episode of care, costs must be evaluated for the cycle of care in its entirety rather than for individual steps or parts of treatment along the way. Concentrating too narrowly on the technology rather than on the entire cycle of care is a common mistake. In making this change, shared resources must be added to the costs for individual patients to align with actual use as opposed to equally distributing costs among all patients. This process would allow for cost comparisons between patients with the same medical condition (Porter, 2010, p. 2,481). When determining the value of care, there is a tendency to focus on selective indicators for patient benefit than overall measures of long-term value (Porter, Teisenberg, 2006, p. 286). The Medicare Payment Advisory Commission reported that measuring quality is challenging when the number of cases per provider are low, thereby hampering the ability to properly evaluate care. Furthermore, the Commission is concerned that quality measurements of Medicare

rely too heavily on clinical process measures than on outcomes of interest, such as mortality and readmissions (MedPAC, 2016 a), pp. 54-55).
For the MTI, this means that their contribution to the full cycle of care through their device and applicable add-on services must be communicated to providers and payers to negotiate value-based prices.

5.4 Increasing Collaboration Between Different Stakeholders

Value encompasses efficiency as outcomes are relative to costs. A potential limit for effective care is the consideration of cost-reduction alone without regards to outcomes achieved. Value measurements should encompass all services or activities that jointly define success in meeting patient needs. For realized savings to have a systemic impact on the continuum of care, they must be shared among all involved stakeholders. Value is created through combined efforts over the full cycle of care, with effectiveness depending on not one but several interventions. However, joint responsibility for outcomes is not widely accepted by physicians (Porter, 2010, pp. 2,477-2,478). Additionally, other factors may influence physician choice, such as personal relationships with sales representatives and provision of technical support during the procedure from the device company. In an attempt to align the diverging interests of physicians and hospitals, gainsharing might be an appropriate approach, meaning that both groups share financial savings from the collaboration (Obremskey et al, 2012, p. 1,055).
For the MTI, collaboration with physicians and hospitals must increase in order for the industry to contribute to improving the value of healthcare. One possibility would be to prove to physicians the cost-effectiveness of one device compared to others while also enabling risk-sharing between physicians and hospitals. The MTI can take a particularly active part in this effort by taking some risk and base pricing accordingly, a policy that fits with the intention of the CJR model.

5.5 Ensuring Easy Implementation

Reporting quality measures can be quite expensive due to the time spent by physicians and staff participating in direct reporting efforts. Physicians already spend more than 15 hours per week on average preparing challenging external quality measures while attempting to understand performance reports from their own from payers and other outside stakeholders (Casalino et al., 2016, p. 401). With regards to a health system, an efficient hospital purchasing strategy consists of a minimal number of relationships with medical device manufacturers while simultaneously covering the full range of device needs. Although such a model reduces a system’s number of interactions, it also limits physician choices of medical devices (Robinson, 2008, p. 1,527).
For the MTI, these two issues present opportunities to develop strengths as competitive advantages. First, through acquisition and development of innovative technologies, a

firm's product offering can increase while the number of hospital vendors decrease through the elimination of competing inferior products. Second, a firm's research and development arm can focus on medical devices that target physicians' interests, thereby becoming a preferred company among doctors who impact purchasing decisions. Throughout the process, documentation must be standardized and simple. This is best realized with EHR-compatible software that not only manages the devices but complies with the Advancing Care Information component of the MIPS program.

6 Conclusion

The MTI has an opportunity to contribute tremendously to the aim of MACRA through quality improvement, care information advancement, and cost reduction while at the same time fostering collaboration between stakeholders. Although the MTI is not directly integrated into reforms of Medicare's payment systems, the industry must be aware of political developments in order to shape their value in and for the healthcare market. The industry must act outside of producing and selling devices by building relationships with providers to understand and integrate their needs in product research and development both now and in the long run. All payers use Medicare payment regulation as guidance while adjusting to their specific patient population, forcing the MTI to face many different approaches when entering the world of value-based payments. Therefore, companies should adapt their offers accordingly to meet needs and secure business. As a result, segmentation of customers and targeted approaches might be a good tactic. No matter which approach is taken, in the end firms must adapt to meet the needs of stakeholders to create value, remain competitive, and contribute to a more efficient US healthcare system.

References

Casalino, L. P., Gans, D., Weber, R., Cea, M., Tuchovsky, A., Bishop, T. F., Miranda, Y., Frankel, B. A., Ziehler, K. B., Wong, M. M. and Evenson, T. B. (2016), 'US Physician Practices Spend More than $15.4 Billion Annually to Report Quality Measures', *Health Affairs*, vol. 35, no. 3, pp. 401–406.

Center for Medicare & Medicaid Services (2016), *The Merit-Based Incentive Program*, Center for Medicare & Medicaid Services [Online]. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Merit-based-Incentive-Payment-System-MIPS-Overview-slides.pdf (Accessed May 10, 2017).

Center for Medicare & Medicaid Services (2017), *Comprehensive Care for Joint Replacement Model*, Center for Medicare & Medicaid Services [Online]. Available at: https://innovation.cms.gov/initiatives/cjr (Accessed May 02, 2017).

Center for Medicare & Medicaid Services (2017), *What Are Value-Based Programs?* [Online], Center for Medicare & Medicaid Services. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs.html (Accessed May 10, 2017).

Clemens, J. and Gottlieb, J. (2013), *In the Shadow of a Giant: Medicare's Influence on Private Physician Payments*, National Bureau of Economic Research 19503.

Clough, J. D. and McClellan, M. (2016), 'Implementing MACRA - Implications for Physicians and for Physician Leadership', *JAMA*, vol. 315, no. 22, pp. 2397–2398.

Clyde, A. T., Bockstedt, L., Farkas, J. A. and Jackson, C. (2008), 'Experience with Medicare's New Technology Add-On Payment Program', *Health Affairs*, vol. 27, no. 6, pp. 1632–1641.

Department of Health and Human Services (2016), *Executive Summary, Quality Payment Program*, Department of Health and Human Services.

MedPAC (2016), *Health Care Spending and the Medicare Program*, MedPAC.

MedPAC (2016), *Report to the Congress: Medicare and the Healthcare Delivery System*, MedPAC.

MedPAC (2016), *Report to the Congress: Medicare Payment Policy*, MedPAC.

Obremskey, W. T., Dail, T. and Jahangir, A. A. (2012), 'Value-Based Purchasing of Medical Devices', *Clinical Orthopaedics and Related Research*, vol. 470, no. 4, pp. 1054–1064.

Porter, M. E. (2010), 'What is Value in Health Care?', *The New England Journal of Medicine*, vol. 363, no. 26, pp. 2477–2481.

Porter, M. E. and Lee, T. H. (2015), 'Why Strategy Matters Now', *The New England Journal of Medicine*, vol. 372, no. 18, pp. 1681–1684.

Porter, M. E. and Teisenberg, E. O. (2006), *Redefining Health Care: Creating Value-Based Competition on Results*, Harvard Business School Press.

Prina, L. L. (2017), 'Health Professions Workforce: Recent Grants Awarded', *Health Affairs*, vol. 36, no. 1, pp. 190–191.

Quality Payment Program Service Center (2017), *What are Alternative Payment Models (APM)?* [Online], Quality Payment Program Service Center. Available at: https://qpp.cms.gov/learn/apms (Accessed May 02, 2017).

Quality Payment Program Service Center (2017), *What's the Merit-Based Incentive Payment System (MIPS)?* [Online], Quality Payment Program Service Center. Available at: https://qpp.cms.gov/learn/qpp (Accessed May 02, 2017).

Robinson, J. C. (2008), 'Value-Based Purchasing for Medical Devices', *Health Affairs*, vol. 27, no. 6, pp. 1523–1531.

Rudnicki, M., Armstrong, J. H., Clark, C., Marcus, S. G., Sacks, L., Moser, A. J. and Reid-Lombardo, K. M. (2016), 'Expected and Unexpected Consequences of the Affordable Care Act: The Impact on Patients and Surgeons-Pro and Con Arguments', *Journal of Gastrointestinal Surgery*, vol. 20, no. 2, pp. 351–360.

Shaikh, U. and Roth, A. (2017), 'Five Organizational Strategies to Deliver High-Value Health Care', *American Journal of Medical Quality*, vol. 32, no. 5, pp. 566–568.

Sorenson, C., Drummond, M. and Burns, L. R. (2013), 'Evolving Reimbursement and Pricing Policies for Devices in Europe and the United States Should Encourage Greater Value', *Health Affairs*, vol. 32, no. 4, pp. 788–796.

System Partnerships between Medical Device Companies and Health Care Providers

Elisabeth Ludwig

The American health care system has some of the worst quality outcomes and highest costs internationally. In order to address these issues, the Medicare Access and CHIP Reauthorization Act (MACRA) was passed in 2015 by Congress. MACRA is a new value- and quality-based payment model which rewards providers for high quality care and penalizes providers with low quality outcomes. Under the law, two health care payment models, the Merit-based Incentive Payment System and Alternative Payment Models, put patients as the focus to promote patient-centered health care. Providers have difficulties adapting to these new models, but through system partnerships they can be supported. System partnerships are relationships between medical device companies and providers which are more than common customer-vendor relationships. In fact, system partnerships aim to develop complex treatment solutions together. This paper reviews whether system partnerships can effectively lower costs and improve the quality of health care systems. In addition, the advantages of the system partnerships, such as digitalization, are compared to the risks they pose to patients and providers, such as information asymmetries. At present, analysis of these factors shows that the advantages outweigh the risks. Therefore, the use of system partnerships as a means to lower costs and improve quality is recommended.

Contents

1 Introduction

The American health care market is one of the largest in the world and acts as a role model for other countries. Every legislative change is observed and discussed because its size can illustrate problems and advantages more explicitly than other, smaller markets can.
This paper will discuss whether system partnerships between medical device companies and providers save costs and improve the quality of care. To accomplish this, MACRA is briefly explained (section 2) and its impact on providers is detailed in section 3. Section 4 presents how the providers deal with the new regulation and what problems might occur. A description follows of possible solutions that could be implemented to support the providers with adapting to this legislation, emphasizing system partnerships as a possible solution (section 5). Thereafter, the advantages and opportunities a system partnership provides, the risks presented by these partnerships under MACRA, as well as cost savings and quality improvement will be discussed (section 6). At the end, a conclusion will be drawn which considers the presented results of the previous sections.

2 MACRA

The American health care system has some of the world's highest expenses for health care, but also some of the worst quality outcomes when compared to different countries (Squires, Anderson,2015, w.s.). In order to tackle this imbalance, the government introduced the Medicare Access and CHIP Reauthorization Act (MACRA) in 2015 (Medicare Access and CHIP Reauthorization Act, 2015, w.s.). With MACRA in place, CMS strives to achieve better, more patient-focused care. The system is intended to be understandable and flexible for each participating physician. It rewards high-quality patient care through two options: The Merit-based Incentive Payment System (MIPS) or the Alternative Payment Model (APM). Both payment systems and their rewards are described in the following section.

2.1 Merit-based Incentive Payment System

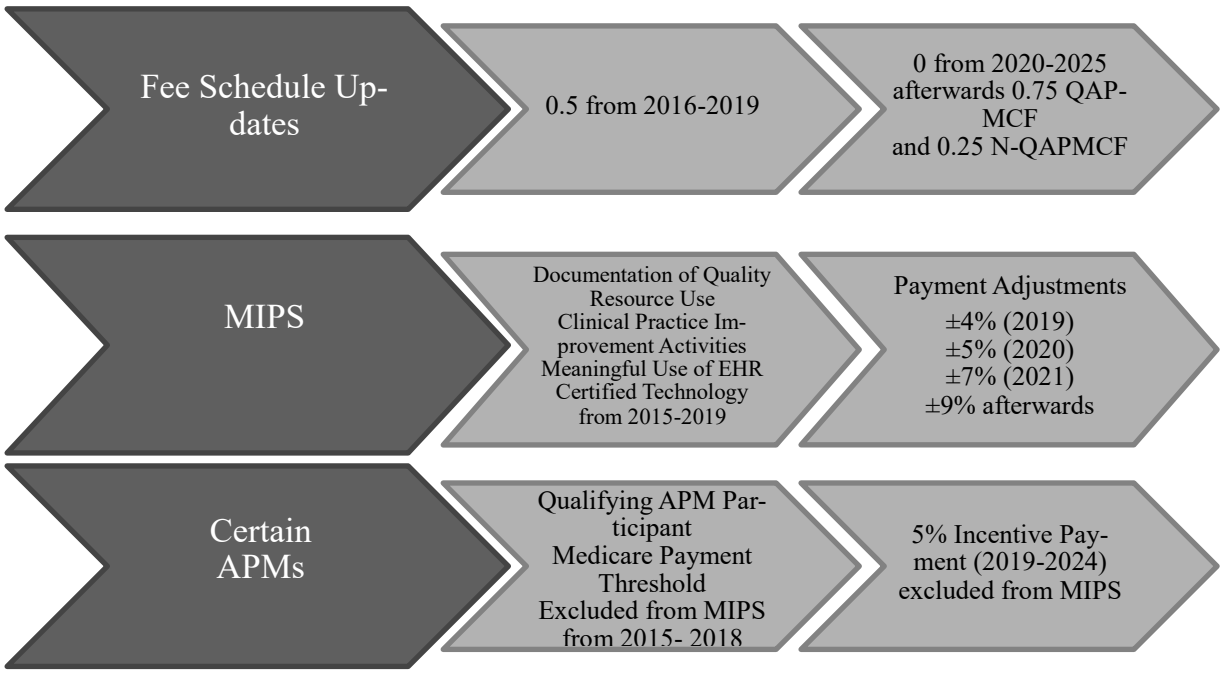
The Merit-based Incentive Payment System (MIPS) will affect almost every physician because any physician which earns at least $10,000 from Medicare payments is involved in this payment reform (Shinkman, 2016, w.s.). The new system combines and unites multiple quality and value programs which were formerly separate into one.
MIPS mainly lays focus on three aspects: quality, resource use, and use of certified electronic health record (EHR) technology. Performance will be measured and reported in four performance categories. The first, quality, will compose 50% of the measurement taken in the first years of MACRA and is therefore the most important part of the meas-

uring. The second one is resource use, which is the only category that is directly measured by CMS and will compose 10%. The third one clinical practice improvement activities has rather lower importance at the beginning of the reporting period because it was not included in former laws and needs to be introduced to the physicians. The last one is the meaningful use of EHR certified technology (Yaraghi, 2016, w.s.).
The four performance categories will be pooled together into a MIPS composite performance score (CPS). This CPS will be used to decide whether a physician receives an upward, downward, or even no payment adjustment to either reward or penalize the provider. Quality, resource use, and meaningful use of certified EHR technology were present in former laws and have now been modified, extended, and transformed into one. The report for quality performance must include at least six measures, one transsectoral measure, and, if possible, one outcome measure (Medicare Access and CHIP Reauthorization Act, 2015, w.s.). In lieu of an outcome measure, there is the option to add a high priority measure such as patient safety. The required clinical practice improvement activity, the only new regulation, addresses population management and care coordination. CMS will annually establish a new performance list with additional detailed information about changes to MIPS and the metrics of the CPS after the collected data is submitted.

2.2 Alternative Payment Model

The second payment system reform option is the Alternative Payment Model (APM). To be part of the program, a physician must meet a higher Medicaid revenue or patient threshold than under MIPS. It will only affect 5% of health care systems and is used to establish some kind of better and newer accountable care organizations (ACO). Most ACOs are APMs, but not all APMs are ACOs because there are a variety of possible models for APMs. The requirements for an advanced APM are the following: having a quality measure component, using EHR certified technology, and either bearing more than a nominal financial risk or being part of a Medical Home Model (an expansion under the authority of the Medicare and Medicaid Innovation Center) (Medicare Access and CHIP Reauthorization Act, 2015, w.s.). Those who participate in the most advanced APMs will be upgraded to Qualifying APM Participants (QP). QPs are physicians and practitioners who have a certain percentage of their patients or payments through an eligible APM. Those who qualify to be a QP gain a 5% bonus payment from 2019 – 2024 and after 2026 receive higher fee schedule updates than under MIPS as detailed in figure 9.1 (Hussey, Liu, White, 2017, pp. 697-705).

Figure 1: MACRA fee schedule timeline comparing Fee Schedule Updates, MIPS, and APMs



Source: own illustration

MIPS will include all eligible clinicians except those who participate in an APM. Whereas APMs are designed for larger practices, MIPS is designed for smaller and solo practices. APMs have a greater risk, however, and this is rewarded with higher bonuses than in MIPS.

Both models are applicable to payment for Medicare and Medicaid patients. Those two forms of public insurance originate from the federal government and cover about 34% of the American population (Kaiser Family Foundation, 2015, w.s.). These models often align with CMS regulations closely as they consider them important guidelines for health care payment system success.

3 Providers´ challenges with MACRA

MACRA mainly affects providers, meaning they must now adjust to the new payment models, which often implies a difficult process.

According to MACRA, there are four main domains to which the providers must adjust. The first domain is quality, where providers have to measure the quality of their performance in six different ways. Within this process, providers can choose their own means of measurement (Pullen, 2017, pp. 591-592). This is a difficulty because it might invite providers to exploit the system (Yaraghi, 2016, w.s.). Consequently, providers can easily manipulate the measurements and present themselves as better than they actually are. In general, quality measurement is complicated because the patient as well as the physician should ideally describe results of care episodes. Quality is often a personal perception and therefore it is challenging to design a conclusive survey which depicts the situation

in an objective way. In addition, health care providers do not have the ability to access all data being submitted to CMS (Deloitte Report, 2017, p. 5).

The second domain is resource use, with its performance being calculated by using administrative data. Therefore, physicians and providers do not have to submit any additional data (Medicare Access and CHIP Reauthorization Act, 2015, w.s.). However, obtaining this data is very complex because it cannot be extracted from one source (Deloitte Report, 2017, p. 6). Usually, CMS also does not communicate the results to providers more than once a year, which can lead to invalid responses to the system, which means that changes cannot be made without the data. However, this issue has already been detected and addressed by simplifying the reporting requirements for the first year of MACRA.

The third domain involves clinical practice improvement activities. These are difficult to identify because there is no data infrastructure yet to measure performance in this domain (Deloitte Report, 2017, p. 11).

The meaningful use of EHR certified technology is the last domain. EHR certified technology is expensive, hence it is easier for larger providers to equip themselves with than it is for solo practitioners. More than 600 EHR manufacturers sell the technology to providers across the US health system (Deloitte Report, 2017, p. 5). Even though 60% of the provider market is supplied through 5 EHR companies, the large variety of systems and vendors make it complicated to synthesize and compare data by setting or provider. Consequently, there are many different and incompatible EHR systems in the American health care market.

Many physicians reported that the MACRA performance documentation may distract them from actual patient care due to the excessive bureaucratic burden (Shinkman, 2016, w.s. and Shyrock, 2016, p. 2). CMS reacted to these objections by loosening the restrictions. Currently, providers can select between three options in order to avoid a negative payment adjustment. All these options introduce the participant to the new value-based payment system to encourage conformity with the requirements of the system over time (Medicare Access and CHIP Reauthorization Act, 2015, w.s.).

It is expected that MACRA will drive physicians to join larger organizations and networks to be part of APMs and their payment advantages, thus increasing participation in value based-payment agreements (Survey of US Health Care Executives, 2016, p. 7). However, the law might disrupt the relationships between health care systems, physicians, and life science companies like medical device companies and pharmaceuticals, creating barriers. Nevertheless, these parties need to work together to overcome obstacles in providing quality care. Therefore, alliances between health care systems and life science companies will be significant in order to evaluate which products work best on which type of patient to achieve better treatment outcomes and improve cost efficiency (Lohmann, Rippmann, 2014, pp. 127-131).

4 System partnerships

Providers need to optimize and digitalize medical processes in order to secure quality and efficiency in the health care sector, an endeavor that is complicated and expensive. Often providers cannot afford these expensive innovations, so they simply try to save costs by dismissing staff. This in turn leads to poor quality care and eventually leads to negative payment adjustments (Lohmann/Rippmann, 2014, p. 122). Add something here about how system partnerships can avoid that scenario and how you will discuss the positive and negative aspects of these partnerships in this section.

4.1 Positive aspects of a system partnership

To be successful under MACRA, providers need to completely change the way they have been working (Deloitte Report, 2017, p. 1). One way to become successful is to establish a system partnership with a medical device company. Such a partnership means that the two entities have more than a common customer-vendor relationship; this implies a full partnership where they develop and establish treatment solutions together (Siemens Healthineers, 2015, w.s.). A variety of partnerships exist, creating tailored solutions for every possible cooperation between medical device companies and providers. On one hand, providers often need to invest in their digital infrastructure or innovate in general (Lohmann, Rippmann, 2014, pp. 122-131), but they often do not have the financial reserves to do so. On the other hand, Medical device companies are able to support these changes financially through multiple payment models which ease the payment for providers. Additionally, they can provide them with medical devices to clear the way for further innovation processes, given that they are in a system partnership. As a result, the provider can participate in the progress of medical technology without worrying about financial resources.

The provider can further benefit from cooperation with a medical device company by using the company as a positive role model for modernization of health care (Lohmann, Rippmann, 2014, p. 126). Currently, medical device companies are global players who have to align to the market. Providers are protected by law and thus never had to adjust to the global market in the same way. However, now that the market is changing through MACRA, providers are forced to compete on a higher level. Medical device companies can encourage providers to take steps in the direction of digitalization. They can assist providers in terms of restructuring and reorganizing while also relieving the company financially and motivating the staff through quick wins in digitalization.

Medical device companies can also teach staff how to optimally operate devices and technology, generating an efficiency gain (Lohmann, Rippmann, 2014, p. 128). Also, the companies have the expertise to analyze weak points in a process and subsequently

help to optimize those. Together, the two partners have the opportunity to use the development work of the medical device company to create change more swiftly than previously possible.
If the providers and medical device company cooperate closely together, they are also able to establish clinical pathways together. Clinical pathways are the unitary way, agreed upon by all concerned parties, a provider treats patients with steady, proficient quality (Lohmann, Rippmann, 2014, pp. 122-131). It is determined to be the most efficient way to treat a patient and is complex to develop. When the provider and all relevant employees along with the medical device company agree to devise a clinical pathway, it will be especially efficient.
Sometimes medical device companies collaborate to facilitate product improvements (Siemens Healthineers, 2015, w.s.). There are various products that can be innovated and upgraded, such as Magnetic Resonance Imaging (MRI) and Computerized Axial Tomography (CAT) scans. A partnership with a provider allows scrutiny of workflows and improvement of the device accordingly. For example, Siemens Healthineers and Northwell Health have been collaborating since December 2016 as a research partnership in order to improve the outcomes of Northwell's Imaging Clinical Effectiveness and Outcomes Research Program (Business Wire, 2016, w.s.). According to their first published paper, 'Value of Advanced Imaging in Improving Health Outcomes and Healthcare Spending in Acute Stroke', they already discovered that during a stroke the best choice for an imaging exam, whether to use an CT or MRI, depends on the personal characteristics of the patient. With this finding, Siemens Healthineers and Northwell Health hope to illuminate new pathways to treat patients more effectively and influence health policy rulings to improve population health.

4.2 Negative aspects of a system partnership

There are some factors, however, which providers and medical device companies should bear in mind when considering a partnership. Both parties need to be completely honest about their intentions when establishing a working relationship (Lohmann, Rippmann, 2014, p. 130). If there are any discrepancies it is highly likely that the cooperation will not work. Constant risk management is a necessity to detect possible inconsistencies early enough to rectify the situation. Also, credibility is an important matter. If the provider does not believe the intentions of the medical device company are genuine there is no basis to build on and thus it is likely that the partnership will not come about (KMU-, Krankenhausstudie 2000, 2000, pp. 94-100).
Furthermore, not every medical device company is able to establish a system partnership. There are special features needed for a partnership to occur. The structure of the company has to be more like a service company than a simple vendor (Lohmann, Rippmann, 2014, p. 127). These service qualities are essential to be successful in such a

partnership due to the thorough preparations which are needed to determine if the two partners fit well together before founding the partnership.

5 Discussion

In the following part, the focus lies on the central question: to what extent can a system partnership between a provider and a medical device company can save costs and simultaneously improve the quality?

First of all, it is apparent that there is a need for change in the health care market (Squires, Anderson, 2015, w.s.). MACRA expresses these needs and tries to take a step toward a better functioning health care market. To accomplish this, providers have to leave old pattern of fee-for-service logic. MACRA is a law propels providers into value-based payment reform and therefore makes changes inevitable.

The providers also have to digitalize. This might be expensive at first, however, as soon as the provider gets used to it expenses can be saved. In a partnership, the medical device company may help the provider to acclimate to new devices and new technology, allowing providers to benefit from the profound knowledge of the device company. The medical device company is then able to develop the products and sell them to the provider. Naturally, the company has more detailed insight into the product than the provider. This insight can be communicated to the provider and customized to the specific requirements the provider requests. Both can benefit from economies of scale and the medical device company can profit from economies of scope as well. A medical device company usually has more than one provider with whom it collaborates. After the new technology is incorporated, the provider is highly likely to receive higher revenues under MACRA, under the condition that the medical device company provides EHR certified technology and the provider reports the performance categories correctly.

Research partnerships, especially, can play an integral part in quality improvement. The medical device company and the provider work together to scrutinize topics which can contribute to excellent patient care provision. For example, imaging techniques can be enhanced and the evaluation of images can be simplified for physicians. Consequently, the rate of misinterpreted images might decrease and thus might lower the rate of incorrect diagnoses. There may then be more satisfied and correctly treated patients, which is an indicator for high quality as well as value in the health care market. If there are less wrong diagnoses, there are fewer follow-up treatments, which also would lead to decreasing costs. As a further result, quality would be improved as well by decreasing unnecessary care. Additionally, medical device companies can use collected data to improve all their devices and develop new devices. Older technologies will be replaced through this process in the near future. Consequently, providers will be provided with better technologies and the medical device companies can market more products.

When the medical device company tackles the burden of inefficient processes by optimizing them, both partners can focus on their core activities. It is particularly important for providers to focus on their core capacity to revise actual treatments. This is required to have a competitive edge against other providers (Lohmann, Rippmann, 2014, p. 129). If a provider has established clinical pathways together with a medical device company, both better concentrate on the maximal performance. The medical device company supports the provider to implement the provider's ideas, expectations, and suggestions. Together, they are able to achieve state-of-the-art medicine and improve the quality of treatments dramatically. Additionally, both can improve their images. Hence, the medical device company will gain more customers and the provider more patients. Both benefit from an excellent status and thus can save costs through economies of scale, leading to a positive effect on their revenue as well.

Physicians in a system partnership focus more on medical outcomes because their partner releases them of incidental economic, technical, and organizational issues to a great extent. Also, nursing staff is disburdened from supplementary documentation obligations and other administrative tasks so they can concentrate more on patients. Through such a system partnership, resources are efficiently used and will be reimbursed to a greater extent by MACRA.

Another notable point is that medical device companies can support providers by building up a good data infrastructure. It simplifies data collection and data transfer to fulfill MACRA reporting requirements, which is likely to result in higher payments. Also, together they can evaluate the data better to review the number of mistakes made by each physician and create competition by rewarding physicians who made the least mistakes. This will also increase the quality of care and is an effective incentive to save costs from unnecessary follow-up treatments.

Additionally, if the provider receives all the required devices from the same medical device vendor, there is only one maintenance contract to negotiate. Consequently, the maintenance complexity is reduced and more standardization is achieved. Every device is similarly programmed and this leads to simplified usage for every physician. Now only one introduction from the medical device company is needed for the staff to explain how to use a device properly and in the best, fastest way. In general, standardization is essential for faster and more efficient working practice. Also, the reduced complexity of maintenance contracts saves time and resources. Fewer staff members are required to check the contracts with each individual device company and therefore costs are reduced.

However, only a functioning system partnership offers the advantages listed above. If a system partnership does not achieve this there are severe disadvantages which must always be kept in mind.

The many barriers to effective cooperation are seen as a negative aspect. Partners must compromise, a process which distracts the provider from focusing completely on providing health care. Also, medical device companies do not wish to cooperate with every provider. They mainly focus on larger health providers to get better outcomes. Smaller health providers do not have the scope the medical device companies want to reach with those partnerships. Additionally, the larger providers supervise a higher number of patients each day. If they can save costs through system partnerships, it will affect the health care economy more than if the medical device companies would only cooperate with smaller providers. Furthermore, larger providers have a higher negotiation level than smaller ones. They can achieve better conditions for the system partnership due to their size. More medical devices and technologies are needed in larger organizations and it is a greater challenge for the medical device company. Therefore, more costs can be avoided by the providers due to volume discount. However, the medical device company has a secure customer through the system partnership, who relies on its products and to whom it can sell more as an economic benefit despite the volume discount.
A major aspect of the partnership is the dependency between the provider and medical device company. Once a partnership is established, the provider is dependent on the medical device company. The provider needs to believe in the good intentions of the medical device company (KMU-, Krankenhausstudie 2000, 2000, pp. 94-100) and try to keep the possible dependencies as minimal as possible. This can be accomplished through customer-vendor relationships with other medical device companies. Along the same lines, the medical device company is prompted to reveal all its intentions so it is evident that the company does not want to exploit the provider. If such abuse took place, it would first lead to significantly higher costs for the provider and the system partnership would finally end in a collapse.
Nevertheless, the advantages of correctly aligned system partnerships between two parties outweigh the risks of a partnership not properly functioning. Even though it is expensive at first, innovation is necessary. Through this process, quality can be significantly increased and costs decreased due to modification of health care systems in the US through various system partnerships.

6 Conclusion

The health care market is a fast-changing market. MACRA takes a step in a new direction which has significant influence on how providers function. The need for change had been obvious before the law passed through Congress. MACRA now helps the health care market adjust faster to the new circumstances it faces. Providers are now required to change within the next couple of years. They have four years to align with the new payment models and become quality- and value-based providers. System partnerships between providers and medical device companies are a model which will support those

changes and help both parties perform at their best. Though smaller providers will not benefit as much from system partnerships now, they are expected be attractive for medical device companies as well in a few years.

System partnerships facilitate the repositioning providers to focus on their core competencies in order to improve medical outcomes. The medical device companies take burdens from providers and support them with technological knowledge and innovations. Clinical effectiveness and economics can significantly be improved through these partnerships as well, creating another benefit for both participants.

Already established partnerships demonstrate the huge advantages both sides have experienced from their system partnership. These also show the possible variety of partnerships. Every system partnership differs and the medical device company has to adjust to each provider. This process leads to creative and innovative solutions which exemplify how system partnerships benefit providers, medical device companies, and the health system as a whole, especially in the future. Therefore, this concept of system partnerships has to be further developed in order to minimize the risks and focus on the advantages.

References

Business Wire (2016), Siemens Healthineers, Northwell Health Announce Research Partnership to Improve Health Outcomes, Reduce Costs, Business Wire [Online]. Available at: http://www.businesswire.com/news/home/20161201005214/en/ (Accessed May 30, 2017).

Centrum für Krankenhaus-Management (2000), KMU-, Krankenhaus-Studie 2000, Ministerium für Wirtschaft und Mittelstand, Technologie und Verkehr des Landes Nordrhein-Westfalen, Düsseldorf.

Deloitte Report (2017), Rebuilding Foundation of Health Care under MACRA, Deloitte Development LLC.

Deloitte Survey (2016), Survey of US Health Care Executives Taking a Pulse on MACRA, Deloitte Development LLC.

H.R.2 (2015), Medicare Access and CHIP Reauthorization Act of 2015 (42 USC 1305).

Hirsch, J. A., Harvey, H. B., Barr, R. M., Donovan, W. D., Duszak, R., Nicola, G. N., Schaefer, P. W. and Manchikanti, L. (2016), 'Sustainable Growth Rate Repealed, MACRA Revealed: Historical Context and Analysis of Recent Changes in Medicare Physician Payment Methodologies', American Journal of Neuroradiology, vol. 37, no. 2, pp. 210–214.

Hussey, P. S., Liu, J. L. and White, C. (2017), 'The Medicare Access and CHIP Reauthorization Act: Effects on Medicare Payment Policy and Spending', Health Affairs, vol. 36, no. 4, pp. 697–705.

Kaiser Family Foundation (n.d.), Health Insurance Coverage of the Total Population [Online], Kaiser Family Foundation. Available at: http://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (Accessed August 22, 2017).

Lohmann, H. and Rippmann, K. (2014), 'Strukturierte Medizin braucht digitale Industrialisierung: Erfolgsfaktoren einer Systempartnerschaft zwischen Industrie und Krankenhaus', in Schwegel, P., Ulrich, H. and Oberender, P. (eds.) Medizinprodukte-Management, Bayreuth, P.C.O.-Verl.

Pullen, L. C. (2017), 'MACRA is Here to Stay', American Journal of Transplantation, vol. 17, no. 3, pp. 591–592.

Shinkman, R. (2016), Physician Frustration and Fear of MACRA, NEJM Catalyst [Online]. Available at: http://catalyst.nejm.org/physician-frustration-fear-macra/ (Accessed June 01, 2017).

Shyrock, T. (2016), Physicians Frustrated, Confused by Final MACRA Rule, Medical Economics [Online]. Available at: http://medicaleconomics.modernmedicine.com/medical-economics/news/physicians-frustrated-confused-final-macra-rule?page=0,1 (Accessed May 31, 2017).

Siemens Healthineers (2015), Mit Systempartnerschaften zur patientenzentrierten Medizin, Siemens Healthineers [Online]. Available at: https://www.healthcare.siemens.de/news/systempartnerschaften.html (Accessed May 30, 2017).

Squires, D. and Anderson, C. (2015), U.S. Health Care from a Global Perspective, The Commonwealth Fund.

Yaraghi, N. (2016), MACRA Proposed Rule Creates More Problems than it Solves, HealthAffairsBlog [Online]. Available at: http://healthaffairs.org/blog/2016/10/12/macra-proposed-rule-creates-more-problems-than-it-solves/ (Accessed May 31, 2017).

Regulatory Processes & Innovation Cycles in Times of Digitalization – a Contradiction?

Peter Konrad

Digitalization - without a doubt - is the main driver of innovation nowadays. This phenomenon takes place in almost every business, even within the medical device industry digital development is an important driving force. Digitalization allows a broad range of people to create their own mobile applications, as demonstrated by the enormous number of digital products available for mobile devices. While the simplified creation of digital products accelerates innovation in the medical device industry, regulatory processes remain the same yet seem to be necessary to provide a safe market entry. This work examines the influence of digital innovation on medical devices and compares the regulatory processes in the US and Germany. Therefore, a theoretical background of innovation and regulation theory is given. Subsequently, the regulatory systems of medical devices in the US and Germany are analyzed regarding their fit for mobile applications. After describing problems arising due to long and inappropriate regulation systems, recommendations are given by a fictive regulatory system on how regulatory processes can be adjusted to accommodate mobile medical applications.

Contents

1 Introduction

Innovative developments within healthcare industry are often regarded as both a boon and bane at the same time. On one hand, making progress in medical devices offers huge potential: Processes may be simplified and optimized, providers better connected, and patient care improved. On the other hand, technological progress is blamed as a main driver for the continuous increase in healthcare costs (Sorenson et al., 2013). A substantial role within innovation in healthcare is played by digitalization. The range of benefits of digitalization for the healthcare industry and health systems can still hardly be imagined, though it is evident that digital products have had a huge impact (Malvey and Slovensky, 2014, p. 1). This rapid change to digitalization leads to several challenges: The subordinate problem deals with a still missing coherent terminology for digital, innovative products in healthcare (Albrecht and Jan, 2016, pp. 48–52). Of greater importance is the creation of an appropriate regulatory system, which allows fast access to the market but still considers and eliminates potential threats (Kramer et al., 2012, p. 853). Due to health systems often being strictly regulated, beneficial circumstances for creating innovative products are scarce. Nevertheless, the number of digital products seems to grow without any limits while the political and regulatory frameworks around the globe struggle to keep pace (Bierbaum and Bierbaum, 2017, pp. 255–256; Boulos et al., 2014, p. 1; Roh and Kim, 2017). There is no doubt that regulation of medical devices is a mandatory part within every health system to secure patients' health. Regulatory processes must fit adequately to the fast cycles of innovation and follow the rapid changes initiated by digitalization as well as the confusing number of digital products which claim to be part of the healthcare system.

This work examines the problems within the medical device industry due to rigid and long regulatory processes in addition to the dynamic innovation cycles within the industry. Because the meaning of digitalization for innovation in healthcare is still to be determined this work will just focus on digital products within the medical device industry. A theoretical framework about regulation and innovation forms the basis for this topic. Afterwards, the application of regulatory processes on digital medical devices is investigated. Corresponding to the topic of the book, the focus is on these processes in the US and Germany. An evaluation of the suitability of the current situation and potential suggestions for improvement closes this essay.

2 Innovation and regulation – a theoretical background

2.1 Theory of regulation and the principal-agent phenomenon

The act of regulating market entry and distribution of medical devices within a health system has the intention of protecting people from undesirable effects on their health status (Cheng, 2003, pp. 3–8). This is based on a very fundamental understanding of

regulation: The interaction of normative objects and private interests demands governmental action, which is represented through politics (Baron, 2007, p. 1,349). Regulation is commonly separated into *economic regulation*, *social regulation* and *administrative regulation*. While economic regulation is used for improving the performance of markets (e.g. through restrictions, standards, market entry conditions, etc.), social regulation relates to the protection of public health and well-being. Finally, administrative regulation determines governmental actions in private and public sectors, e.g. taxes and healthcare administration (OECD, n.a.).

Within markets, those regulatory interventions are required because of asymmetric information, a main part within the principal-agent theory. This phenomenon occurs when there are parties contracting with each other which are suffering an unequal level of information and individual action cannot be observed. As a consequence, this leads to moral hazard, which prohibits "first best" solutions (Holmstrom, 1979, p. 74). In the case of asymmetric information, regulation serves as mediator to create equal conditions between the principal and agent and to eliminate economically inefficient behavior (Baron, 2007, p. 1,349). Regarding regulation of medical devices, asymmetric information can be observed in different scenarios: the manufacturer of a medical device (both physical and digital) has a strong advantage in information compared to customers; customers may be patients acquiring the product directly from the manufacturer or distributor and uses it for himself; or the customer is represented by a care provider, who acquires the medical device for commercial use and applies the medical device for patient treatment. The user in the last two cases is unable to assess the benefit of a medical device in advance, as is common in health economics (Zweifel and Manning, 2000, pp. 412–413). Furthermore, the manufacturer has an incentive to maximize his profit. A corresponding minimization of the costs to achieve greater profits in this situation could lead to a reduction of efforts to protect the interests of consumers. This legitimatizes governmental regulation to reduce economic costs and guarantee patient safety (Cheng, 2003, pp. 7–8). Regarding medical devices affecting peoples' health, the role of governmental regulation is mainly to introduce and adopt a minimum standard of quality.

There are several theoretical mechanisms through which asymmetric information can be solved by governmental regulation (Baron, 2007). In a concrete setting with a regulatory framework, the manufacturer of the medical device would have to pass a predefined and comparable standard, which allows the users to trust the product is at least a certain level of quality. Attention should be paid to changing circumstances, though. Regulatory processes may be adequate for a certain range or type of products, but changes and drifts over time may influence the industry and demand an adoption of new regulatory framework.

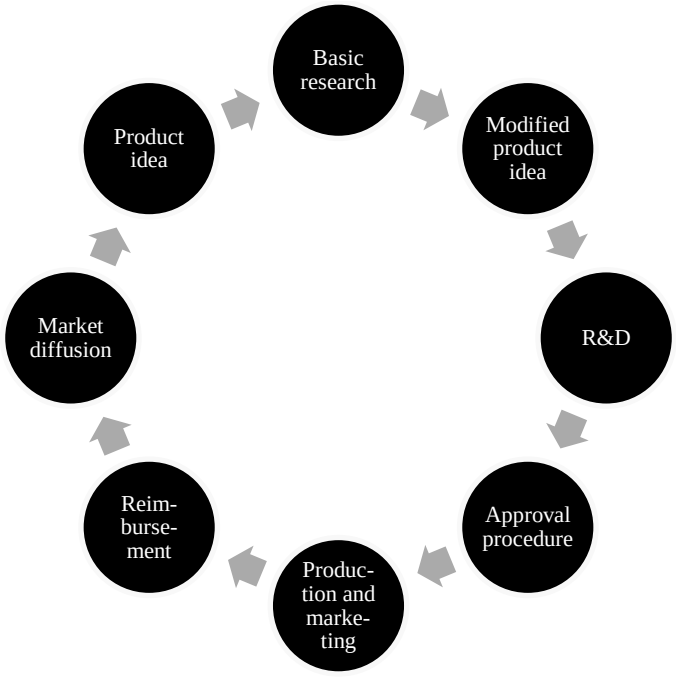
2.2 Theory of innovation and the innovation process

The term “innovation” is widespread and used in several contexts with different meanings (Baregheh et al., 2009). For a better understanding, there should be a common definition of innovation: following the Sociologist Everett M. Rogers and his pioneering book “Diffusion of Innovations” innovation should be understood as something that distinguishes itself through a certain novel characteristic (Rogers, 2003, p. 12). This can be expressed through new processes, products, or changes in organization. The aim innovation strives for - from a company’s point of view - is either to reduce unit costs and/or enlarge demand within the market (Sengupta, 2014, p. 1). Therefore, innovation is also seen as a possible way to create competitive advantage (Porter, 1990, p. 74).
Innovation is often separated into different subtypes. We will just focus on few which are relevant to the medical device industry and digitalization:

- One subtype is technology-based innovation. This term sums up all product innovation, process innovation, investments of the industry in research and development, and the transmission of technology (Sengupta, 2014, p. 1).
- Another separation into subtypes involves endogenous and exogenous innovation. Endogenous innovation develops from the incentives of the market. Innovation in this case is most often created by being the first company with a new technology and earning a monopolistic standing within the industry, e.g. through patent protection. Exogenous innovation describes a form of innovation which develops through a background outside the industry, e.g. academic research (Sengupta, 2014, pp. 1–5).
- Finally, there should be separation between incremental and radical/disruptive innovation. While the first means to make small changes piece by piece on an already existing product, the latter describes a complete substitution of an existing product (Stewart, 2011, p. 2).

These “types” of innovation take place in an innovation process. One of the most common interpretations is from Andrew van de Ven (1999), who distinguishes between a linear and a cyclical model. The main difference between these models is that there are straightforward, defined tasks within the linear model and a more blurry, interdependent, and repeating process within the latter. Additionally, the cyclical model makes it difficult to comprehend which aspects are influencing which development. In comparison to the linear model, a cycle of the innovation process is defined by the obligatory fact that it must repeat itself (Figure 10.1).

Figure 1: Innovation cycle in the medical device industry



Source: Own representation based on Van de Ven, 1999 and Mostardt, Ochs, et al., n.a.

If we consider the previous information about the different subtypes and characteristics, innovation within the medical device industry by digital products can be categorized as follows: The first aspect of innovation arises through digitalization, which represents a divergent technology. Therefore, we see technology-based types of innovation. Second, mainly endogenous innovation can be observed. This is a result of the incentives of the healthcare market and its demand for innovative solutions. Third, digital products represent disruptive innovation. Those products do not only improve but also substitute existing products on the market. All this technology-based, endogenous, and disruptive innovation in the medical device industry happens within a cycle of innovation that creates incremental progress. This means that this new area in the medical device industry is improving through its changes. All these special factors lead to a special demand for regulation of the products created.

This leads us to how innovation is adopted by the users: innovation - digitalization in particular - can hardly be described without diffusion. Diffusion is the process of communicating an innovation through a social system (Rogers, 2003, p. 10). Rogers distinguishes between different types of adopters, according to their innovativeness. This factor determines the rate of adoption of an innovation, i.e. how fast does an innovation establish itself within a system (Rogers, 2003, pp. 22–23). Additionally, innovation must be separated from invention: while innovation means a change in the producing systems of manufacturers, invention describes a shift within the technical opportunities themselves (Brozen, 1951, p. 239). Innovation itself always creates uncertainty, which

depends on the user's possibility to evaluate the risks. Because the risks of medical products can hardly be assessed by the users - according to the principal-agent theory - it is the duty of regulatory procedures to reduce those risks for the patients. The specific aspects of health systems, e.g. the reimbursement system and the number of different actors, influence the diffusion of innovation. In consequence, the economic success of a medical app depends on the rate of diffusion, which in turn benefits from low uncertainty and short regulatory processes. Regulation therefore can have huge impact on diffusion of medical device innovation.

2.3 The mutual impact of regulation and innovation

The governmental approach of implementing regulatory processes in markets represents an interference with the liberal market environment. These actions are mandatory as a result of market failure provoked by asymmetric information as mentioned above (Akerlof, 1970; Samuelson, 1984). Consequently, those diverse conditions have several positive and negative effects on innovation cycles.

On the one hand, different regulatory actions enhance the circumstances for innovation in markets. Regulation can ensure an appropriate level of competitiveness and openness among businesses. This is a main condition to promote innovation in an industry because a certain level of competitiveness sets incentives to achieve a competitive advantage (OECD, n.a., p. 12). Therefore, companies have to reach several requirements which can only be fulfilled by creating product or process innovations (Blind, 2016, p. 3). In contrast to this indirect way of promoting innovation, the straight approach would be realized by handing out intellectual property rights. This form of regulation is explicitly dedicated to enhancing innovation by giving patents to create a monopolistic situation as a reward (Blind, 2016, p. 3).

On the other hand, regulation can lead to massive impediments for innovation. The regulatory burden on the companies requires financial resources and time which could otherwise be invested in innovative approaches. This hits small companies trying to focus on their innovative initiatives especially hard (Stewart, 2011, p. 2). Regulation might also restrict research efforts, the possibility of using different technologies, and the technology diffusion (OECD, n.a., p. 12). Furthermore, competition can be hindered and market entry can be complicated. This leads to a delay in supply or even a cessation of production(Blind, 2016, pp. 8–10). Especially within the medical device industry, the interaction between regulation of and innovation in market entry plays a huge role: how is it possible to ensure patients have access to the newest innovations in a fast way but also make sure that safety is not jeopardized (WHO, 2010, p. 14)?

The relationship between regulation and innovation seems to be one-sided because regulation has huge impact on innovation. Despite this, it can also be mutual and digitali-

zation is a very suitable example. The development of digital products created new sections within many businesses, if not a business itself. Following Rogers (2003), innovation leads to uncertainties about how to treat new products. Consequently, this innovative development encourages the creation of new regulatory mechanisms (Bierbaum and Bierbaum, 2017, p. 249).

3 Regulatory processes as a hurdle for innovation? Data from the U.S. and Germany

3.1 The 'mobile medical device' – an example of innovation

When renowned Harvard professor Clayton M. Christensen stated back in 2000 that healthcare could be "saved" by disruptive innovation, he would not have known that digitalization will maybe make this happen (Christensen et al., 2000). The introduction of digital opportunities created several new but blurry business fields in healthcare, e.g. mobileHealth (mHealth), telehealth and eHealth (Malvey and Slovensky, 2014). Accordingly, the range of digital medical devices is very inconsistent and does not improve with growing technical opportunities (Hudes, 2017, p. 1). For consistency in this work, a common understanding of what is meant with the term "medical device" in the digital spheres should be determined. First, the focus is exclusively on digital products. There is no doubt that innovation in the medical device industry happens in many ways, but digitalization has an outstanding position in the present time. Also, the innovation cycles of digital products differ heavily from physical products, creating several challenges for regulation.
Second, a standard definition of "medical device" should be adopted by the *US Food and Drug Administration* (FDA) and the *Bundesinstitut für Arzneimittel und Medizinprodukte* (BfArM). These institutions are responsible for approval procedures for medical devices in the US and Germany. Accordingly, this essay will focus on the regulatory processes of mobile medical applications and will exclude health applications (programs with only preventive purpose), telemedicine, and any kind of health information systems (BfArM, 2015; FDA, 2017b). The investigated programs are used by patients or professional users. mobile medical apps are software programs running on mobile devices, which fall into the category of medical devices in the US and Germany (BfArM, 2015; FDA, 2017c). This will be further be specified in the following sections.

3.2 Regulatory processes and innovation cycles in the US

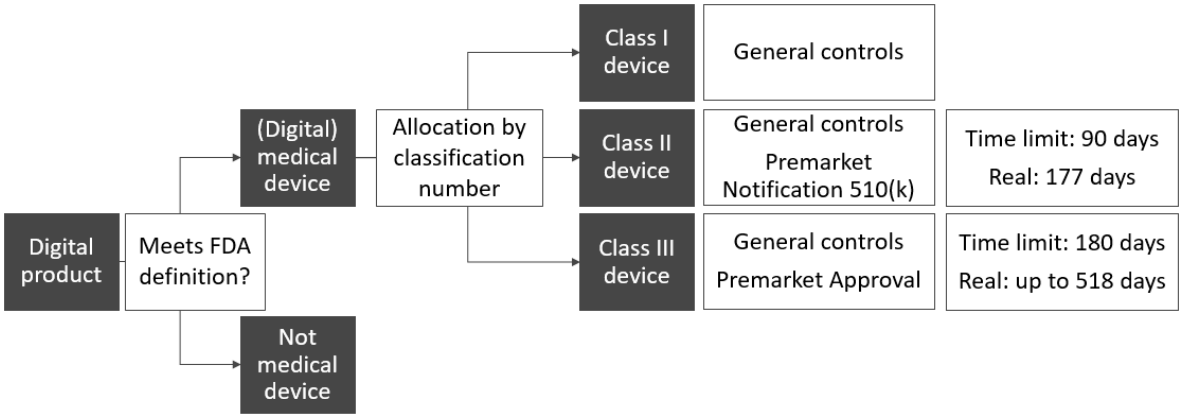
The FDA first published a guideline for mobile medical applications in 2013 and updated this due to dynamic development in 2015. This guideline states that a mobile medical app must fall under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (FDA, 2015, p. 7). This states the app has to be an accessory to a regulated

medical device or has to convert from a mobile platform into a regulated medical device (FDA, 2017c). The section 201(h) also gives a description of which criteria have to be met to be declared as medical device: a medical device has to affect body functions or be involved in "the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease"(FDA, 2015, p. 7). The application of this definition represents the first level of regulation. If the product does not meet this description, there will not be any regulatory process. As soon as the intended use of the digital product meets the definition, the same regulatory processes used for physical medical devices are applied (FDA, 2017c). The process starts with the classification of the mobile medical device into three classes of risk. With a higher risk class, the severity of regulatory requirements increases. The medical device is allocated to one of the risk classes by a classification number, which belongs to the area of application on a human body (FDA, 2014a). No matter which class a medical device is part of, there are general controls like being manufactured under a quality assurance program, fit for the intended use, labeled adequately, and registered as well as listed by the FDA (FDA, 2014b). Class I is the most common for mobile apps and represents devices with low risk for the user which must only fulfill general controls in most cases. Medical devices with moderate risk ranked as Class II must pass a Premarket Notification 510(k) in addition (FDA, 2014a). This process should demonstrate to the FDA that the medical device is safe and effective by comparing it with an already established device on the market. After the 510(k) is found successful by the FDA, the product can be introduced immediately on the condition that there might be inspections at any time by the FDA (FDA, 2016). For high risk devices (Class III), a Premarket Approval is mandatory. This includes scientific, regulatory documentation that demonstrates safety and effectiveness and is often supported by clinical studies (FDA, 2017d). After passing those regulatory processes the mobile medical device can be introduced to the US market (Kramer et al., 2012).

The time-consuming parts within the regulatory process of the FDA are the Premarket Notification 510(k) and the Premarket Approval for risk classes II and III. For the 510(k), the FDA sets itself a time frame of 90 days from the receipt of the 510(k) to come to a decision. If 100 days are exceeded, clarifying communication will take place (FDA, 2017e). In the case of the more strictly handled Premarket Approval for Class III devices, the time frame is extended to 180 days. The FDA confesses that the process may be lengthen if necessary (FDA, 2017d). In practice, the length of both regulatory processes take much longer: an investigation of all 510(k)-processes between 2012 and 2016 shows an average of 177 days in 2016 instead of the proclaimed 90 days (Emergo Group, 2017, p. 5). Not even 20% of all devices are cleared within the proposed timeline (Emergo Group, 2017, p. 7). The same situation can be examined for the Premarket Approval process for class III medical devices. Data varies between 290 and up to 518 days

as average instead of 180 days (AOK-Bundesverband, 2013; Makower et al., 2010; Walter et al., 2016). *Figure 10.2* summarizes the path of a digital product through the regulatory processes of the US.

Figure 2: Regulatory process of a Mobile Medical Device in the US



Meanwhile, innovation in the medical device industry is accelerating and the number of digital products is growing at an annual rate of 25 percent (Cortez et al., 2014, p. 372; FDA, 2017a). A survey under manufacturers carried out, that the most important drivers to gain competitive advantage are product innovation and reduction of time-to-market (PA Consulting, 2016, p. 12). Yet the time-to-market for medical devices takes three to seven years from conception to completing the regulatory processes (Fargen et al., 2013). From the start of communication with the FDA to approval, it takes an average of one to two and a half years (Makower et al., 2010, p. 6; Rising and Moscovitch, 2015). This development provokes reaction from the regulatory institutions. To keep the number of mobile medical applications under control, the FDA sets very strict definitions of what is regulated and which products are not. *Table 10.1* shows a selection of different regulations concerning mobile medical devices. Class III devices were not represented in the given examples of the FDA. A large portion of mobile apps which are per definition a medical device is excluded from regulatory processes because they pose low risk to consumer safety. For these low risk products there is no list with concrete details, only different examples (FDA, 2015, pp. 15–18). The broad exclusion of regulated mobile medical apps suggests an overload of the regulatory capacity. Furthermore, the FDA presents a list of apps which *may* be a medical device (FDA, 2015, pp. 23–26). The FDA also does not make clear how to deal with updates. It is simply stated that "minor, iterative product changes" do not require a re-evaluation of the product (FDA, 2017c). This underlines the uncertainty the institution when handling innovative products.

Table 1: Examples of FDA regulations for Mobile Medical Devices

Device Name	Applicant	Clearance Date	Regulation Description	Risk Class
JiveX	VISUS TECHNOLOGY TRANSFER GMBH	9/16/2016	Picture archiving and communications system	Class II
Lumify Ultrasound System	Philips Healthcare	10/3/2016	Ultrasonic pulsed doppler imaging system	Class II
(If a manufacturer's device falls into a generic category of exempted class I devices as defined, there is no explicit regulation)			(e.g.) Calculator/data processing module for clinical use	Class I

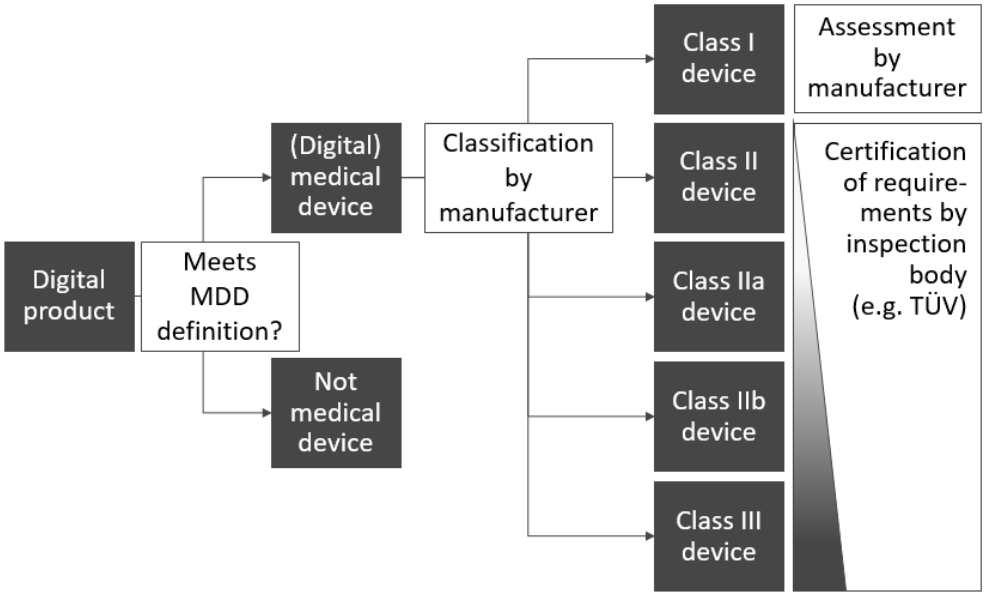
Source: FDA 2015.

3.3 Regulatory processes and innovation cycles in Germany

In Germany, most of the responsibility for defining products as medical devices and regulating market entry is transferred to the European Union. These European laws must be implemented into national law. Therefore, all European regulations are compulsory for the German system.

As in the US, the first aspect for commercial distribution is the definition of the product. The German definition set in the *Medizinproduktegesetz* (MPG) follows the guideline 93/42/EWG of the European Union (also called Medical Device Directive; MDD). The decisive factor for a mobile app being declared as medical device is – similar to the FDA – the intended use. If the device should be used for diagnosis, prevention, supervision, or cure of sickness or injury, to change a physiological process, or for contraception the MDD is applied. Comparable to the FDA, a risk classification for these medical devices is used. Applications are separated into Class I with low risk (with Is for sterile and Im for measuring), Classes IIa and IIb are for middle and increased risk products, respectively, and Class III is for high risk devices. *Figure 10.3* represents the process in Germany. The classification is regulated under the MDD, which defines 18 rules regarding health risks (BfArM, 2015). According to these rules, most mobile medical devices are ranked Class I and sometimes IIa or IIb (BfArM, 2015; Bierbaum and Bierbaum, 2017, p. 255). The MDD further classifies mobile medical devices as *active medical devices* which are dependent on an external power source and often ranked within higher risk classes (BfArM, 2015). If medical apps are changed or expanded by updates, there is no clear way to deal with the change. In cases of a tremendous impact on users health, the responsible authority has to be informed (*Richtlinie 93/42/EWG des Rates.* Europäisches Parlament und Rat, 1993).

Figure 3: Regulatory process of a Mobile Medical Device in Germany



The aim of the regulatory process is the CE-sign, which shows the safety and effectiveness and also allows medical devices to be distributed within the European Single Market. Depending on the risk classification, the product must pass different assessments. Class I devices can be assessed by the manufacturer themselves and no inspection body is needed (e.g. TÜV; *Technischer Überwachungsverein*). For all other classes, an inspection body must be involved and a declaration of conformity must be provided (BfArM, 2015). The declaration of conformity depends on the risk classification and is determined by the regulations of the European Union. The requirements of approval procedures rise to correspond with higher risk classes. These can include risk management, technical documentation up to clinical studies, and cost-benefit-analysis within the MDD (BMG, 2010). In contrast to the US, where the state-owned FDA does the assessment by 510(k) or Premarket Approval, the risk classification and the declaration of conformity is done by the manufacturer itself. Just the certification is performed by a chosen inspection body according to appendix I of the MDD (BMG, 2010). Germany is in a decentralized and less arranged setting compared to the more centralized and transparent one in the US (Kramer et al., 2012, pp. 850–851).

As in the US, the regulatory processes play the leading role on the way to the market. In contrast, the time-to-market is reduced due to decentralized regulation: empirical data shows that the CE-certificate is assigned 36 months earlier in Germany than in the US for devices with Premarket Approval (Hwang et al., 2016, p. 4).Yet, the whole process is still estimated to be between four to six years (Neumann et al., 2016, p. 50). In both countries, the approval for low- and moderate-risk devices seems quite similar, where most mobile medical apps are concerned (Kramer et al., 2012, p. 852). Nevertheless, with a maximum release cycle of less than one year (in comparison to more than three

years for normal medical devices), time-to-market increases and represents a loss of potential due to regulatory processes for innovative digital products (Knöpple et al., 2016, p. 13).

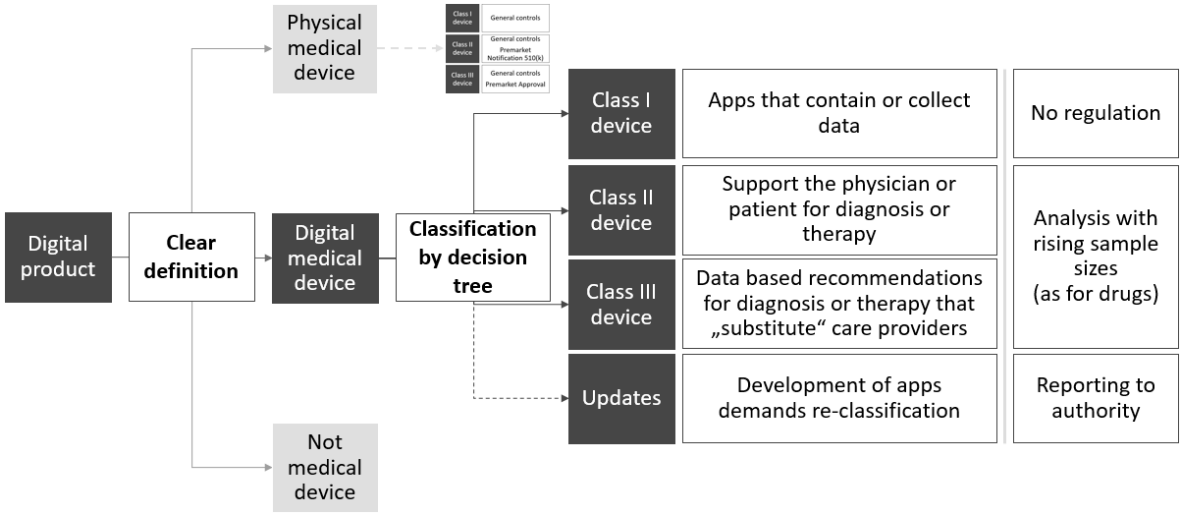
4 Possibilities for a harmonious interaction between regulation and innovation in healthcare

After looking at American and German medical device regulation, both have commonalties and differences. The risk classification systems are obligatory and seem to be quite similar, while the degree of centralization as well was the length of regulatory processes differs (Kramer et al., 2012, p. 850) Theory also provides a necessary component of economic and social regulation to maintain fair market conditions and secure population health. Yet this has partly negative effects on innovation and diffusion of innovation due to long regulatory processes. Since innovation cycles are much shorter for mobile medical apps, the application of the same regulatory processes as for physical devices seems questionable. Regarding the huge number of medical apps, a separate regulatory process would be more appropriate. For a better alignment, such a process is fictively proposed hereinafter:

For manufacturers of mobile medical apps, it is important to get a fast and comprehensive overview of the regulatory requirements. Therefore, a clear definition of a digital medical product must be found. The confusing mixture of terms like eHealth, mHealth, etc. prohibits a clear understanding and impedes the dialogue. The definition should be determined by concrete criteria and not the intended use or blurry examples. After an adequate definition and separation from apps with just preventive character, a classification must take place. The used risk classifications seem to be proven, but the results are biased due to the mixture with normal medical devices. A system tailored for digital products is necessary because the risks of digital products can hardly be compared to risks of physical devices. Lewis & Wyatt (2014) e.g. separate between inherent (those within an app) and contextual risks (which occur through use). A three-stage classification may maintain: Class I includes apps that contain or collect data. Within class II are apps that give support to the doctor or patient for diagnosis or therapy based on data. Class III would contain apps with data based recommendations for diagnosis or therapy that "substitute" care providers (Knöpple et al., 2016, pp. 22–25; Neumann et al., 2016, p. 25). This classification may be executed by a decision tree or similar tool. Of decisive importance is the consideration of updates. The development of digital products often happens through an iterative process and in cooperation with the final user. Furthermore, algorithms may be used, which evolve with increasing application (Neumann et al., 2016, pp. 32–35). This must be considered within the regulatory process and demands a reporting system. This hypothetical regulatory process is depicted in *figure 10.4*.

No approval procedure should be prescribed for class I devices because these would not intervene in treatment. For classes II and III, a procedure similar to that used for drugs can be conceivable: due to the iterative development process of apps, it may be tested step-by-step by raising sample sizes until a market maturity can be attested to (Neumann et al., 2016, pp. 32–35). This process may also lead to an upgrade in risk classes for medical apps. Accordingly, updates must be reported to the competent authority within a post-market surveillance system. If this authority should be centralized or decentralized is hard to answer. Since a decentralized system can accomplish regulatory processes obviously faster, it seems to be more suitable for medical apps to enable an appropriate chance for diffusion (for further inspiration how regulatory processes might be adopted to medical apps see Boulos et al., 2014; Lewis and Wyatt, 2014; Neumann et al., 2016).

Figure 4: Hypothetical regulatory process for Mobile Medical Devices



It remains unclear how such a risk classification system is appropriate for learning algorithms and how to evaluate the storing of personal data. As such, this example of an autonomous regulation for medical apps might go too far for now, but it may give ideas for future improvements to regulatory processes.

5 Conclusion

Innovation in healthcare calls for changes in the rigid systems of the US, Germany, and many other countries. The barriers to creating medical devices decline due to the opportunities presented by digitalization. Strongly altered structures are the consequence and governments must adapt their regulatory processes. Internationally changes are occurring: The European Parliament approved a new Medical Device Regulation in April 2017 with a transitional period of three years. Therein, medical apps earn greater importance, but the regulatory processes will not be simplified, quite the contrary. The old classification system remains but new wording ranks software risks often higher than

before, which leads to longer regulatory processes. This means much more burden on most, often young, innovative companies, which might fail due to this regulation. Instead, a regulatory system that encourages innovative products by enabling an adequate speed of the process would be a better way to promote and enable innovation in the medical device industry.

References

Akerlof, G. A. (1970), 'The Market for "Lemons": Quality Uncertainty and the Market Mechanism', *The Quarterly Journal of Economics*, vol. 84, no. 3, p. 488.

Albrecht, U.-V. and Jan, U. (2016), 'Kapitel 1. Einführung und Begriffsbestimmungen', in Albrecht, U.-V. (ed.) *Chancen und Risiken von Gesundheits-Apps (CHARISMHA)*, pp. 48–61.

AOK-Bundesverband (2013), *Medizinprodukte - Mythen und Wahrheit*, AOK-Bundesverband [Online]. Available at: http://aok-bv.de/imperia/md/aokbv/politik/versicherte/thesenpapier_gross_0713_dt.pdf (Accessed May 02, 2017).

Baregheh, A., Rowley, J. and Sambrook, S. (2009), 'Towards a Multidisciplinary Definition of Innovation', *Management Decision*, vol. 47, no. 8, pp. 1323–1339.

Baron, D. P. (1989), 'Chapter 24 Design of Regulatory Mechanisms and Institutions', in Schmalensee, R. and Willing, R. (eds.) *Handbook of Industrial Organization*, 2nd edn, Amsterdam, Elsevier, pp. 1347–1447.

BfArM (2015), *Orientierungshilfe Medical Apps*, BfArM [Online]. Available at: http://www.bfarm.de/DE/Medizinprodukte/Abgrenzung/medical_apps/_node.html (Accessed April 23, 2017).

Bierbaum, M. and Bierbaum, M. E. (2017), 'Medical Apps im Kontext von Zulassung und Erstattung', in Pfannstiel, M. A., Da-Cruz, P. and Mehlich, H. (eds.) *Digitale Transformation von Dienstleistungen im Gesundheitswesen I*, Wiesbaden, Springer Fachmedien Wiesbaden, pp. 249–263.

Blind, K. (2016), 'The Impact of Regulation on Innovation', in Edler, J., Cunningham, P., Gök, A. and Shapira, P. (eds.) *Handbook of Innovation Policy Impact*, Cheltenham, UK, Northampton, MA, USA, Edward Elgar Publishing, pp. 450–482.

BMG (2010), *Medizinprodukterecht im Überblick*, Bundesministerium für Gesundheit [Online]. Available at: https://www.bundesgesundheitsministerium.de/fileadmin/redaktion/pdf_allgemein/Medizin_Produkte_Marktzugangsvoraussetzungen_fuer_Medizinprodukte.pdf (Accessed May 01, 2017).

Boulos, M. N. K., Brewer, A. C., Karimkhani, C., Buller, D. B. and Dellavalle, R. P. (2014), 'Mobile Medical and Health Apps: State of the Art, Concerns, Regulatory Control and Certification', *Online Journal of Public Health Informatics*, vol. 5, no. 3, p. 229.

Brozen, Y. (1951), 'Invention, Innovation, and Imitation', *The American Economic Review*, vol. 41, no. 2, pp. 239–257.

Cheng, M. (2003), *Medical Device Regulations: Global Overview and Guiding Principles*, Geneva, World Health Organization.

Christensen, C. M., Bohmer, R. and Kenagy, J. (2000), 'Will Disruptive Innovations Cure Health Care?', *Harvard Business Review,* vol. 78, no. 5, pp. 102-112.

Cortez, N. G., Cohen, I. G. and Kesselheim, A. S. (2014), 'FDA Regulation of Mobile Health Technologies', *The New England Journal of Medicine,* vol. 371, no. 4, pp. 372–379.

Emergo Group (2017), *How Long it Takes the US FDA to Clear Medical Devices via the 510(k) Process: An Examination of 15,000 Medical Device Applications Cleared by the US Food and Drug Administration between 2012 and 2016,* Emergo Group [Online]. Available at: https://www.emergogroup.com/sites/default/files/emergo-fda-510k-data-analysis-2017.pdf (Accessed April 29, 2017).

Europäisches Parlament und Rat (1993), *Richtlinie 93/42/EWG des Rates*.

Fargen, K., Frei, D., Fiorella, D., McDougall, C., Myers, P. and Hirsch, J. (2013), 'The FDA Approval Process for Medical Devices: An Inherently Flawed System or a Valuable Pathway for Innovation?', *Journal of Neurointerventional Surgery,* vol. 5, no. 4, pp. 269–275.

FDA (2014), *Classify Your Medical Device* [Online], U.S. Food and Drug Administration. Available at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm (Accessed April 24, 2017).

FDA (2014), *Classify Your Medical Device - Class I / II Exemptions* [Online], U.S. Food and Drug Administration. Available at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051549.htm (Accessed April 29, 2017).

FDA (2015), *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff,* U.S. Food and Drug Administration [Online]. Available at: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf (Accessed April 23, 2017).

FDA (2016), *Premarket Notification 510(k)* [Online], U.S. Food and Drug Administration. Available at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm (Accessed April 29, 2017).

FDA (2017), *Consumer Updates: Keeping Up with Progress in Mobile Medical Apps* [Online], U.S. Food and Drug Administration. Available at: https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm368634.htm (Accessed April 30, 2017).

FDA (2017), *Digital Health* [Online], U.S. Food and Drug Administration. Available at: https://www.fda.gov/MedicalDevices/DigitalHealth/default.htm (Accessed April 23, 2017).

FDA (2017), *Mobile Medical Applications* [Online], U.S. Food and Drug Administration. Available at: https://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm255978.htm (Accessed April 23, 2017).

FDA (2017), *Premarket Approval (PMA)* [Online], U.S. Food and Drug Administration. Available at: https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketapprovalpma/default.htm (Accessed April 29, 2017).

FDA (2017), *Premarket Notification (510k) - 510(k) Submission Process* [Online], U.S. Food and Drug Administration. Available at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm (Accessed April 29, 2017).

Holmstrom, B. (1979), 'Moral Hazard and Observability', *Bell Journal of Economics*, vol. 10, no. 1, pp. 74–91 [Online]. Available at: http://econpapers.repec.org/RePEc:rje:bellje:v:10:y:1979:i:spring:p:74-91 (Accessed October 03, 2017).

Hudes, M. K. (2017), 'Fostering Innovation in Digital Health a New Ecosystem', in *Microelectronics Symposium (Pan Pacific)*, pp. 1–6.

Hwang, T. J., Sokolov, E., Franklin, J. M. and Kesselheim, A. S. (2016), 'Comparison of Rates of Safety Issues and Reporting of Trial Outcomes for Medical Devices Approved in the European Union and United States: Cohort study', *BMJ (Clinical Research Ed.)*, vol. 353, no. 3323.

Knöpple, K., Oschmann, L., Neumann, J. and Neisecke, T. (2016), *Transfer von Digital-Health-Anwendungen in den Versorgungsalltag: Teil 1: Transfermodell, Varianten und Hürden*, Bertelsmann Stiftung.

Kramer, D. B., Xu, S. and Kesselheim, A. S. (2012), 'Regulation of Medical Devices in the United States and European Union', *The New England Journal of Medicine*, vol. 366, no. 9, pp. 848–855.

Lewis, T. L. and Wyatt, J. C. (2014), 'mHealth and Mobile Medical Apps: A Framework to Assess Risk and Promote Safer Use', *Journal of Medical Internet Research*, vol. 16, no. 9.

Makower, J., Meer, A. and Denend, L. (2010), *FDA Impact on U.S. Medical Technology Innovation: A Survey of Over 200 Medical Technology Companies*, MedTech Europe [Online]. Available at: http://www.medtecheurope.org/sites/default/files/resource_items/files/01112010_FDA%20impact%20on%20US%20medical%20technology%20innovation_Backgrounder.pdf (Accessed May 02, 2017).

Malvey, D. and Slovensky, D. J. (2014), *mHealth: Transforming Healthcare* [Online], Boston, MA, s.l., Springer US. Available at: http://dx.doi.org/10.1007/978-1-4899-7457-0 (Accessed October 03, 2017).

Neumann, K., Larisch, K., Dietzel, J., Kurepkat, M., Weißer, M. and Wenzlau, V. (2016), *Digitale Versorgungsprodukte: Chancen nutzen, sichere Wege in den Markt schaffen*, IGES Institut.

OECD (n.d.), *Regulatory Reform and Innovation*, OECD [Online]. Available at: https://www.oecd.org/sti/inno/2102514.pdf (Accessed April 17, 2017).

PA Consulting (2016), *Gaining Competitive Advantage in Medical Devices: How to Optimise Time- and Cost-to-Market in Product Development*, PA Consulting [Online]. Available at: http://www2.paconsulting.com/rs/526-HZE-833/images/Gaining%20competitive%20advantage%20in%20medical%20devices.pdf (Accessed April 30, 2017).

Porter, M. E. (1990), *The Competitive Advantage of Nations: With a New Introduction*, New York, N.Y., Free Press.

Rising, J. P. and Moscovitch, B. (2015), 'Characteristics of Pivotal Trials and FDA Review of Innovative Devices', *PloS One*, vol. 10, no. 2.

Rogers, E. M. (2003), *Diffusion of Innovations*, 5th edn, New York, u.a., Free Press.

Roh, C.-Y. and Kim, S. (2017), 'Medical Innovation and Social Externality', *Journal of Open Innovation: Technology, Market, and Complexity*, vol. 3, no. 1, p. 386.

Samuelson, W. F. (1984), 'Bargaining under Asymmetric Information', *Econometrica*, vol. 52, no. 4, p. 995.

Sengupta, J. (2014), *Theory of Innovation*, Cham, Springer International Publishing.

Sorenson, C., Drummond, M. and Bhuiyan Khan, B. (2013), 'Medical Technology as a Key Driver of Rising Health: Disentangling the Relationship', *ClinicoEconomics and Outcomes Research : CEOR*, vol. 5, pp. 223–234.

Stewart, L. A. (2011), *The Impact of Regulation on Innovation in the United States: A Cross-Industry Literature Review*, Information Technology & Innovation Foundation.

van de Ven, A. H. (1999), *The Innovation Journey* [Online], New York, N.Y., Oxford Univ. Press. Available at: http://www.loc.gov/catdir/enhancements/fy0604/99012927-d.html (Accessed October 03, 2017).

Walter, J. R., Hayman, E., Tsai, S., Ghobadi, C. W. and Xu, S. (2016), 'Medical Device Approvals through the Premarket Approval Pathway in Obstetrics and Gynecology: Process and Problems from 2000 to 2015', *Obstetrics and Gynecology*, vol. 127, no. 6, pp. 1110–1117.

WHO (2010), *Barriers to Innovation in the Field of Medical Devices: Background Paper 6*, WHO [Online]. Available at: http://apps.who.int/iris/bitstream/10665/70457/1/WHO_HSS_EHT_DIM_10.6_eng.pdf (Accessed April 30, 2017).

Zweifel, P. and Manning, W. G. (2000), 'Chapter 8 Moral Hazard and Consumer Incentives in Health Care', in Culyer, A. J. and Newhouse, J. P. (eds.) *Handbook of Health Economics,* Elsevier, pp. 409–459.

Part 4: Innovation in Digital Health

The Role of Digital Health Care Startups

Florian Rinsche

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

Contents

1 Introduction

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

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

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

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

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

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

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

2 Digital Transformation in Health Care

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

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

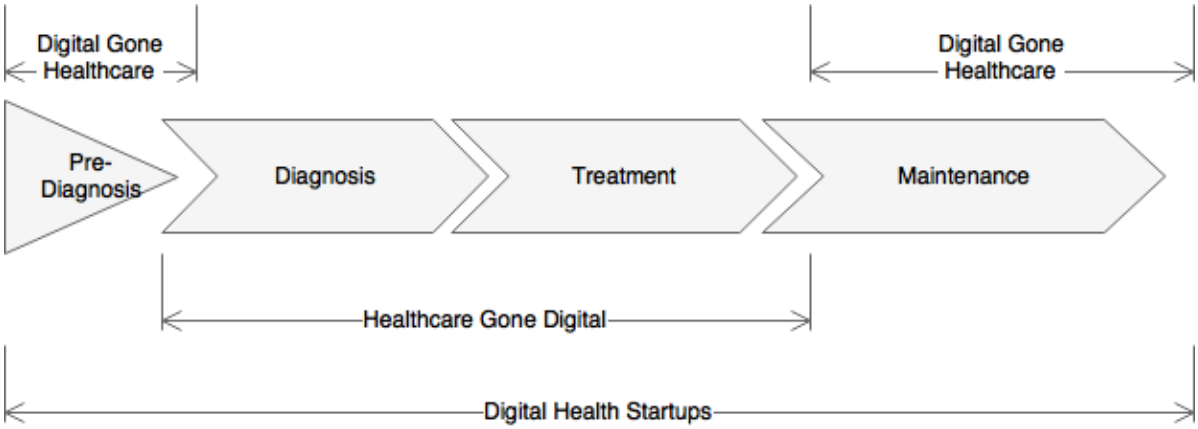
While the term "startup company" was relatively easy to define, the term "digitization" or "digital transformation" is not as easy. Digitization can be understood most simply as the conversion or convergence of analogue products, services, processes, and business models to a digital environment. A Study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

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

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

digital transformation is the startups that seek to solve problems with a new digital business model independent of huge companies.
Whereas most of the "Digital Gone Healthcare" Companies focus on business-to-consumer (B2C) business models, the "Healthcare Gone Digital" Companies have a stronger focus on the business-to-business (B2B) sector. The startups, however, are not limited to either model. Figure 11.1 shows the typical points of contact for each of the three sources of the digital transformation in healthcare.

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



In comparison to other industries, experts attest to a lower level of digitization in healthcare systems. Especially within the media, finance, and communication industries, the digital transformation has happened very quickly.
In the future, digital applications in healthcare will become more important. The growing demand for healthcare services will be a major driver of digital health all over the world, especially in ageing societies like Germany. It is expected that by 2060 more than one third of the entire population of Germany will be 65 years or older. The demand for healthcare services is expected to rise due to the increased proportion of elderly people (Statistisches Bundesamt, 2015). The number of care dependents is estimated to be around 3.25 to 4 million people till 2060.
The ageing population of Germany is expected to have a positive effect on the adoption of digitization within the healthcare system. While providers are slowly adopting digitization, most Germans are open to modern technologies. More and more elderly people are increasingly accustomed to using digital products in everyday life, so they want to use it for healthcare issues as well. The prevalent myth about digital healthcare was that only younger generations are receptive to it, and thus, digitized healthcare systems would not reach the core stakeholders of the health system. However, patients from all age groups are more than willing to use digital healthcare services and the number continues to grow.

3 Digital Health Startups in Germany and the US

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

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

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

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

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

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

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

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

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

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

4 Future Trends of Digital Health

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

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

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

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

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

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

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

5 Concluding Remarks

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

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

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

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

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

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

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

In conclusion, to achieve digitization of healthcare and improve care in the US and Germany, regulations must be changed to promote innovation from digital healthcare startups and other companies taking steps to digitize the health system.

References

Bauer, M. (2017), Das sind die Top 3 Trends der Health-Startup-Branche [Online]. Available at: http://healthcare-startups.de/das-sind-die-top-3-trends-der-health-startup-branche/ (Accessed December 05, 2017).

Bertelsmann Stiftung (2016), Digital-Health-Anwendungen für Bürger: Kontext, Typologie und Relevanz aus Public-Health-Perspektive, Bertelsmann Stiftung.

Berwick, D. M., Nolan, T. W. and Whittington, J. (2008), 'The Triple Aim: Care, Health, and Cost', Health Affairs, vol. 27, no. 3, pp. 759–769.

Centers of Disease Control and Prevention (2016), Chronic Disease Overview [Online], Centers of Disease Control and Prevention. Available at: https://www.cdc.gov/chronicdisease/overview/ (Accessed January 06, 2017).

Digital Charter (2016), Charter of Digital Fundamental Rights of the European Union, Digital Charter [Online]. Available at: https://digitalcharta.eu/wp-content/uploads/2016/12/Digital-Charta-EN.pdf (Accessed October 03, 2017).

Elton, J. and O'Riordan, A. (2016), Healthcare Disrupted: Next Generation Business Models and Strategies, Hoboken, Wiley.

Jordan, J. F. (2015), Innovation, Commercialization, and Start-Ups in Life Sciences, Boca Raton, CRC Press.

Lindekamp, C. and Lücker, L. (2014), 'MySugr: Das Diabetes-Monster zähmen', Handelsblatt, 2014 [Online]. Available at: https://docs.google.com/document/d/1v0fJrpTIryJ-cRpfYCZJ7F-r3xIue3-f_N9z1djppQY/edit?usp=drive_web (Accessed February 05, 2017).

Robehmed, N. (2013), What is a Startup?, Forbes [Online]. Available at: https://www.forbes.com/sites/natalierobehmed/2013/12/16/what-is-a-startup/ (Accessed February 05, 2017).

Statistisches Bundesamt (2015), 13. koordinierte Bevölkerungsvorausberechnung: Variante 1 bei schwächerer Zuwanderung, Statistisches Bundesamt Wiesbaden.

Stoakes, U. (2016), Where the Money is Flowing in Digital Health - Q1 2016, Forbes [Online]. Available at: https://www.forbes.com/sites/unitystoakes/2016/04/03/where-the-money-is-flowing-in-digital-health-q1-2016/ (Accessed January 06, 2017).

Westermann, F. (2017), A Mindset Shift is Needed for Europe to Become a Champion of Health Innovation, Digital Health VC [Online]. Available at: http://digitalhealthvc.com/mindset-shift-needed-europe-become-champion-health-innovation/ (Accessed January 06, 2017).

White&Case (n.d.), The Cutting Edge: Shaping the Future of Digital Healthcare.

The Big Deal with Big Data: Innovations and Perspectives for the United States

Marianthi N Hatzigeorgiou

As healthcare continues to see both vertical and horizontal system integration, systems struggle to handle large aggregates of patient data. Big Data has aided in reducing costs and increasing profits, in understanding patient risk stratification, and helping to determine appropriate interventions. More recently, widespread dissatisfaction with overall healthcare costs and suboptimal quality has led to healthcare leaders searching for new strategies to improve. Big Data not only affords physicians an epidemiological insight necessary to implement widespread change, but also uses retrospective insight, pattern recognition, and predictive power to offer direct and indirect interventions, often coupled with devices or preexisting interventions. Despite some challenges in addressing patient privacy, the paradigm shift from singularly managed patients and data to Big Data systems is underway. Big Data methodologies construe the provider as an agent within a larger community or population organism, one that must adapt and change to suit the needs of those it serves. It allows for the provision of better care, in terms of the care itself provided and the logic of its distribution. In the right hands, if Big Data is the face of healthcare's future, it will be a humanitarian one.

Contents

Siemens Healthineers provided valuable financial support to make this project happen. Furthermore, Marianthi N Hatzigeorgiou, a masters of health services administration candidate from the University of Michigan, Ann Arbor, USA, had the opportunity to intern at Siemens Healthineers working on concepts for strategy consulting projects in the Healthcare Consulting and Transformation Services team.

1 Big Data: From ‘Me’ to ‘We’

As healthcare expenditures in the United States continue to rise to levels well above the national inflation rate, there is a continued interest and obligation to shift towards strategies and innovations that contain costs and further improve quality and outcomes. Though the United States spends almost twice the OECD average on healthcare spending (in USD per capita), national quality and outcome benchmarks continue to place well below those of less developed countries. For a country that often fashions itself as a world-best provider of healthcare, the growing chasm between healthcare expenditures and outcomes has led to the prioritization of reforms and new initiatives aimed at mitigating this discrepancy. As medical record keeping and documentation moves towards electronic platforms, large datasets are available for computational analysis, often revealing patterns, trends, and associations on the individual and group level. In recent years, ‘Big Data’ has been a trending topic for many in the healthcare industry, allowing systems to utilize technological advances and opportunities in the hopes of providing better care, while lowering costs in the process.

The consideration of Big Data in studying population health only began about 200 years ago (Siemens Healthineers, 2015). In tracking the cholera epidemic throughout London, John Snow’s map helped to dispel the miasma theory and locate the source of the outbreak. In in the brief span of time thereafter, there has been much improvement in trending and forecasting, largely due to technology. The application of epidemiological purposes has gradually undergone a paradigm shift from individual tracking to tracking for population health benefits, resulting in technologies and device adaptation to allow for both of these activities during data collection. From a financial perspective, Big Data has allowed systems to identify opportunities to improve profits and reduce overhead (Bresnick, 2017). Electronic Medical Records (EMRs), for example, have allowed physicians and health systems to collect large quantities of data and patient information, which can then be used for risk stratification, to forecast patient trends, and to identify possible interventions.

Considering both perspectives, Big Data has fostered an innovative methodology for systems: data gleaned from the individual are used to attain better understanding of the overall population -- and vice versa. On the one hand, Big Data is often used in the service of heavily-personalized medical care pathways as part of a strategy to help guide patient care throughout a patient’s care encounter; said strategies fall under the umbrella of what is commonly deemed 'population health management'. On the other, aggregated data is used to study disease trends for populations and to tailor community-based interventions and strategies, which may then contribute to improved population health through decreases in patient morbidity and mortality. Furthermore, countries with aging populations can use data to try and find far-reaching solutions to manage patients with

high disease burden and chronic care issues (Bresnick, 2017). But with such widespread opportunities for health improvement come manifold challenges in the spheres of implementation and regulation, especially as pertaining to patient privacy.

2 Transition to Big Data: Why Now?

Widespread public dissatisfaction with overall health care costs and soaring premiums has led to wide-spread dissatisfaction with current reimbursement schemas. The shift from fee-for-service (FFS) models to value-based models of care has resulted in new ways to quantify success in disease management at both the individual and system level, contain costs, and enable equal access to and quality of care. This shift, initiated by the Affordable Care Act (ACA), also precipitated a shift in reimbursement methodologies toward an emphasis on patient outcomes, which in turn has resulted in many systems embracing and accepting Big Data as part of their fabric and foundation (McDonald, 2017). Value-based reimbursement schemas, such as that targeting a reduction in 30-day hospital readmissions, have necessitated systems to manage large swaths of patient data, to find trends and opportunities for improvement (Koufi, Malamateniou and Vassilacopoulos, 2015)(OFIs). Better understanding of upstream social and clinical contributors to hospital readmission allows physicians and hospital administrators to increase communication and coordination through the system; with multiple departments working on the same patient and tracking the same information, better care is expected to result from increased diligence towards patient communication, compliance, and oversight (Groves et al., 2013).

Bundled payment programs offer another point of intervention for Big Data. Though recent administrations have further delayed widespread implementation of this cost containment strategy, most systems have implemented bundled payments in cardiology and orthopedics that help track outcomes and costs through the entire episode of patient care. Concurrent with bundled payments, multiple interventions, physicians, and services are tracked and tied to quality and improvement, offering further opportunities to improve care usage data. However, manipulation of datasets requires additional expertise and education, and an efficient data analytics/ information technology (IT) team remains key to ensuring that new payment systems are able to be implemented successfully (McDonald, 2017).

Though Big Data is far from a new phenomenon for companies and strategists, the healthcare industry represents a large opportunity for its integration and application. Patient management and patient-centric approaches have been part of the evolutionary trends that healthcare in the United States has recently experienced, and the efficacy of these approaches stands to increase from the simultaneous adoption of Big Data strategy. The shift toward evidence-based medicine has caused physicians to tailor approaches

and interventions based on scientifically-verified results that have shown a special degree of promise among patient populations (Bresnick, 2017). Big Data has allowed evidence-based medicine to be collected at a systemic (and additionally, a national) level. As systems collect vast amounts of patient information, data may be easily manipulated by algorithms to identify trends, successful interventions, and cross-check strategies with additional comorbidities. For physicians practicing in regions of the country that experience high disease-burden with multiple chronic conditions (ex., rural expanses, many CEAC-classified counties, the Deep South), such trending allows them to track large groups of patients and see how different interventions influence results and quality (Wood, 2017).

The overutilization of costly technologies and procedures can drive up hospital and system spending. Global clinical decision support system markets are expected to rapidly rise in the coming years to help address this and other clinical inefficiencies. Such support systems can aid physicians during triaging, diagnosing, and treatment, which would further reduce costs and overutilization of the system. Per reporting by MarketsandMarkets, these global support systems are estimated to surpass $550 million by 2018, at a compound annual growth rate close to 10% between 2013 and 2018 (Siemens Healthineers, 2015). The United States is the foremost user of such systems to date, with over 3500 petabytes of stored data within these. Europe follows with about 2500 petabytes, and then -- a distant third -- Japan with 400 petabytes. As countries continue to shift to EMRs and computerized systems with greater integrative potential, Big Data will be more available to them, leading to expected increases in petabytes stored. Reducing costs is hypothesized as the main driver of this increased uptake, though improved quality and care outcomes, aging populations, and rising disease incidence also play important roles in the uptake.

3 Current Uses of Big Data in Device Sector

The increased utilization of medical apps and smartphone technology has presented a new opportunity for patient tracking and Big Data management. In 2016, mobile health raised $1.3 billion between 622 completed deals, constituting the largest component of total healthcare IT virtual care (VC) funding (Mukherjee, 2017). Increased utilization of smartphones in emerging markets solidifies their place in future markets. Public sentiment is arguably in line with the data: some research has even indicated that over two-thirds of Americans have shown favor for digital health over physical (Elias, 2015). As wireless technology plays an ever-larger role in the day-to-day lifestyle of a working American (i.e., forty-hour workweeks, heavy childcare and supplemental domestic work burdens), prioritizing convenience and ease-of-access will lead more systems to focus on tech-based platforms for patient interactions. Health smartphone apps currently have

the highest number of downloads of any category of application (Elias, 2015). Consumerization will further drive physicians to adapt a new, tech-friendly practice, at risk of network leakage to other practices and physicians should they fail to adapt. Regardless, this technological integration of medical information into the hands of patients and consumers will only continue to drive innovation. A concurrent trend is unfolding in wearable devices; serving as a bellwether for this new trend, FDA Commissioner Scott Gottlieb has recently written of a 'Digital Health Innovation Plan' that would allow third-parties to easily and rapidly certify new products that are not as 'high risk' as devices (Gottlieb, 2017). It would be expected that Big Data and patient tracking/monitoring apps (Fitbit, etc.) will continue to expand offerings on the market (Ventola, 2014).

As a physician's tools for diagnosis shift from stethoscope to smartphone, and the doctor's office waiting room shifts to the patient's living room, other non-patient facing areas of medicine are also utilizing virtual platforms. One promising current technology, teleradiology, allows for the storage and transmission of radiological images. This Big Data trend comes as a way to ease the access issues radiologists and other physicians experience when trying to compare images, interpret images, and use images as part of evidence-based medicine. Picture Archiving and Communication systems (PACS) is just one example of an IT system used currently (Benjamin, Aradi and Shreiber, 2010). Teleradiology and PACS allow for improved clinical results (final reports that contain useful information) and business results (in scenarios of improved speed of result turnover, patient care, etc.). SuperPACS—a system that allows radiology group serving multiple sites having disparate PACS, research information systems (RIS), and reporting platforms, to view these sites as virtually one site and use one desktop (Benjamin, Aradi and Shreiber, 2010)—help improve global functionality of the radiological sector. Minimizing the burden on local sites and increasing the global nature of the images and information helps to standardize the practice and better identify workflow issues and opportunities for improvement. Additionally, implementation of such systems allows for global access for all referring physicians. Using SuperPACS portals, physicians are able to access information and have a central location and folder for their patients. This sort of communications technology has been reported to be cost efficient, increases remote access to data, and is a logical solution to manage multiple files across multiple locations as the United States continues to see mergers and acquisitions throughout the healthcare and hospital industry (Groves et al., 2013). Unlike other technologies and innovations in radiology, this particular example and application places radiologists as some of the main stakeholders in application, increasing buy-in.

4 Further Reforms and Opportunities in Big Data

Applications and use cases or opens up the potential for interventions and opportunities. The ability to aggregate patient data has been present since the introduction of EMRs,

though the brunt of the healthcare industry's capacity to analyze and manipulate these data has only come into play the past couple of decades. As technologies continue to improve and the capability of Big Data extraction expands, healthcare will see furthered developments involving Big Data and healthcare IT. A McKinsey analysis listed four categories that most, if not all, healthcare-related Big Data encompasses (Kayyali, Knott and Van Kuiken, 2013). As healthcare IT continues to expand, and technology increases consumerization, we may expect to see further varieties of Big Data.

4.1 Retrospective Insight

Prior to more recent years, initial applications of Big Data have focused on retrospective insight via retrospective data analysis. Applications and technologies were equipped to take large sums of data and analyze them for researchers. Previously -- and, by most, currently -- patient safety was studied in retrospect: clinical events were identified after being flagged for issues, and then analyzed to identify opportunities for improvement (Weinger et al., 2003)(OFIs). Reducing medical errors and safety concerns is a common goal of systems, and ties into many reimbursement schemas. Big Data, when applied retrospectively, is simply one of the parts to the pathway to reduce medical errors. Data must be extracted from flagged patient files and stratified to identify breakdown and issues in the workflow. Usually in-house committees study these and find common flaws that can be disseminated to medical staff in an effort to reduce future instances of workflow breakdown. While this approach has been the common norm for most system structures and data reporting, real-time monitoring and flagging of misuse or issues would likely increase safety and quality outcomes in healthcare systems.

4.2 Predictive Power

Pattern recognition artificial intelligence has been proposed as one of the more promising innovations for the future of radiology. Though this does not require radiologist stakeholders, the technology could vastly improve the efficiency and accuracy of imaging. However, research is varied and inconclusive at this stage. The issue of contention is that, though pattern recognition can provide great promise, it requires a pseudo-customization that makes it difficult to implement quickly across systems. In a study (Woo and Kim, 2017), utilization and application of US, CT, MRI technologies was shown to have led to an increase in the frequency of small renal masses being detected. This results in more renal cell carcinoma and benign tumor diagnosis, but no one pattern was found to be sufficient; rather, multiple imaging patterns should have been considered in tandem to then begin to narrow down remarkable images and possibly note malignancy. Should several imaging patterns be integrated and an algorithm created, then there could be a potential for widespread use of pattern recognition, hopefully leading in turn to faster image interpretation with less error. Though initial investments in technology

would be quite costly, the return on investment would be more than enough to recoup startup costs, as systems could reduce the amount of budget allocated to overhead costs (specifically: personnel) in the department. Currently, Houston Methodist Hospital employs AI technology that interprets breast x-rays 30 times faster than physicians, and which diagnoses with 99% accuracy (Patel et al., 2017). Though there is a fear that current pattern recognition and the incorporation of AI will eradicate jobs among radiologists, the coexistence of human and machine is an inevitable phenomenon as automation increases and most studies indicate that AI is unlikely to replace radiologists (Krittanawong, 2017). To compensate for any possible disruption, radiologists could continue to subspecialize, and focus on interventions and a more technical application of skills, ones not yet able to be imitated by digital counterparts.

Simultaneously, predictive power can also be applied to help detect and prevent further fraud, waste, and abuse. Systems use patient bills and records to analyze trends and detect anomalies such as overutilization of services, discrepancy of treatment spanning several hospitals within a system and lack of coordination around diagnoses, and prescription filling issues. For example, in implementing Big Data, the Centers for Medicare and Medicaid Services (CMS) prevented more than $210.7 million in healthcare fraud in a year (McDonald, 2017). Similarly, after transitioning to a predictive modeling environment, UnitedHealthCare generated a 2200% ROI after developing methodology to identify inaccurate claims (McDonald, 2017).

4.3 Data Management: Population Health

Big Data's role in population health is not a novel application; however, its potential applications are great and can have a larger impact than present-day. Big Data is able to help providers assess and manage the risk of the populations they serve. Disease trending can allow practitioners to prioritize and strategize initiatives that are most far-reaching for their populations. Community clinics, coalitions, and health fairs are becoming more common as health systems try to increase market share, and provide improved care for their patients and catchment areas.

4.4 Direct Intervention

Diabetes Mellitus (DM) I and II monitors, and continuous feedback loops, have been enabled by the application of real-time Big Data. In constantly relaying information back to a physician or device manufacturer, trends can be analyzed, using target values to indicate when insulin injections are automatically needed (Ventola, 2014). Technologies such as these alleviate the disease burden on the patient, allowing them to potentially live life with less expenditure of effort. In the case of DM patients, continuous feedback devices alleviate the need for the patient to rely on timekeeping values and self-injections. For younger patients (DM I), and those with anxiety and aversion to injections

(DM I or II), continuous feedback devices do the work for the patient and only require routine checkups with the physician and device manufacturer. Large aggregations of patient data also allow physicians to not only study individual disease trends, but also study trends within the patient population in general (Ventola, 2014). This enables them to improve practices and workflow processes. This technology is more cost-efficient than traditional insulin injections and physician visits. Additionally, continuous improvement would drastically decrease ED and physician visits as a result of unmanaged diabetes. Reduction in unnecessary admissions could further help drive down healthcare expenditures.

Wearables, those less invasive than the continuous feedback insulin regulators, also show promise and hope in using patient data in order to help improve patient outcomes in a less invasive approach. Project DETECTED, an "intelligent bra", is a wearable that is able to detect breast cancer with greater acuity than a mammography, while also reducing a patient to unnecessary exposure (Ferenstein, 2012). Temperature sensors that screen breast tissue are able to track, record, analyze, and identify inconsistencies. These offer an invaluable alternative to mammographies, which have recently been found by multiple studies to be less accurate in detection of abnormalities in women with dense breast tissue. As over 40% of women currently have dense breast tissue, the inaccuracy leads to unnecessary biopsies and a furthering of costly technologies and surgeries. As systems try to consolidate costs, devices such as these offer the possibility for major cost savings and convenience for providers and patients.

5 Implications for Healthcare & Big Data

Going forward, the biggest challenge to the use of Big Data will likely be the integration of Big Data during the paradigm shift from FFS to value-based care. Value-based care, as aforementioned, is organically a more patient-centric approach. As episodes of care are redefined and value-based models are implemented, there will be a necessity to upgrade reporting systems, claims processing, and process automation. Redefining these will lead to patient-centric improvements and outcomes as physicians, nurses, managers, and other healthcare employees will be encouraged to communicate and work together more closely. The alignment of patient and provider incentives, in addition with updated technology that could lead to cost transparency, will help to alleviate the current clinical nuance that plagues the system.

Alleviating the clinical nuance between provider and patient will help to transform current systems from low-value to high-value services. Current models, by contrast, pit the provider and patient against one another and the incentives for patients may not fit into standards and benchmarks set for physicians -- and vice versa.

Patient privacy is one of the top concerns when considering the implications Big Data may have on a system. In light of the summer 2017 cyber-attack on England's National

Health Service (NHS), additional protections and firewalls should be mandated for Big Data sets, especially those stored in cloud-based platforms (Gordon, Fairhall and Landman, 2017). Unfortunately, studies have cited low organizational vigilance, inadequate staffing and training, and insufficient technology investment as enablers for the susceptibility to healthcare data attacks. With more than 50% of hospitals reporting at least one ransomware attack in the past 12 months, increased budgetary allocations towards intensive training and IT upgrading is an absolute *necessity* of health systems (Gordon, Fairhall and Landman, 2017). Inquiries into the cyberattacks indicated that, while providers had been warned about possible NHS attacks, several computer and processors were outdated and unable to access and download the firewalls necessary to prevent the ransomware attacks. While 'Big Data methodologies' greatly facilitate collection and analysis of data, the pressure to stay abreast of security developments in the IT landscape poses a severe, essential challenge, given that the penalty for failing to do so can be no less than total data exposure (Harsh, Patil and Seshadri, no date).

6 Conclusion

Healthcare's greatest challenge in the era of Big Data will be the necessity of providers to stay updated to change processes, especially with respect to informational security. Continual education and training will need to be added as security updates and technological advances become common-norm of healthcare practices. In particular, Big Data's storage on cloud-based applications requires a market level of protection. The Health Information Technology for Economic and Clinical Health (HITECH) Act was enacted in 2009 to extend HIPAA's requirements to all parties that have access to protected health information (PHI) ('Big Data and Health Disparities -Zhang et al., 2017), but in light of recent provider data breaches, more remains to be done in this area.

As current payment reforms help to alleviate the divide between patient and provider, there will be a new clash—an exaggerated one—between providers and other stakeholders. Owners or manufacturers of imaging technologies may use Big Data to identify underserved patients and disease areas. While possible to be construed as an attempt to provide overall improvement to population health, this initiative could exacerbate overutilization of healthcare, leading to an *increase* in provider costs.

Such phenomena are the growing pains of paradigm shifts. Reconceiving the way providers think about the provision of care necessitates similar shifts in methodologies, workflows, even technologies. And this particular adjustment, this motion from 'Me' to 'We', is one to be embraced, both for its cost-saving potential and for its intrinsic philosophy of holism. Big Data methodologies construe the provider as an agent within a larger community or population organism, one that must adapt and change to suit the needs of those it serves. It allows for the provision of better care, in terms of the care

itself provided *and* the logic of its distribution. In the right hands, if Big Data is the face of healthcare's future, it will be a humanitarian one.

References

Benjamin, M., Aradi, Y. and Shreiber, R. (2010), 'From Shared Data to Sharing Workflow: Merging PACS and Teleradiology', *European Journal of Radiology*, vol. 73, no. 1, pp. 3–9.

Bresnick, J. (2017), *Population Health, Big Data Strategies Could Reduce $2B Waste*, Health IT Analytics [Online]. Available at: https://healthitanalytics.com/news/population-health-big-data-strategies-could-reduce-2b-waste (Accessed June 28, 2017).

Elias, J. (2015), *In 2016, Users Will Trust Health Apps More than Their Doctors*, Forbes [Online]. Available at: https://www.forbes.com/sites/jenniferelias/2015/12/31/in-2016-users-will-trust-health-apps-more-than-their-doctors/ (Accessed July 12, 2017).

Ferenstein, G. (2012), *Breast Cancer-Sensing Bra Detects Tumors Years before Some Mammograms* [Online], TechCrunch. Available at: https://techcrunch.com/2012/10/11/breast-cancer-sensing-bra-detects-tumors-years-before-some-mammograms/ (Accessed July 27, 2017).

Gordon, W. J., Fairhall, A. and Landman, A. (2017), 'Threats to Information Security', *The New England Journal of Medicine*, vol. 377, no. 8, pp. 707–709.

Gottlieb, S. (2017), *Fostering Medical Innovation: A Plan for Digital Health Devices*, FDA U.S. Food and Drug Administration [Online]. Available at: https://blogs.fda.gov/fdavoice/index.php/2017/06/fostering-medical-innovation-a-plan-for-digital-health-devices/ (Accessed July 27, 2017).

Groves, P., Kayyali, B., Knott, D. and van Kuiken, S. (2013), *Accelerating Value and Innovation*.

Kayyali, B., Knott, D. and van Kuiken, S. (2013), *The Big-Data Revolution in US Health Care: Accelerating Value and Innovation*, McKinsey&Company [Online]. Available at: http://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/the-big-data-revolution-in-us-health-care?_sm_au_=iVV7rPs0vW5qNQrM (Accessed June 28, 2017).

Koufi, V., Malamateniou, F. and Vassilacopoulos, G. (2015), 'A Big Data-Driven Model for the Optimization of Healthcare Processes', *Studies in Health Technology and Informatics*, vol. 210, pp. 697–701.

Krittanawong, C. (2017), 'The Rise of Artificial Intelligence and the Uncertain Future for Physicians', *European Journal of Internal Medicine*.

Kupwade Patil, H. and Seshadri, R. (2014), 'Big Data Security and Privacy Issues in Healthcare', *2014 IEEE International Congress on Big Data*. Anchorage, AK, 27.06.2014 - 02.07.2014, IEEE, pp. 762–765.

McDonald, C. (n.d.), *Five Big Data Trends in Healthcare,* ITProPortal [Online]. Available at: http://www.itproportal.com/features/five-big-data-trends-in-healthcare/ (Accessed July 27, 2017).

Mukherjee, S. (2017), *Mobile Health App Venture Funding Hits Record in 2016,* Fortune [Online]. Available at: http://fortune.com/2017/01/17/vc-funding-mobile-health-record/ (Accessed July 27, 2017).

Patel, T. A., Puppala, M., Ogunti, R. O., Ensor, J. E., He, T., Shewale, J. B., Ankerst, D. P., Kaklamani, V. G., Rodriguez, A. A., Wong, S. T. C. and Chang, J. C. (2017), 'Correlating Mammographic and Pathologic Findings in Clinical Decision Support Using Natural Language Processing and Data Mining Methods', *Cancer,* vol. 123, no. 1, pp. 114–121.

Siemens Healthineers (2015), *Big Data in the Healthcare Industry,* Siemens Healthineers [Online]. Available at: https://www.healthcare.siemens.de/magazine/mso-big-data-and-healthcare-1.html (Accessed October 03, 2017).

Ventola, C. L. (2014), 'Mobile Devices and Apps for Health Care Professionals: Uses and Benefits', *Pharmacy and Therapeutics,* vol. 39, no. 5, pp. 356–364.

Weinger, M. B., Slagle, J., Jain, S. and Ordonez, N. (2003), 'Retrospective Data Collection and Analytical Techniques for Patient Safety Studies', *Journal of Biomedical Informatics,* vol. 36, no. 1-2, pp. 106–119.

Woo, S. and Kim, S. H. (2017), 'Differentiation of Small, Solid Renal Masses: A Pattern Recognition Approach', *Seminars in Ultrasound, CT, and MR,* vol. 38, no. 1, pp. 28–36.

Wood, D. F. (2017), *Health Disparities: Big Data to the Rescue?,* U.S. National Library of Medicine [Online]. Available at: https://nlmdirector.nlm.nih.gov/2017/05/16/health-disparities-big-data/ (Accessed June 24, 2017).

Zhang, X. e. a. (2017), 'Big Data and Health Disparities', *Ethnicity & Disease,* vol. 27, no. 2.

Big Data: A Panacea to the Health Care System's Challenges?

Valmir Hajdari

In the last two decades, "Big Data," the analytics of enormous amounts of data files, has had an exponentially growing impact on the economy. Software solutions are being heavily researched, although so far, both technological and scientific advances are not developed enough to create programs able to accommodate the necessary sample size and thus, truly reliable information. There are countless possible applications for "Big Data" analyses, especially in industries that heavily rely on statistical data sets, such as the health care sector. Due to the current lack of software solutions capable of coping with the large data sets, today's analysis and usage of "Big Data" is limited. Nonetheless, today's software is still able to sort through unstructured patient data much faster than any manual process could. The results of first programs in the US have shown great potential in solving problems in health care. These improved financial savings, as well as being able to take preventive measures concerning certain diseases, through to the data analysis of a whole society, and even saving lives by accelerating diagnostic procedures. Although there are certain concerns about privacy and security, this paper shows that in the future "Big Data" analysis will tackle numerous heath care related problems and increase the efficiency and efficacy of public health.

Contents

1 Big Data: Could the Use of Big Data help to solve problems of the Health care?

The first use of the term “Big Data” is documented in a 1997 paper by NASA scientists. They described an issue which concerned the problem of the visualization of large data sets (Cox, 1997, p. 235). “Big data” as it is understood today, is defined as large electronic records which are so large and complex that they are almost impossible to analyze with conventional software programs (Kayyali, 2014, p. 2). A report from 2012, which was presented to the US Congress, defines “Big Data” as: "large quantities of high-speed, complex, and variable data that require advanced techniques and technologies to facilitate the capture, storage, distribution, management and analysis of data" (IHTT, 2014). The data management tools developed so far are inadequately suited for managing these records (Frost & Sullivan, 2015). “Big Data” is not only unique because of the volume, but also because of its variety and velocity (Frost & Sullivan, 2015).

Looking at health care, we can see that the health care system historically has collected and stored a very large amount of data (Kayyali, 2014, p. 5). The numerous records and measurements of patient and hospital information can be defined as “Big Data”. It includes data such as medical imaging, clinical decisions, doctor's letters, laboratory tests, prescription and insurance data, as well as other patient records. However, some patient-specific pieces of information, such as social media contributions on social networks, can also be part of Big Data (Bian et al., 2012, p. 26). A study published by McKinsey sees health care as one of the five sectors with the greatest potential for “Big Data” applications (Kayyali, 2014, p. 2). Compared to the past when the data was mostly available in printed form, the trend nowadays is heading further towards the digitization of these existing data sets. Numerous healthcare challenges (demographic changes, co-morbidities, etc.) and the rising cost of healthcare have led many researchers to believe the vast amount of data is the solution to many problems in health care. “Big Data” can be used to support clinical decision making, disease monitoring of a patient, or to improve public health (Fernandes et al., 2012, pp. 38-42).

Previously published reports show the potential uses of health data. According to one report, in 2011 alone, a quantity of 150 exabytes of health-related data were stored in the US. Due to the advancing digitalization and technological approaches, the amount of data is expected to rise to yottabytes and far beyond this in the foreseeable future (IHTT, 2014). For the healthcare industry, the very large amount of data provides numerous opportunities to improve the status quo of health care. An algorithm that would be able to understand all this data and connect them in the right order could potentially lead to lower costs in health care, and therefore improve public health. The use of “Big

Data" in health care thus holds many significant advantages available (Ikanov, 2014, p. 4-7).

This essay will examine if the use of "Big Data" could help to solve problems of the health care system. It provides an overview of data analysis in the health care sector. It is shown what benefits of Big Data could have for the health care. Afterwards, the characteristic properties of "Big Data" are described in more detail, followed by an architectural framework of big data analytics for healthcare and some examples of "Big Data" in current use.

2 Big Data analytics in Healthcare

Data analysis refers to the examination of data sets which is intended to draw a conclusion from the displayed data (Ikanov, 2014, pp. 4-7). Data analytics is used in all business areas. For example, it may be used to help determine the favorite car color of the population for the respective year, or how the new electronic product launch was adopted on the market. In costly emergency care, data analysis can help select the most efficient treatment and preserve resources. Additionally, data analysis can also provide improvements in preventive care, including predictions of population-related diseases and preparations for preventive treatment (Ohlhorst, 2012). "Big Data" can also be used to provide prognoses for specific epidemiological developments or ensure that specialists are already preparing for a case of flu before the outbreak of a flu epidemic. Medical research, especially, can benefit greatly from "Big Data". The ability to collect all data from a particular case and then filter it according to specific results helps to draw the right medical conclusions about a disease (Deross et al., 2011, pp. 52-67).

Due to the new possibilities such as the Big Data, medical research and the rising cost pressure in medical treatment, the health care sector has had to redefine the reimbursement models. The trend of reimbursement models has gone from the fee-for-service variant to diagnosis-related case groups with flat-rate reimbursement rates. In addition, models such as the "pay-for-performance" are gaining more and more interest from the cost carriers. The "pay for performance" model is primarily about achieving a certain treatment outcome and, in the best case, surpassing this result (Burghard, 2014). The better the treatment outcome at the end of a medical intervention, the higher the service provider is compensated for his or her services. However, the additional financial profit should not be the only reason for the implementation of "Big Data." Improvement of treatment quality as well as treatment result are reason enough for the implementation of "Big data" analyses. (Lavelle, 2011, pp. 23-25).

3 The characteristics of Big Data – Volume, Variety, Velocity

"Big Data" is defined by three main features: volume, velocity, variety. Over time, health-related data is still being created and collected continuously, with a vast amount of data coming together. Although this technical progress has some negative effects, the positive developments and improvements far outweigh the costs. Advances in data management, especially in the context of the visual mix and cloud computing, allow for more effective data collection, storage and evaluation (Feldman et al., 2011). The health-related data can now be accumulated in real-time and at a very high rate. This ever-increasing data represent new challenges. With the increased volume and the change in the variety of old, accumulated and new data, new algorithms for retrieving, analyzing and comparing the data are necessary in order to arrive at a result-oriented treatment decision.

Previously, the majority of health data was statistically comparable files in paper form, such as radiographs and medical reports. Nowadays, a large part of the health data consists of real-time data from patients, which could be analyzed in real-time (Feldman et al., 2011). For example, a particular algorithm could use the data of the operating room monitor in real time to suggest a specific treatment recommendation or a particular medication. The analysis of real-time data may in some cases make the difference between life and death (Ikanov, 2014, pp. 4-7). An example of this could be automatic defibrillators which read the analyses the patient's heart rhythm and suggest treatment.

Through the future use of programs that analyze health data in real time, service providers would be able to reduce mortality and morbidity of the patients with proper and quickly-implemented treatments, and possibly even prevent whole disease outbreaks. An example of this real time data analysis in healthcare in current use is the monitoring of newborns via real time streaming in some Intensive Care Units (ICU), allowing the interception of life threatening infections (IHTT, 2014). The possibility to analyze and evaluate all the collected data of an individual patient would greatly improve the health of the individual but also of the society (Feldman et al., 2011).

3.1 Structured, Unstructured and semi-structured Data

Not only the amount, but also the nature of health data has changed over time. Therefore, future algorithms and analysis methods will have to adapt to new job and economic environmental conditions in order to counteract the speed, the volume and the diversity of the data being collected. In fact, the health data are more of a multimedia format and are often unstructured. The high number of structured, unstructured and semi-structured

data provides the health sector with interesting challenges that must be solved in order to ensure a functioning analysis of health data (Feldman et al., 2011).

Structured data is used to describe data that is easy to query, store, retrieve or even analyze. In addition, structured as well as semi-structured data contain electronic recordings of the instruments and other digital examination data. Further, all the data converted from paper form into electronic data are also added to this group of data. Unstructured data is the common form of data that arise during the care of the patient. These include hand-written notes of care, prescriptions, examination images (MRI, CT), etc. Nowadays, there are also many ways to gather data about one's own health (Manyika et al., 2011). There are smart watches and fitness machines which, if desired, that are capable of recording vital functions and many other health data. Also, on social media platforms, many tools are offered to check out one's own constitution, such as track measuring devices. However, the evaluation of this data is far from being as efficient as desired. An actual synthesis of all data to ensure an evidence-based result is not currently possible. Therefore, to make an interpretable result from this data, it requires more efficient programming capable of evaluation of all collected data, as well as the ability to perform an automatic conversion of unstructured as well as structured data (Kesh et al,. 2007, pp. 39-57).

Consequently, it is stated that the positive potential of "Big Data" lies in the merging of all possible data types. The synthesis of data can help individual patients, as well as an entire population. Today, the large amounts of data support scientific research and development of new processes or pharmaceuticals (Manyika et al., 2011). Enhanced data synthesis could assist the development and approval of improved medicines at cheaper prices and in a faster time period. Also, the prescription of the best possible therapeutic option could be made easier and more effective by the use of "Big Data" (Feldman et al., 2011). "Big Data's" potential to improve efficacy and decease cost is very high throughout healthcare and can lead to the resolution of many current challenges. The scarcity of resources and the consequences of the demographic changes could be mitigated by "Big Data".

3.2 The fourth characteristic of Big Data – Veracity

Beside the three stated characteristics of "Big Data," volume, variety and velocity, scholars have introduced a fourth characteristic feature called veracity. It describes the flawlessness and credibility of "Big Data" sets, as well as their analysis and results. Genuine matching data, especially in health care, is of immense importance (Fernandes et al., 2012, pp. 38-42). Genuine means that the data must be correct and true, and that

the records must be complete. Any decision based on false evidence, in the worst case can decide between life and death. In particular, the unstructured data, which usually arise during the care of the patient, must be checked for their veracity, as this data and its analysis is often very difficult and can produce incorrect results. An example of unstructured data causing poor veracity is the handwriting of a doctor, which can be difficult to read and difficult to interpret, resulting in an end point error. This can lead to a false prescription of medicine or worse, even death. (Feldman et al., 2011).

Veracity is a characteristic which not only is required in health care, but also covers all economic sectors, especially on the payers' side. In many treatment cases the reimbursement of a large amount of money is necessary and therefore the correctness of all data is a prerequisite (including the correct patient, hospital, DRG code, money amount, treatments, and prescriptions) (Fernandes et al., 2012, pp. 38-42). In order to achieve accurate yearly results, it is extremely important that all relevant data correspond correctly to the event.

4 Architectural Framework for Big Data analytics

The conceptual framework for a "Big Data" analysis project is very similar to the widely available health information systems or other analysis programs (Fernandes et al., 2012, pp. 38-42). The basic difference lies in the processing execution. Because analysis of "Big Data" is to be done with very large data sets, the processing of this data is divided into several sections. This method is not simple due to the high volume of data. In addition to the large size, the variety of data is also a reason to divide the data (Deross et al., 2011, pp. 52-67). The processing of such large data sets is a recent development. With the processing of "Big Data," various service providers hope to be able to make better informed health-related decisions, and thereby save resources. The algorithms and models for processing "Big Data" are very similar to the existing analysis tools. The user interfaces used to edit "Big Data", on the other hand, differ completely from the traditional data analysis programs. This is, on one hand, due to the volume and the variety of the data, and on the other hand to the diversity of results displayed. The conventional data analysis tools are generally very user-friendly and transparent. Data analysis tools for "Big Data", conversely, are very complex, require a great deal of skill in the evaluation and visualization of the results, and they are also highly program-intensive. The complexity of the programs results from the high complexity of the data sets (Capgemini, 2013, p. 4). The content of "Big Data" in healthcare can come from internal or external sources. The internal sources are the electronic patient records, clinical reports on treatment and diagnosis, and computerized physician order entry, etc. Data from external sources can come from pharmacies, insurances, labs, etc., and are available in different formats from different locations (Lavelle, 2011, pp. 20-32).

In the first step, the data must be pooled before processing. The data is still raw at this time and must be processed or transformed into system-compatible formats in the next step (Kesh et al., 2007, pp. 39-57). The data can also remain in the raw form and can be processed by commands. Another possibility to edit "Big Data" is the so called "data warehouse." With a data warehouse, data from different sources are aggregated and adapted for processing. After extracting, transforming and uploading the data, these are cleaned up and prepared for analysis. Depending on whether the data is structured or unstructured, several data records can also be entered into the data analysis programs for processing (Ikanov, 2014, p. 5).

In the next step, when creating a conceptual framework, further decisions must be made regarding individually relevant functions. It is, for example, necessary to decide which possibilities for editing or inputting information must be available. It must also be decided on possible transmission functions to other carriers or devices. Of course, decisions on the tool selection for processing the data records are still required.

An existing platform for data processing of "Big Data" is offered by the freely accessible Hadoop program. This platform has the possibility to edit very large records by distributing the records to different servers which work parallel to the solution of the problem. Finally, the results of all servers are integrated into one (Deross et al., 2011, pp. 52-67). Hadoop has great potential for the processing of large data sets and thus allows companies more alternatives. However, the operation of Hadoop can be very difficult as there are limited professional staff who are able to use this program. Furthermore, the software is difficult to install, maintain, and configure and qualified employees are rare and very costly. Nonetheless, the program is a first step in the right direction to solving future challenges in health care via "Big Data" analysis.

5 Applications of Big Data in health care

Several "Big Data" applications are already in use today. These programs have mainly been implemented to either achieve advanced cost efficiency or to streamline medical processes and treatments. In one example, IBM reported the usage of a software tool by an unnamed, large healthcare provider that collects and analyses unstructured data sets such as physicians notes and reports. Through this process, the data is available quicker which reduces the time sorting through documents and thus saving cost (IBM, 2014).

A different approach is being taken by the Columbia University Medical Center. Their "Big Data" program aims to analyze data files of patients with brain injuries. Correlations that signify serious complications can be diagnosed up to 48 hours faster than by

a manual sorting processes (IBM, 2014). Furthermore “Big Data” programs can have unforeseen positive effects as well. While creating a “Big Data” set, the US insurance company, Kaiser Permanente, found adverse effects concerning a drug used to treat rheumatic pain which has since been withdrawn from the market. A similar process was used to classify groups of persons with increased risks of developing diabetes. “Big Data” software can therefore not only be used to tackle economic issues, but also to further scientific medical discoveries as well (IHTT, 2014).

5.1 The Data Revolution

Nowadays, a large data revolution is in progress, especially in the health care sector. There are many different reasons for this, but above all, this is happening due to the strong increase in the availability of information. Over the past decades, many pharmaceutical companies have gathered years of research and development data into medical databases. Suppliers and payers have also participated in the digitalization process by introducing an electronic patient records, among other things. Gradually, the US federal government and other public interest representatives have opened their medical information in the form of data for research purposes. This includes data from clinical trials or patient-related information.

In the case of “Big Data,” cost-policy considerations are also the most powerful drivers in the demand for big data solutions. After a steady increase over the past 20 years, US health spending has risen to 16.4 percent of GDP (OECD, 2014, p. 219). This value corresponds to nearly $600 billion more than the benchmark for a country of the size and wealth of the USA. In order to counter the resource shortage, many payers like Medicare and Medicaid have changed their remuneration system from fee-for- service model, which rewards the service provider, to high-volume risk sharing agreements that prioritize results. The changes in remuneration have had an impact on pharmaceutical companies, as their medication needs to demonstrate evidence-based benefits. With this new competitive environment, health care professionals have a strong interest in reducing the cost of health care spending through “Big Data” applications (Kayyali, 2014, p. 3).

5.2 Data protection

The use of Big Data in health care requires special data protection guidelines and laws due to the very sensitive information contained in health care data. The current coalition agreement of the Federal Government in Germany already contains keywords such as "opportunities for digitization," "telemedicine," "data protection," "e-care" and "electronic health card." The introduction of the e-health law by the Ministry of Health has

integrated a roadmap for the introduction of a digital infrastructure with very high security standards (Koalitionsvertrag, 2014, pp. 137-144). Furthermore, for the evaluation of health data, a high level of data protection is required in order to obtain public acceptance for the use of Big Data. For example, the start of the big-data project "care data" of the Health and Social Care Information Center (HSCIC) in Great Britain had to be postponed because the confidentiality of the health data to be evaluated, the cancellation in the event of a contradiction from a patient, and the limitation of the data evaluation could not be guaranteed. In addition, the data could also have been used and abused for police and commercial purposes (Striegler, 2014).

Without a public conversation about Big Data and technical and legal solutions regarding data protection, etc., there will be no acceptance for Big Data in society overall or in health care, specifically. Ensuring a high level of acceptance and ensuring a high level of security when using Big Data are two tasks to fulfill.

5.3 Advantages of Big Data for health care

Due to the digitization and the effective use of large data, health care organizations have been able to gain significant advantages (Burghard, 2014). Among other things, diseases can be recognized and treated in earlier stages than before. In addition, numerous questions which have not been answered so far can be solved by the use of "Big Data." Certain developments or results may be predicted and estimated by the analysis of collected data (e.g., Length of stay) and therefore, be better controlled. Potentially medically-unsuitable interventions also can be canceled in advance due to extended data analysis which can provide information about possible complications (including bleeding, clotting, rejection) or the possible risk of infection of a patient (Burghard, 2014). According to McKinsey's business consultancy, "Big Data" and the use of data analysis could save up to $300 billion a year in US health care. Two-thirds of $300 billion would be generated by an eight percent decrease in the current health issues because of a reduction in health expenditures. In addition, according to McKinsey, $165 billion could be saved in the field of clinical operations, and $108 billion could be saved in in the field of research and development (Manyika et al., 2011). In principle, McKinsey states that the use of "Big Data" can reduce the waste in healthcare and, in addition, it can improve efficient treatment of patients. For example, "Big Data" makes it possible to perform a precise comparison between different treatment methods at a clinical operations level, thus providing a response to more cost-effective treatment methods. Additionally, more effective treatment methods can be converted into treatment guidelines with a better result in the treatment of the patient. The use of "Big Data" has a positive impact on the patient and the care provider.

"Big Data" could also be used in research & development. By using different algorithms and statistical methods, the different clinical studies can be carried out more precisely and more effectively. For example, the choice of the trial design or the determination of the participants in a study opens possibilities for more suitable practice through data analysis, since all relevant details are included. Furthermore, the subsequent analysis of the clinical trial is detailed by an algorithm and thus ensures the unwanted effects of an intervention can be quickly recognized (Manyika et al., 2011).

Important long-term changes can be also generated in public health. Through the use of an algorithm, real-time data can perform the monitoring of certain diseases, thereby allowing for a better understanding of the causes and spread of these diseases. In addition, the results obtained can be used to improve public health. Intervention of a possible influenza wave or epidemic may also be made quicker by the analysis of health data and thus protects larger population groups (Manyika et al., 2011). The use of all accessible data also makes the development of interventions or required vaccines faster. The large amounts of data can also be used to determine the needs of patients. This can be used to ensure that the services offered to the patient are increased in a more efficacious manner. A highly developed public health sector can ultimately lead to improved evidence-based medicine (IBM, 2014). By combining data from different areas (clinical data, operational data and financial data), the most efficient treatment and better care can be implemented. The use of "Big Data" and the corresponding data analysis, therefore, has financial and qualitative improvements in health care for the stakeholders as well as the patients.

6 Conclusion

A usable and effective data processing platform that makes it possible to use "Big Data" must include the necessary tools for data analysis if it is to improve both efficiency and clinical outcomes of the health care system. Important factors in such a platform include the user-friendliness of the program, the ability to manipulate the data, the security of the private data, as well as the scalability of the system (Bollier, 2010). In addition, real-time data analysis allows for a quick reaction and important intervention, which is a critical prerequisite for healthcare-associated analysis programs. Similarly, the gap between data collection and data processing should be closed. In addition, special management questions about ownership and governance of and rules surrounding data must also be taken into account. The fact that health data is often not standardized should also be addressed when creating a big data analysis program (IHTT, 2014).

The analysis of large data records, called "Big Data," has the ability to improve the health economy. "The use of Big Data" has the propensity to change the ways of thinking in the health care system by using new technologies and taking into account large data sets. On the one hand, the new findings may reveal new treatment alternatives, and on the other hand, "Big Data" can reduce the consumption of resources and improve the financial efficiency in health care. Therefore, it is only a question of time as to when "Big Data" will used, via appropriate programs, for the benefit of the health care sector. Furthermore, of course, all the issues mentioned above must be addressed. Privacy, in particular, should be taken into account. The violation of privacy would mean a serious loss of public trust in "Big Data" and therefore in healthcare. This could delay the entire implementation of data processing with "Big Data" or prevent it completely.

In general, the use of "Big Data" can help solve numerous health-related problems. Advantages of such applications range from furthering cost savings, or being able to take population based preventive measures, to even saving lives by accelerating diagnostic procedures. Furthermore, precisely planned treatments can be used to avoid wasting resources and double testing. Predictions of different scenarios, such as influenza epidemics, are also made more possible by analysis of "Big Data." For "Big Data" analysis to be advantageous and not misleading, the data sets must be large and extensive enough. This leads to concerns about both privacy and security.
Nonetheless, a widespread availability of "Big Data" software solutions could tackle these issues while solving problems in all areas of the health care system.

References

Bian, J., Topaloglu, U. and Yu, F. (2012), 'Towards Large-Scale Twitter Mining for Drug-Related Adverse Events', *Proceedings of the 2012 International Workshop on Smart Health and Eellbeing - SHB '12.* Maui, Hawaii, USA, 29.10.2012 - 29.10.2012. New York, USA, ACM Press.

Bollier, D. (2010), *The Promise and Peril of Big Data*, Washington, DC, Aspen Institute.

Burghard, C. (2014), *Big Data and Analytics Key to Accountable Care Success,* IDC Health Insights.

Capgemini (2013), *The Deciding Factor: Big Data & Decision Making,* Capgemini [Online]. Available at: http:// www.capgemini.com/thought-leadership/the-deciding-factor-big-datadecision-making (Accessed May 04, 2017).

Cox, M. (1997), *Application-Controlled Demand Paging for Out-of-Core Visualization,* MRJ/NASA Ames Research Center [Online]. Available at: http://delivery.acm.org/10.1145/270000/267068/p235cox.pdf?ip=144.200.17.42&id=267068&acc=ACTIVE%20SERVICE&key=FC66C24E42F07228.59B42124C4E2603D.4D4702B0C3E38B35.4D4702B0C3E38B35&CFID=942547473&CFTOKEN=69237990&acm=1496150945_7f580282c0c126f21747fae7904392ea (Accessed May 04, 2017).

Deroos D., Deutsch T., Eaton C., Lapis G. and Zikopoulos P. (2011), *Understanding Big Data: Analytics for Enterprise Class Hadoop and Streaming Data,* McGraw-Hill: Aspen Institute.

Feldman B., Martin E. and Skotnes T. (2011), *Big Data in Healthcare Hype and Hope* [Online]. Available at: https://www.west-info.eu/it/il-medico-in-tasca/big-data-in-healthcare/ (Accessed October 04, 2017).

Fernandes, L., O'Connor, M. and Weaver, V. (2012), 'Big Data, Bigger Outcomes', *Journal of AHIMA*, vol. 83, no. 10, pp. 38–42.

Frost & Sullivan (2015), *Drowning in Big Data?: Reducing Information Technology Complexities and Costs for Healthcare Organizations,* Frost & Sullivan [Online]. Available at: https://www.emc.com/collateral/analyst-reports/frost-sullivan-reducing-information-technology-complexities-ar.pdf (Accessed May 07, 2017).

IHTT (2013), *Transforming Health Care through Big Data Strategies for Leveraging Big Data in the Health Care Industry,* IHTT [Online]. Available at: http://c4fd63cb482ce6861463-bc6183f1c18e748a49b87a25911a0555.r93.cf2.rackcdn.com/iHT2_BigData_2013.pdf (Accessed October 04, 2017).

Ikanow (n.d.), *Data Analytics for Healthcare: Creating Understanding from Big Data,* Ikanow [Online]. Available at: http://info.ikanow.com/hs-fs/hub/163225/file-18212299-pdf/docs/data-analytics-for-healthcare.pdf (Accessed October 04, 2017).

International Business Machines Corporation - IBM (2012), *IBM Big Data Platform for Healthcare Solutions Brief,* International Business Machines Corporation - IBM [Online]. Available at: http://public.dhe.ibm.com/common/ssi/ecm/en/ims14398usen/IMS14398USEN.PDF (Accessed May 04, 2017).

International Business Machines Corporation - IBM (2013), *Data Driven Healthcare Organizations Use Big Data Analytics for Big Gains,* International Business Machines Corporation - IBM [Online]. Available at: http://www-03.ibm.com/industries/ca/en/healthcare/documents/Data_driven_healthcare_organizations_use_big_data_analytics_for_big_gains.pdf (Accessed April 29, 2017).

Kayyali, B., Knott, D. and van Kuiken, S. (2014), *The Big Data Revolution in US Healthcare,* McKinsey&Company [Online]. Available at: http://healthcare.mckinsey.com/big-data-revolution-us-healthcare (Accessed May 03, 2017).

Koalitionsvertrag (2014), *Deutschlands Zukunft gestalten, zwischen CDU, CSU und SPD,* Die Bundesregierung [Online]. Available at: https://www.bundesregierung.de/Content/DE/_Anlagen/2013/2013-%2012-17-koalitionsvertrag.pdf?%20%20%20blob=publicationFile (Accessed October 04, 2017).

Lavalle, S., Lesser, E., Shockley, R., Hopkins, M. and Kruschwitz, N. (2011), 'Big Data, Analytics and The Path from Insights to Value', *MIT Sloan Managing Review*, vol. 52.

Manyika, J., Chui, M., Brown, B., Buhin, J., Dobbs, R., Roxburgh, C. and Byers, H. (2011), *Big Data: The Next Frontier for Innovation, Competition, and Productivity,* McKinsey Global Institute.

OECD (2016), 'Gesundheitsausgaben', in OECD (ed.) *Die OECD in Zahlen und Fakten 2015-2016* [Online], pp. 218–219. Available at: http://www.oecdilibrary.org/docserver/download/3015045ec094.pdf?expires=149642 0229&id=id&accname=guest&checksum=35EA292ED211115B59BA28981ABE4725 (Accessed October 04, 2017).

Ohlhorst, F. J. (2012), *Big Data Analytics: Turning Big Data into Big Money*, USA, John Wiley & Sons.

Raghupathi, W. and Kesh, S. (2007), 'Interoperable Electronic Health Records Design: Towards a Service-Oriented Architecture', *e-Service Journal*, vol. 5, no. 3, pp. 39–57.

Striegler A. (2014), 'Britische Hausärzte rebellieren gegen Big Data', *Ärzte Zeitung*, 2014 [Online]. Available at: https://www.aerztezeitung.de/politik_gesellschaft/gesundheitspolitik_international/article/855099/glaeserne-patient-britische-hausaerzte-rebellieren-big-data.html (Accessed October 04, 2017).

Part 5: Public Health

The Public Health System in Germany and the U.S. – a Comparison

Verena Schiefelbein

The main goal of public health is to prevent disease and to promote health. To reach this aim, it is important not only to focus on health education, but also implement policies. Although the American and German public health systems are structured in a similar manner (federal, state, and local-components), the American system is unique in that it is particularly fragmented, with many people uninsured and health care costs which are exceptionally high. Prevention is one of the most important aspects of public health as it not only includes measures that reduce risk factors and lower the probability of acquiring a disease, it also stops the progression of a disease or reduces the consequences of the condition once it has occurred. In order to best prevent disease, one must consider the risk factors that cause diseases. This paper focuses on three risks factors: tobacco consumption, alcohol consumption, and obesity. While Germany is burdened with a high prevalence of tobacco and alcohol consumption among adults, the United States faces a serious issue regarding the prevalence of obesity. Both countries have introduced various measures to reduce the prevalence of the risk factors. By curtailing the pervasiveness of risk factors, diseases and chronical diseases, especially, can be prevented thus minimizing health care costs resulting from medical treatment of such conditions.

Contents

1 Introduction

Today, multiple factors affect health. Besides environmental influences and the consequences of climate change, nutrition and individual lifestyle are also important determinants that may increase the occurrence of diseases. There are two different types of diseases: communicable diseases (like Ebola and HIV/AIDS) and non-communicable diseases (such as diabetes, multiple sclerosis, coronary heart disease, and cancer). In addition to the type of disease, the diverse risk factors are relevant and influence the state of health. Today, many diseases (heart diseases) have epidemiological dimensions and are widespread in populations across the world (Nationale Akademie der Wissenschaften Leopoldina et al., 2015, p. 3).

Epidemiology describes the health status of a population and determines the factors causing disease, their processes, and intervention options. It examines the distribution of outcomes, which are mainly the number of diseases and deaths, as well as risk factors in a population (Egger and Razum, 2014, pp. 23-24). Over the last century, infectious diseases have been treated more effectively and efficiently due to better and newer medications. Current issues in public health are a result of the growing prevalence of chronic diseases and their risk factors, population aging, and widening social inequalities (Gerlinger et al., 2012, p.764). Public health is unique in concentrating not only on the health of individuals, but also on the health of society as a whole (Nationale Akademie der Wissenschaften Leopoldina et al., 2015, p. 3).

The following paper gives a general overview of the German and American public health systems. To begin, it is important to understand how public health is defined and what aspects are included as they will influence the practice of public health institutions. Additionally, an explanation will be provided on how the public health systems in Germany and the United States (U.S.) are organized. Following this, the difference between Germany and the U.S. regarding three main risk factors considered in this essay (tobacco consumption, alcohol consumption, and obesity), will be analyzed. Once these aspects are considered a conclusion will be provided.

2 Introduction to the public health systems of Germany and the U.S.

2.1 Definition of public health

Public health is an expansive, multidisciplinary subject including multidimensional fields such as the promotion of good health or the prevention of non-infectious diseases (Ashton, 1988, p. 232; Committee for the Study of the future of Public Health Division of Health Care Services (Committee), 1988, p. 7). Besides the prevention of diseases, public health is comprised of sectors such as environmental health, nutrition, food and

drug control, sanitation, immunization, traffic laws, firearm control, and health education (Tulchinsky and Varavikova, 2014, p. 536).

Winslow, who was responsible for encouraging public health at the beginning of the 20th century, defines public health in the following way: "Public health is the science and the art of preventing disease, prolonging life, and promoting physical health and efficiency through organized community efforts […]" (Winslow, 1920, p. 30).

Public health should be focused on a clean and healthy environment. This implies protecting the public from pathogens such as waterborne disease (e.g. cholera) that are spread through unsanitary environments and cause illness. The control of community infections that are spread through direct contact from one individual to another is also important. Typical communicable infections which can be monitored and prevented are pneumonia and influenza. It is even more important to educate and support individuals in practicing daily personal hygiene so they remain healthy. Lastly, the organization of health care services for early diagnosis and preventive treatments as well as the development of the social machinery are vital to public health programs as well as through them public health can be improved too (Winslow, 1920, pp. 24-27).

One of the main aspects of public health is prevention. This includes measures to hinder the occurrence and spread of diseases. Prevention aims to reduce risk factors, lower the probability of getting a disease, stop the progress of disease and lessen consequences from illness or injury (Walter et al., 2012, p. 196; world health organization, 1984, p. 17). As one of public health's most important tasks, it is necessary to implement a comprehensive approach including education and the establishment of safety structures to carry out prevention effectively (Cohen and Swift, 1999, p. 204).

In 1983 Larry Cohen, who has been an advocate for public health since 1972, founded *the spectrum of prevention*. He established this system since he believed that prevention was not fully understood by most people and only seen as an educational practice and not as complex process. The tool improves the approach to injury prevention and encourages practitioners to implement various initiatives. Cohen placed the main emphasis on influencing policy and legislation (Cohen and Swift, 1999, p. 203). In the following section the six levels of Cohen's *spectrum of prevention* will be explained (Cohen and Swift, 1999, pp. 204-206).

Figure 1: The spectrum of prevention

Source: Own graphic based on Cohen, L. and Swift, S. (1999), The spectrum of prevention: developing a comprehensive approach to injury prevention, in: *Injury Prevention*, Vol. 5, No. 3, p. 203.

1) Strengthening individual knowledge and skills

On this level, the focus lies on the transfer of knowledge and skills from physicians, human service professionals, and non-professional workers trained in health or wellness to individuals in order to increase their understanding and capacity for self-prevention.

2) Promoting community education

Community education should reach a broad range of people, a large group or the whole population, and communicate information to improve health. Mass media campaigns are used because they have a further reach than other methods and attract more people. Through mass media, individuals become increasingly aware of public health issues and understand the necessity of finding solutions on a societal level and their responsibility to be part of the solution. If communities are able to use media strategically, this can also attract the attention of legislators who have the power to advocate for policy change. This process is called *media advocacy* and it is a key part of keeping a community educated.

3) Educating providers

Since providers are responsible for transfering their knowledge to the general public, it is necessary that they also improve their understanding of prevention to transmit the best

information that is currently available. This can be accomplished through continuing education for health providers.

4) Fostering coalitions and networks

Coalitions, formed by several participants in the public health system, are crucial to achieve vital public health goals. Only by working together is it possible to ensure success, reduce expenses, and increase the credibility of the participants. Coalitions have a greater impact to achieve a community effort than any individual could have.

5) Changing organizational practices

Key organizations in Germany and the U.S. for health are law enforcement agencies, health departments, and schools. Through examining their practices this can affect the health and safety of the greater community. If these institutions change their internal organization (e.g. regulations and norms) this influences the behavior, the health, and the safety of their members. Changes in legislation often initiate a change in organizational practice as well.

6) Influencing policy and legislation

The enactment of a law is most important because it has the broadest influence and ability to improve health outcomes. Laws may already exist, but in order to make a law more effective, changes or adaptions might need to be made.

2.2 Organization of the public health systems

The Centers for Disease Control and Prevention (CDC) generally defines a public health system as "all public, private, and voluntary entities that contribute to the delivery of essential public health services within a jurisdiction" (CDC, 2013).
Public health's mission is to guarantee conditions in which people can live a sustainably healthy life. The aim is to achieve an organized community effort which transmits knowledge about how diseases can be prevented and addressed to public agencies, private organizations, and individuals (Committee, 1988, p. 7). Public health participants are the government, nongovernmental organizations (NGO), and community groups (Schneider, 2017, p. 25).
There are three core functions of public health agencies at all levels: assessment, policy development, and assurance. Each public health agency is obligated to collect, analyze, and release community health data (assessment). The aim is to develop public health policies within their jurisdiction to protect the interest of the public. Lastly, they must also assure that all necessary services are provided and accessible for everyone (Committee, 1988, pp. 7-8).

Structure of the public health system in the U.S.

When discussing the U.S. health care system, it is necessary to touch on the legal preconditions, which are the basis of the system. Public health is under the purview of the states because it is not specifically delegated to the federal government. Therefore, the responsibility is reserved by the states (Schneider, 2017, p. 26). The public health system in America is divided into several parts. There are governmental public health agencies at the federal, state, and local level, which carry the majority of responsibilities, but there is also an active exchange with private-sector organizations and NGOs (like health care providers, insurers, charities, and other groups) that concentrate on education, lobbying, and research in public health (Salinsky, 2010, p. 5; Schneider, 2017, p. 36). The following section will focus on governmental public health agencies at all levels.

On a federal level, the Department of Health and Human Services (HHS) is responsible for public health activities. Tasks of the federal government include establishing nationwide health objectives, supporting knowledge development, and providing funds and technical assistance to states. HHS is separated into three major agencies: The Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA).The CDC, also known as the epidemiologic agency for the nation, fights disease no matter how it occurred and supports communities and individuals to do so as well. Its aim is to increase the health security of the nation. The health protection agency provides and analyzes huge amounts of health information, tracks disease to find out where disease occurs and how to prevent it, and brings knowledge to every individual with the mission to protect the citizens against health threats and to respond to them when they arise (CDC, 2014b).The NIH carries out and supports biomedical research and is one of the largest research institutions in the world. The FDA is the organization that evaluates all new drugs entering the market, helps to bring new innovations on the market that improve public health, and provides science-based information to individuals to use drugs in a proper way. The FDA protects the public health as it ensures the safety, efficacy and security of drugs, but also biological products, and medical devices. It further regulates the distribution and manufacturing of tobacco products to reduce tobacco use by children and young adults (Schneider, 2017, pp. 32-35; FDA, 2017).

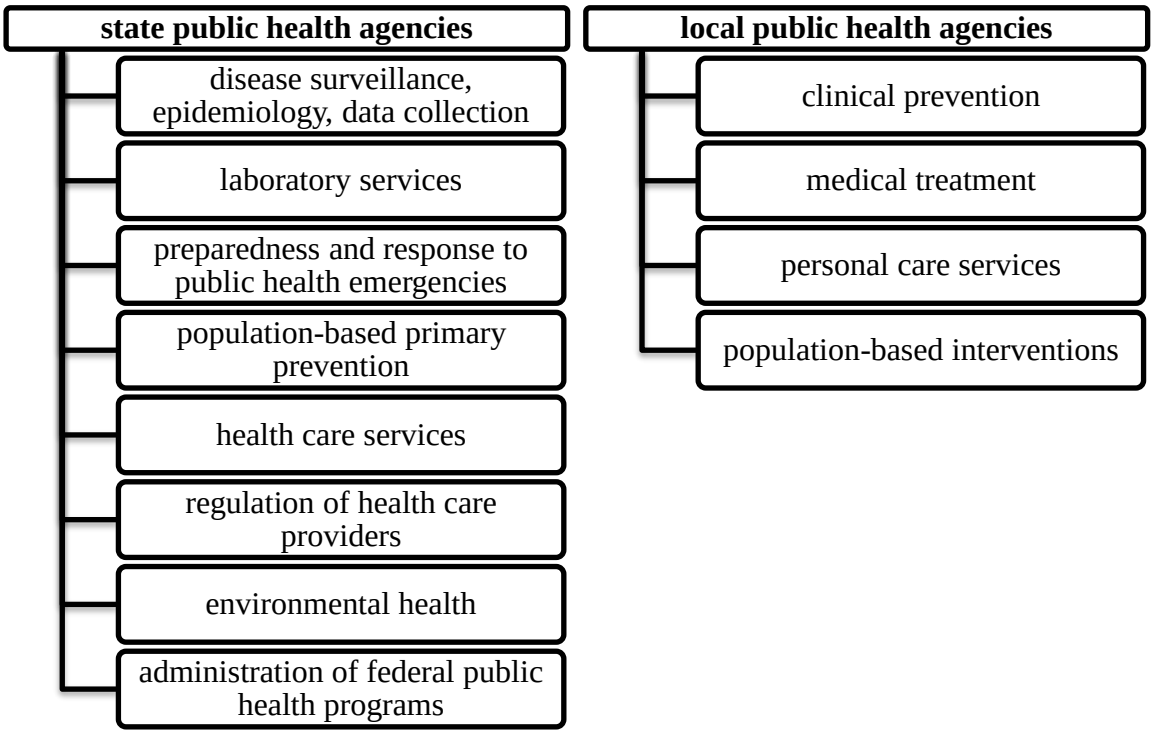
State's public health agencies are responsible for fulfilling the states task to protect health, safety, and the general welfare of the population (Schneider, 2017, p. 30). Due to this responsibility, state are the primary authority for public health in the U.S. (Salinsky, 2010, p. 7). States are autonomous and authoritarian in providing population-based and personal health services through statutes (Lister, 2005, p. 11). Each state has an established state health agency, which assumes governmental public health activities. The state public health systems as a whole are very fragmented because each state has a

high degree of flexibility in choosing how to structure its syytem (Salinsky, 2010, p. 8). State health department activities are mainly funded by state taxes, federal grants, and fee-for-service payment structures (Schneider, 2017, pp. 30, 32).

At a local level, the extent to which public health agencies have authority is limited by state policy, but local policymakers have the flexibility to determine which activities are provided and how they are provided (Salinsky, 2010, p. 15). Public health organizations differ among states because size, powers, and funds vary. In general, every county must establish a health department that serves cities as well as rural areas. These organizations are responsible for the day-to-day public health matters, such as the surveillance of local health problems and assuring that high-quality services are available in their community. In addition, local health departments are also responsible for tending to the health and well-being of underserved, less privileged persons. Aside from governmental funding, local health departments are typically financed by local property taxes, sales taxes, and fees for provided health services, but this varies from state to state (Schneider, 2017, pp. 29-30; Committee, 1988, p. 9).

Local and state health agencies are strongly connected. State health agencies delegate responsibility to local health agencies, but the authority given differs and depends on the chosen structure (centralized, decentralized, and hybrid approach). Within a centralized approach the control and responsibility for health care services rests with the state health agencies, whereas within a decentralized approach total responsibility for public health services provided in a specific jurisdiction is delegated to local agencies. Within a hybrid approach state and local health agencies both provide services and share responsibility (Lister, 2005, p. 11). State and local health agency activities are shown in the table below.

Figure 2: State and local health agency activities



Source: Own graphic based on Salinsky, E. (2010), *Governmental Public Health: An overview of state and local public health agencies*, No. 77, Washington DC, pp. 11-16.

Different kinds of treatment services are provided through local public health agencies. Some offer primary health care services, but most provide testing and treatment for communicable diseases, such as tuberculosis and sexually transmitted diseases like HIV. Other personal care services are implemented as well, particularly services for maternal and child health such as perinatal home visitation (Salinsky, 2010, p. 15).

Structure of the public health system in Germany

The main tasks of public health services in Germany are the surveillance of communicable diseases, health reporting, supervision of environmental hygiene, and health education as well as promotion (Busse et al., 2013, p. 3).
In the German public health system governmental institutions, public corporations and independent organizations as well as their associated agencies work on federal, state, and local levels (Walter et al., 2012, p. 272). On the federal level, there are ministries and institutions. In 1961 the first self-operating Federal Ministry for Healthcare was established. The ministry was responsible for all questions regarding healthcare, including environmental aspects like sanitation or clean air. It was substituted by the Federal Ministry for Health in 1991. The new ministry is divided in several subdivisions such

as prevention, which deals with health promotion and legal issues of prevention or disease control. Also, general healthcare activities are overseen by the ministry including information and health education as well as early detection and prevention of diseases. Since public health is a widespread field, as previously mentioned, there are various other federal ministries that tackle public health issues like the Federal Ministry of Education and Research, which is responsible for educating the population, or the Federal Ministry of Labour and Social Affairs which is responsible for rehabilitation. A federal institution with resemblance to the American CDC is the Robert-Koch-Institut (RKI). Its task as a federal institution for infectious diseases and non-communicable diseases is to identify, prevent, and combat these diseases. It is also responsible for the Federal Health Monitoring System (Walter et al., 2012, pp. 273-275).

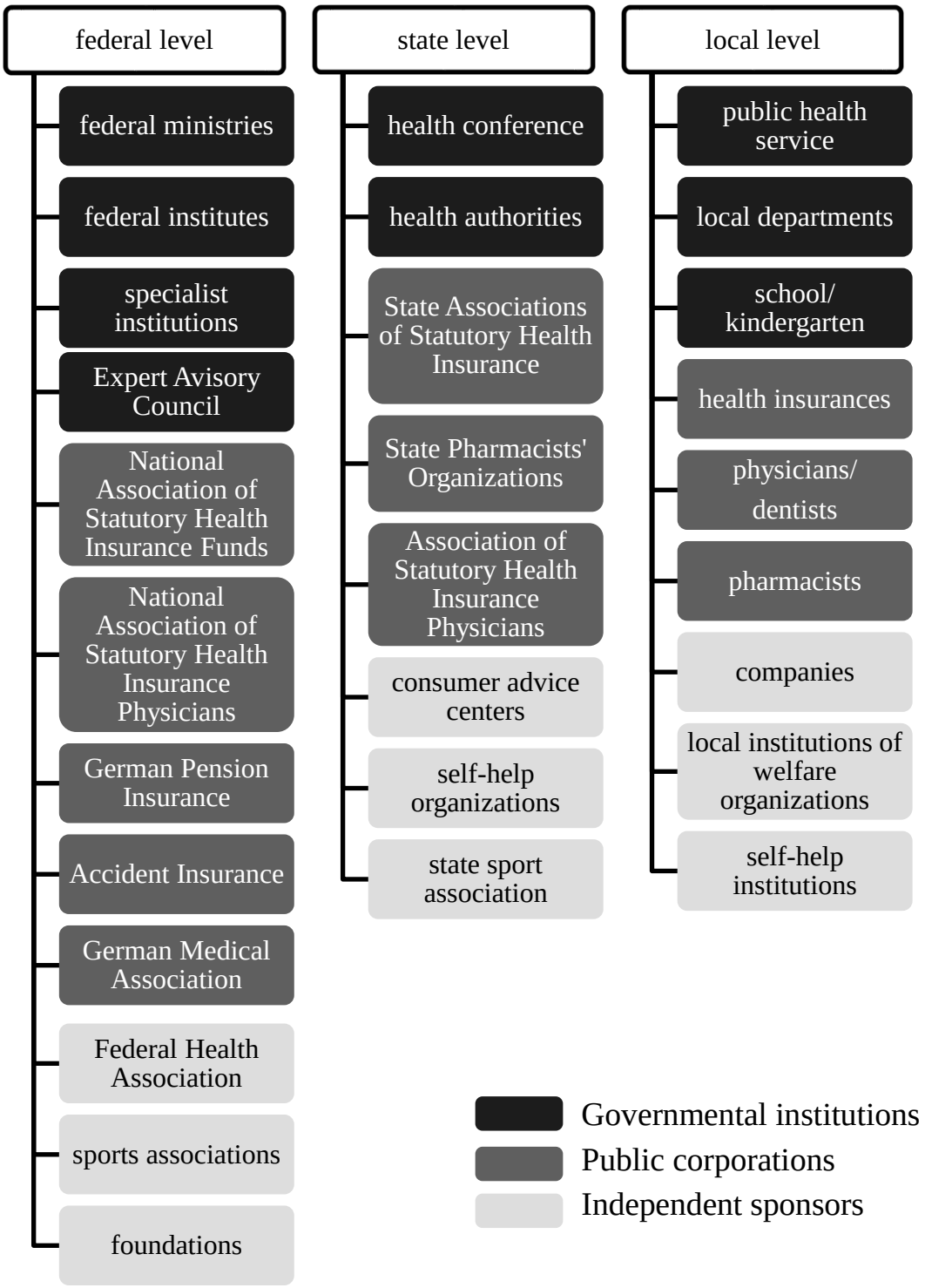
Besides federal ministries and institutions, health insurance companies play an important role as it is their statutory mandate to promote, recover, or improve the health of their policy holders by offering information, consultation, and services. With statutory health insurance reformation in 1989 measures of the health promotion and disease prevention were established for the first time in the healthcare system. In §§20-24i in the German Social Security Code, Book V (SGB V) the main services of health insurance companies are recorded to include services for the prevention of diseases, workplace health promotion, the prevention of work-related risk factors, promotion of self-help, and services during pregnancy and motherhood. Different program offering for prevention and health promotion are a substantial part of health insurance competition and lead to two positives effects. On the one hand, people who want to stay healthy are attracted to join the health insurance and on the other hand already insured people stay healthier and therefore costs stay at lower level, because the insurance risk pool is better. It can be said that promotion and prevention programs are an adjusting screw on the health insurance market, which means that they are an important decisive criterion regarding the decision making of individuals to join an insurance agency (Walter et al., 2012, pp. 279-280).

Although legislation for health prevention is the responsibility of the federal government, states also have a main task regarding health prevention due to constitution. On a state level, ministries with a special department for health are responsible for the implementation of laws and control of public healthcare. The Conference of Health Ministers and the Association of the State Board of Health coordinate activities of national ministries on the federal level. Tasks of state ministries vary and include financially supporting State Associations, National Offices, and State Working Groups for health. They are established in nearly every German State and have the aim of coordinating, promoting, and cooperating within health education and health promotion on a state level to improve the health of the population. Practical examples are information events, work groups or training programs (Walter et al., 2012, p. 281).

With facilities very accessible to and in direct contact with citizens, prevention and health promotion play an important role on local level. Health departments are particularly relevant as they are represented in every district and have the legal responsibility to prevent disease and promote the health of the population. Their tasks include combating communicable diseases, providing vaccines, offering consultancies for different patient groups, and performing check-ups for children. Services for early detection of disease were introduced in 1971 and nowadays include prenatal care, cancer-screening, and screenings for an early detection of heart-diseases, kidney diseases, and diabetes. Although medical consultation is effective, it has only a marginal importance. Other facilities that act on a local level and in direct contact to the citizens are schools, sports clubs, pharmacies, welfare centers, and churches. All of them have the same task: to give health information, health education, and health care provision (Walter et al., 2012, pp. 281-285).

A special governmental institution in the public health system is the public health services (Öffentlicher Gesundheitsdienst=ÖGD), located at the local level, which can be associated with a service-orientated administrative structure. Its main tasks are to create conditions in which people can be healthy, to promote public health needs as an impartial player, to act practical, and to protect the human dignity of every individual. The ÖGD is sometimes called the third pillar of the healthcare system besides ambulatory and stationary medical treatment. Although its percentage of total healthcare expenditures is lower than one percent, this institution has a great importance for the quality of life and the life expectancy which have both increased. Services the ÖGD provides are essentially health protection (reducing infection and improving hygiene), health promotion and prevention (strengthening of resources and boosting health-related opportunities), and healthcare management (developing the healthcare system and improving quality). The ÖGD is regulated differently by every state legislation and therefore has a heterogeneous profile (Wildner et al., 2016, pp. 289-292).

Figure 3: Institutions at all levels in the German public health system



Source: Own graphic based on Walter, U., Schwartz, F. W. and Plaumann, M. (2012), Prävention: Institutionen und Strukturen, in: Schwartz, F. W., Walter, U., Siegrist, J., Kolip, P., Leidl, R., Dierks, M. L., Busse, R. and Schneider, N. (Ed.), Public Health: Gesundheit und Gesundheitswesen, third edition, Urban&Fischer, München, p. 272.

3 Risk factors

According to the World Health Organization (WHO), a risk factor is "any attribute, characteristic or exposure of an individual that increases the likelihood of developing a disease or injury" (WHO, 2017). Through health promotion and prevention, the probability of risk factors occurring and subsequently resulting in disease can be reduced (OECD, 2015a). The effectiveness of the preventive action is proven by a decrease in the prevalence of a disease (Egger and Razum, 2014, pp. 23-24).
The number of possible risk factors is high and includes a large variety of risks from high blood pressure, tobacco use, alcohol use, high blood glucose, high cholesterol, and high body mass index to physical inactivity and low fruit and vegetable intake. These factors can increase the risk for chronic diseases like heart disease, diabetes, and cancer and risk factors affect all income groups of all countries. Unsafe sex, alcohol use, polluted water, poor sanitation, and low hygiene affect the population in different ways, sometimes causing serious issues, especially in low-income countries, for example Ebola in many African countries (WHO, 2009, p.v; Tulchinsky and Varavikova, 2014, p. 243). This paper focuses on the three risk factors mentioned in the OECD report from 2015: smoking, alcohol consumption, and obesity.

3.1 Tobacco use in Germany and the U.S.

Tobacco use affects nearly all organs of the body and causes cardiovascular diseases, several types of cancers, and pulmonary diseases (OECD, 2015a). In Germany, 28.7% of the adult population smoked in 2015, with 26.1% of women and 32.2% of men smoking cigarettes (Piontek et al., 2017, p. 43). It is notice-able that as age increases the number of regular smokers grows, especially for men. Furthermore, the percentage of smokers decreases as social status increases (Pötschke-Langer et al., 2015, pp.39, 44-45). In particular, the highest proportion of smokers among both genders is between the ages of 18 and 44 years (Robert-Koch-Institut, 2014, p. 113). The tobacco-based health expenditure in Germany totaled € 79.09 billion in 2015, of that amount € 25.41 billion (7.4% of total health care expenditures) could be attributed to direct costs for treatment, care, rehabilitation, and costs for secondhand smoke victims. Indirect costs that burdened the economy amounted to two-thirds of tobacco expenditure (€ 53.68 billion) through the loss of resources such as death, permanent disability, care, and unemployment of potential workers (Pötschke-Langer et al., 2015, pp. 66-67).
In the United States, 15.1% of adults smoked cigarettes in 2015, with more men (16.7%) than women (13.6%) having smoked. Most of the smokers were between the ages of 25 and 44 years. Moreover, the prevalence of cigarette smoking is higher in people with lower education or if they live below the federal poverty level (Jamal et al., 2016, pp. 1,207-1,208). The annual costs for lost productivity attributable to death from cigarette

smoking amounted to $150.7 billion in 2009 (U.S. Department of Health and Human Services, 2014, p.671). Annual health care spending on tobacco-related conditions in 2010 amounted to $170 billion, which was 8.7% of the total health care expenditures (Xu et al., 2015, p. 326). The economic costs for smoking and exposure to secondhand smoke amount to around $300 billion annually.
When comparing the direct health care costs in both countries regarding smoking, the percentage of total health care expenditures is 1.3% higher in the U.S. than in Germany, although there are twice as many smokers in Germany.

3.2 Alcohol consumption in Germany and the U.S.

Alcohol use causes diverse illnesses such as liver cirrhosis, strokes, and several cancers, but it also leads to accidents, injuries, and violence (OECD, 2015a). In 2015 the 30-day prevalence of any alcohol consumption among adults amounted to 72.5% in Germany. 77.1% male persons and 67.8% female persons consumed alcohol over a month time period. 21.4% of the population practices risky consumption, meaning that on average more than 12 grams of pure alcohol are consumed daily for women and more than 24 grams for men, whereby more men than women practiced it (Piontek et al., 2017, pp. 67-68). The most at risk consumers are between 18 and 29 years old. Women from the age of 30 onwards and from a higher social and educational status are at a higher risk of harmful alcohol consumption than women with a lower social and educational status (Robert-Koch-Institut, 2014, p. 117). Another alarming aspect of alcohol consumption is binge drinking. This is defined as the consumption of at least five alcoholic drinks a day. 46.5% of males and 21.6% of females were identified as binge drinkers in the 30-day prevalence. Binge drinking is especially pronounced within the 18 to 24-year-old range (Piontek et al., 2017, p. 69). Economic costs were quantified to total € 39.30 billion in 2015. Indirect costs amounted to € 30.15 billion, whereas direct costs totaled € 9.15 billion, which account for 2.7% of total health care expenditures (Effertz, 2015, p. 315).
In America, excessive alcohol use consists of binge drinking, heavy drinking, alcohol consumption by pregnant women, and alcohol use by people younger than 21 years. In contrast to Germany, binge drinking in the U.S. means consuming more than five alcoholic drinks for men and four or more drinks for women on one occasion. Heavy drinking is defined as consuming eight or more drinks per week for women and 15 or more drinks per week for men (National Center for Chronic Disease Prevention and Health Promotion, 2016). In 2015, the 30-day alcohol consumption prevalence among adults in the U.S. was 56%, whereby 61.3% men and 51.1% women consumed alcohol (Center for Behavioral Health Statistics and Quality (CBHSQ), 2016, p. 939). The 30-day binge drinking prevalence in 2015 among adults was 26.9%, with more men binge drinking than women. Persons aged 26 to 29 participated most in binge drinking. 7% practiced

heavy alcohol use, where men consumed twice as much as women. In the U.S., full-time employed people and people with a college degree are more at risk for excessive alcohol consumption than unemployed people with a lower educational status (CBHSQ, 2016, pp. 893, 949). The excessive drinking costs amounted to $249 billion in 2010. 72% of the total costs are related to losses in workplace productivity and 11% are related to direct health care expenses. The other 17 % made up criminal justice expenses, motor vehicles crash costs, and property damage (CDC, 2017).
Comparing Germany and the U.S., the prevalence of adults consuming alcohol is 15% higher in Germany, but the proportional part of directly related costs on total health care expenditures in the U.S. is 8.3% higher than in Germany.

3.3 Obesity in Germany and the U.S.

Overweight and obese adults and children are at a very high risk of developing many diverse diseases such as hypertension, high cholesterol, diabetes, cardiovascular diseases, respiratory problems (asthma), and musculoskeletal diseases like arthritis (OECD, 2015a). Obesity is an abnormal or excessive fat accumulation that is measured with the body mass index (BMI)[1]. A BMI higher or equal to 25 is defined as being overweight, whereas obesity is having a BMI higher than or equal to a BMI of 30 (World Health Organization, 2016).
According to OECD measures, in 2013 the obesity prevalence among adults in Germany was 23.6% (OECD, 2015a). In 2012, 67.1% of men and 53.0% of women between the ages of 18 and 79 years were overweight. The prevalence of obese people amounts to 23.3% of males and 23.9% of females. The percentage of overweight men is higher than the percentage of overweight women, whereas the percentage of obese people is roughly equal in both genders. The number of overweight women increases continuously with increasing age, whereas men have a peak at around 30 to 39 years of age, with the number of overweight men nearly doubling in between these ages. Women with a high social and educational status have a lower prevalence of being overweight or obese than women with a lower social status (Mensink et al., 2013, pp. 791-792). In 2015, € 63.04 billion were spent on obesity related costs. Direct costs including sickness benefit, care, and accident costs amount to € 29.39 billion (6.8% of total health care expenditures) and indirect costs (€ 33.65 billion) covered productivity losses and premature mortality (Effertz, 2015, p. 316).
In the United States, 35.3% adults suffered from obesity in 2013 (OECD, 2015a). By 2014, the percentage was already over 37%. Women had a higher prevalence of obesity (40.4%) compared with men (35%). Middle-aged individuals of both genders, men and women between the ages of 40 to 59, were especially affected by obesity (Flegal et al.,

[1] BMI = person's weight in kilograms / square of his height in meters [kg/m2]

2016, p. 2,287). In total, 70.7% American adults were overweight or obese (National Center for Health Statistics, 2016, p. 200). The obesity prevalence among men is quite similar on all income levels with the tendency to be higher for people at higher income levels or with higher educational status. Women earning more or having a college degree have a lower prevalence of being obese (Ogden et al., 2010, pp. 1-3). According to Finkelstein, the estimated national medical care costs for obesity-related illnesses amounted to $147 billion in 2008, which made up 9.1% of national health expenditures (Finkelstein et al., 2009, p. 828). Total annual economic costs amounted to $215 billion (Hammond and Levine, 2010, p. 294).

The rate of obesity in America is more than 10% higher than in Germany and as a result, the percentage of direct healthcare costs related to total health care expenditure is higher in the U.S.

4 Comparison

In general, the risk factors that occur are similar in Germany and the U.S., but the prevalence and costs to both countries vary. For example, the prevalence rates for tobacco and alcohol use are much lower in the U.S. in comparison to Germany, yet they spend more money due to these risk factors (as a percentage of total health care expenditure). With regards to obesity, the U.S. has a higher prevalence rate and also spends more on this issue. The question that arises out of these results is: Why does the U.S. spend so much money on health care despite limited gains?

Health care expenditures as a share of the GDP amounted to 16.4% in the U.S. and 11.0% in Germany in 2013 (OECD, 2015a, p. 169). The U.S. has worse health outcomes for every condition, except for cancer, when compared to most other developed countries (OECD, 2015a, pp. 45-64). So, the American society is paying more and getting less. The reasons for high health care costs can be attributed to high administrative costs due to a lack of coordinated care in a multi-player system. Higher prices for treatments and pharmaceuticals in addition to investment in new technology increases costs as well. The fact that Americans consume more in the form of treatment, diagnostic tests, prescription drugs and pharmaceuticals than any other developed country also attributes to their significant health expenditures (Cutler, 2013). In addition, Americans pay doctors more than most other countries do (Yglesias, 2013).

Looking at the organizational structures, both have basically equal elements as both countries have entities at the federal, state, and local level with different jurisdictions for each segment. However, the American public health care system is more fragmented and therefore contributes to higher health care costs in addition to many of the other factors already mentioned above. The risk factors Americans are exposed to are mainly responsible for many chronic diseases (diabetes, cancer or heart disease), which are then

the main drivers of high health care expenditures (Sturm, 2002, p. 245). Therefore, it is important to introduce effective preventative measures to contain costs.

The key reasons that the U.S. succeeded in reducing the prevalence of smoking was because their public health policies not only prohibited smoking in indoor public and private workplaces, but also increased the tobacco product excise taxes while implementing mass-media campaigns (CDC, 2014a, p. 133). In comparison, Germany has not implemented any measures over the last seven years aiming to reduce consumption and they are the only country to allow unlimited outdoor advertisement (Deutsches Krebsforschungszentrum, 2017). It is worth mentioning that Germany already implemented a law successfully years ago. The Non-Smoker Protection Law was established in 2007 and includes a smoking ban in public institutions of government, sport, and education institutions as well as a ban in children and youth facilities as well as in restaurant and eateries.

The U.S. was able to decrease the alcoholism and dangerous drinking probability by reducing commercial and social access as well as economic availability ((Hingson et al., 2006, p. 739). This was achieved by setting the minimum legal drinking age to 21 and by prohibiting the consumption of alcohol in public places (Voas and Fell, 2011, p. 225). In addition, the U.S. introduced further strategies, for example, a school-based program to strengthen adolescents' ability to avoid peer pressure and resist alcohol consumption. Extracurricular activities also reduce alcohol use and so does family involvement (Komro and Toomey, 2002, pp. 5-14). Germany sets their focus instead on awareness and information campaigns, for example "Kenn dein Limit".

With regards to obesity, the U.S. has not been as successful. Causes for obesity in America are countless. However, physical inactivity, consumption of high-calorie foods, high stress, and a low-income drastically increase the probability of becoming obese (University of Maryland Medical Center, 2015). Germany guarantees a better work-life-balance, allowing more time for sports and other activities which decrease the risk for becoming overweight or obese (OECD, 2015b).

The U.S. introduced good strategies for reducing alcohol and tobacco consumption, but still has higher health care expenditures. Looking at prevention expenditures as a share of total health expenditures in 2014, Germany spends 3.1% and the U.S. 2.9% (OECD, 2016, p. 134). Higher health care expenditures are not attributable to higher investments in preventative strategies, but to faults in the organizational structure of the health care system. In comparison to Germany, who spent far less, America does not work in an as cost-effective manner.

5 Conclusion

Implementing policies to address public health issues is not always easy. This is particularly a concern in the U.S. To succeed, a problem must be recognized, a solution must

be available, and the political conditions must be right to implement a health policy through an open policy window. In the U.S., the bipartisan structure and disagreements in the Congress often impede the development of new policies (Kingdon, 1993, pp. 41-43). In addition, politicians want to achieve short term solutions to get re-elected. Therefore, big public health solutions that are needed to solve pressing public health issues are rare. It is important to focus on upstream measures as they are more effective than downstream measures. Upstream measures take place on a macro policy level and seek to diminish the cause of the cause, whereas downstream measures act on an individual level and seek to change the effects of the cause (National Collaborating Centre for Determinants of Health, 2014, p. 3). U.S. politicians prefer to focus on downstream measures as opposed to upstream measures because their implementation is easier, faster, and typically costs less (Rutter et al., 2017, p. 61). It is important to consider the imbalance of the U.S. health care system in comparison with the German system when looking at policy solutions and interventions for public health issues. Despite the shortcomings that any health care system may have, the public health agencies in the U.S. and Germany, ultimately serve to reduce the prevalence of risk factors in society. As a result of this reduction, these systems prevent diseases and improve the health status of individuals and reduce health care expenditures, even when combating complex risk factors such as tobacco, alcohol and obesity (Maciosek et al., 2010, p. 1,656).

References

Ashton, J. (1988), 'Acheson: A Missed Opportunity for the New Public Health', British Medical Journal (Clinical Research Edition), vol. 296, no. 6617, pp. 231–232.

Busse, R., Blümel, M., Rice, T., Rosenau, P., Unruh, L. Y. and Barnes A. J. (2013), Public Health: The Health Systems and Policy Monitor, European Observatory on Health Systems and Policies.

Center for Behavioral Health Statistics and Quality (2016), 2015 National Survey on Drug Use and Health: Detailed Tables, Substance Abuse and Mental Health Services Administration.

Centers for Disease Control and Prevention (2013), The Public Health System and the 10 Essential Public Health Services [Online], U.S. Department of Health and Human Services. Available at: https://www.cdc.gov/nphpsp/essentialservices.html (Accessed May 17, 2017).

Centers for Disease Control and Prevention (2014), Best Practices for Comprehensive Tobacco Control Programs - 2014, U.S. Department of Health and Human Services.

Centers for Disease Control and Prevention (2014), Mission, Role and Pledge [Online], U.S. Department of Health and Human Services. Available at: https://www.cdc.gov/about/organization/mission.htm (Accessed September 14, 2017).

Centers for Disease Control and Prevention (2017), Economic Costs [Online], U.S. Department of Health and Human Services. Available at: https://www.cdc.gov/alcohol/data-stats.htm (Accessed May 17, 2017).

Cohen, L. and Swift, S. (1999), 'The Spectrum of Prevention: Developing a Comprehensive Approach to Injury Prevention', Injury Prevention, vol. 5, no. 3, pp. 203–207.

Committee for the Study of the future of Public Health Division of Health Care Services (1988), The Future of Public Health, 11th edn, Washington, D.C., National Academy Press.

Cutler, D. (2013), Why Does Health Care Cost So Much in America? Ask Harvard's David Cutler, PBS Newshour [Online]. Available at: http://www.pbs.org/newshour/rundown/why-does-health-care-cost-so-much-in-america-ask-harvards-david-cutler/ (Accessed May 17, 2017).

Deutsches Krebsforschungszentrum (2017), Raucherparadies Deutschland, Deutsches Krebsforschungszentrum no. 15.

Effertz, T. (2015), Die volkswirtschaftlichen Kosten gefährlichen Konsums: Eine theoretische und empirische Analyse für Deutschland am Beispiel Alkohol, Tabak und Adipositas, Frankfurt am Main, Wien, PL Academic Research Imprint der Peter Lang GmbH.

Egger, M. and Razum, O. (2014), 'Public Health: Konzepte, Disziplinen und Handlungsfelder', in Egger, M. and Razum, O. (eds.) Public Health: Sozial- und Präventivmedizin Kompakt, Berlin, De Gruyter, pp. 1–26.

Finkelstein, E. A., Trogdon, J. G., Cohen, J. W. and Dietz, W. (2009), 'Annual Medical Spending Attributable to Obesity: Payer-and Service-Specific Estimates', Health Affairs, no. 5, pp. 822-831.

Flegal, K. M., Kruszon-Moran, D., Carroll, M. D., Fryar, C. D. and Ogden, C. L. (2016), 'Trends in Obesity Among Adults in the United States, 2005 to 2014', JAMA, vol. 315, no. 21, pp. 2284–2291.

Gerlinger, T., Babitsch, B., Blättner, B., Bolte, G., Brandes, I., Dierks, M.-L., Faller, G., Gerhardus, A. and Gusy, B. (2012), 'Situation und Perspektiven von Public Health in Deutschland-Forschung und Lehre: Positionspapier der Deutschen Gesellschaft für Public Health e. V', Gesundheitswesen (Bundesverband der Arzte des Öffentlichen Gesundheitsdienstes (Germany)), vol. 74, no. 11, pp. 762–766.

Hammond, R. A. and Levine, R. (2010), 'The Economic Impact of Obesity in the United States', Diabetes, Metabolic Syndrome and Obesity : Targets and Therapy, vol. 3, pp. 285–295.

Happe, K., ed. (2015), Public Health in Deutschland: Strukturen, Entwicklungen und globale Herausforderungen, Halle (Saale),.

Hingson, R. W., Heeren, T. and Winter, M. R. (2006), 'Age at Drinking Onset and Alcohol Dependence: Age at Onset, Duration, and Severity', Archives of Pediatrics & Adolescent Medicine, vol. 160, no. 7, pp. 739–746.

Jamal, A., King, B. A., Neff, L. J., Whitmill, J., Babb, S. D. and Graffunder, C. M. (2016), 'Current Cigarette Smoking Among Adults - United States, 2005-2015', MMWR. Morbidity and Mortality Weekly Report, vol. 65, no. 44, pp. 1205–1211.

Kingdon, J. W. (1993), 'How do Issues Get on Public Policy Agendas?', in Wilson, W. J. (ed.) Sociology and the Public Agenda, Newbury Park, SAGE Publications, pp. 40–51.

Komro, K. A. and Toomey, T. L. (2002), 'Strategies to Prevent Underage Drinking', Alcohol Research & Health, vol. 26, no. 1, pp. 5–14.

Lister, S. A. (2005), An Overview of the U.S. Public Health System in the Contect of Emergency Preparedness, United States Congressional Research Service.

Mensink, G. B. M., Schienkiewitz, A., Haftenberger, M., Lampert, T., Ziese, T. and Scheidt-Nave, C. (2013), 'Übergewicht und Adipositas in Deutschland: Ergebnisse der Studie zur Gesundheit Erwachsener in Deutschland (DEGS1)', Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz, 5/6, pp. 786–794.

National Center for Chronic Disease Prevention and Health Promotion (2016), Alcohol Use and Your Health [Online], U.S. Department of Health and Human Services. Available at: http://www.cdc.gov/alcohol/fact-sheets/alcohol-use.htm (Accessed May 17, 2017).

National Center for Health Statistics (2016), Health, United States, 2015: With Special Feature on Racial and Ethnic Health Disparities, U.S. Department of Health and Human Services.

National Collaborating Centre for Determinants of Health (2017), Let's Talk: Moving Upstream, National Collaborating Centre for Determinants of Health.

OECD (2015), Health at a Glance 2015: OECD Indicators, OECD Pusblishing.

OECD (2015), Work-Life-Balance [Online], OECD. Available at: http://www.oecdbetterlifeindex.org/de/topics/work-life-balance-de/ (Accessed May 17, 2017).

OECD (2016), Government at a Glance: How Korea Compares, OECD Pusblishing.

Ogden, C. L., Lamb, M. M., Carroll, M. D. and Flegal, K. M. (2010), 'Obesity and Socioeconomic Status in Adults: United States, 2005-2008', NCHS Data Brief, no. 50, pp. 1–8.

Piontek, D., Gomes de Matos, E., Atzendorf, J. and Kraus, L. (2017), Substanzkonsum und Hinweise auf klinisch relevanten Konsum in Bayern, Hamburg, Hessen, Nordrhein-Westfalen, Sachsen und Thüringen: Ergebnisse des Epidemiologischen Suchtsurvey 2015, IFT Institut für Therapieforschung No. 189.

Pötschke-Langer, M., Kahnert, S., Schaller, K., Viarisio, V., Heidt, C., Schunk, S., Mons, U. and Fode, K. (2015), Tabakatlas Deutschland 2015, Papst Science Publishers.

Robert-Koch-Institut (2014), Daten und Fakten: Ergebnisse der Studie „Gesundheit in Deutschland aktuell 2012": Beiträge zur Gesundheitsberichterstattung des Bundes, RKI.

Rutter, H., Bes-Rastrollo, M., Henauw, S. de, Lahti-Koski, M., Lehtinen-Jacks, S., Mullerova, D., Rasmussen, F., Rissanen, A., Visscher, T. L. S. and Lissner, L. (2017), 'Balancing Upstream and Downstream Measures to Tackle the Obesity Epidemic: A Position Statement from the European Association for the Study of Obesity', Obesity Facts, vol. 10, no. 1, pp. 61–63.

Salinsky, E. (2010), Governmental Public Health: An Overview of State and Local Public Health Agencies, National Health Policy Forum No. 77.

Schneider, M.-J. (2017), Introduction to Public Health, Burlington, MA, Burlington, MA, Jones & Bartlett Learning.

Sozialgesetzbuch, Fünftes Buch (1998), Gesetzliche Krankenversicherung, zuletzt geändert durch Art. 1 G v. 4.4.2017 I 778 (SGB V).

Sturm, R. (2002), 'The Effects of Obesity, Smoking, and Drinking on Medical Problems and Costs', Health Affairs, vol. 21, no. 2, pp. 245–253.

Tulchinsky, T. H., Varavikova, E. and Bickford, J. D. (2014), The New Public Health, San Diego, Elsevier.

U.S. Department of Health and Human Services (2014), The Health Consequences of Smoking: 50 Years of Progress: A Report of the Surgeon General, Centers for Disease Control and Prevention.

U.S. Food and Drug Administration (2017), What We Do [Online], U.S. Food and Drug Administration. Available at: https://www.fda.gov/AboutFDA/WhatWeDo/default.htm (Accessed September 17, 2017).

University of Maryland Medical Center (2015), Obesity, University of Maryland Medical Center [Online]. Available at: http://www.umm.edu/health/medical/altmed/condition/obesity (Accessed May 17, 2017).

Voas, R. B. and Fell, J. C. (2011), 'Preventing Impaired Driving: Opportunities and Problems', Alcohol Research & Health, vol. 34, no. 2, pp. 225–235.

Walter, U., Robra, B.-P. and Schwartz, F. W. (2012), 'Prävention', in Schwartz, F. W., Walter, U., Siegrist, J., Kolip, P., Leidl, R., Dierks, M.-L., Busse, R. and Schneider, N. (eds.) Public Health: Gesundheit und Gesundheitswesen, 3rd edn, München, Urban&Fischer, pp. 196–223.

Walter, U., Schwartz, F. W. and Plaumann, M. (2012), 'Prävention: Institutionen und Strukturen', in Schwartz, F. W., Walter, U., Siegrist, J., Kolip, P., Leidl, R., Dierks, M.-L., Busse, R. and Schneider, N. (eds.) Public Health: Gesundheit und Gesundheitswesen, 3rd edn, München, Urban&Fischer, pp. 271–287.

Wildner, M., Müller, W., Jaeschke, B. and Zapf, A. (2012), 'Der Öffentliche Gesundheitsdienst', in Schwartz, F. W., Walter, U., Siegrist, J., Kolip, P., Leidl, R., Dierks, M.-L., Busse, R. and Schneider, N. (eds.) Public Health: Gesundheit und Gesundheitswesen, 3rd edn, München, Urban&Fischer, pp. 289–294.

Wildner, M., Niehoff, J.-U. and Hoffmann, W. (2016), 'Entwicklungslinien der Sozialmedizin und Öffentlichen Gesundheit in Deutschland', Gesundheitswesen, vol. 78, no. 2, pp. 113–119.

Winslow, C. E. (1920), 'The Untilled Fields of Public Health', Science (New York, N.Y.), vol. 51, no. 1306, pp. 23–33.

World Health Organization (1984), Glossary of Terms: Used in the "Health for all" Series No. 1-8, WHO Press, Health for all.

World Health Organization (2009), Global Health Risks: Mortality and Burden of Disease Attributable to Selected Major Risks, WHO Press.

World Health Organization (2016), Obesity and Overweight [Online], WHO. Available at: www.who.int/mediacentre/factsheets/fs311/en/ (Accessed May 17, 2017).

World Health Organization (2017), Risk Factors [Online], WHO. Available at: http://www.who.int/topics/risk_factors/en/ (Accessed May 17, 2017).

Xu, X., Bishop, E. E., Kennedy, S. M., Simpson, S. A. and Pechacek, T. F. (2015), 'Annual Healthcare Spending Attributable to Cigarette Smoking: An Update', American Journal of Preventive Medicine, vol. 48, no. 3, pp. 326–333.

Yglesias, M. (2013), America's Overpaid Doctors, Moneybox [Online]. Available at: http://www.slate.com/articles/business/moneybox/2013/02/american_doctors_are_overpaid_medicare_is_cheaper_than_private_insurance.html (Accessed May 29, 2017).

Serving the City of Detroit – The Detroit Health Department

Jenny Reinold and Simone Leeb

The Detroit Health Department is an institution with a diverse set of responsibilities. It offers a wide range of services and programs to secure and to maintain Detroiters health and well-being, especially for those people who are not able to take care of themselves. The upheaval in the Detroit automobile industry caused unemployment, decreasing habitants and fiscal problems. In the consequence amongst other things, the investments in the Health Department have been reduced, which led to downsizing and ending health services and programs. Subsequently, Detroit had to struggle with socioeconomic problems and public health. With its key role in populations health, the Health Department is a central contact point for people living in the Detroit Area. In order to maintain the resurfacing strength of Detroit's Health Department and to make it even better it is necessary to collaborate with different sectors and other Departments for a mutual exchange and to generate money for the Health Department with funding partnerships.

Contents

1 Introduction

The Detroit Health Department provides public health services and partners with neighborhood and community stakeholders to improve the health and the quality of life of the people in the Detroit metropolitan area (CITY OF DETROIT, 2001A - 2017, 2001A - 2017). To get a general idea of the health programs in Detroit and to understand further improvement in community health needs, this paper initially outlines the history of Detroit. The second chapter will give an overview of how the determinants of health are influencing Detroit´s health services and which steps the department has implemented to face the problems that result from poor health. Finally, there is a discussion of how the health department could improve Detroiter's health based on the determinants of health and what future challenges they might address.

2 Theoretical Principles

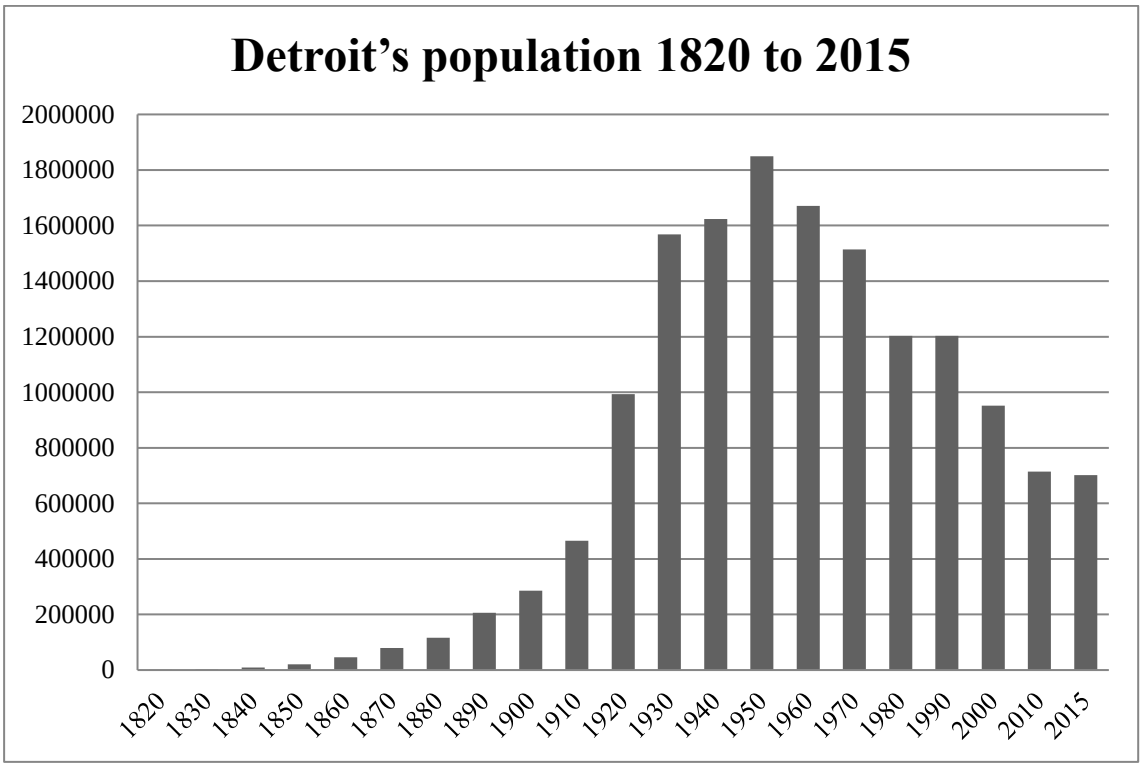
2.1 Detroit History

To get a better understanding of what the Detroit Health Department is and the work that they do, it is necessary to get an overview about Detroit's history. Detroit originally was the "motor-city." The factories produced passenger vehicles, weapons, and equipment for the U.S. military in the twentieth century. It was a thriving time for Detroit in the automobile industry and manufacturing (LOUGHEED, 2014, p. A325). Even today, the space reflects how it was laid out is based on cars. The city initially was built over a large area because it was assumed that everyone would have a car. Therefore, no major subway-system was built in the city, and this continues to have a big impact on the city's infrastructure and how people think of health. (KHALDUN, J.S., 2017)

Back in 1950, Detroit's population peaked at more than 1.8 million (U.S. CENSUS BUREAU, 2005, p. 1) but as the car industry collapsed, the people left as well. The consequence was a decreasing tax-base and decreasing habitants. Today, the population is only a third of its original size. From 2000 (with a population number of 951,270) to 2010, the population dropped by 25 percent to 713,777. Detroit's population has been declining for more than 60 years. (WORLD POPULATION VIEW, 2017)

In the following diagram, you can see the populations' development in the past decades.

Figure 1: Detroit's Population from 1820 to2015



Source: Authors' own presentation, data from WORLD POPULATION VIEW, 2017.

Because of the rough economic situation, Detroit had to struggle with socioeconomic problems. Due to economic decline, people moved away. On the one hand, people lost their jobs and now were looking for better job opportunities. On the other hand, the housing vacancy in the city caused a drop in the property-values. (WORLD POPULATION VIEW, 2017; LOUGHEED, 2014, p. A325).

The fiscal problems of Detroit were substantial enough to cause nearly the largest municipal bankruptcy in U.S. history. In 2013, it also affected the health department. (DAVEY, M. 2014, p. A21). All these factors contributed to public health issues and crime. Therefore, there are a lot of areas in Detroit today which are vacant and are declining instead of growing.

The Detroit Health Department plays a major role in public health. In the next chapter, you will find important keynotes about the Health Department before the department's programs will be introduced.

2.2 Detroit Health Department

The first recorded actions taken by the city in developing an environmental health program were in 1827 (Molner, J.G. and Getting, V.A., 1955, p. 855). After the implementation of public health services in Detroit, the department of health was able to extend its services not only to face one problem but to implement several programs at a time. Today the department follows the vision, "A healthier Detroit and healthier Detroiter."

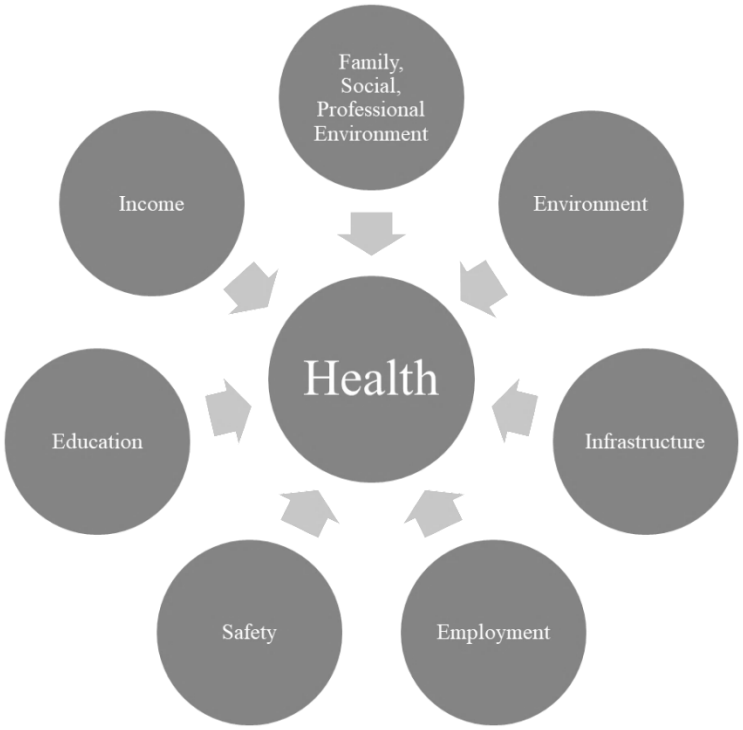
Therefore, it tries to improve the health and quality of life of the citizens through programs, policy promotion and partnerships in neighborhood and around the city (Molner, J.G. and Getting,V.A., 1955; Khaldun, J.S., 2016).
As a consequence of the bankruptcy – in the end of 2011 the City of Detroit had $12 billion debts in long-term liabilities – the public health services were privatized in 2012. This step was a result of the declining population of the City of Detroit and the accompanying decrease of fiscal revenues. Outsourcing the health department to a public institute saved the city money. Instead of receiving money from the city, the institute would be funded with government and foundation grants. Health services like immunizations and tuberculosis treatment were turned over to the Institute for Population Health in order to prevent closing any clinics. (Bouffard, K., 2014; Huffpost, 2012)
Since the city is currently getting out of the bankruptcy, it is starting to regain responsibility for some of the services. In Fall 2014, the health services also returned to the Detroit Health Department (R. Pool and K. Stratton, 2015; Bouffard, K., 2014). With the new start after returning all health services to the department, a new health department director was announced. Dr. Abdul El-Sayed is committed to reconstruct the programs of the health department and public health services by reducing the disparities (The Detroit News, 2015).
Detroit Health Department services include amongst others:

- Environmental Health and Safety
- HIV/AIDS Program
- Immunizations
- Lead Prevention
- Maternal Child Health
- Office of Public Health Emergency Preparedness
- Vision Screening
- Women, Infants, and Children (WIC) Program (City of Detroit, 2001b - 2017)

2.3 Facing Problems / Determinants of Health

Health and diseases result from a complex interplay of several effects. Health-related behaviors, as well as access and quality of health care, have an enormous impact on health status. Socioeconomic factors, especially, are important not only for an individual's health but also for the health of the whole population.
The following illustration shows different determinants which all contribute significantly to how healthfully we live.

Figure 2: Social Determinants of Health



Source: Authors' own presentation, data from SENTERFITT, J.W. ET AL., 2013, p. 2.

Personal surroundings, education, neighborhood safety, employment, income, infrastructure and the environment are components that all belong to the social and economic, known as socioeconomic, factors of health (SENTERFITT, J.W., ET AL., 2013, p. 2).
Detroit in particular is facing issues related to these determinants of health. As shown in 2.1, after the huge economic breakdown, a lot of inhabitants lost their employment and left the city. Because of the declining population, some areas of Detroit nowadays are like a ghost town which contributes to a high rate of crime.
Today Detroit is one of the metro areas with the highest rate of concentrated poverty in the U.S (KNEEBONE, E. AND HOLMES, N. 2016). A high rate of poverty entails a lot of challenges. NEIGHBORHOODSCOUT found that, compared to other cities, Detroit has one of the highest crime rates in America. (NEIGHBORHOODSCOUT, 2017) 39.8% of the residents are below the poverty line and almost 60% of the children grow up in poverty. 79% of the residents in Detroit are African-American. According to KHALDUN, life in Detroit is rough especially for them. They still have disadvantages compared to white residents and are also not free in the choice of areas in which they can live. Moreover, about 20% of the residents are uneducated, don't have education qualifications and barely have a possibility to enhance their chance of obtaining a better job and life. The rate of unintended teen-pregnancy is higher in Detroit than in other cities and areas. Six percent of the women between 15 to 19 years gave birth during past year (CENSUS REPORTER, 2015 AND KHALDUN, J.S., 2017).

Beside these socioeconomic factors also the infrastructure in the Detroit area has an impact on the individual's health status. In 2011, nearly one in four households in Detroit had no access to a vehicle (DATA DRIVEN DETROIT, 2012, p. 10). A well-organized public transportation system is crucial for these people. But currently, transportation services in Detroit are infrequent, not on time, and are thus, unreliable. Beside this the system is facing problems with the regional connections, which makes it almost impossible for some people to reach their jobs and even grocery stores (REGIONAL TRANSIT AUTHORITY OF SOUTHEAST MICHIGAN, 2016, p. 2).
Moreover, SHANNON ET AL. found that the grocery stores, which provide healthy food are mostly located in white neighborhoods. This fact makes it even harder for people living in impoverished neighborhoods to buy healthy food and thus has a direct impact on their health status (ZENK ET AL., 2005, p. 664). The environmental exposures in Detroit are another issue for residents. Asthma is one of the most common chronic disease of childhood in the world. Due to the proximity of industrial pollutant and the interstate motorways a high number of children in Detroit are struggling with asthma (KEELER ET AL., 2002, pp. 176.-179). Another example for the unhealthy environmental conditions is the Flint Water Crisis. It started in 2014 when the drinking water supply in nearby Flint, MI was switched from Lake Huron to the Flint-River to save money. About four weeks later over 100,000 residents were exposed to high levels of lead in the drinking water due to the insufficient water treatment. It turned out that elevated blood lead levels found in children in Flint are associated with the Flint drinking Water Crisis (HANNA-ATTISHA ET AL., 2016, p. 283).

3 Interventions

The Detroit Health Department tries not to create programs only focused on individuals. It tries to create a public health infrastructure and support this in consideration of the determinants of health and the issues of Detroit. According to KHALDUN, creating healthy conditions where people are able to live a healthy life is the definition of public health (KHALDUN, J.S., 2017, p. 17). The Detroit Health Department pursues the principle "health across the lifespan", divided into "healthier beginnings," healthier childhoods," as well as "healthier lives" (KHALDUN, J.S., 2017, p. 18). The health department offers different programs for every stage of life as well as for "healthier places" (DETROIT HEALTH DEPARTMENT, 2017A). The following chapters will explain some elected programs.

3.1 Healthier Beginnings

Hearing and Vision Screening
The Hearing and Vision Screening Program addresses children of Detroit between three and ten years (DETROIT HEALTH DEPARTMENT, 2017A). Hearing and vision screenings are essential in order to prevent speech or cognitive disorders and to support the child's development. The screenings are free of charge and take place at school (MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES, 2017). The screenings are an important intervention, because 15% of children show abnormalities regarding the hearing and vision screening.

Maternal-Child-Health
Within the framework of the program a variety of services is offered to young mothers, for example (DETROIT HEALTH DEPARTMENT, 2017A):

- Dental care
- Car Seat Safety (help with the correct seat and safety measures)
- Safe Sleep (ABCs´: Alone in the childrens' bed, on their Backs, in a safe Crib, in a Smoke-free room)
- Activity Program
- Baby Hotline for individual help

Sentinel Flu Surveillance Network
The Michigan Health Department is part of the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), a cooperation between the Centers for Disease Control and Prevention (CDC), health departments and the State of Michigan (MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES, 2017B). Some elected medical providers in contact with patients with influenza are so-called "sentinel physicians." Sentinel physicians report the number of patients with Influenza-like illness (ILI).
These patients are divided into five different age groups:

- 0 - 4 years
- 5 - 24 years
- 25 - 49 years
- 50 - 64 years
- 65+ years

Moreover, sentinel physicians collect some respiratory specimens of a certain amount of patients with ILI for respiratory virus panel testing.

3.2 Healthier Childhoods

Lead Safe Detroit

To face the challenges among children younger than six with elevated blood levels the Detroit Health Department developed a coalition named "Lead Safe Detroit". City departments work with community partners to coordinate childhood lead prevention and removal in the city. The program is about prevention and education. They eliminate the lead from the houses to decrease the risk to exposure the children. Nurses visit homes with children affected by lead. The nurses support the families and work with them to improve the compliance by educating how to prevent from lead exposure.

The health department also conducts water testing in schools, preschools, and homes to guarantee a health environment. Another part of the program is the environmental standards for lead. For this initiative the Detroit Building Authority and the Detroit Health Department are working together to locate potential lead exposures and to eliminate them for children (CITY OF DETROIT, 2001C - 2017).

Women Infants and Children Program (WIC)

The "Women Infants and Children Program" (WIC) embraces determinants of nutrition for children under the age of five (DETROIT HEALTH DEPARTMENT, 2017A). The program aims to establish a good health status for children by considering important issues of nutrition as well as breastfeeding. Furthermore, the program aims to educate young mothers about important nutrition facts, because this is an important part of health prevention (COHEN & SWIFT, 1999, p. 203).

Sister Friends Detroit

The volunteer community "Sister Friends Detroit" aims to help mothers of Detroit to establish a healthier live for themselves and their children (SISTER FRIENDS, 2017).

Background of the establishment of Sister Friends Detroit is the fact that the mortality rate of Black babies is at twice the mortality rate of other babies in Detroit. The reason for that is that mothers are often exposed to high risk factors such as stress or no access to prenatal medical care which can have negative effects on pregnancy.

Sister Friends Detroit follows the following principles:

- Taking care of each member
- Creation of a culture of care
- Support for pregnant mothers as well as young mothers with newborn babies

Sister Friends Detroit tries to find the right programs for pregnant mothers to get the help they need in order to guarantee a normal course of pregnancy. Moreover, the goal is to establish a growing community where the members help each other.

3.3 Healthier Lives

HIV/ AIDS program

There exist two programs helping people with Human Immunodeficiency Virus (HIV)/ Acquired Immune Deficiency Syndrome (AIDS). The Ryan White Program gives advice for medical issues. The Detroit Health Department cooperates with the Sexually Transmitted Diseases Clinic, which offers a wide range of services to people with HIV/ AIDS, for instance (CITY OF DETROIT, 2017A):

- Screening, testing and treatment
- Pre-Exposure Prophylaxis (PrEP): Pre-oral medication
- Post-Exposure Prophylaxis (PEP): Medication after an exposure
- Condoms free of charge

The Housing Opportunities for Persons with AIDS program helps with concerns about appropriate accommodations (DETROIT HEALTH DEPARTMENT, 2017A). Both programs even help in cases of uninsured people infected with HIV.

3.4 Healthier Places

Environmental Health and Safety

The program embraces environmental health issues, for instance checkups of institutions of child care or public swimming facilities (DETROIT HEALTH DEPARTMENT, 2017A). The program aims to protect the inhabitants of Detroit from health-damaging effects. Furthermore, the program deals with expressions of dissatisfaction from the population about certain institutions.

Related to the Environmental Health and Safety program are the institutions of the Medical Marijuana Caregiver Centers (MMCC). MMCC are health care centers, which were established and opened after the Michigan Medical Marijuana Act of 2008. The centers distribute marihuana prescribed by physicians and offer consultations to the population (CITY OF DETROIT, 2017B). MMCC are exposed to between four and nine inspections during the beginning of a new business. Later, inspections are conducted every three months in order to maintain high quality and health standards.

Food Safety

The Food Safety Program's goal is the protection of the population from health-endangering foodstuff (DETROIT HEALTH DEPARTMENT, 2017A). For that reason, there are special checkups for food establishments. In this context, the Detroit Health Department points out, that the offer of any favor to the inspectors are expressly prohibited.

Another task of the program is the education of the inhabitants about food and how to prevent illnesses of food. In addition, the Department of Food Safety supports new food startups how to achieve the necessary licenses to open their businesses.

Public Health Emergency Preparedness

The Office of Public Health Emergency Preparedness coordinates tasks in the case of a public health emergency (DETROIT HEALTH DEPARTMENT, 2017A). The definition of a public health emergency is an event, which exposes a high amount of people to a health risk, such as tornadoes, extreme heat, or flood (Michigan Prepares, 2017). The consequence can be epidemic (US DEPARTMENT OF HEALTH AND HUMAN SERVICES, 2017). Public Health Emergency Preparedness consists of different tasks:

- Comprehensive emergency planning: plans are written, how to save the population in case of public health emergency
- Emergency training and exercises: training of the Detroit Health Department stuff
- Coordination with local, state and federal partners: close collaboration with the police and fire department of Detroit, the American Red Cross, etc.
- Community engagement: consideration of different ethnic groups' needs, special needs of older residents etc.

4 Future Challenges and Conclusion

Public health of Detroit still faces the problem of being underfinanced. For instance in 2009, the Detroit Health Department budget was $96.8 million compared to $28 million in 2016 (PAREKH & UDOW-PHILIPPS, 2016). There was a considerable increase of city investments in public health from $1.6 million per capita in 2015 to $11.1 million per capita in 2017 (KHALDUN, J.S., 2017, P. 16; PAREKH & UDOW-PHILIPPS, 2016).

In comparison to the state's statistics, Detroit shows an overall bad public health outcome. The infant mortality rate in Detroit was 13.6% compared to 6.8% of Michigan, and the Diabetes rate in Detroit, with a percentage of 14.6, was also significantly higher than the diabetes rate in Michigan with a percentage of 10.4.

The reasons for these results are due to socioeconomic, economic as well as educational factors. In recent years, there was a great economic development in Detroit. Nevertheless, a high amount of Detroit's residents still live under poor conditions. The Detroit Health Department has achieved a lot of improvements in recent years, but there is still a lot of work to do. According to PAREKH & UDOW-PHILIPPS there must be more collaborations and partnerships between the different sectors. Partnerships, especially with potential funding partners, are essential to generate more money for the Detroit Health Department (PAREKH & UDOW-PHILIPPS, 2016).

Additionally, other city departments have to strengthen the Detroit Health Department and there has to be a continuous mutual exchange between them. Also, public schools should intensify their efforts in health programs for young people, because a low education level is related to a poor health status. Only if these obstacles are overcome in the future will the public health outcome of Detroit will improve significantly.

References

Bouffard, K. (2014), 'Detroit to Retake Control of Health Programs', *The Detroit News*, 2014 [Online]. Available at: http://www.detroitnews.com/story/news/local/wayne-county/2014/09/30/detroit-retake-control-health-programs/16515661/ (Accessed April 30, 2017).

Census Reporter (2015), *Detroit, MI* [Online], Census Reporter. Available at: https://censusreporter.org/profiles/16000US2622000-detroit-mi/ (Accessed April 30, 2017).

City of Detroit (2001), *About the Health Department* [Online], City of Detroit. Available at: http://www.detroitmi.gov/Government/Departments-and-Agencies/Detroit-Health-Department/About-Health-Department (Accessed May 05, 2017).

City of Detroit (2001), *Find Health Programs* [Online], City of Detroit. Available at: http://www.detroitmi.gov/How-Do-I/Find-Health-Programs (Accessed May 04, 2017).

City of Detroit (2001), *Making Detroit Lead Safe* [Online], City of Detroit. Available at: http://www.detroitmi.gov/leadsafe (Accessed May 05, 2017).

City of Detroit (2017), *Detroit Health Department: Divisions and Programs* [Online], City of Detroit. Available at: http://www.detroitmi.gov/health (Accessed May 07, 2017).

City of Detroit (2017), *Medical Marihuana FAQs* [Online], City of Detroit. Available at: http://www.detroitmi.gov/How-Do-I/Find/Medical-Marihuana-FAQs (Accessed May 07, 2017).

City of Detroit (2017), *Sexually Transmitted Diseases Clinic* [Online], City of Detroit. Available at: http://www.detroitmi.gov/Government/Departments-and-Agencies/Detroit-Health-Department/Sexually-Transmitted-Diseases (Accessed May 01, 2017).

City of Detroit (2017), *The Detroit Health Department's Infant Safe Sleep Program* [Online], City of Detroit. Available at: http://www.detroitmi.gov/Government/Departments-and-Agencies/Detroit-Health-Department/Health-Department-News-and-Alerts/ArticleID/1274/The-Detroit-Health-Departments-Infant-Safe-Sleep-Program (Accessed April 30, 2017).

Cohen, L. and Swift, S. (1999), 'The Spectrum of Prevention: Developing a Comprehensive Approach to Injury Prevention', *Injury Prevention*, vol. 5, no. 3, pp. 203–207.

Data Driven Detroit (2012), *State of the Detroit Child: 2012 Report,* Data Driven Detroit [Online]. Available at: https://datadrivendetroit.org/files/SGN/D3_2012_SDCReport_Updated.pdf (Accessed April 29, 2017).

Davey, M. (2014), 'Detroit Out of Bankruptcy but Not Out of the Woods', *The New York Times*, 11 December [Online]. Available at: https://www.nytimes.com/2014/12/11/us/detroit-bankruptcy-ending.html?_r=0 (Accessed April 27, 2017).

Hanna-Attisha, M., LaChance, J., Sadler, R. C. and Champney Schnepp, A. (2016), 'Elevated Blood Lead Levels in Children Associated With the Flint Drinking Water Crisis: A Spatial Analysis of Risk and Public Health Response', *American Journal of Public Health,* vol. 106, no. 2, pp. 283–290.

Huffpost (2012), 'Detroit Department of Health and Wellness Promotion May Be Converted to Public Health Institute', *The Huffington Post,* 2012 [Online]. Available at: http://www.huffingtonpost.com/2012/05/11/detroit-department-of-health-and-wellness-promotion-converted-to-public-health-institute-_n_1510155.html (Accessed April 30, 2017).

Keeler, G. J., Dvonch, T., Yip, F. Y., Parker, E. A., Isreal, B. A., Marsik, F. J., Morishita, M., Barres, J. A., Robins, T. G., Brakefield-Caldwell, W. and Sam, M. (2002), 'Assessment of Personal and Community-Level Exposures to Particulate Matter Among Children with Asthma in Detroit, Michigan, as Part of Community Action Against Asthma (CAAA)', *Environmental Health Perspectives*, vol. 110, Suppl 2, pp. 173–181.

Khaldun, J. (2016), *About the Health Department* [Online], City of Detroit. Available at: http://www.detroitmi.gov/Government/Departments-and-Agencies/Detroit-Health-Department/About-Health-Department (Accessed April 30, 2017).

Khaldun, J. (2017), *Building a Culture of Health in Detroit,* City of Detroit.

Kneebone, E. and Holmes, N. (2016), *U.S. Concentrated Poverty in the Wake of the Great Recession,* Brookings [Online]. Available at: https://www.brookings.edu/research/u-s-concentrated-poverty-in-the-wake-of-the-great-recession/ (Accessed May 04, 2017).

Lougheed, T. (2014), 'Arising from the Ashes? Environmental Health in Detroit', *Environmental Health Perspectives,* vol. 122, no. 12, pp. 324-331.

Michigan Department of Health and Human Services (2017), *Hearing Laughter. Seeing Smiles.: Michigan's FREE Hearing and Vision Screening Programs* [Online], Michigan Department of Health and Human Services. Available at: http://www.michigan.gov/mdhhs/0,5885,7-339-73971_4911_4912-260177--,00.html (Accessed May 07, 2017).

Michigan Department of Health and Human Services (2017), *Influenza Sentinel Providers* [Online], Michigan Department of Health and Human Services. Available at: http://www.michigan.gov/mdhhs/0,5885,7-339-71550_2955_22779-122498--,00.html (Accessed May 07, 2017).

Michigan Prepares (2017), *Learn About Michigan's Natural Threats* [Online], Michigan Prepares. Available at: http://www.michigan.gov/michiganprepares/ (Accessed May 07, 2017).

Molner, J. G. and Getting, V. A. (1955), 'Medical Care Functions of the Detroit Health Department', *American Journal of Public Health,* vol. 45, no. 7, pp. 855–861.

Neighborhood Scout (2017), *Detroit, MI: Crime Rates* [Online], Neighborhood Scout. Available at: https://www.neighborhoodscout.com/mi/detroit/crime (Accessed May 03, 2017).

Parekh, A. and Udow-Philipps, M. (2016), 'Investment a Prescription for Detroit's Health Crisis', *Detroit Free Press*, 14 April [Online]. Available at: http://www.freep.com/story/opinion/contributors/2016/04/14/investment-prescription-detroits-health-crisis/82999326/ (Accessed May 07, 2017).

Pool, R. and Stratton, K. (2015), *Bringing Public Health into Urban Revitalization: Workshop Summary*, Washington, D.C., The National Academies Press; National Academy of Science.

Regional Transit Authority of Southeast Michigan (2016), *RMTP Executive Summary: Regional Master Transit Plan*, Regional Transit Authority of Southeast Michigan [Online]. Available at: http://www.rtamichigan.org/wp-content/uploads/WEB_RTA_RMTP_Executive_Summary_FINAL-1.pdf (Accessed April 29, 2017).

Senterfitt, J. W., Long, A., Shih, M. and Teutsch, S. M. (2013), *Social Determinants of Health: How Social and Economic Factors Affect Health*, County of Los Angeles Public Health [Online]. Available at: http://publichealth.lacounty.gov/epi/docs/SocialD_Final_Web.pdf (Accessed April 28, 2017).

Sister Friends (2017), *I am My Sister's Sister* [Online], Sister Friends. Available at: http://sisterfriendsdetroit.com/about/ (Accessed May 07, 2017).

The Detroit News (2015), 'Detroit Names Health Department Director', *The Detroit News*, 2015 [Online]. Available at: http://www.detroitnews.com/story/news/local/detroit-city/2015/09/09/detroit-names-health-department-director/71958014/ (Accessed April 27, 2017).

U.S. Census Bureau (2005), *Michigan - Race and Hispanic Origin for Selected Large Cities and Other Places: Earliest Census to 1990*, U.S. Census Bureau [Online]. Available at: https://www.census.gov/population/www/documentation/twps0076/MItab.pdf (Accessed April 29, 2017).

US Department of Health and Human Services (2017), *Public Health Emergency Preparedness* [Online], US Department of Health and Human Services. Available at: https://archive.ahrq.gov/prep/ (Accessed May 07, 2017).

World Population View (2017), *Detroit Population 2017* [Online], World Population View. Available at: http://worldpopulationreview.com/us-cities/detroit-population/ (Accessed May 03, 2017).

Zenk, S. N., Schulz, A. J., Israel, B. A., James, S. A., Bao, S. and Wilson, M. L. (2005), 'Neighborhood Racial Composition, Neighborhood Poverty, and the Spatial Accessibility of Supermarkets in Metropolitan Detroit', *American Journal of Public Health*, vol. 95, no. 4, pp. 660–667.

Serving the City of Detroit – The Henry Ford Health System

Arne Birkner

The Henry Ford Health System (HFHS) is one of the largest comprehensive, integrated health systems in the United States. Since its foundation in 1915, the system has been regionally rooted in the City of Detroit and the Detroit metropolitan area. Detroit itself faces huge challenges. The decrease of the manufacturing sector caused a large decrease in population and employment. The HFHS serves the city not only as a high-quality healthcare provider, but plays other roles as well. As one of the largest employers, the HFHS has been a stable economic and social factor for many years. Reduced investments in the cityscape and in community health are affecting long-term support in Detroit´s future. The social and economic importance of HFHS for the Detroit metropolitan area creates a relationship between the HFHS and the City of Detroit that ensures mutual dependency and cooperation.

Contents

1 Introduction

The Henry Ford Health System (HFHS) is one of the nation's oldest and largest comprehensive, integrated health systems in the U.S. With the mission "to improve human life through excellence in the science and art of health care and healing", HFHS is providing a wide range of health care services in the Detroit metropolitan area (Henry Ford Health System, 2016). The non-profit organization is one of the key contributors to economic and social life in Detroit. While looking at Detroit's structural challenges, this paper is intended to analyze the medical, social, and economic significance and contribution of HFHS to the Detroit metropolitan area. Thus, particular attention is paid to the regional focus and educational programs of the HFHS. Based on the discussion and analysis of key aspects, the paper draws a conclusion about the role of the HFHS supporting the structural change of the City of Detroit.

2 The Henry Ford Health System

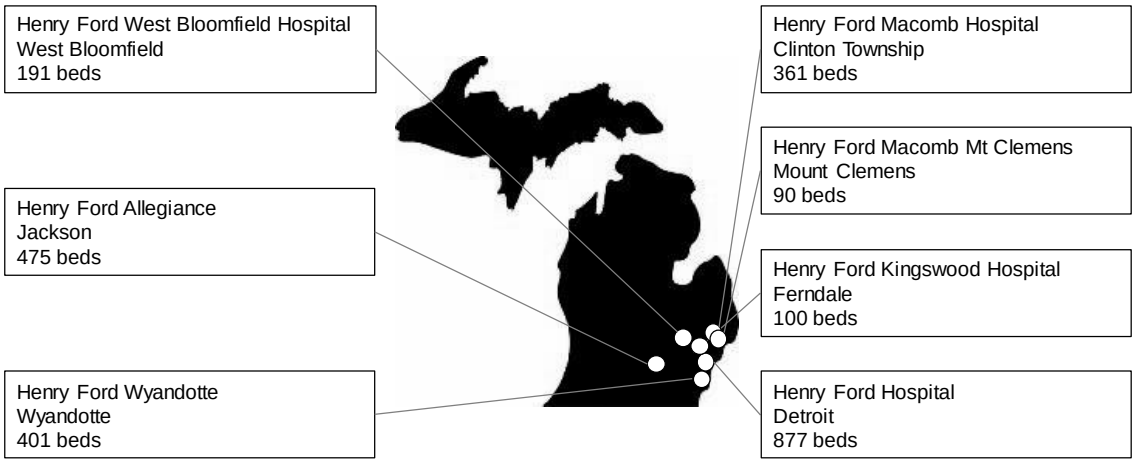
The Henry Ford Health System is a non-profit corporation committed to improving health and well-being of the Michigan community. Headquartered in Detroit, it provides healthcare and medical services, especially in south-western Detroit. Founded in 1915 by auto-pioneer Henry Ford, it has become one of the nation's leading and largest comprehensive, integrated health systems. The Henry Ford Health System also provides health insurance as well as a research and education program for its medical staff. The system is made up of seven Henry Ford hospitals, the Henry Ford Medical Group with 37 Medical Centers, Community Care Services, the HFHS health insurance service, and the Henry Ford Accountable Care Organization (HFACO) (Henry Ford Health System, 2016).

Through its mission, the HFHS strives to achieve the goal of "transforming lives and communities through health and wellness – one person at a time" (Henry Ford Health System, 2016). The HFHS, therefore, pursues continuously improving "patient-centered, integrated, equitable, high quality, safe, and efficient health care". Health at HFHS is based on innovative clinical excellence, medical education, and research. With the goal of optimizing health and well-being for all patients while maintaining equal quality of care, the system uses its experience and leverages the synergy effects of the organization. HFHS is pursuing a holistic approach in health care, while focusing their efforts on the individual person. Therefore, the HFHS aims to achieve the optimal result and treatment for single patients, customers, and employees (Hawkins et al., 2013, pp. 16-17).

The Henry Ford hospital system is comprised of four acute medical-surgical and two behavioral hospitals. The Henry Ford Hospital in Detroit is considered the HFHS flag-

ship. The 877-bed tertiary care hospital and level 1 trauma center includes its own education and research complex. It is recognized for clinical excellence and innovation in the fields of cardiology and cardiovascular surgery, neurology and neurosurgery, orthopedics and sports medicine, organ transplants, and treatment for cancer care (Henry Ford Health System, 2015a).

Figure 1: The Henry Ford Health System Hospitals



Source: Author's own representation based on Henry Ford Health System, 2016

The HFHS health insurance service, the Health Alliance Plan (HAP), has 675,000 enrolled members. The HAP is a non-profit health plan that provides Group Insured Commercial, Individual, Medicare, Medicaid, self-funded and Network Leasing product lines (Henry Ford Health System, 2016). In 2016, Health Plus of Michigan joined the HAP, making it one of the largest health insurers in the State of Michigan. Because of the merger, synergies in product and service areas, as well as provider networks resulted in increasing revenues, and the system as a whole was supported in its strive to achieve its vision (Health Alliance Plan of Michigan, 2017, and Henry Ford Health System, 2016).

In 2016, the HFHS established the Henry Ford Accountable Care Organization. With the combination of the expertise of more than 1,000 physicians, its hospitals, clinics and medical centers, the HFHS pursues this path in order to achieve healthier outcomes, while reducing patients' burden and the costs of care (Henry Ford Health System, n.d.a). Besides its health and insurance services, the HFHS includes a research and education program. This program provides innovative physician training programs, which helps HFHS to initiate and collaborate in the field of medical research. The academic medical center of HFHS includes 200 medical specialists and 80 research scientists working on more than 2,000 research projects. The program continuously provides medical education and training opportunities for more than 80,000 physicians, nurses, and allied health professionals to date.

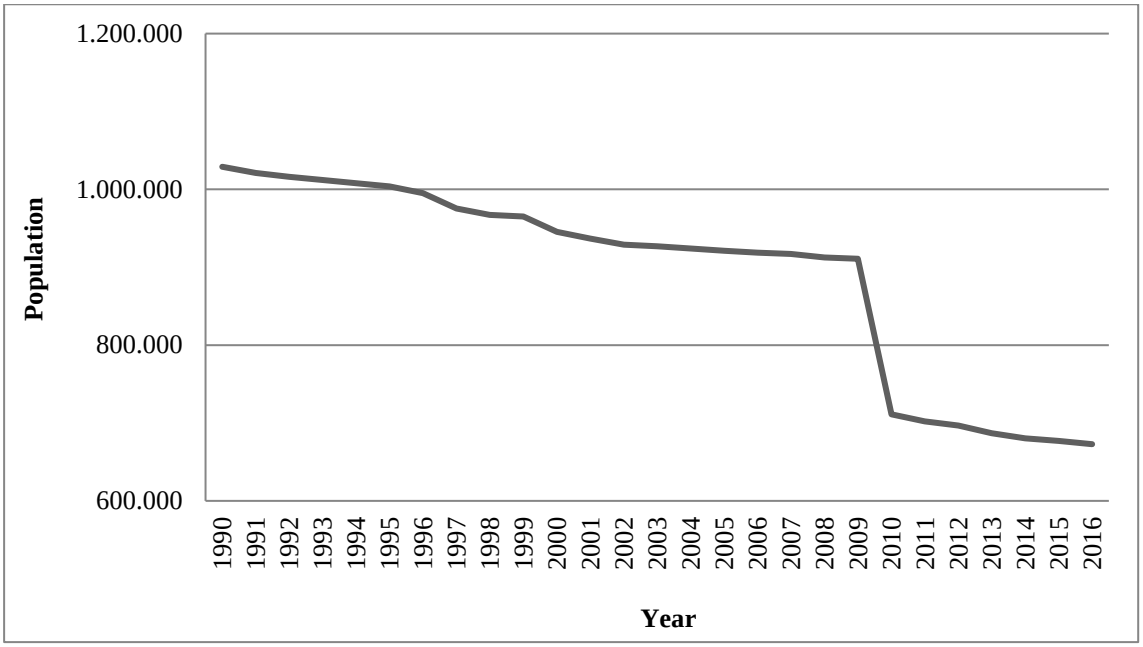
The Henry Ford Medical Group was founded in 1915 and stands out as one of the nation´s largest medical groups. It includes more than 1,200 physicians specialized in over 40 practice methods throughout the 37 Henry Ford medical centers in the Detroit suburbs of Wayne, Oakland, and Macomb Counties.
In order to support innovation across the HFHS and in the metropolitan area of Detroit, HFHS founded the Henry Ford Innovation Institute in 2011. The establishment of the institute was supported by many founding partners with expertise in the fields of medicine, science, technology, product design, and education, such as the Wayne State University College and the College for Creative Studies in Detroit. The Innovation Institute develops medical products, devices, and therapies in multidisciplinary collaborations in order to improve patient outcomes and cost effectiveness. In so doing, the Henry Ford Innovation Institute holds multiple license agreements, and received more than one million dollars in license revenue alone in 2015 (Hawkins et al., 2013, p. 17, and Henry Ford Health System, 2015b, p. 19).
A valuable asset of the HFHS is its diversity. HFHS has employees with many cultural backgrounds, is proud of its diversity and strives to ensure diversity in all of its health system areas. Using the diversity in its employees from over 60 countries, HFHS develops and studies ways to affect the health of its patients and the population in the Detroit metropolitan area. HFHS has been awarded several times for this commitment to diversity (Henry Ford Health System, 2016).

3 The City of Detroit

Detroit is a city in the Mid-Western U.S. with a population of around 680,000, and is the most populous city in the state of Michigan. Detroit has been historically shaped by and heavily dependent on the automobile industry since the industrial revolution. It is, therefore, known as a predominantly working-class city (Bentley et al., 2016, p. 785). Like other formerly industrial shrinking cities, Detroit continues to face a perpetual decline in population (Adhya, 2017, p. 3). From the 1970's to the present, its population has been reduced by more than half (Bentley et al., 2016, p. 789).
While there is a noticeable decline in American manufacturing jobs due to aspects of globalization and increasing automation since the 1970s, Detroit is also facing several structural challenges. Because of the loss of employment opportunities, the working class shrank, and the city's overall population decreased. Furthermore, the real estate market declined, the tax base was undermined and city services suffered (Bentley et al., 2016, p. 785-786). Detroit´s problems with a decreasing population have further been accentuated by the global economic crisis beginning in 2008. The collapse of the real estate and financial market had violent effects on Detroit´s economy (Adhya, 2017, p. 4). The bankruptcy, especially, of two of Detroit´s three big automotive companies in 2009, General Motors and Chrysler, had huge effects on the local labor market situation.

As a result, the population experienced another heavy reduction. The related continuous loss of population and taxes reached its climax with the bankruptcy of the City of Detroit in 2013.

Figure 2: Population of Detroit between 1990 - 2016



Source: Author's own representation based on United States Census Bureau, n.d.a

Today, poverty, unemployment, and housing vacancies are a globally recognized characteristic of the City of Detroit. The median household income in Detroit is less than half of the average income across the United States. A very high poverty rate of more than 40 percent illustrates the unfavorable social situation in Detroit. Furthermore, a below average level of education (measured at a high school graduation or higher) and a low rate of people with health insurance are characteristics of the socioeconomic situation of the Detroit metropolitan area (Figure 16.3). To illustrate the low population density, an example is provided. The total area of Detroit is larger than the accumulative area of Manhattan, Washington D.C., and San Francisco. However, the population of these three regions is about 470 percent higher than in Detroit (author's own calculation based on United States Census Bureau QuickFacts). The poor economic and social situation has serious implications for investments in the future of Detroit and is deteriorating the quality of life for its communities.

Figure 3: Comparative socioeconomic parameters

	USA	Detroit
Median Household income	$ 53,889	$ 25,764
Educational Attainment	86.7 %	78.3 %
Poverty Rate	13.5 %	40.3 %
Persons without health insurance	13.0 %	16.7 %

Source: Author's own representation based on United States Census Bureau, n.d.b, and United States Census Bureau n.d.c

4 Medical Importance of HFHS

Serving a market area of 4.5 million people in Southeast Michigan (Hawkins et al., 2013, p. 6), the HFHS records about 130,000 visits to the emergency departments, 3.77 million outpatient visits, and about 100,000 hospital admissions annually. The HFHS performed 75.000 surgical procedures and recognized 22,500 new patients in 2015 (Henry Ford Health System, 2016). Given these figures, HFHS is one of the most important hospitals in the region.

Overall, the seven Henry Ford hospitals, providing close to 2,500 beds in the Detroit metropolitan area, enjoy an excellent reputation. In the prestigious U.S. ranking of the regional hospitals in Detroit and the surrounding area of 25 miles, the HFHS was twice ranked, along with the Henry Ford Hospital Detroit and the Henry Ford Macomb Hospital, at ninth. With sole regard to the City of Detroit, the two clinics are even in second place (Figure 16.4).

Figure 4: Best regional hospitals in Detroit up to 25 miles surrounding

#	Hospital	City
1	University of Michigan Hospitals and Health Centers	Ann Arbor
2	Beaumont Hospital-Royal Oak	Royal Oak
3	Harper University Hospital	Detroit
4	Beaumont Hospital-Troy	Troy
5	Genesys Regional Medical Center	Grand Blanc
6	St. Joseph Mercy Ann Arbor Hospital	Ypsilanti
7	Beaumont Hospital-Dearborn	Dearborn
8	Providence Hospital	Southfield
9	Beaumont Hospital-Grosse Pointe	Grosse Pointe
9	Henry Ford Hospital	Detroit
9	Henry Ford Macomb Hospital	Clinton Township
9	St. John Hospital and Medical Center	Detroit

Source: Author's own representation based on U.S. News, n.d.

The eight Centers of Excellence of the HFHS have received acclaim and have gained an excellent international reputation for their clinical medical services. Along with the Innovative Institute, the HFHS Centers of Excellence are the Heart and Vascular Institute, the Josephine Cancer Institute, the Neuroscience Institute, Orthopedic Surgery, Transplant Institute, Vattikuti Urology Institute, and the Behavioral Health. Three of these institutions stand out as the most remarkable. The Josephine Cancer Center, one of the largest cancer centers in Michigan, has a global catchment area and provides cancer therapy for all clinical pictures. The Vattikuti Urology Institute performed the first robotic surgery, which has become medical standard. Finally, the Behavioral Health treatment has received multiple awards and provides inter-alia services in inpatient and outpatient medical services.

5 Social Commitment and Community Health

As one of the largest companies in Detroit, HFHS is also committed to social responsibility and efforts to improve community health in Detroit. The goals of HFHS are promoting the health of the Michigan population, as well as the health of its employees.
In order to achieve these goals, HFHS has several Community and Health, Equity and Wellness (CHEW) programs. To support healthier nutrition, HFHS provides smartphone apps to educate children and hospital visitors about the basics of nutrition and food services. Furthermore, it performs Community Care Services through conducting home health care visits or nursing homecare, and offers school-based community health programs (Henry Ford Health System, 2016).
To promote urban development, HFHS established the "Live Midtown" which supports urbanization by paying a bonus to its employees for moving into downtown Detroit. Each employee gets a $20,000 incentive for buying a house in midtown for the first time or a $2,500 one-off payment for the first rented residence (Henry Ford Health System, 2016). Furthermore, HFHS invests in various ways in the cityscape of Detroit. One example of that capital-intensive project is seen on West Grand Boulevard. The HFHS spent more than $500 million for restructuring of the environment surrounding the Henry Ford Hospital. Along with creating facilities for the medical services of the HFHS, including a new Cardinal Health Distribution Center, the HFHS created a school, green spaces, and foot and bike paths to encourage people to be healthier (Henry Ford Health System, 2016, and Kash, 2015, p. 383).

6 Economic Importance of HFHS

Considering the economic influence of the Henry Ford Health System for the city of Detroit, its position as an employer is of particular importance. With a total of more than 29,000 employees, HFHS is the fifth-largest employer in the Detroit metropolitan area, and has a great significance for the Detroit labor-market. The organization provides

9,200 jobs and 11,500 jobs related to the HFHS in Detroit alone (Henry Ford Health System, n.d.b). In the ranking of the Detroit Economic Growth Corporation, HFHS is considered the third-largest employer in Detroit and the second largest in the healthcare sector (Figure 16.5). Considering the high impact of the automotive industry in Detroit, these figures are remarkable in describing the economic importance of the HFHS and the healthcare sector for Detroit. Due to the poor labor market situation and the high poverty rate, the HFHS is one of the economic pillars of the city.

Figure 5: Largest Employer in Detroit

#	Organization	Detroit Employees
1	Detroit Medical Center	12,398
2	City of Detroit	10,92
3	Henry Ford Health System	9,014
4	Detroit Public Schools	7,839
5	U.S. Government	6,454
6	Quicken Loans/Rock Financial Inc.	5,984
7	Wayne State University	5,924
8	Blue Cross Blue Shield of Michigan	5,172
9	State of Michigan	4,555
10	Chrysler Group LLC	4,042
11	General Motors Corp.	3,947
12	St. John Providence Health Systems	3,863

Source: Author's own representation based on Detroit Economic Growth Corporation, n.d.

With its revenue of $5 billion and a net income of $72 million in 2015, the HFHS provided a total economic impact of $6.018 billion on the Detroit metropolitan area (Henry Ford Health System, 2016). Regional suppliers, subcontractors, partners and other affiliated companies are gaining economic benefits from the operations of the HFHS.

The regional connection of the HFHS also results in a strong belief in the future of Detroit. Thus, the HFHS is constantly investing in the region and its own system. With the establishment of the Henry Ford West Bloomfield Hospital during the global financial crisis in 2009, the HFSH set a strong signal for its future in Detroit. By investing about $350 million in the Henry Ford Hospital Campus in Detroit, the opening of new ambulatory centers and the expansion of existing ambulatory clinics, the HFHS supported Detroit not only as stabilizing factor in the labor market, but it also helped improved the forecast of surviving the financial crisis (Kash, 2015, p. 382).

The HFHS also has prospective plans to further expand its system and facilities. The "Henry Ford - Detroit Pistons Performance Center", a combined complex planned in cooperation with the NBA's Detroit Pistons and Wayne State University, is one of the new facilities to be established. It will provide space for training facilities for the sports

team and corporate headquarters for the NBA franchise. It will include a comprehensive sports medicine and treatment and rehabilitation facility managed by the Henry Ford Health System as well (Henry Ford Health System, 2017). Besides the structural investments, those joint ventures between Detroit´s institutions and HFHS will support a stable future for the city. As part of the agreement, the Henry Ford Health system will be the official healthcare provider for the NBA sports team.

For a long-term stabilization of its position as a significant employer in Detroit, the HFHS relies on its education and training program. The Henry Ford Health System is categorized as academic medical center because of its teaching, research, and advanced patient care supply. The HFHS trains about 1,800 medical students, residents, and fellows on an annual basis. Medical education is provided for 80,000 physicians, nurses, and allied health professionals (Henry Ford Health System, 2016). The Henry Ford Health System University (HFHSU), established in 2004, provides education programs across the system. The range of education includes classroom events, as well as online-courses. Special focus at the HFHSU is also given to leadership trainings (Hawkins et al., 2013, pp. 14-15).

7 Discussion

The significance of HFHS, with its wide range of medical services, is undisputed. HFHS' position as a non-profit organization ensures that economic interests and corporate-centered goals of healthcare remain in the background. Employee, as well as community, health and well-being are instead pushed to the forefront. The Henry Ford Accountable Care organization and the Health Alliance Plan established as part of the Henry Ford Health System are setting additional strong incentives to supporting long-term health and optimal medical outcomes for the patients. The integration of financing and delivery are not only achieving benefits for the patient care. Employment contracts for physicians ensuring fixed salaries consolidate the patient focus and eliminate possible interests in optimizing personal revenues during medical care. Furthermore, the ACO-model creates even lower costs for the HFHS (Kash, 2015, p. 382).

Along with its economic influence on the Detroit metropolitan area, HFHS tries to revitalize the city in various other ways. Incentives created by an attractive education and continuing-training program help to strengthen HFHC's position as an important employer. Furthermore, HFHC is eager to help make to downtown Detroit more attractive for its employees, and thus renew Detroit as a city. In addition, HFHS established many partnerships with various institutions in Detroit to improve health outcomes. Moreover, these newly-created networks are good chances to stabilize Detroit´s economy in the long run. Continuous expansions of the HFHS in the metropolitan Detroit area will generate other new jobs for the region and help counteract the high unemployment-rate in Detroit. With the creation of new job opportunities, increasing the city's population by

bringing in new employees or by encouraging current employees to move into midtown, HFHS is making a major contribution in tackling Detroit´s problems.
Expanding its system and investing high amounts into Detroit´s social development, does however, increase HFHS's dependence on the city. A failure of the urban development in Detroit would directly relate to significant difficulties for the HFHS. Conversely, the dependence of Detroit on the HFHS increases with a growing engagement and support from HFHS to Detroit´s structure. With a continuing decrease of the manufacturing sector, Detroit´s dependence on the service sector, and thus the HFHC, could increase further.
Serving the city of Detroit, the HFHC is not just focused on providing medical services. The HFHS has made strong efforts to create long-term community health and well-being as well as to achieve a restructuring of Detroit.

8 Conclusion

Considering the economic, medical, and social importance of the HFHS, it is obvious that HFHS has an enormous impact on the development of the Detroit metropolitan area. As a major employer and a highly respected health system, HFHS has a significant impact on the stabilization of the economically battered city of Detroit. Besides contributing to getting through the financial crisis, the HFHS supports the belief in a positive development of the city with its investments in Detroit´s cityscape and a long-term commitment to its roots. Since its foundation, the HFHS has been directly linked to Detroit and its good intention to stabilize and shape the region is clearly recognizable. The HFHS significantly consolidates the city and the metropolitan area with its social engagement and economic impact, as well as its position as provider of medical services, and is partly responsible for the ability of a positive development in Detroit. On the other hand, high investments on the part of the HFHS into the shrinking city of Detroit involve economical risks. The city of Detroit and HFHS have entered into a mutual dependency, and both are relying on a positive economic and population development in the city in order to ensure a successful future.

References

Adhya, A. (2017), Shrinking Cities and First Suburbs: The Case of Detroit and Warren, Michigan, Cham, s.l., Springer International Publishing.

Bentley, G. C., McCutcheon, P., Cromley, R. G. and Hanink, D. M. (2016), 'Race, Class, Unemployment, and Housing Vacancies in Detroit: An Empirical Analysis', Urban Geography, vol. 37, no. 5, pp. 785–800.

Detroit Economic Growth Corporation (n.d.), Major Employers [Online], Detroit Economic Growth Corporation. Available at: http://www.degc.org/site-selectors/major-employers (Accessed June 02, 2017).

Hawkins, S. S., Glenn, R., Oswald, K. and Conway, W. A. (2013), 'Creating a Culture of Performance Excellence at Henry Ford Health System', Global Business and Organizational Excellence, vol. 2, no. 32, pp. 6–22.

Health Alliance Plan of Michigan (2017), Fact-Sheet, Health Alliance Plan of Michigan [Online]. Available at: https://www.hap.org/-/media/files/hap/hap-fact-sheet.pdf (Accessed June 02, 2017).

Henry Ford Health System (n.d.), About Us: Improving Health and Well-Being in our Community [Online], Henry Ford Health System. Available at: https://www.henryford.com/about (Accessed June 02, 2017).

Henry Ford Health System (n.d.), Accountable Care Organization (ACO) [Online], Henry Ford Health System. Available at: https://www.henryford.com/about/aco (Accessed June 02, 2017).

Henry Ford Health System (2015), 2015 System Report, Celebrating 100 years, Henry Ford Health System.

Henry Ford Health System (2015), By the Numbers, Henry Ford Health System [Online]. Available at: https://www.henryford.com/-/media/files/henry-ford/about/giving/hfhs-fact-sheet201415web-1.pdf?la=en (Accessed June 02, 2017).

Henry Ford Health System (2016), Henry Ford Health System Fact Sheet, Henry Ford Health System.

Henry Ford Health System (2017), Detroit Pistons and Henry Ford Health System Announce State-of-the-Art Training, Rehabilitation and Sports Medicine Complex, Henry Ford Health System [Online]. Available at: https://www.henryford.com/news/2017/02/detroit-pistons-and-henry-ford-health-system (Accessed June 02, 2017).

Kash, B. A. (2015), 'Interview with Nancy M. Schlichting, FACHE, CEO of Henry Ford Health System', Journal of Healthcare Management, vol. 60, no. 6, pp. 381–385.

U.S. News (n.d.), Best Hospitals in Detroit, Michigan, U.S. News [Online]. Available at: http://health.usnews.com/best-hospitals/area/detroit-mi (Accessed June 02, 2017).

United States Census Bureau (n.d.), Detroit City, Michigan [Online], United States Census Bureau. Available at: https://www.census.gov/content/census/en/search-results.html?searchtype=web&stateGeo=none&q=poverty%20rate%20detroit%20city%20mi&disambFipsCode=2622000 (Accessed June 02, 2017).

United States Census Bureau (n.d.), QuickFacts Detroit, Michigan, United States Census Bureau [Online]. Available at: https://www.census.gov/quickfacts/table/PST045215/2622000 (Accessed June 02, 2017).

United States Census Bureau (n.d.), United States: 2016 Poverty Statistics, All People Below Poverty Level Percent [Online], United States Census Bureau. Available at: https://www.census.gov/search-results.html?page=1&stateGeo=none&searchtype=web&cssp=&q=poverty+rate+USA&search.x=0&search.y=0 (Accessed June 02, 2017).

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Peter Konrad was born in 1992. His interest in the healthcare system raised by volunteering at a retirement home. Afterwards he started a Bachelor's program in Munich and graduated in 2015. The focuses of his Bachelor's program were on hospital management and management accounting. Subsequently he started his Master's program at university of Bayreuth. He is mainly interested in hospital management and health policy. During his studies, Peter could collect broad working experience at several companies, e.g. Siemens Healthineers and Allianz.

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Crossing Borders – Innovation in the U.S. Health Care System

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.

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