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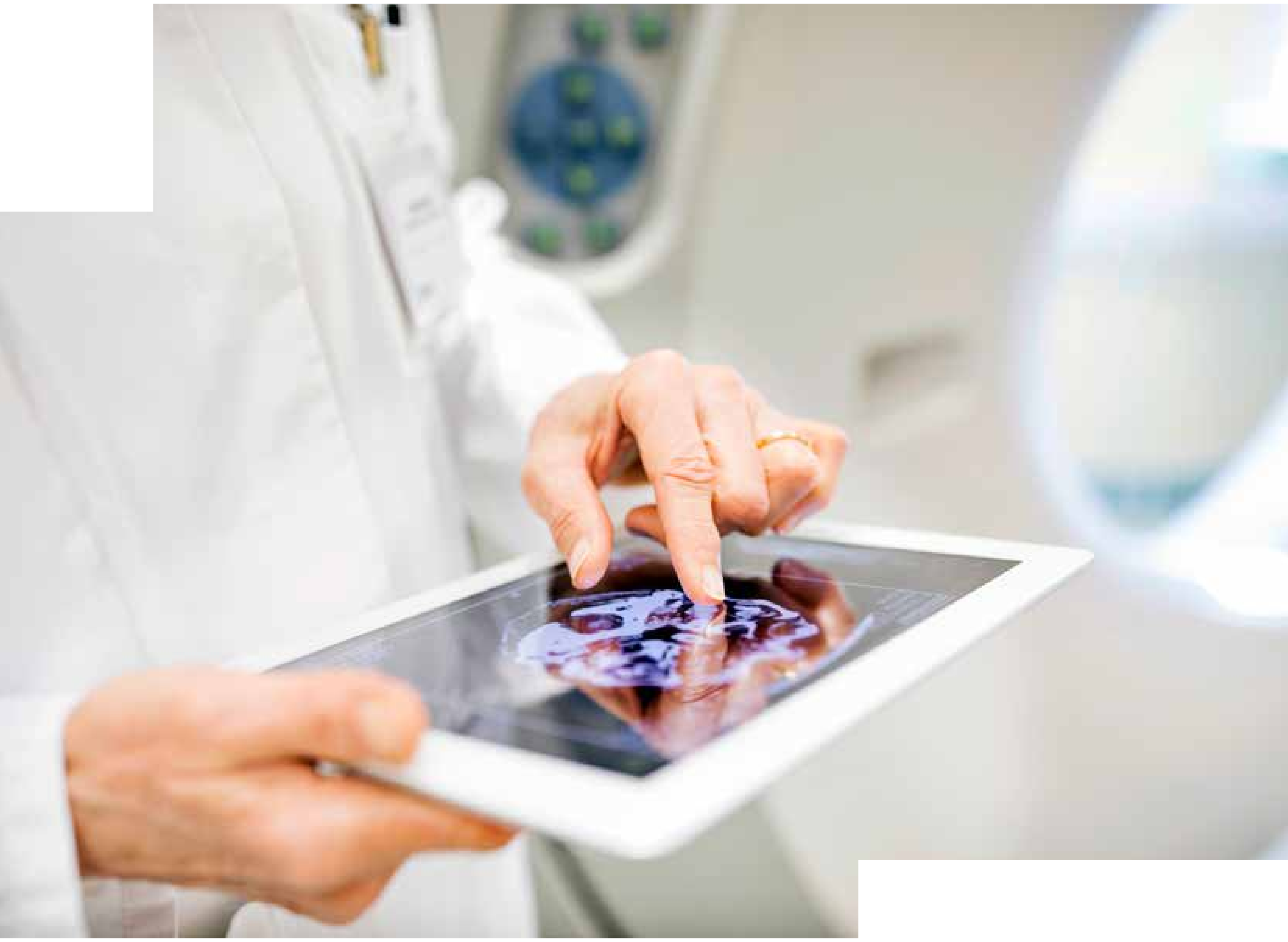
Research Institute

Healthcare transformation



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Introduction

Since the end of World War I, the average worldwide life expectancy at birth has doubled. Nowadays, it is more than 80 years in the 35 OECD countries. The United Nations estimates that, by 2050, global population will rise to nearly 9.7 billion people, placing an even greater strain on health resources.

The digital revolution – from artificial intelligence (AI) to robotics and personalized medicine – is beginning to make its presence felt and promises to help make healthcare more efficient and safer. It is expected to "democratize" medicine by supporting patient access to online automated medical diagnosis and allowing people to collect and analyze more "medical" data at home. Further, it promises to personalize healthcare delivery, support phone-based behavioral health intervention and change how people communicate with doctors and hospitals.

While the improvements in healthcare can especially help the underserved countries, AI will nevertheless raise a multitude of policy and regulatory issues. On the one hand, the need for regulation arises from the risk of discrimination, and on the other, there are concerns about safety and privacy, and the question of accountability in case of undesired outcomes.

Technological progress is changing the way healthcare is provided, but at what cost and how should these medical costs be allocated? Health expenditures have been constantly increasing faster than Gross Domestic Product in all OECD countries. In the USA, statistics show that health expenditures amounted to 17.15% of GDP in 2017, which has led to considerable debate about sustainability and financing mechanisms – not only in that country, but also in the majority of developed economies.

The report also takes China as an example, providing insight into a country faced with an aging population in a fast-changing environment. In addition to technological innovation, local governments have placed healthcare at the top of their agendas in order to improve the quality of development. China's tech giants are currently transforming the Chinese healthcare system as companies like Ping An, Tencent and Alibaba build closed ecosystems to improve customer experience.

We hope that our findings prove valuable and wish you an insightful and enjoyable read.

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AI and healthcare: The road to modern health

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Artificial Intelligence (AI) promises to radically change healthcare, "democratizing" it by supporting patient access to online automated medical diagnosis, allowing people to collect and analyze far more "medical" data at home, personalizing healthcare delivery, supporting phone-based behavioral health intervention, and changing how people communicate with doctors and hospitals. While greatly improving health-care in underserved countries, AI will also raise a host of policy and regulatory issues in more developed economies.

Managing health and healthcare

Artificial Intelligence (AI) will affect healthcare in many ways. The greater effects in terms of market size, the use of AI in areas such as robot-assisted surgery, administrative workflow and fraud detection, will be almost invisible to healthcare consumers. They will reduce hospital costs in the same way that AI is already being used by large companies such as Amazon and Tencent to more efficiently operate everything from supply chains to customer interaction.

Physician support systems will increase in sophistication, summarizing information and double-checking prescriptions to check for dosage errors or potential drug interaction. Customer-facing AI will gradually become more prevalent, allowing people to use their phones to share images, blood pressure readings, blood sugar levels and other information with their healthcare providers, and to eventually use such data collection and online diagnosis and advice systems to take more ownership in managing their own health and healthcare.

In the foreseeable future, AI will not replace doctors, but will instead automate small portions of a very complex workflow, such as providing routine interpretations of images to screen for retinopathy, glaucoma or breast cancer, checking for errors in prescriptions, and optimizing when patients should next see their doctors. In wealthier nations, AI will primarily screen patients to determine who needs to see a doctor or assist physicians in interpreting increasingly large volumes of patient data. In countries lacking physicians, the short-term effect will be much larger, giving large populations affordable access to high-quality medical diagnosis, at least for a set of common diseases.

AI is a broad field that includes three main approaches to building systems with "intelligent" behavior: rule-based systems such as the core of IBM's Watson, which are derived by interviewing experts (e.g. physicians) to extract rules describing how they, for example, conduct diagnoses, optimization-based systems, such as those used for supply chain management or to compute, for example, optimal schedules for patient visits, and machine learning systems, which use historical data to build predictive models.

These machine learning approaches (including artificial neural networks, or deep learning) are progressing the fastest and having the largest effect on industries, including healthcare. The most common models simply take a set of inputs (e.g. images of an eye) and labels (e.g. diagnoses such as "has glaucoma" or "doesn't have glaucoma") and learn models that predict labels for future inputs. Given large training sets – tens or hundreds of thousands of labeled images – such machine learning models are often slightly more accurate than experienced physicians.

Medical imaging

The most impressive successes to date in the use of AI for healthcare have come in medical imaging. Automating the interpretation of medical images, such as magnetic resonance imaging (MRI) scans, CAT scans, and retinal fundus photographs is relatively easy because vast collections of images exist that have already been "labeled" by physicians to indicate whether patients are at risk or in good health. Unlike many practices where physicians "lay hands" on patients, most radiologists never see patients, but only see images.

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One of the earliest successes in using deep learning for diagnosis from images came in diagnosing eye problems such as retinopathy, diabetic macular edema, and glaucoma. A typical "training set" of over 100,000 retinal images was used in 2016 to build a highly accurate classifier.[1] With millions of diabetics needing screening for diabetic retinopathy, there is an obvious immediate market for such models. Companies such as DreamUp Vision and IDx are producing products for the American market, while Google, among others, is running trials in countries including India and Thailand. Eyes are relatively easy to photograph, so smartphone-based camera attachments can be used to collect the eye images, which is particularly attractive in remote areas of countries such as India, which often lack trained personnel.

Deep learning systems to identify metastatic breast cancer from digital whole slide images, when trained on a relatively small dataset of 270 images[2], yield accuracies comparable to those of pathologists. With larger training sets, predictive accuracy increases up to 99% and the model allows pathologists to review a slide for metastases in one minute instead of two.[3] A host of start-ups are using deep learning on radiology images for screening, real time clinical support (e.g. detection of tiny fractures) and retrospective analyses for quality assurance.

Clinical decision support

One of the first big medical uses of AI will be for pre-screening, risk scoring and early warning. The start-up Enlitic, for example, offers patient screening and triage, real-time clinical support and retrospective analysis, all from diagnostic radiology. They claim their technology can judge the malignancy of nodules in chest CT images 50% more accurately than an expert panel of radiologists and that they "can detect tiny fractures as small as 0.01% of an X-ray image." One of the advantages – and potential drawbacks – of AI is that it can detect small fractures and lesions that are often overlooked by physicians. This is cited as an advantage by the companies selling the services, and may indeed lead to early detection of cancers, but may well also lead to overtreatment of previously overlooked "problems" that would resolve themselves with time.

Many AI systems are being built for prediction: predicting hospital visits and no-shows, epileptic seizures, the longevity of patients, etc. These then feed into clinical care decisions. Several university hospitals, including one at Stanford, are investigating the use of AI systems to identify patients who are good candidates for palliative care (based in part on life expectancy), often replacing current ad hoc referral methods. There is also hope that AI systems will be able to determine when patients should make follow-up visits, gaining efficiency over current "across-the-board" visit scheduling.

1. Development and Validation of a Deep Learning Algorithm for Detection of Diabetic Retinopathy in Retinal Fundus Photographs. Varun Gulshan, et al. JAMA. 2016; 316(22):2402-2410. doi:10.1001/jama.2016.17216

2. Diagnostic Assessment of Deep Learning Algorithms for Detection of Lymph Node Metastases in Women With Breast Cancer; Babak Ehteshami Bejnordi, Mitko Veta, Paul Johannes van Diest, Bram van Ginneken, Nico Karssemeijer, Geert Litjens, Jeroen A. W. M. van der Laak, and the CAMELYON16 Consortium JAMA. 2017;318(22):2199-2210. doi:10.1001/jama.2017.14585

3. https://ai.googleblog.com/2018/10/applying-deep-learning-to-metastatic.html and the papers cited there.

At a more mundane level, AI systems are increasingly being used to check for errors in prescriptions, including possible drug interactions. Researchers are trying to find more sophisticated ways to analyze electronic health records, e.g. generating concise summaries of complex medical histories. But, unlike radiology, such work does not seem poised for commercial viability.

The most famous, and most contentious, foray into automating diagnosis is IBM's Watson for Oncology. After a major investment of time and money (billions of dollars, according to the Wall Street Journal), many critical reports surfaced, claiming that Watson often returned "multiple examples of unsafe and incorrect treatment recommendations" and that "its cancer applications have had a limited impact on patients," and that its "tools didn't add much value." This is consistent with the general finding that AI works well for automating very specific tasks; but has failed in more open-ended applications. Fears of physicians being replaced by computers seem to be, at least for the foreseeable future, entirely unfounded.

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Data collection (e.g. via smartphones)

In the longer run, artificial intelligence, when coupled with the ability to link relatively inexpensive devices to cell phones, is poised to more broadly change the practice of medicine. Having frail elderly people live at home becomes much more feasible when sensors can detect whether they are getting out of bed in the morning and call family if a potential problem is detected.

A host of devices for analyzing blood, urine, saliva and skin to detect malaria, AIDS, flu, and a range of cancers are currently under development. Most are still in the proof of concept stage and few have been commercialized. However, if validated, they offer huge promise, particularly for medically underserved regions such as parts of Africa. One may not think of such devices as "AI," but they mostly rely on complex data analytics as part of a broader system. In fact, they are part of a larger trend toward the "internet of things" which is pushing AI out of central data servers in the cloud to local devices such as cell phones.

Smartphone-based blood pressure monitors are widely available commercially, often for under USD 100. Dozens of mobile apps for dermatology are now available, although studies suggest that only 20% of them may be worthwhile. Medical apps offer a huge potential for taking healthcare to patients and are proving useful for self-management of some diseases like diabetes, but are not only largely unregulated, but also not rigorously evaluated. How to decide which apps to prescribe is becoming a major problem for hospital systems.

AI will also change the nature of communication between patients and caregivers. Chatbots are coming first to simpler industries, such as financial services. Patients will, however, increasingly seek to "chat" (SMS) with their physicians, necessitating sophisticated triage systems similar to those used by companies such as Amazon, e.g. chatbots for simple responses such as scheduling or prescription refills, nurses for intermediate questions, and physicians when needed.

Behavioral health and communication

Healthcare is not just diagnosis; it includes preventive medicine and, more generally, exercise and stress reduction. Beyond that, having good social support seems to increase life expectancy by at least five years[4], making personal relationships comparably important for health as not smoking. Depression is a known risk factor for cardiovascular disease – as is anger. Scalable solutions to behavioral health remain elusive; AI-based apps might help. Many apps have, of course, been created to encourage exercise, healthy eating and stress reduction (e.g. through meditation); others are being developed to treat mental problems including posttraumatic stress disorder (PTSD), anxiety and depression. If AI can be used to pick the products people are most likely to buy, perhaps it can be used to encourage the health behaviors they are most likely to follow.

4. Holt-Lunstad J, Smith TB, Layton JB.
Social relationships and mortality risk: A meta-analytic review. PLoS Med. 2010;7(7):e1000316

Few of these apps currently use AI, but researchers are starting to explore how to use machine learning to personalize such interventions, particularly with regard to screening for mental health problems, including suicidal ideation, and building virtual therapists – AI-based chatbots – for PTSD and depression, often for use in conjunction with human therapists. Start-ups like Ginger.io are building AI-based systems to deliver digital mental health services, using a mix of AI and human therapists who use cognitive behavioral therapy to help people address anxiety and depression. As of 2019, there are over a thousand apps available to address mental health.[5] However, only around a half of them use evidence-based methods and almost none of them have been validated to test efficacy.

Challenges and opportunities

Key to the success of most healthcare AI apps is the collection of good data to train the deep learning models. Privacy laws in Europe and the USA complicate such sharing; China and India have been more relaxed about such concerns. New developments such as privacy-preserving "federated computing" may enable models to be built without sharing individuals' data; but such methods are still to be tested. Collection of good data for machine learning remains the limiting step for many deep learning applications.

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> As of 2019, there are over a thousand apps available to address mental health.

Another key challenge is the validation of AI methods in the clinical context. Accurate performance on one set of data is no guarantee that methods will work well in clinical settings. Deep learning models learn correlations, which may or may not reflect underlying causality. This tends to be relatively unimportant for medical image analysis (if the image has the correlates of cancer, the patient is likely to have cancer), but far more challenging for diagnosis from electronic medical records where correlational structures may differ across subpopulations, hospitals, and countries. AI researchers are highly concerned that many machine-learned models may be less accurate for some populations and that unintentional discrimination can occur when "black box" methods (those whose internal workings cannot be examined) are used.

Finally, no countries or hospital systems have fully figured out how to test, validate, and regulate AI systems. Deep learning models are intrinsically complex and difficult to interpret in spite of strong efforts by AI researchers in this direction. Randomized clinical trials remain the gold standard, but many companies sell apps directly to consumers, typically bypassing critical validation. The next decade will see vast numbers of AI systems developed and integrated in a multitude of ways into healthcare systems. AI use will be vastly different between wealthy urban medical environments where AI will primarily provide decision support to physicians, and medically underserved rural regions of the world where AI and phone-based measurements will increasingly be used in lieu of the physicians that are not there.

Concluding thoughts

Overall, this is a golden era for AI. The increasing availability of data is fueling a renaissance of applications, and healthcare seems well-positioned to incorporate many of the technologies that have driven the rise of companies like Google, Facebook and Amazon. Back-office processing in hospitals systems will become vastly more efficient. Deep learning technologies very similar to those used for face-recognition are being applied to ever-increasing types of medical images. Finally, consumers will collect more and more of their own data and turn to third-party AI diagnostic systems, much as they now search for medical information on the web as part of their healthcare management.

5. https://www.nature.com/articles/s41746-019-0093-1 Using science to sell apps: Evaluation of mental health app store quality claims Mark Erik Larsen, Kit Huckvale, Jennifer Nicholas, John Torous, Louise Birrell, Emily Li and Bill Reda. npj Digital Medicine 2019.

How should medical costs be allocated?

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Health expenditures have been constantly increasing faster than Gross Domestic Product in many countries. While this development has spurred discussions about the sustainability of health systems around the world, many fundamental drivers of the observed rise in costs are still ill-understood. Besides the two central forms of financing (private or public), many sharing agreements and health management concepts have been applied in order to reduce problems of asymmetric information and to improve efficiency within the system.

Soaring health expenditures

A consistent pattern in most developed economies is the surge in total health expenditures, be it in absolute terms or relative to income during the last half century. Health systems in all the Organisation for Economic Co-operation and Development (OECD) countries are growing faster than Gross Domestic Product (GDP). In the USA, health expenditures in 2017 amounted to a vast 17.15% of GDP (see OECD data pool via https://data.oecd.org/chart/5z12). This development has stimulated the need for discussions about sustainability and financing mechanisms not only in the USA, but in practically all developed economies. Obvious explanations for the increasing health expenditure trend such as population aging, the development of new treatments, and increasing incomes are not hard to find, but the discussion is far from conclusive, with alternative explanations also pointing toward unintended and undesirable incentives and an almost complete lack of understanding of the actual costs of delivering healthcare (see Kaplan and Porter 2011).

In this chapter, we provide a brief overview of the general problems of resource allocation in health systems, balancing the two conflicting health policy goals of improving population health and distributing that health fairly, and discuss the resulting implications for financing health. For the latter, we specifically focus on the most widespread financing schemes – public and private.

Health policy objectives

Understanding fundamental goals of health policy is important for an informed discussion of reasonable financing schemes as it is the incentive structure that determines the behavior of the parties involved in the system. In a health system with finite resources, a fundamental problem is the allocation of resources: a resource unit spent on one health risk or person cannot be spent on another. Resource allocation in health systems thus forces a decision about which health risks to reduce for whom (Daniels 2016). In that sense, the efficiency of a particular health system becomes an ethical obligation (not just an economic one) because an increase in efficiency implies being able to meet more health needs per resource unit – treating either more people or health risks or both (Daniels, Light, and Kaplan 1996). If we agree on the notion that meeting more health needs is better than meeting less health needs, we then have the basis of an ethical rationale for economic efficiency in health systems.

While meeting more health needs and thus improving population health as a whole appears to be a reasonable policy goal, a focus on efficiency alone disregards how health benefits are distributed. A second, somewhat competing, health policy goal is thus to distribute health benefits fairly (Daniels 2008).[1] In light of the debate on financing or cost allocation schemes of health systems that we will discuss in the subsequent sections of this article, it is important to consider the implications of different schemes for the two main goals in designing health systems – efficiency and equity.

Financing health systems

Most health systems today are a blend of both private and public funding schemes. Figure 1 illustrates this point by showing the relative share of public and private funding of health systems among OECD countries in 2017. Health system financing has converged from a rather extreme allocation between public and private funding to a narrower band ranging between 15% and 48% of the private part in 2017. If we were to make a statement on the average trend, it appears to be in the direction of a lower share of private funding with approximately 33% in 1970 compared to 27% in 2017. This is also in line with a more global pattern suggesting that, as the economic development of countries improves, the share of private funding decreases (Dieleman et al. 2017).

Public funding usually comes from either general taxes or hypothecated taxes such as social insurance contributions or mandatory health insurance premiums. Private funding is generated through user charges such as insurance deductibles and copayments, private supplementary insurance or out-of-pocket payments.

As the discussions in the subsequent sections reveal, efficiency can be achieved with any form of financing in theory. Among the public funding options, relative to general taxes, social insurance has the advantage of being more transparent with regard to the development of health costs over time – because changes in contributions can be observed – and in many settings provides options to select between different levels of coverage. Most private funding options provide that same level of transparency and coverage flexibility, but potentially suffer from risk selection. From an economic theory perspective, user charges in private funding schemes generally serve two purposes: first as a mechanism for resource collection and, second, as a mechanism to attain a more efficient allocation of resources (Stabile and Thomson 2014). Sharing in the cost of health services should incentivize people to invest in prevention and limit the use of unnecessary treatments, thus increasing efficiency and potentially achieving higher levels of cost control of the system (Zweifel and Manning 2000). Whether private funding schemes actually increase efficiency and cost control in real markets, however, remains an empirical question and we will try to elaborate on this later by discussing the differences between general and hypothecated taxes, and then looking at different private funding schemes.

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Government revenues are considered to be the predominant source of health expenditure.

Public funding

Government revenues are considered to be the predominant source of health expenditure (Savedoff 2004). There are two main forms of public funding used to finance the health system: general taxation and earmarked taxation. We discuss these two forms of public funding below.

General taxation

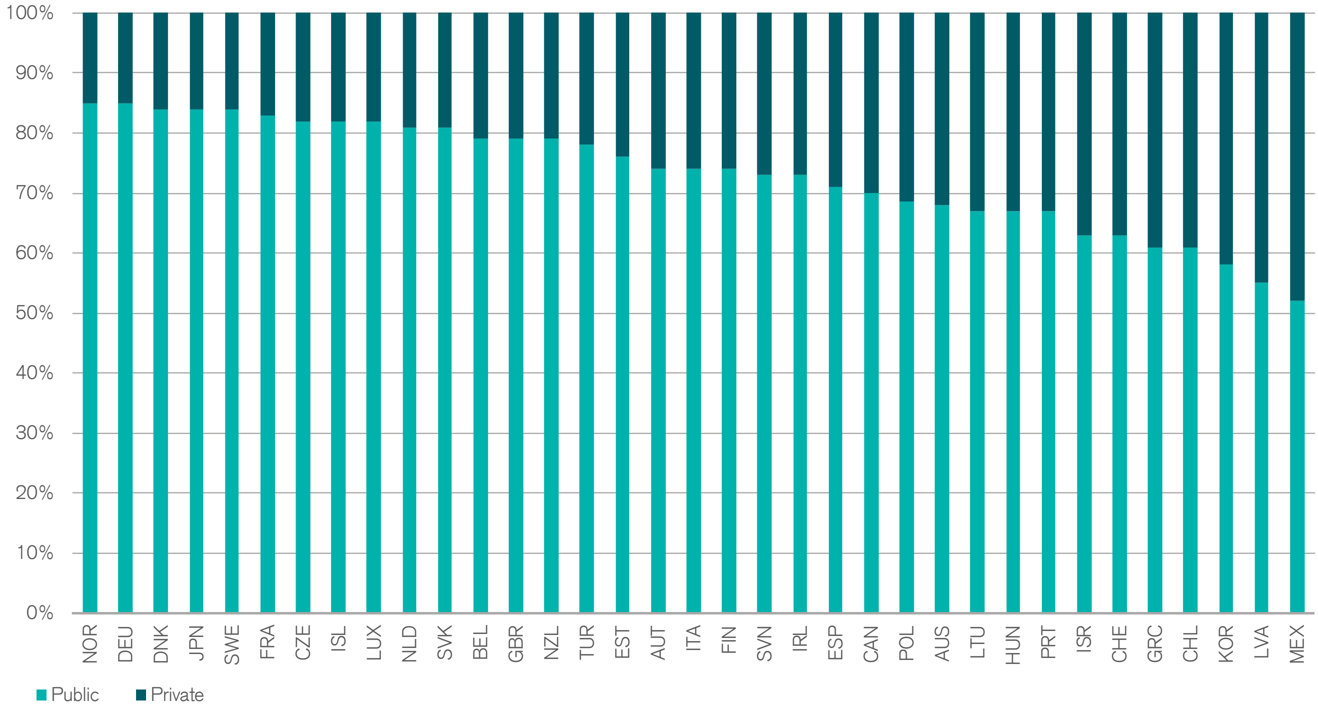
Savedoff defines tax-based systems as “those in which more than half of public expenditure is financed through revenues other than earmarked payroll taxes, and in which access to publicly-financed services is, at least formally, open to all citizens.” According to Savedoff, the main advantages attributed to this funding scheme are:

- Health-risk pooling across a larger contributor base – funds are collected among a general base, regardless of their health status, income, etc. This characteristic addresses a common issue in other forms of health expenditure funding, i.e. adverse selection.

- Costs are spread over a larger share of the population – especially relevant in countries with a high informal economy where many employers avoid payroll taxes and the social insurance burden falls on formal sector employees.

1. While there is much disagreement on how to measure efficiency in real markets, there is even more disagreement on measuring equity.

Figure 1: Financing through public and private resources among OECD countries in 2017



Note: public funding includes government spending and compulsory health insurance, while private funding includes voluntary health insurance and private funds such as households' out-of-pocket payments, NGOs and private corporations. Source: OECD

- The taxable base is larger, considering that not only salaries, but also other forms of revenues such as capital gains, etc., are taxed. This might make the system more progressive than the social insurance systems.

Despite the above-mentioned advantages, the general taxation health-funding scheme has also been criticized. The main critics address the separation of contributions from the individual likelihood of needing healthcare services. Although this characteristic is considered an advantage by those who claim that healthcare should be considered a human right that is not dependent on income or health status, many see it as the cause of reduced responsibility for one's own health. Furthermore, health funding via general taxation is considered to reduce accountability of healthcare providers to those using their services.

Among the countries that finance their health systems through a general tax-based system, there is still a large variety of taxation schemes utilized. The different systems are based on income or consumption taxation, national or local taxes, etc. The specific taxation scheme determines the level of redistribution.

Hypothecated or earmarked taxation
According to a 2017 study by Cashin et al., earmarking can be defined as separating all or a portion of total revenues from a tax or group of taxes and using it for a designated purpose. The arguments for the use of earmarked taxes as a source of funding include:

- Earmarked taxes serve as a guaranteed funding source not subject to competing political interest.
- This form of funding can provide a better link between taxes and the benefit provided from it, which in turn may lead to less public resistance to taxation.
- Earmarked taxes make both the government and the service providers more accountable.
- Earmarking can provide better information to the public regarding the cost of certain health programs.
- It can be used to discourage unhealthy behavior (e.g. tobacco taxes as a deterrent) and simultaneously ensure a higher contribution from people who engage in unhealthy activities and are therefore more likely to require health services.

Besides the stated advantages, hypothecated taxation is also subject to criticism, especially in terms of the rigidity that it introduces to the budget. Moreover, funding healthcare via a pre-specified source can limit its coordination with other social sectors and cause economic distortions.

There is no conclusive evidence as to whether earmarking increases overall health funding. Given that this funding is usually combined with funds from general taxation, it is possible that the additional contribution from the budget to health expenditure is adjusted to offset movements in earmarked funds. Cashin at al. analyze the experience of six focus countries (Indonesia, Philippines, South Africa, Vietnam, Estonia and Ghana) and suggest that earmarking is only effective for a limited time-period. Government priorities change over time, which increases the likelihood of offsetting the earmarked tax effect by adjusting other parts of the overall health budget. The authors note, however, that earmarking is a useful tool in some countries to mobilize funds for a particularly pressing policy without undergoing the entire government budgeting process.

An especially widespread form of earmarking for health financing is a payroll tax for social health insurance (SHI) coverage. SHI systems are usually characterized by a purchaser-provider-contracting model – in contrast to the (mainly) directly managed provider network of tax-financed systems (Stabile and Thomson 2014). In a 2009 study, Wagstaff analyzed SHI systems versus tax-financed systems in terms of costs and their effect on public health outcomes. His analysis suggests that SHI systems have certain characteristics that make them more costly, but do not seem to perform better in terms of public health outcomes. Furthermore, there is evidence that SHI systems may perform worst in terms of premature death due to breast cancer. This suggestion could be plausible given that, as Colemann et al. (2008) note, reducing breast cancer deaths requires organized, broad population-based screening programs, whereas SHI promotes a more individualized health system and less general public health campaigns.

Private funding

There are several types of private healthcare funding, e.g. private health insurance as the dominant, complementary or supplementary form of cover, out-of-pocket expenditures such as copayments and deductibles, and donation-based crowdfunding.

There are different reasons for using private health insurance that vary by country, history, and social values of the population. For instance, in the USA, private insurance serves as a dominant form of healthcare where health insurance is funded by employee and employer contributions and might also involve copayments and other out-of-pocket expenditures. Publicly funded health insurance programs such as Medicare and Medicaid only cover elderly or disabled people as well as people with low incomes. However, the USA still faces a significant coverage gap, which was addressed by former US President Barack Obama in the 2010 Affordable Care Act ("ObamaCare"), targeting the uninsured population that does not qualify for Medicaid or Medicare programs.

In some countries, the government might incentivize private health insurance by way of tax relief, thus easing financial pressure in the public system. This sometimes results in duplicate cover (so-called "double" cover) or supplementary cover, when people have both private and public health insurance. This type of coverage usually benefits higher income groups as they are entitled to easier and faster access to medical services as well as to a broader choice of providers.

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> **Private insurance markets are based on risk selection that might result in barriers to access health insurance for some individuals.**

Similar to public forms of funding healthcare, private health insurance as a form of private funding has its advantages and disadvantages. On the one hand, it might encourage competition between healthcare providers and thus drive up the standard of healthcare while driving down premium prices. Moreover, it might relieve the tax burden and ease financial pressure in the public system resulting from current aging and longevity trends. On the other hand, health insurance markets are characterized by a number of market failures, such as asymmetric information and adverse selection, and need to be regulated.

Moreover, private insurance markets are based on risk selection that might result in barriers to access health insurance for some individuals, e.g. older people or individuals with pre-existing medical conditions who can be denied health insurance or charged a higher premium.

Out-of-pocket charges represent another form of funding healthcare. In most OECD countries, out-of-pocket expenditures represent a relatively small share of health spending and are more common in developing economies (Dieleman et al. 2017). The main problem with relying too heavily on charging customers for healthcare is that it can lead to financial hardship and impoverishment of people with severe or long-term illnesses. Hence out-of-pocket expenditures might discourage some people from using certain services, which might lead to a deterioration of their health.

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> Charging customers for healthcare can lead to financial hardship and impoverishment of people with severe or long-term illnesses.

As a result, people who cannot afford to pay for certain medical services themselves might start seeking financial aid using crowdfunding[2] platforms based on donations. Crowdfunding is a growing source of financing healthcare, especially in countries with a high percentage of uninsured and underinsured people, such as the USA. Online crowdfunding platforms such as GoFundMe, YouCaring, Crowdfund Health, GiveForward, etc., help to raise millions of dollars every year to fund out-of-pocket expenses, not-for-profit health initiatives, health research and commercial health innovation (Renwick and Mossalios 2017). However, crowdfunding cannot be considered a reliable funding source of healthcare and represents a controversial solution to the existing problems. The concept of charity and healthcare is not an adequate answer to the shortcomings of healthcare systems in some countries. Besides, crowdfunding of healthcare bears some economic risks that mostly stem from principal-agent relationships and information asymmetry, a lack of efficient priority-setting, inconsistent regulatory policies, and concerns about intellectual property rights and fraud (Renwick and Mossalios 2017). Moreover, some people claim that crowdfunding worsens existing inequalities in accessing healthcare (Hiskes 2017).

2. According to typology developed by Renwick and Mossialos (2017), there are three main types of crowdfunding: (1) reward-based crowdfunding that involves contributing money for a reward; (2) donation-based crowdfunding characterized by philanthropic contributions; (3) and investment-based crowdfunding characterized by financing projects with high-interest loans.

In the last decades, global health markets face a so-called “health financing transition” (Fan and Savedoff 2014), which refers to two different health financing trends: (1) the increase in health spending per person, and (2) the decline in the out-of-pocket share of health spending. In general, this trend can be seen as a positive development in healthcare. On the one hand, increasing health spending per person has resulted in better population health (Bokhari et al. 2007; Moreno-Serra and Smith 2012). On the other hand, pooling health spending while limiting out-of-pocket expenditures helps in preventing financial hardship and impoverishment of people seeking healthcare (Fan and Savedoff 2014). However, it is important to bear in mind that out-of-pocket health spending also increases in absolute terms, but its share in total health financing decreases due to the faster growth of pooled health expenditures.

There is an extensive body of research dealing with the determinants of total health expenditure that identifies five sources of growth, i.e. rising national income, technological advance in medicine, population aging and longevity, rising prices, and changes in health insurance coverage and healthcare management (Fan and Savedoff 2014). By contrast, the declining share of out-of-pocket spending along with simultaneous growth of pooled health spending is primarily explained by political and institutional changes (Immergut 1992; Bump 2010; Fan and Savedoff 2014).

Comparative analysis

Evidence on the effects of the mix of private and public funding on efficiency and cost control is relatively scarce. However, as private versus public funding is the major source of variation in financing schemes for health systems, this is a key discussion.

Most extant studies correlating the share of private versus public financing with healthcare costs do not provide clear evidence in one or the other direction (Leu 1986; Hitiris and Posnett 1992; Xu et al. 2011; Basu et al. 2012), which seems in line with the theoretical arguments. Studies analyzing certain reforms initiated to increase the private financing share also find no effects, e.g. hospital-financing reform in Switzerland (Braendle and Colombier 2016), variations in co-payments in Sweden (Jakobsen and Svenson 2016), or an increased private health insurance supply that increases total costs relative to GDP (Colombo and Tapay 2004).

> "On average, the tradeoff between private and public financing does not seem to be the key for higher efficiency and cost control.

One exception is the recent study by Eriksen and Wiese (2019), who use health system reforms that increase the share of private financing among a set of 20 OECD countries to robustly identify effects of private versus public financing. In particular, they focus on reforms that exhibited a particular focus on increasing user charges such as insurance deductibles and copayments. They find annual average cost savings of 0.09 percentage points of GDP resulting from increasing the private financing share, but also document a fast decay of the effects, approaching zero after five years.

In summary, the empirical literature suggests relatively small and short-lived effects of the private share in financing health systems. Accordingly, a key review by Stabile and Thomson (2014) concludes that "there is little evidence to suggest that collection mechanisms alone are effective in managing the cost or quality of care." However, this is not to say that a particular form of private financing might not have an efficiency-enhancing effect in a specific setting as private financing schemes are heterogeneous. On average, however, the tradeoff between private and public financing does not seem to be the key for higher efficiency and cost control.

Conclusion

An empirical assessment of the public versus private financing debate suggests that the question of the mix of these sources of financing does, in a generic sense, not seem to be the key element if we are interested in increasing efficiency and improving cost control. Both financing options bring context-dependent efficiency gains that need to be considered holistically. Aside from the financing question, health policy discussions have centered on several other aspects of system design that have the potential to increase efficiency and cost control. This includes incentives for prevention and healthy lifestyle, reducing asymmetric information, and value-based healthcare with a focus on patient outcomes.

China’s tech giants delivering smart health services

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China’s tech giants are transforming its healthcare system. Companies like Ping An, Tencent and Alibaba are building closed ecosystems to improve customer experience. Using cutting-edge technologies such as blockchain, artificial intelligence or advanced biometrics, they provide a faster and better way to cope with the increasing demand for healthcare services and significantly reduce waiting times through AI-assisted online consultation services. With internet-supported telemedicine, essential medical services can also be provided to remote rural areas.

The Chinese healthcare market

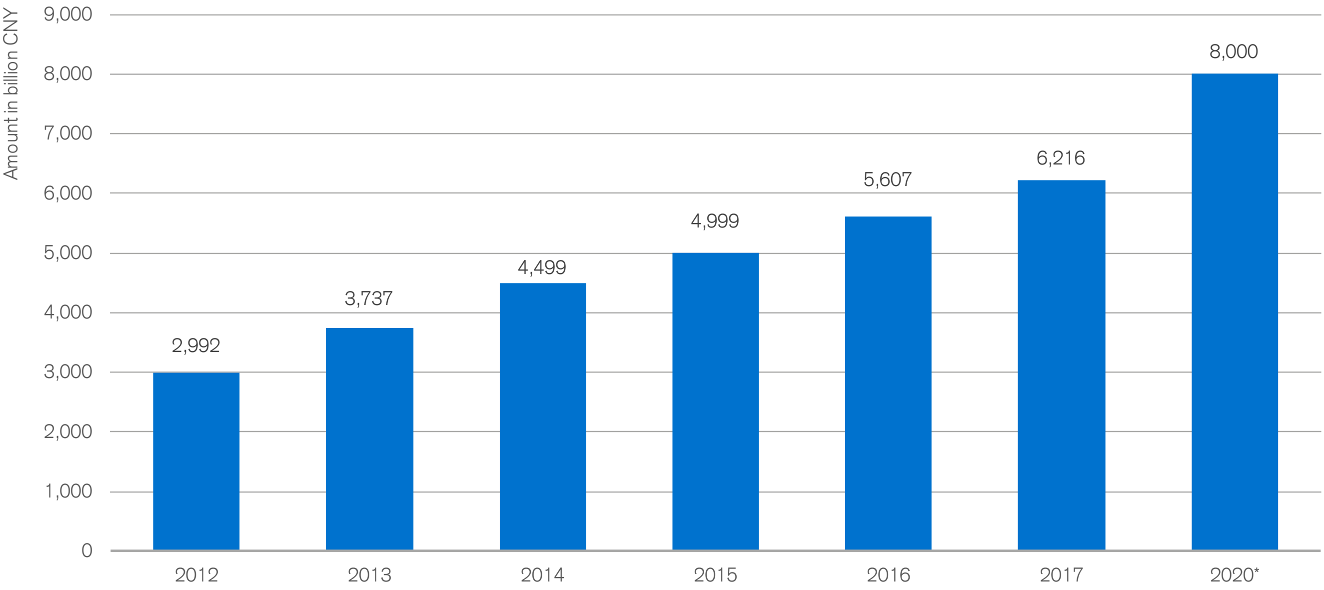
The Chinese health service industry is growing fast. Figure 1 shows government projections until the year 2020. The industry is expected to reach CNY 8 trillion in revenues, which is around three times more than ten years ago (Chinese Government, 2016). This dynamic growth is driven by rising income levels and higher life expectancies of Chinese customers. However, the Chinese healthcare system faces a number of challenges that are closely linked to the transformation from an emerging market to an industrial country.

One of the biggest challenges is a demographic transition to an aging society, characterized by significant growth of the elderly population, especially in relation to the working population (Chinese Government 2016). In China, this trend was exacerbated further by the one child policy. The rise of chronic diseases like cancer and osteoporosis, typical for an aging society, leads to soaring medical expenses per capita. Moreover, a vast number of people within China’s working-age population are classified as “sub-healthy,” i.e. they experience a range of uncomfortable symptoms like nausea or chronic fatigue, but their pain is not linked to an obvious, easily diagnosable illness (see Lin 2013). This is a huge problem as recent research shows that 76% of all white-collar workers in major cities are categorized as sub-healthy (Dahong 2009).

In 2006, the Chinese government conducted a healthcare reform that led to improvements in the healthcare system, especially in rural areas, and to an increase in medical insurance coverage. Over 95% of the population now has some type of basic health insurance (Le Deu et al. 2012). However, the quality of healthcare in rural areas often does not reach the quality provided in the major cities.

It is generally relatively difficult to access medical services in China. The usual process is as follows: people in need of medical treatment go to hospitals and stand in a queue for hours to make an appointment. Then they go into another queue to pay the consultation fee. After that, they will see the doctor who usually prescribes some medicine. Then, they stand in a line again to pay for the medicine. Finally, another queue forms at the medicine pickup desk (Lew 2018). There have also been several scandals due to the troubled drug industry. For instance, over 100,000 people were injected with a faulty vaccine in 2016 (Hernandèz 2018).

Figure 1: Size of the Chinese health service industry



* forecast; Source: https://www.statista.com/statistics/880789/china-healthcare-service-market-value/

Another drawback of the Chinese healthcare system is the virtually nonexistent primary care. In other countries, sick people usually go to a general doctor who either prescribes an adequate medicine or transfers patients to a specialist. In China, however, this first step does not exist. People go immediately to a hospital and seek the advice of a specialist, even if they just have a headache (Hernandèz 2018), which exacerbates the undersupply of doctors and imposes high costs on the healthcare system.

> One of the biggest challenges is a demo-graphic transition to an aging society.

Moreover, there have been many cases of medical corruption, where some doctors overprescribe, order unnecessary procedures, or take bribes from patients or pharmaceutical companies (Dandan 2017), thus leading to a general mistrust of doctors and hospitals. Another problem is that hospitals are severely understaffed, especially the tertiary public ones (He 2017). While countries like Switzerland or Germany have a medical doctor density of 42 per 10,000 people, China's is only 18 (WHO 2015). This leads to an extreme shortage of qualified personnel and overworked doctors. Information opacity, high hospitalization rates, and the rising cost of medications all add to the problems. Due to the absence of a market that would enact a price setting mechanism, pharmaceutical prices in China are often arbitrary or even directly influenced by bribes (Xie and Zhang 2014).

Ping An

Ping An is one of the leading health insurance companies in the world. It has over 538 million online customers and the healthcare portal alone has over 265 million users in 257 cities. This translates into revenue of over CNY 1,082 billion, representing around a 40% increase in the past two years. It is also one of the most innovative companies in this segment, which can be seen by a total of 12,051 patent applications since the company was founded (Ping An 2017). Ping An bases its healthcare operations on modern technologies such as AI, blockchain technology, and cloud computing.

It started as a joint stock insurance company in 1988 and quickly diversified its services to become a multi-industry company with a huge asset management branch. As such, it orchestrates five ecosystems: financial services, auto services, real estate services, healthcare, and smart city. Its health service ecosystem has over 265 million users and approximately 3,000 participating hospitals. This creates strong network effects and synergies in the health service industry (Ping An 2017).

Ping An's healthcare ecosystem is based on three relevant entities: the client (patient), medical service providers, and payers (see Figure 2). Medical service providers are, for example, clinics, doctors or pharmacies. Payers consists of private insurance companies such as Ping An's own core business and the Chinese government, which provides basic healthcare protection.

Customers access the healthcare ecosystem through portals like the "Ping An Good Doctor App." The latter serves as a link between patients, medical service providers and payers. It also includes an online consultation service. The process flow from the perspective of a patient is as follows: first, the user can access the online consultation for a first screening at any time day or night. If necessary, patients can then use the offline follow-up treatment to visit a specialist in a hospital. Furthermore, they can buy their prescribed drugs online and avoid long queues (Ping An 2018b). The portal is linked to the health insurance provider, which bears the costs of the treatment. With the Good Doctor App, Ping An pursues a one-stop solution, implying that customers have a single app to cover all of their healthcare needs.

> "76% of all white-collar workers in major cities are categorized as sub-healthy.

Ping An Good Doctor is one of the largest online healthcare portals in China. It addresses the gap in the underdeveloped primary healthcare system through online consultations. To this end, Ping An employs over 1,000 medical experts and over 5,000 external doctors. The productivity gains of this model become obvious when considering the coverage capacity of the medical personnel. Advanced technologies enable the Ping An ecosystem to conduct between 300,000 and 400,000 consultations daily (Ping An 2018a), which is roughly 8–10 times the usual consultation capacity in China. This very high rate of efficiency would not be possible without technological assistance.

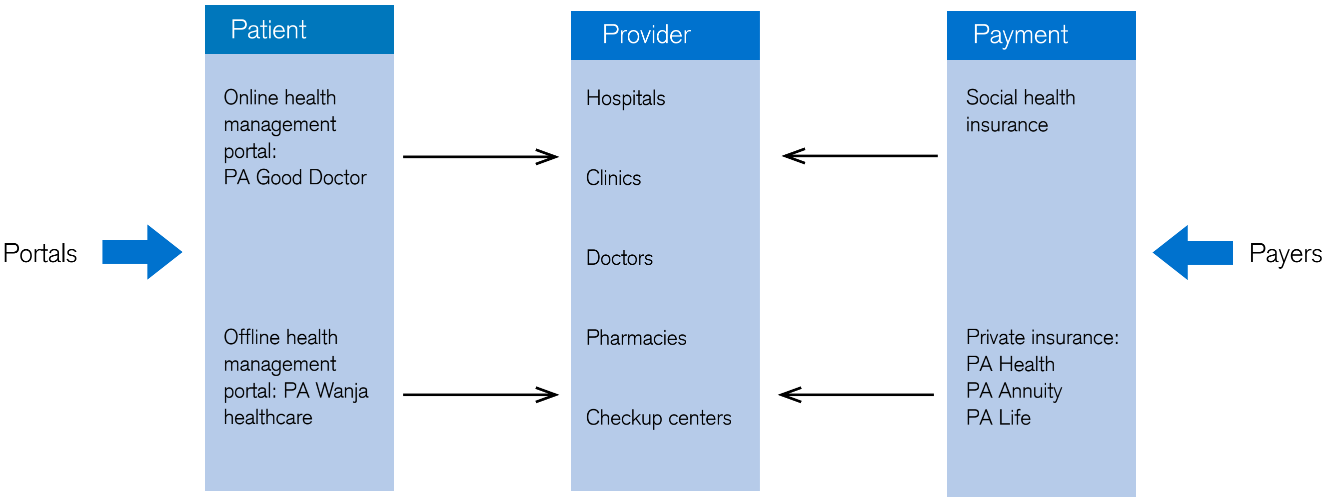
The most notable elements are AI-assisted screening and AI-assisted consultation, which work in the following way. Patients describe their symptoms on the platform. The AI system collects that information and asks further questions that could be relevant for possible treatments. It also makes a pre-diagnosis, trying to forecast ailments. Then the AI system issues a preliminary report, which is then sent to a doctor (Ping An 2018a) who conducts a professional diagnosis and decides on further steps. The doctor may prescribe medicine or send the patient to a specialist in a clinic. The transition is seamless so that the patient may not even notice the switch between the AI system and the actual doctor. The decisions made by the doctor together with the consultation protocol are saved and entered into a machine learning system. Hence, the AI model can further improve on its diagnoses and predictions with the goal of being able to treat patients completely independently of human input.

> "Over 95% of the population now has some type of basic health insurance.

The Ping An Good Doctor portal connects the 265 million users after the online consultation with the offline service providers. This is possible through its collaboration with over 3,000 clinics. In addition, more than 2,000 dental clinics, aesthetics, and checkup centers, and over 15,000 pharmacy outlets ensure a comprehensive offline service (Ping An 2018a).

The Ping An ecosystem is not limited to sick people. Instead, the portal also offers services for healthy and so-called "sub-healthy" people, such as a sophisticated health management system. With this tool, customers can view their health information and set up an e-health profile. Furthermore, via the ecommerce platform, they can buy health-related products like protein supplements or participate in a reward program to lower their health insurance premiums.

Figure 2: The Ping An Ecosystem



Source: Tan 2017

They also have constant access to healthcare consultation services, such as a family doctor, an individual health profile and a health management plan (PA Good Doctor 2017). The scalable model helps to provide better-quality healthcare and lower costs through substantial efficiency gains. Moreover, consumers benefit from significant reductions in waiting time in regard to offline services (Ping An 2018b).

> Another drawback of the Chinese healthcare system is the virtually nonexistent primary care.

The internet plays a leading role in this system because medical resources can be shared in real time across regions. This is especially important for rural areas. Urban medical resources can be channeled through the Good Doctor portal to provide healthcare in rural areas. This form of telemedicine works, because many chronic and common diseases can be managed online. It also reduces the pressure on hospitals.

Another technology working in the background is the Ping An Cloud service, which stores all the data. The cloud service helps to conveniently share medical data and health reports with the relevant entities (e.g. pharmacies) and works in synergy with Ping An HealthKonnect. The latter runs a program that automatically extracts information from a patient's medical record, then parses, cleans, and exports it, before uploading the standardized data into the cloud-based platform (Li 2018).

Moreover, the company's Ping An Biometrics technology is used in the healthcare and finance ecosystem (PA Good Doctor 2017). A key element of this technology is facial recognition, which can identify faces with 99.8% accuracy. Another feature is voice print recognition, which analyzes unique acoustic signals from the voice with 99% accuracy (Wilson 2014). The last element is the analysis of micro-expressions from the face of the customer. The combination of all elements allows Ping An to verify a person's identity with a very high accuracy. Therefore, Ping An can automate the identity verification for registration and check-ups by linking a person's identity to their online profile and thus preventing identity theft and fraud.

Finally, the backbone of the whole system is the Ping An blockchain, called Onechain. This proprietary technology is faster and more efficient than its open source counterparts and can process over 100,000 transactions per second. It is fully encrypted and provides an effective way to record all transactions made in the Ping An ecosystem (PA Good Doctor 2017).

Tencent

Tencent is the second-largest tech company in China with a revenue of CNY 313 billion (Tencent 2018). Its approach to serve the Chinese healthcare market resembles that of Ping An. Both run a healthcare portal connecting patients and medical providers on the one side, and providing AI-assisted solutions on the other. Tencent calls its platform "the Tencent Doctorwork." It arose through a merger with Trusted Doctors and features convenient AI-supported online consultation and appointment booking with offline contractors (Koh 2019). Like Ping An, Tencent is developing medical chatbots and clinical decision support software to increase the efficiency of their online consultation network (Taylor 2018).

Similar to Ping An Good Doctor, Tencent Doctorwork connects over ten million patients with around 440,000 certified doctors and 30,000 hospitals (Reuters 2019). Around 50 of these clinics work primarily for the portal, including general practices, day surgery centers, and specialist clinics (Tuna 2019). The platform also features booking of health check-ups and convenient access to medical reports.

> “The most notable elements are AI-assisted screening and AI-assisted consultation.

While Ping An has a dedicated app, Tencent provides access to its healthcare service system through the messaging app Wechat, which is similar to Whatsapp (Medical Futurist 2019a). Wechat has over 820 million users (Ross 2018), so that in contrast to Ping An, Tencent is building its health ecosystem inside its bigger Wechat ecosystem. In this Wechat ecosystem, customers can not only communicate with each other, but also order food or read magazines (Maize 2018). The first advantage of the Wechat ecosystem is the possibility to link a person's account to his/her ID. This enables a safe link between medical records to a patient's phone (Medical Futurist 2019b). A further advantage of Tencent's larger Wechat ecosystem is that users can pay their medical bills directly through the Wechat Pay payment service. Of course, the ecosystem itself also features ecommerce opportunities in the health division, allowing customers to purchase medications or protein supplements.

To complete this vast ecosystem, Tencent offers the WeSure insurance service. While WeSure does not insure customers like Ping An, it provides a partnership with over 20 insurance companies, including Ping An (WeSure Insurance 2018). Thus, WeSure essentially acts as a broker. With products like WeCare, it offers closely integrated health insurance solutions that can be explained to the customer in a few illustrations (Gin 2017). Customers can also pay their premiums through Wechat Pay and benefit from a reward system. For instance, the app connects to their insurance contract and they receive a small amount of money if they walk over 8,000 steps in a day (Lew 2018).

> “Tencent Doctorwork connects over ten million patients with around 440,000 certified doctors and 30,000 hospitals.

To compensate for the missing expertise in the healthcare market, Tencent collaborates with the German pharmaceutical company Merck. With its help, Tencent can offer digital services that increase the awareness of allergy and disease symptoms. They also add tools to better manage chronic diseases, e.g. by encouraging people to adhere to their treatment plan (Merck 2019).

While Ping An uses its own core business to build its ecosystem and buy startups in search of missing expertise, Tencent's strategy is to build strategic partnerships with different health service companies like Merck. Another example of such a partnership is the recent collaboration with WebMD, a US online publisher of health information and news. WebMD provides recommendations for a healthy life, health trends, drug information sheets, and symptom checklists for possible illnesses (Yiran 2018). This knowledge is translated into Chinese and complements the Tencent health ecosystem.

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> With its healthcare ecosystem, Alibaba Group aims to pursue “health and happiness” for its customers.

Alibaba

Another big tech company that plays a major role in the Chinese healthcare market is Alibaba. Alibaba is a tech giant, which started as a global wholesale marketplace. Today it commands over CNY 377 billion in revenue and operates a fast-growing cloud service division (Alibaba 2019). With its healthcare ecosystem, Alibaba Group aims to pursue “health and happiness” for its customers (Li 2017). Hence, in contrast to Ping An and Tencent, Alibaba builds its ecosystem not only around central healthcare functions, but also targets wellness and health lifestyle products. On the technology side, it also features an AI diagnostic system called DoctorYou, which assists doctors in their diagnosis and decision-making. Furthermore, Alibaba operates an AI-assisted processing system called ET Medical Brain (Alibaba Cloud 2018). The latter works in the background and takes over numerous managerial processes and workflows. However, Alibaba Group so far only applies this AI support on the business-to-business (B2B) side. This is because Alibaba does not have an AI-assisted online consultation service or a portal that connects medical service providers and customers. Instead, it tries to integrate its services into its marketplace ecosystem. For instance, customers can buy urgent medicines through the Taobao marketplace or seek medical advice. Their orders will arrive within an hour, regardless of the time they are submitted (Warc 2018).

While Tencent leverages the Wechat messaging platform to build its ecosystem, Alibaba uses its marketplace and cloud service. Since Alibaba Cloud is the biggest cloud service provider in China, it can exploit its market-leading position to collect data more easily. The fact that many healthcare organizations are already business customers of Alibaba Cloud facilitates data sharing with them (Yingwei 2019).

Similar to Tencent, Alibaba also collaborates with healthcare companies to access knowledge. More specifically, it has formed multiple strategic partnerships, including the German pharmaceutical company Merck. While the focus of this partnership is more on medication tracking, health e-commerce and AI-solutions are also planned (Merck 2018). Another example of Alibaba’s strategic partnerships is the cooperation with Allergan, an Irish pharmaceutical company specialized in medical aesthetics such as wrinkle relaxation. Through this collaboration, Alibaba adds another solution beyond basic healthcare service (Business Insider 2018).

The regulatory response to AI in healthcare

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There is a consensus that AI will fundamentally transform modern economies and societies, and be applied across numerous day-to-day activities of work and life. While the expectations are large, there are also concerns. For regulators, in particular, it is crucial to understand the different dimensions of AI, what needs to be regulated and why. The need for regulation could arise from the risk of discrimination as well as safety and privacy concerns, also raising the question of accountability in case of undesired outcomes.

The general need for AI regulation

There are manifold definitions of artificial intelligence (AI), but they all share the idea of a machine performing intelligent human behavior (see Barr & Feigenbaum, 1981). To accomplish that, machines are trained with large amounts of data to recognize patterns and to apply their learned abilities to unknown data sets. As AI is defined quite vaguely, it is often used as a buzzword and mixed with other current technological trends. To some extent, the discussion can be considered as mystic and esoteric, with major expectations and at least comparable concerns about how machines will affect our work and lives in the coming decades. Concerns exist on the ethical and legal side, raising the need for regulation of AI technology and the companies that develop and implement it. The need for regulation could arise from the risk of discrimination as well as safety and privacy concerns, also raising the question of accountability in case of undesired outcomes.

Machine learning and deep learning are some important methods for training machines (see Sharma, 2018), comparable to educational methods used in schools to teach children. However, in contrast to human intelligence, machines cannot make their own experiences and learn from emotions and feelings. For example, a child touching a hot cooking plate will immediately learn that this was not a good idea, without being told by his/her parents. Once accurately trained, however, machines can perform tasks in a much more efficient way. It is thus important to understand that the learning process is different for machines. They are not intelligent per se, but quickly and efficiently perform and repeat the tasks they are trained for. In this respect, they can be more powerful and more efficient than humans.

These abilities can and should be used by humans to support and improve our lives. But we must also not forget that there is hardly anything worse than a badly programmed AI system, which automatically makes bad decisions. This goes from something as trivial as bad advice from chatbots to something as dangerous as weaponized drones powered by artificial intelligence. History has taught us that everything that is technically possible may be realized at some future date, emphasizing the immense importance of thinking about AI regulation now. National and international institutions such as the Organization for Economic Co-operation and Development (OECD) and the European Commission have recognized this and established working groups and discussion tables. AI is a field where careful planning and testing is needed, along with some form of regulation.

AI research goes back to the 1950s, but only recent advances in computing power, availability of data and new algorithms have led to today's possible applications (Mesch, Penzel, Peters, & Weber, 2019). Even so, today's AI systems are viewed as "narrow" AI systems that are trained to perform one task only, e.g. an AI chess computer cannot be used to play poker. Of course, these "narrow" AI systems are not the ultimate goal of the tech companies investing billions of dollars in the development of improved systems. These companies try to develop AI systems that are able to mimic human behavior, e.g. think abstractly, be innovative and creative, and also make judgements in uncertain conditions (Uj, 2018). Without knowing if the development of these AI systems is actually possible, experts expect the first system to be ready in the next 10–30 years (Uj, 2018). Given this relatively vague time horizon, regulations need to focus on the technology which is in place now (i.e. "narrow" AI). Nevertheless, it is important to track the technological development and to continuously update potential regulatory frameworks in this dynamic field of research and practice.

To perform human-like tasks and ultimately adapt human behavior, AI systems depend on detailed and large amounts of data from various data sources. To recognize patterns, they need frequent personal interactions. Today's AI applications are basically in the areas of text and natural language processing, image or video analysis, and pattern recognition in large, often unstructured data sets. Recent developments in the healthcare industry have already given a glimpse of the impact and potential of AI systems, which can be categorized in three broad applications: (1) medical monitoring of people and continued data generation, (2) administrative process optimization, and (3) medical assistance with treatment, care, support and surgery. Each of these three fields might need special regulatory attention.

Medical monitoring and data generation

With respect to the first category, telematics or smart devices can be used to measure various health-related data, e.g. heart rates, activity levels and periods of sleep. Additionally, people can track nutrition and workouts with other apps. Moreover, online search results and credit card payments can be used as a good proxy for shopping behavior. Combining the given input data with other personal data, individuals could receive recommendations for better workouts, incentives for optimizing their nutrition or information about the right amount of sleep. Besides these more natural prevention measures, AI systems can help to recognize health-related irregularities through access to telematic data. While the benefits of prevention measures are easy to see, there could be adverse issues with respect to data protection and adverse usage of data collected. As health data is very sensitive, data protection and the prevention of unauthorized third-party usage is a key issue. As cyber-crimes are becoming more frequent, it must be clarified which data is relevant for innovation. Moreover, users need to know what happens if they do not follow the suggested AI advice. Negative consequences could conflict with human dignity and freedom of choice.

Optimization of administrative processes

With regard to administrative process optimization, chatbots are already able to schedule an appointment via text or language processing. In the near future, it will be possible for patients to call their physician and a chatbot will answer the phone, record the health issue and schedule, if needed, an appointment with the doctor. Moreover, virtual assistants can be used for text transcription and other administrative tasks, allowing time and resources to be used more efficiently. Better planning of human resources could have a major impact on the healthcare industry, given the shortage of medical personnel in some areas. For example, using all the data generated by connected telematic devices, existing symptoms can be analyzed to help identify patients at risk of developing an illness, thus enabling prevention or early treatment. Furthermore, claims can be settled much faster with insurance companies.

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> Research results could also be entered and analyzed by AI to recommend new methods of treatment.

Medical assistance

AI could probably have the greatest impact in the area of medical assistance. Today, image recognition is already used for diagnoses when analyzing computed tomography (CT) or x-ray images. Furthermore, a huge database with information on symptoms, diseases and recommended treatments can be built and structured with AI. Doctors could access this database via a virtual assistant and obtain a second opinion on their courses of treatment. Research results could also be entered and analyzed by AI to recommend new methods of treatment. This would ensure that doctors would always be up to date with the latest research results. It is also imaginable that medical incidents might be handled directly by a virtual assistant without the patient even needing to see a doctor. This scenario might still seem far away as today's generation is used to talking to a trusted doctor. But when interacting with machines becomes more realistic and normal, it all becomes possible. Moreover, robots with integrated AI, comparable to autonomous driving, can help surgeons with critical operations as they do not get tired and can work with extreme precision. Also, they could be built to support hospitals and nursing homes, e.g. robots in long-term care. In particular, this third category raises relatively large ethical and legal issues and thus a potential need for regulation. Who is liable in case something goes wrong (the end-user or the producer of the technology, i.e. typically a software firm)? How can we ensure the safety of the technology, e.g. against hacking? How can unfair discrimination be avoided? How do we ensure the right to informational self-determination?

Economic and social reasons for regulating AI in healthcare

Regulation can be defined as governmental laws backed by sanctions to control the market development or the behavior of market participants, with the aim of preventing economically or socially undesirable events (Black, 2002; Lodge & Wegrich, 2012). Often, regulation is a reaction to perceived market or societal malfunctioning and can differ between countries, depending on each country's objectives. Assuming the existence of an AI system that can perfectly mimic human behavior, regulation should not be fundamentally different compared to today's existing laws. If this system has a knowledge of what is right and wrong, it could theoretically be treated equally as a human being. But a number of regulatory questions remain, such as who is liable for proper documentation or the quality of advice? With respect to AI systems in healthcare, there are two principal stakeholders that can be regulated: entities developing AI systems and entities deploying AI, i.e. offering AI services.

The development of AI systems seems to be a key research field of the big tech companies like Google, Apple, Amazon, and Microsoft. In healthcare, they could use information about patients' willingness to pay and offer customized treatments. Moreover, as developers look at the predictive power of lines of code, they might overlook discriminatory features. Another key issue with respect to regulation of these tech companies will be the ownership and protection of data. As further advances in AI systems demand more diverse and granular data, sharing data is almost unavoidable. If, for example, people with a bad health condition decide not to share their data because they fear it could affect their insurance premiums and then they later need a diagnosis, the AI system might give poor advice because their risk type is not representative in the existing data set (Forbes, 2019). But even if the existing data set is representative, decisions by the AI system could be still discriminatory because the decisions in the training data set are discriminatory. For example, people with private health insurance receive different treatment options than people without. The access to the data would give the tech companies a competitive advantage. Their AI systems could make better predictions and would be used more, which again would improve their access to data. Moreover, they could sell the data to other market participants like insurers and employers or start competing with them.

Today, the Hippocratic Oath taken by physicians prevents third parties from accessing patient data without permission. With respect to market concentration, only a few tech companies would control the whole healthcare industry and could influence individual lifestyles, e.g. by promoting certain products over others. Moreover, as the decision-making process (i.e. computer code) is the property of the tech company, decisions cannot be easily verified. Individuals have to more or less believe in a "black box" without any knowledge of its internal workings. However, great dependencies also create high risks, e.g. system failures or hacking. So far it is not clear who should be held responsible in these cases.

Other regulatory aspects should be considered in the deployment of AI systems. The healthcare industry builds on trust – when people see a doctor, they want a medical assessment of their symptoms, but they also seek to establish a rapport with their doctor and look for sensitivity. As the interaction between humans and machines has not been intensively studied so far, it is hard to imagine how the interaction could look in future. Diagnoses might be fast and unemotional because the data has already been collected via telematic devices and patients may not even have to see a doctor, being basically left alone with a machine. Moreover, they may have to forgo their privacy in return for treatment. Furthermore, when it comes to medical treatments, more than one single option should be considered. The question remains how an AI system that cannot deal with doubts and non-unique answers should decide which answer to choose. Probably doctors will still play an important role, as they must make sure that the AI systems make the right decisions. Questions arise with respect to liability for wrong decisions. Can the AI system be held responsible or only the doctor? Who guarantees that the AI systems have not been not manipulated, e.g. by feeding in false training data? As the decisions made by AI systems are often not transparent, it is difficult to judge them after the event (see Finlayson et al., 2019).

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Individuals have to more or less believe in a "black box" without any knowledge of its internal workings.

Current regulatory developments

As the current capabilities of AI systems are fairly limited to narrow tasks and even experts cannot predict how the capabilities of AI systems will change in the next decade, an overall law for regulation of AI systems has not been implemented. This is simply because it is not clear what exactly should be regulated and if regulation is really necessary. Moreover, as regulation might hinder innovation in the area of AI, some countries such as the USA and China do not want to overregulate or regulate at all, as they compete for the worldwide leading role in the development of AI systems (House of Lords, 2017). Thus some countries have started initiatives to develop non-binding guidelines to tackle the societal and ethical challenges of AI systems (National Science and Technology Council, 2016, for the US; House of Lords, 2017, for the UK; European Commission, 2019, for the EU, BaFin, 2018, for Germany and the financial services industry). Regarding the use of AI in healthcare, the American Medical Association (AMA) also issued its first guidelines on how to develop, use and regulate AI (Forbes, 2019). Notably, the association refers to AI as "augmented intelligence," reflecting its belief that AI will enhance, not replace, the work of physicians.

In May 2019, the OECD published a guideline with principles for the development and use of AI systems, requiring that AI systems respect the rules of law, human rights and democratic values, and be transparent, safe, robust and secure. Moreover, entities developing (i.e. research, design and coding), deploying (i.e. offering AI solutions) and operating AI systems are held responsible for the proper use of AI technology. Based on these principles, the OECD asks governments to invest in AI technology, to build open AI ecosystems to share data and knowledge and to create a policy environment for developing trustworthy AI systems (OECD, 2019; Delcker, 2019a). These guidelines seem to represent the first worldwide agreement on AI principles.

An expert group from the European Commission has already gone one step further by publishing ethics guidelines for trustworthy AI systems (European Commission, 2019). To compete with the USA and China, which are so far dominating AI development, Europe is trying to differentiate by ensuring that AI systems follow ethical rules and base their decisions on fair and transparent criteria (Delcker, 2019b). Based on this transparent and trustworthy environment, the European Commission hopes that companies will have an incentive to develop products and services with ethical considerations. In its report, the European Commission introduces three characteristics that should be considered in the development, deployment and end-use of AI systems – AI systems should be lawful, ethical and robust.

Lawful AI systems
Even though the published guidelines are not binding, AI developers, deployers and users must follow existing laws. For example, tech companies are currently more in the data collection stage to improve their AI systems, but the EU has introduced the General Data Protection Regulation (GDPR). Focused on personal data usage, the GDPR allows individuals, for example, to obtain information about how their data is used and even to delete it. Moreover, stored data should be reduced to a minimum and only be held if absolutely necessary (Hanania, 2018).

Consequently, the GDPR makes individual data usage quite transparent. Also, the GDPR regulates automated decision-making by giving individuals the right to ask for human interaction. Exemptions are possible where it is necessary to enter a contract, where it is authorized by law or where the individual is willing to allow it (Hanania, 2018). However, if healthcare providers rely on AI systems, they also must prove that they meet the remaining GDPR requirements (e.g. the right to transfer or correct data, actively informing individuals about data usage), and could be sued if they do not comply. Other existing laws relevant for the development of AI systems involve product liability, free flow of non-personal data, anti-discrimination, and human rights (European Commission, 2019).

Ethical and robust
As laws often react to social and technological developments, AI systems need to go one step further in following ethical norms that go beyond existing fundamental rights and more in the direction of the moral status of human beings, and therefore have to be readjusted from time to time. To convince society that it can use AI systems confidentially, they must also be robust, i.e. their decisions can be trusted from a technical and social perspective. Addressing both characteristics, the development, deployment and usage of AI systems should always take four ethical principles into consideration: respect for human autonomy, prevention of harm, fairness, and explicability.

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> A patient should have the right to know how and why the AI system makes a decision.

According to the European Commission, these principles would guarantee the wellbeing of society as they are also based on fundamental rights. “Respect for human autonomy” ensures freedom of choice for individuals. In the context of healthcare, this principle ensures that individuals should have the opportunity to choose from a meaningful set of treatments or that telematic devices support and complement rather than manipulate individuals. The “prevention of harm” principle is meant to prevent AI systems from negatively affecting individuals, with a special focus on vulnerable persons. Moreover, it specifies that AI systems should be technically safe and not misused. For example, this principle should prevent health insurers from calculating premiums based on certain individual characteristics and emphasizes the importance of including all health risks and even focusing on bad risk types.

The introduction of AI systems should not result in anyone being worse off than before. The “fairness” principle tackles discrimination in AI decisions, i.e. every individual should have the same access to healthcare, but they should also be free in their choice of healthcare. It also emphasizes that data used should be reduced to a minimum or be at least be proportional. Moreover, the decision-making process and the entity responsible for it should be identifiable. The principle of “explicability” addresses the transparency of automated decisions. For example, a patient should have the right to know how and why the AI system makes a decision. Even the outcome of black box decisions should be to some extent traceable and explicable. The European Commission nevertheless admits that the principles are relatively abstract and only offer guidance.

From the four principles, the European Commission derives seven key requirements of equal importance for a trustworthy AI system:

1. Human agency and oversight
2. Technical robustness and safety
3. Privacy and data governance
4. Transparency
5. Diversity, non-discrimination and fairness
6. Societal and environmental wellbeing
7. Accountability

Moreover, the European Commission presents some technical (e.g. white/blacklist of rules, testing and validating) and non-technical (e.g. regulation, standardization, certification and education) methods to attain the goal of ethical and trustworthy AI.

Future regulatory requirements

So far, most industry experts agree that, when it comes to AI systems, regulation should not be strictly implemented as it would hinder innovation and could lead to a competitive disadvantage (House of Lords, 2017). Some even compare AI systems with the internet and think that it is almost impossible to regulate AI or only possible to regulate it with better AI (Spencer, 2019). However, they all agree that AI systems should follow ethical norms and standards and support rather than manipulate individuals. Thus the principles for ethical AI systems defined by, for example, the OECD or European Commission, are only the first step and probably need to be more specific for each application and each industry. It is difficult to imagine a “one size fits all” regulation that can deal with all the relevant and emerging issues.

Specifically in healthcare, society must reach a consensus as to what form future diagnoses and treatments should take. If only an AI system is needed for diagnoses, fewer doctors will be necessary and more IT engineers with medical backgrounds instead. On the other hand, who will train the AI system as new symptoms and illnesses occur? From today’s perspective, it is very likely that many people will still prefer the personal interaction with a doctor, supported by, but not completely replaced by AI. Furthermore, concentration of market power could lead to the situation where one healthcare company might become too big to fail. Moreover, as we live in a connected world, ethical and regulatory requirements should be internationally harmonized. Otherwise, countries with fewer or no regulations could exploit their competitive advantage to innovate and develop AI systems faster and sell them to other countries.

Hence, as discussed earlier, the liability aspects must be clarified. Who is liable if AI systems make dangerous and/or wrong recommendations? Can the developer be held responsible after handing the AI system over to doctors for failing to input correct data or provide the necessary updates? Should users be held responsible if they enter false data (unintentionally or deliberately)? Further, how can liability questions be answered if the AI decision process is not transparent? All these questions illustrate how the discussion about the potential regulation of AI systems is only just beginning.

Conclusion

The need to regulate AI does not come as a surprise if we consider that the internet in the 21st century is to some extent like the Wild West, i.e. a lawless territory where companies and individuals are exposed to many unregulated risks that they are struggling to control. The questions raised in this article show a clear need for discussion on how AI systems, their developers, and the companies that use them should be regulated to avoid the risk of discrimination and maintain the right to informational self-determination. This also includes the question about which data should be used in the future. In the European Union, the new data protection regulations (GDPR) offer a first legal framework that needs to be further discussed and developed.

From a scientific point of view, the changes in the asymmetry of information and the associated economic welfare effects are particularly interesting. Linked to this is the question of the value of data from the point of view of customers and providers, i.e. what is privacy really worth? Positive effects of digitalization on economic welfare can also be found in the field of prevention at the collective level when it comes to better understanding large amounts of data and using them for the benefit of the customers. At an individual level, however, the welfare effects are not trivial because, as indicated above, there may be both winners and losers in digital monitoring by AI systems.

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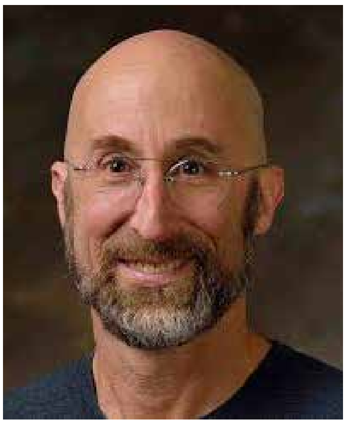

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