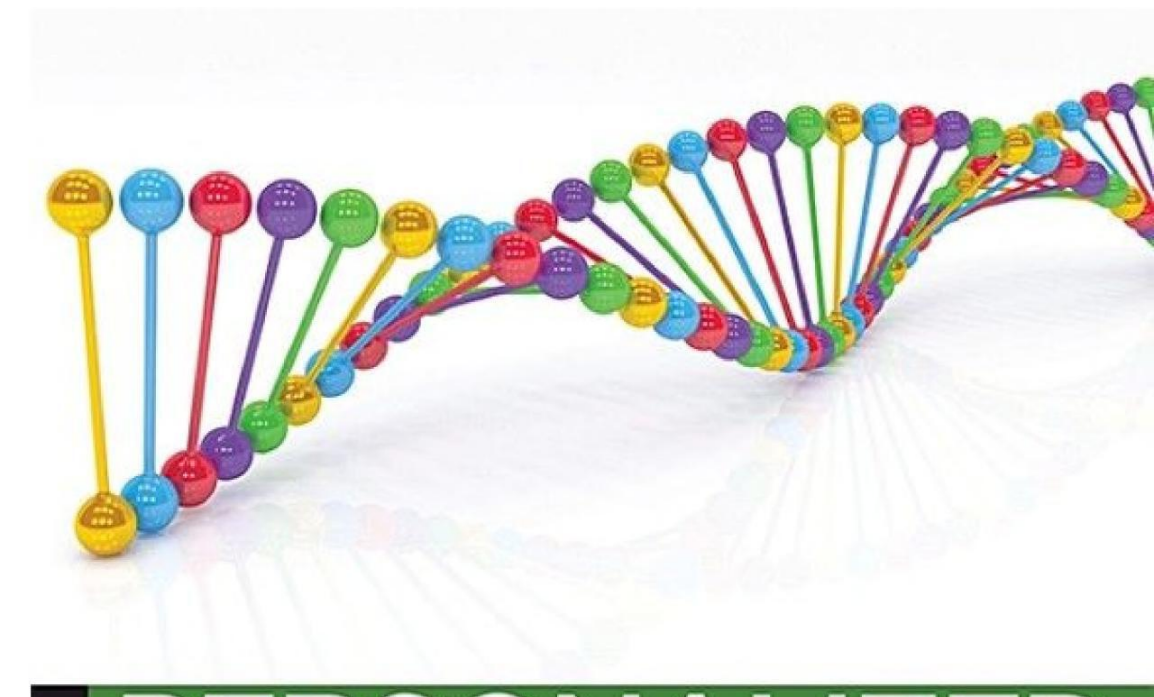

PERSONALIZED MEDICINE

Empowered Patients in the 21st Century?

Barbara Prainsack

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Preface and Acknowledgments

For many years my work has focused on the governance of DNA technologies. From this perspective I saw personalized medicine mostly as a new buzzword, a way of labeling old practices in a different way to open new doors for funding. It was during the European Science Foundation's *Forward Look on Personalised Medicine for the European Citizen* (European Science Foundation 2012), a two-year long scoping and consultation exercise that I had the privilege of helping to lead, that I was convinced of the deeper significance of the idea of personalization. Many practitioners, scientists, and policy makers that I spoke to in those years and the years that followed, from Europe, North America, the Middle East, and other parts of the world, saw personalization as a way to use technological advances to make medicine more "precise." But many of the same people also saw it as an attempt to address the challenges posed by rising health care costs and aging societies. They regarded it as a cost-saving strategy with patients in the driving seat. The role envisioned for patients went far beyond having to manage individual risks: One of the key tenets of personalized medicine is its data-driven nature, including wider ranges of data than clinical or medical ones. Many of personalized medicine's proponents are very open about the fact that patients need to play a key role also in collecting and "sharing" these data.

At the same time that the work required from patients expands, patients' influence over what data and information will be used, how they will be used, and for whose benefit, is waning. The "tapestries of health data" that are envisaged to underpin medical practice and research are prescriptive in what they can include and what they cannot. Narrative, unstructured information and personal meaning have little room in them, and data and information from marginalized populations are often

not included at all. This all stands in a clear tension with the pronounced rhetoric of patient empowerment and patient participation. The mission of this book is to address this seeming paradox. Why is it that the work required from patients is becoming more expansive and less self-directed at the same time that the flag of patient empowerment and participation is raised over ever wider territories in medicine and health care?

A lot of people and institutions have supported this book project. I am deeply grateful to the Rockefeller Foundation for inviting me to spend a month at its Bellagio Center in the summer of 2016. I had planned to use that month to try to forget about personalized medicine and start a new project. I ended up doing the opposite: I forgot about my new project and started rewriting the book. The final manuscript has benefited greatly from numerous conversations with my fellow residents, including Isher and Montek Ahluwalia, David Autor, Kate Bredeson, Edith Brown Weiss, Medora Dutton Ebersole, Alec Freund, Matthew Goulish, Ann Hamilton, Ben Hecht, Lin Hinxson, Lynn Leibovitz, Michael Mercil, Pam and Jim Murray, Eric Nordstrom, Auma Obama, Catherine O'Regan, Tania and Antonio Patriota, Sanchita and Somitra Saxena, Stephen Rapp, Donatha Tibuhwa, Charles Weiss, and Karl Zimmerer. I am particularly grateful also to the Center's managing director, Pilar Palacia, and everybody else at the Foundation and the Bellagio Center who has made my time there so special.

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Adele Clarke, Carrie Friese, Gabriel Krestin, Gisli Palsson, and Tamar Sharon have not only read and commented on several chapters but have also believed in this project at times when I did not; it is not an exaggeration to say that the book would not be here without them.

I dedicate this book to my husband, Hendrik Wagenaar, who I admire for many reasons; one of them is that he understands the world better than I do and has not given up on it. I thank him for his support and inspiration, and for his love.

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Technical Terms and Acronyms

ALS: *Amyotrophic Lateral Sclerosis,* a rapidly progressive neurological disease that is also called Lou Gehrig's disease, or motor neuron disease.

Amygdala (pl. amygdalae): Two almond-shaped parts of the brain that play an important role in decision making, memory, and emotional reactions.

BOP consumers: "*Bottom of Pyramid*" consumers—the largest but poorest group of people in the world.

Care.data: A program that would have allowed the English NHS to share patient data with health care organizations and commercial companies in the UK and beyond. It led to public resistance due to an alleged lack of transparency about the goals of the program and the plan to have patients opt-out instead of opt-in.

Crowdsourcing: A composite of the words "crowd" and "outsourcing," that is, the enlisting of large numbers of people (crowds) in a task, often online.

CSR: *Corporate Social Responsibility* refers to programs and strategies that combine profit maximization with the creation of social benefits.

CT: *Computed tomography,* a technology in medical imaging.

Deep phenotyping: A person's phenotype comprises her actual physical, personal, and behavioral characteristics (to be contrasted with genotype). Deep phenotyping refers to the description of (often disease-related) phenotypes using a data-rich approach.

DTC: *Direct-to-consumer.*

Epigenetics: The study of changes in organisms stemming from modifications of gene regulation or expression rather than changes in the DNA sequence.

ESF: The *European Science Foundation* is a nongovernmental nonprofit association of public and private research-related organizations in Europe and beyond.

EU: *European Union.*

FDA: The *Food and Drug Administration* is the U.S. government agency responsible for approving medical products, including pharmaceutical drugs and medical devices.

FTC: The *Federal Trade Commission* is an independent agency of the U.S. government, tasked with consumer protection and anticompetitive business practices.

GBM: *Glioblastoma multiforme,* one of the most aggressive and most common brain tumors.

High-throughput technologies: The computational tools and methods that enable the simultaneous and rapid examination of large amounts of genes, proteins, and other substances.

HIPAA: The *Health Insurance Portability and Accountability Act* was passed by the U.S. Congress in 1996 and established a set of national standards for the protection of certain types of health information.

Hippocampus (pl. hippocampi): Parts of the brain that play important roles, for example, in memory and special processing.

IOM: The *Institute of Medicine* is a division of the National Academies of Science, Engineering, and Medicine (NAS).

IoT: The term *Internet of Things* refers to connected computing devices (such as sensors) without requiring

human-to-human or human-to-computer interaction. Some people expect that our entire physical environment will start to wirelessly "talk to" one another in this way.

IP address: *Internet Protocol address,* a numeric label assigned to a device participating in a computer network.

MRI: *Magnetic resonance imaging.*

MS: *Multiple sclerosis.*

NAS: U.S. *National Academies of Science, Engineering, and Medicine* are private nonprofit institutions providing expert advice to policy makers, funders, and similar.

NHS: *National Health Services,* the public health services of England, Scotland, and Wales.

NIH: The *National Institutes of Health* in the United States, a research agency within the U.S. Department of Health and Human Services.

ODL metrics: Metrics for *observations of daily living.* ODL metrics can be very personal sensory and behavioral indicators for the purpose of health monitoring (and often also for behavior modification).

Omics: Derived from terms such as biome or genome, "Omics" is an umbrella term for the study of datasets representing different types of molecules in a cell. More recently also disciplines outside of biology have started to use the "Omics" label to denote the analysis of large sets of social or demographic data.

Privacy-by-Default: An approach that prescribes that only the minimum set of personal data necessary for a purpose should be processed, and that service providers need to offer customers the strictest possible privacy setting by default. It is enshrined in the General Data Protection Regulation in Europe.

Privacy-by-Design: An approach committed to designing privacy-enhancing measures into hardware and software. It was originally developed by Ontario's information and privacy commissioner, Ann Cavoukian, and is now enshrined in a number of laws and regulations, including the General Data Protection Regulation in Europe.

PROM: *Patient-reported outcome measures.*

Prosuming: A composite of the words "*pro*ducing" and "con*suming,*" referring to the practice of users or consumers creating value for corporations by producing some or all of the content or products that they then consume (for example, social media).

Redlining: Discrimination against specific groups of people on the basis of socioeconomic, behavioral, or other profiling. Redlining is often used to refer to practices that are not illegal (such as not offering certain discounts in specific ZIP codes, or not offering shipment to some regions).

Smart glasses: Eyeglasses that are wearable computers.

Social biomarkers: Information reflecting nonsomatic characteristics of patients that matter to them in connection with their health care.

STS: *Science and Technology Studies,* an interdisciplinary field of studying how scientific knowledge and technologies are produced in conjunction with social and political order.

Theranostics: A composite of the terms "therapeutics" and "diagnostics." It refers to strategies to combine diagnostic and therapeutic capabilities in one single agent or process to tailor both more closely to individual characteristics and needs of patients.

1

Setting the Stage for Personalized Medicine

The Changing Meaning of Personalized Medicine

When proponents of personalized medicine explain the concept, they typically tell a story of technological progress. Medicine used to be hit-and-miss, they say. We used to treat all people with a certain disease the same, despite all their differences. With today's technological tools we have become much better at measuring individual difference. Personalized medicine—especially in its iteration of precision medicine, which seeks to include ever wider types of information and monitoring—is the future. It is time to say farewell to "blockbuster medicine."

This future has already started. The idea that medicine and health care should become personalized—in the sense that they should be tailored more closely to individual characteristics of patients—has entered almost every domain of health care. Let us take the example of Type-1 diabetes, which is a relatively common disease. In the United States and in Europe, about two to three in a thousand people are affected by it, most of them at a young age (Menke et al. 2013; Patterson et al. 2009). Historically, the prevalence of diabetes has been highest among European populations, but now it is on the rise also in low- and middle-income countries. In contrast to Type-2 diabetes, which has been known as "adult onset diabetes" and can often be managed by diet and exercise, most Type-1 diabetes patients rely on insulin injections. Before the discovery of insulin treatment in the 1920s, Type-1 diabetes sufferers were put on so-called starvation diets. Fasting and restricted food intake, it was believed, could prolong the lives of patients. Despite this, many patients died within months of the diagnosis.

After the introduction of insulin treatment, the tools required consisted of a simple finger prick set to determine glucose levels, and a syringe to inject insulin. Then, in the late twentieth and early twenty-first century, companies developed more complex monitoring and treatment systems, including microchip sensors, automated insulin pumps, and insulin inhalers. Today, "smart socks" can measure changes in temperature in patients' feet to detect inflammation that could lead to foot ulcers, which affect many diabetes sufferers. And insulin meters can send text messages to parents about their child's glucose levels. Patients in high-income countries are encouraged to use these tools to tailor their diabetes treatment more closely to their individual needs. Every diabetes sufferer is different, so the story goes, and monitoring blood glucose within very narrow ranges with the help of close monitoring leads to better health outcomes—at the cost of five hundred dollars per month or more, with treatment tools and insulin increasing in quality and price.

Another example of the personalization of diagnosis and treatment is the molecular classification of tumors. It is well known by now that the treatment of breast cancer can be improved by looking at the specific characteristics of the tumor. But this practice is not restricted to breast cancer alone. Glioblastoma

multiforme (GBM), for example, is a rare but very aggressive brain cancer. Its prevalence is not known exactly because it remains undiagnosed in many resource-poor regions. In high-income countries, it is estimated that GBM makes up about 15 percent of all brain tumors. Once diagnosed, most patients die within three years. GBM tumors are resistant to conventional therapies, and treatment options vary depending on the tumor's location. For a long time, surgery, chemotherapy, radiation, and palliative treatment were the only options available. More recently, gene transfer has been explored as an additional treatment option, and promising results were achieved with the use of a nonpathogenic version of an oral poliovirus type in clinical trials at Duke University (Gromeier 2018). Moreover, factors such as the precise location of the tumor, patient age, and molecular markers such as the concentration of certain growth factors allow probabilistic inferences regarding treatment response and survival rates. The molecular classification of tumors is thus seen as a way to more individualized therapies that "will ideally lead to better outcomes in both the quantity and quality of life" (Choudhry et al. 2013: 303).

Is personalized medicine the crown of the evolution of medicine? Is it a step toward truly individualized medicine, and is the latter something that we should strive for? While many advocates of personalized medicine would answer these questions with a resounding yes, others are less enthusiastic. They remind us that medicine has long been personalized. Physicians, nurses, and carers have always considered the individual characteristics and circumstances of their patients when diagnosing, treating, and caring for them (Hunter 1991). In the days before professionalized medicine, and certainly before medicine's reliance on instruments that only trained professionals could operate, patients played a key role in medical decision making processes: Their stories and descriptions of symptoms were often indispensable for determining diagnosis. Patients and their families have also participated in deciding on and administering care (see also Strauss et al. 1982; 1997). Historically, "bedside medicine," with its close interactions between patients, doctors, and families and with its consideration of the specific circumstances and experiences of the patient, has been the rule, and not the exception.

If we accept that medicine has always been personalized, why is it, then, that the concept of personalized medicine has received so much traction recently? Is there anything new about the kind of personalized and "precision" medicine that is the topic of policy papers, funding calls, and government initiatives today? Although I agree that we should be cautious not to celebrate personalized medicine as an entirely novel phenomenon, it is clear that several developments within the last two decades have changed the institutions, practices, and stakes of medicine. The spread of digital technologies and the "biomarkerization" (Metzler 2010) of medicine—that is, the increasing reliance on objectively measurable somatic markers representing specific stages of physiology and pathology—have changed the meaning of evidence that is used to personalize medicine. In the 1960s, the British novelist Peter Berger portrayed the life of an English country doctor. For decades to come, his book was on the reading list of people training to become doctors. In order to recognize a patient's illness, Berger noted, doctors "must first recognize the patient as a person" (Berger and Mohr 1967: 76). In other words, doctors, when assessing the likely cause and nature of a disease, need to

consider wider ranges of factors than the immediate symptoms that a person presents with. This statement is very similar to the slogans of proponents of personalized medicine today: The U.S. Precision Medicine initiative, for example, explores how genes, environment, and lifestyle come together to create a "unique thumbprint" of each patient (National Institutes of Health 2016a). What has changed is thus not the commitment to focus on individual characteristics of patients but the very characteristics that should be considered. When diagnosing and prescribing treatments, Berger's country doctor considered the living circumstances of his patients, their family and social relationships, and their mental state. These were all aspects that doctors who still made house calls used to know—or explore in a dialogue with their patients. Within contemporary personalized medicine, it is a person's genetic predispositions, her lifestyle information, and clinical data that should be brought together into personal health maps informing diagnosis and treatment. It is no longer unstructured narrative information that is seen as the key to personalization, but structured, digital, quantified, and computable data (see also Hartzband and Groopman 2016; de Mul 1999; Nettleton 2004; Webster 2002).

Another push toward such a new understanding of evidence has come from the advance of high-throughput technologies—the devices and computational tools that enable the simultaneous examination of large amounts of genes, proteins, and metabolites. A standard reference in this context is Moore's Law, named after Intel founder Gordon Moore; it predicts that the number of transistors on integrated computer circuits doubles every two years (G. Moore 1965). The cost of sequencing a human genome—the sum of a person's DNA—has decreased faster in the last decade than predicted even by Moore's Law. At the same time, the speed of analysis has increased drastically (National Human Genome Research Institute 2014). Advances in the production of data on gene expression, blood glucose levels, or brain function, for example, have contributed to a situation in which Western biomedicine is now faced with unprecedented amounts of digital data. Finding a way to transform these data into something meaningful and, if possible, clinically actionable, is one of the main challenges that clinicians, patients, enterprises, and health authorities struggle with.

In policy papers, politicians' speeches, and newspaper articles today, personalization appears as the data-intense characterization of individuals at different stages of health and disease in the course of their lifetime. This is different from how the term was understood in the 1990s and early 2000s, when personalized medicine largely meant tailoring drug treatments to genetic characteristics of population sub-groups (Hedgecoe 2004). Today's vision of personalization seeks to make use of much wider ranges of molecular and nonmolecular data and information, including imaging data, information about lifestyle and diet, and records of physical examinations (European Science Foundation 2012; PerMed Consortium 2015; Weber, Mandl and Kohane 2014). This is also how I use the term personalized medicine in this book. I understand precision medicine (National Research Council of the Academies 2011; see also Juengst et al. 2016) and stratified medicine[1] as variants of the idea that I subsume under the generic label of personalization.

Where Patients Come In: The "Google Maps" of Health Data

Former U.S. President Obama made personalized medicine prime time news when he announced the allocation of $215 million to the study of "individual differences in people's genes, environment and lifestyle" in his State of the Union address in 2015 (White House 2015). He referred to this new type of medicine as precision medicine. The paradigmatic vision of precision medicine was first formulated in a report by the Committee on a Framework for Developing a New Taxonomy of Disease within the U.S. National Academies of Sciences in 2011 (National Research Council of the Academies 2011). The report proposed to replace traditional, symptom-based disease classifications with a new taxonomy based on data-rich characterizations of individuals and disease states. The report used the "Google Maps" feature, with its different layers of data—including data on transportation, land use, and postal codes—as a template for what a new map of patient-centered information could look like. The report's vision was that this map should serve both clinical and research needs (17). In such a system of patient-centered data, genetics may still play the first violin in some contexts, but it is part of a bigger orchestra.

But where do the data for such a personalized health data map come from? Many kinds of nonmolecular data that are envisaged to be part of such a health-data system—including information about the details of a person's lifestyle, mood curves, or data from the daily tracking of functional changes following the start of a new medication—are not readily available from clinical or biomedical research contexts. Some of the data would need to come from other, non-biomedical research contexts, remote sensors, or people's personal domains.

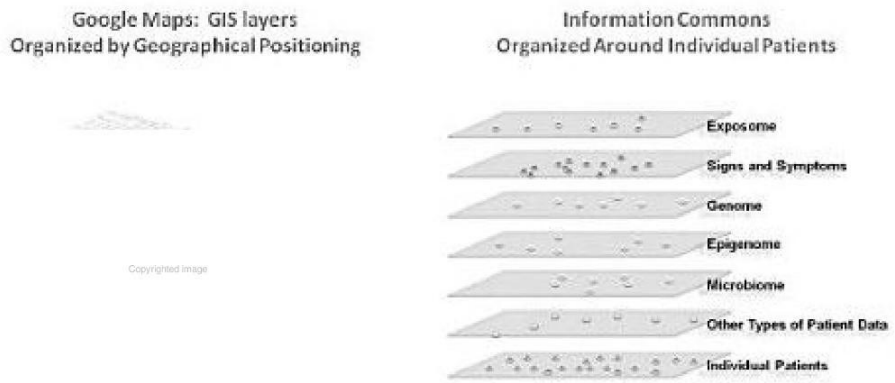

Figure 1.1. An Information Commons might use a GIS-type structure. The proposed, individual-centric Information Commons (right panel) is somewhat analogous to a layered GIS (left panel). In both cases, the bottom layer defines the organization of all the overlays. However, in a GIS, any vertical line through the layers connects related snippets of information since all the layers are organized by geographical position. In contrast, data in each of the higher layers of the Information Commons will overlay on the patient layer in complex ways (e.g., patients with similar microbiomes and symptoms may have very different genome sequences). Source: FPA (Fire Program Analysis) 2011, GIS Overview, FPA Project, Idaho State Office, Bureau of Land Management, Boise, ID, www.fpa.nifc.gov, accessed August 19, 2011 (left panel); screenshot from Insel 2011 (right panel). Reprinted with permission of the National Institute of Mental Health. Original caption was retained.

Since the report was published, the "Google Maps for health" metaphor has become a trope, popularized also by physician researcher and author Eric Topol's use of the comparison between geographical information systems and personal health maps (Topol 2015). Topol argues that in the near future, personal health maps will enable patients to carry out most diagnoses themselves. Even visionaries and practitioners who do not believe that algorithmically supported patients will take over the role of doctors any time soon see the integration of diverse types of data sets as crucial for the realization of personalized medicine. And they agree that this goal, in turn, will depend on the willingness of people to participate in the generation and analysis of data.

Many technologies to help patients with this task are already here. Touch-screen-fitted and portable devices make it technically easier to collect and transfer data and information. Websites and platforms "pull" data from users seeking to access information on the Internet—often without their being aware of what it is they are contributing (Wellcome Trust 2016). In other words, the Internet[2] has ceased to be primarily a provider of information and has become a tool for data collection from patients and citizens (Kallinikos and Tempini 2014; Prainsack 2013; Tempini 2015). Data that were not previously considered relevant in the health care context—such as mood-tracking data stored on smart phones—are now seen as potentially useful resources. Viktor Mayer-Schönberger, an information governance expert, and Kenneth Cukier, an editor at *The Economist,* use the term "datafication" to refer to this process. According to these authors, we

are taking “information about all things under the sun—including ones we never used to think of as information at all, such as a person’s location, the vibrations of an engine, or the stress on a bridge—and transforming it into a data format to make it quantified” (Mayer-Schönberger and Cukier 2013: 15).

That increasing parts of our lives, bodies, and environments are “datafied” does not mean that these data can always be integrated and interpreted in a meaningful way. Improving the interoperability between different data sets and data repositories, data integration, and quality control at the point of data entry remains a difficult challenge, despite promising attempts of tech developers. But here, too, it is apparent that these challenges cannot be addressed without active participation by patients who are needed to collect, hand over, or help analyze data and information.

The central role of patients in personalized medicine was apparent also in Barack Obama’s vision: collaborative health care and “patient-powered” research form central pillars of the U.S. Precision Medicine Initiative (White House 2015). With this emphasis on patient-centered personalized medicine, the United States is not alone: Proponents of personalized medicine around the world believe that it can kill two birds with one stone: to render medicine more effective and, at the same time, “empower” patients.

Whom Does Personalized Medicine Empower?

But are patients “empowered” by personalized medicine? Social scientists who have been studying twentieth- and twenty-first-century versions of personalization in medicine draw a nuanced picture. Sociologist Richard Tutton, for example, grounds his analysis in the sociology of expectations, which treats speculative claims about the future of a field of science or technology as “fundamental to the dynamic processes that create new socio-technical networks” (Hedgecoe and Martin 2003: 328). In other words, visionary statements about the development of a field often create facts on the ground. In the case of personalized medicine, Tutton argues, the notion serves to overturn the fiction of the *standard patient* (Tutton 2012; 2014). The idea that every disease was marked by a list of specific characteristics and symptoms that all patients in this group would typically display was a central theme within the scientific ideal of Western medicine in the nineteenth century. The current version of personalized medicine, in contrast, draws attention to the innumerable differences between patients and the ways in which their diseases affect them. It highlights the ways in which the same disease develops and expresses itself differently between people, due to differences in lifestyle, diet, genetic makeup, and so forth. In fact, the more we know about differences between people in molecular, lifestyle, and other terms, the farther we get away from the notion that any two people express *the same* disease in the same way (European Science Foundation 2012; Harvey et al. 2012). In its extreme form, personalized medicine means that there are as many diseases as there are people. Diseases could still be bundled together in clusters that display similarities, but the idea of common disease labels would be obsolete (National Research Council of the Academies 2011; Prainsack 2015a).

Tutton argues that this discursive and technological shift draws attention away

from social determinants of health toward an illusion of a technological fix for health problems in our societies. In such a context, personalized medicine appears as an overhyped idea that benefits companies and uses the notion of risk to enlist patients in governing themselves more effectively (Tutton 2014; see also Tutton and Prainsack 2011). Similarly, Donna Dickenson, in her book *Me Medicine vs. We Medicine* (2013), sees personalized medicine as a political rhetoric that makes people believe that it is good for them, while it is really driven by corporate interests and fosters questionable values such as ruthless individualism. Also other critical authors consider the main function of the concept of personalized medicine to be a political one: They see it as diverting attention away from the failure of big science and heroic medicine to make a tangible difference for people's health (Nuffield Council on Bioethics 2010). This diversion is achieved by implying a shift "from industrial mass production to targeted fabrication" (Prainsack and Naue 2006: 349), which runs the risk of reiterating racial, gender, and class biases in a more concealed way than ever (Clarke et al. 2010b; see also Prainsack 2015a).

Here, the examples of personalized diabetes management and the molecular classification of brain tumors at the beginning of this chapter are instructive. First of all, in both scenarios, key aspects of personalization are out of reach for people in low-income countries. That the majority of the world's population will be excluded from enjoying the benefits of personalization has indeed been a key concern of critical observers (Khoury and Galea 2016). But it is not only populations in low-income countries that would be deprived of access to personalizing technologies such as blood-monitoring instruments or tumor analysis, but also less-privileged people within high-income countries. Even for people who could have access to technologies and services used to personalize their health care, social circumstances such as the lack of transportation, the fear of missing days from work, or unconscious racial bias represent factual obstacles to accessing health care, or detract from the quality of care received (Brawley and Goldberg 2012; Matthew 2015; Roberts 2011). Moreover, the increasing digitization of tasks and services—ranging from booking doctor's appointments to using video calls for consultations to managing health records electronically—creates new patterns of exclusion. People who cannot or will not do these things risk being disadvantaged. And among those who are happy to do these things online, new divisions are emerging. Although some of us have sufficient skills and bandwidth to assert our needs and interests, and to create content, others are mostly passive data sources whose data help to improve algorithms and services for the more privileged.

Although this problem is not specific to personalized medicine, the current focus on expensive high-tech solutions within personalized medicine is particularly likely to exacerbate existing inequalities. Moreover, while medicine in general is becoming more data-driven, personalized medicine in particular risks increasing inequalities by focusing on populations that are already well researched and characterized. In connection with genomic research, this is a well-known problem: At the time of writing this book, more than 80 percent of the roughly 35 million samples used in genome-wide association studies—a type of study that can help to identify disease-causing genomic markers—came from people of European descent. Taken together, samples from people of African and Latin American

descent, and from those belonging to native or indigenous peoples, amounted to less than 4 percent of all samples analyzed (Popejoy and Fullerton 2016). This means that much of the genomic research that underpins personalized medicine uses samples from a small minority of the world's population with, relatively speaking, similar genetic ancestry. Although our genetic makeup is only one of many factors influencing health and disease, it is still important to include people living in different parts of the world, with different genetic ancestry, and different lives, diets, and environments. Although race is not genetic, it is biological: People who suffer racial discrimination, for example, who live in deprived neighborhoods, and who are exposed to high levels of stress and financial worries are more likely to be of poor health than others (Marmot 2015). If such people are missing from genetic and other biomedical databases, their clinical and environmental data is absent as well. Also for this reason, some initiatives, such as the Precision Medicine Initiative introduced by President Obama—the name of which was changed to the "All of Us Research Program" in 2016 (National Institutes of Health 2016b)—make extra efforts to include underserved populations.

Another concern that is frequently voiced in connection with personalized medicine is that patients become enlisted in multi-layered treatment and monitoring regimes that restrict rather than enhance the agency of patients (see also Mol 2000). Instruments that need to be used in particular ways and at particular times, sensors that collect data that patients cannot access and control, or drugs that are offered to patients at a discounted price if patients pay with access to their personal data (Hiltzik 2015) all impose additional tasks and duties on patients. This is quite a contrast to the empowerment rhetoric used by promoters of personalized medicine. Being more active "partners" in their own health care here means that people need to be more alert, do more work, and allow for their lives to be more closely monitored by others. And patients are not the only actors affected in such a manner: Health care practitioners, carers, and family members all need to slot into personalized disease management plans and other types of digital health surveillance. In addition, with devices and software that are protected by intellectual property rights, users—including health care professionals—lose the ability to fix, replace, or modify tools as they wish. They become part of a complex treatment script that they cannot alter or opt out from without incurring excessive transaction costs (see also Oudshoorn 2011; Ratto and Boler 2014). Last but not least, more sophisticated tools to "personalize" diagnosis or treatment regularly mean higher costs for patients or their insurance providers.

It is at this juncture that the growing popularity of notions such as patient empowerment, patient-centered medicine, or participatory medicine appears in a problematic light. It is not a coincidence that we see a renewed emphasis on patient participation[3] at a time when medicine is particularly hungry for data and other contributions from us all.

Patient Work in the Era of Personalization

Historically, patients have participated in medicine in many ways: by caring for themselves and for each other, by discussing symptoms, by contributing to medical research or advocating for new treatments, research, protocols, or new

public and environmental health measures (see, for example, P. Brown 2013; S. Epstein 1995; 1996; Kickbusch 1989; Klawiter 2008; Rabeharisoa and Callon 2002; Rabeharisoa, Moreira and Akrich 2014). Scholarship in the social studies of biomedicine has made this kind of work more visible (e.g. Clarke et al. 2003; 2010a; Cooper and Waldby 2014; M. Stacey 1984; 1997; Strauss et al. 1982). The current push toward personalization in medicine, however, increases the amount and type of work that is required from patients. It also moves more of this work outside the boundaries of the clinic and includes ever wider groups of people. Importantly, it includes the witting or unwitting contributions that many of us make when engaging with online tools, when using mobile applications, or when "sharing" information. Without patients contributing data, time, effort, and self-care, current visions of personalized medicine cannot be realized. I call this "personalization from below." Telling this yet untold story of such personalization from below is the main objective of this book.

Overview of the Book

To understand the factors that have created this need for personalization from below, several developments need to be considered in conjunction. I already mentioned the movement toward more data-intensive medicine, both in the domain of research and in the domain of practice (for example, Khoury et al. 2013; Murdoch and Detsky 2013). Data-rich characterizations of people at various stages of health and disease are considered necessary to understand variations in disease biology, which is central to the idea of personalization. Another relevant development is the increasing reliance on web-based tools to collect, process, analyze, and communicate data. Tasks that had to be done face-to-face can now be carried out by people in separate locations. In telemedicine, for example, diagnosis or treatment can be carried out in a different place from where the patient is located (Andersson 2009; Nicolini 2007; Oudshoorn 2009; 2012; Topol 2012). While these developments are often hailed as enhancing health care services in remote areas, or enabling patients to interact with their doctors without leaving their homes, cost reduction is also a driver. In particular, the possibility of sending digital data sets across large distances in real time opens up opportunities for the offshoring of entire tasks or steps of medical service provision to places where they can be done more cheaply: to radiologists in low-wage countries, for example, to call centers on other continents, or to patients themselves.

The first part of this book investigates these developments and organizes them along four main themes: how old and new forms of patient participation in medical practice and research come together in the name of personalization (chapter 2), the new role of patients as continuous data transmitters (chapter 3), the power shifts involved in personalized medicine (chapter 4), and the marriage of health idealism and commercial interest in many of the initiatives and corporations in the field of personalized medicine (chapter 5). In the second part of the book I move from describing and analyzing these developments to addressing the challenges that they pose. Chapter 6 probes the understanding of personhood that underpins Western biomedicine. It argues that we need regulatory and ethical frameworks

that overcome an unduly narrow focus on individual autonomy if we want to achieve a kind of personalization that foregrounds aspects that are valuable and meaningful to patients. Chapter 7 discusses concrete ideas and initiatives that serve as guiding examples for this purpose. It also addresses the concern that the reliance of personalized medicine on digital and computable evidence will crowd out human experience and high-touch practices, and proposes ways to prevent this. In the final chapter of this volume (chapter 8) I bring together the different themes discussed in the book. I formulate an answer to the question of what types of participation and empowerment can contribute to a desirable kind of personalized medicine.

Data, Methods, and Theory

Before I start, a note on the data, methods, and theory guiding my analysis is in place. This book is not the result of one single research project. Instead it brings together different strands of research and policy-related work that I have carried out over the last ten years. I have studied policy documents, public discussions, and scholarly research on the governance of databases for health and security purposes (Hindmarsh and Prainsack 2010; Prainsack 2007; Prainsack and Gurwitz 2007). I have worked with identical twins to learn how people with genetically identical others think about similarity and difference (Cherkas et al. 2010; Prainsack and Spector 2006). I have spoken to marginalized people such as prisoners about their views on DNA technologies (Prainsack and Kitzberger 2009; Machado and Prainsack 2012), and I have been involved in exploring the views of research participants on data ownership, consent, and solidarity in the health domain (Kelly et al. 2015) and studied the emergence of governance approaches to biotechnological innovation (for example, Prainsack 2006). In the domain of policy, I have advised governmental bodies on the governance of bioinformation and on other issues pertaining to biomedical research and practice. Most importantly for the topic of this book, I have had the privilege to lead the European Science Foundation's *Forward Look on Personalised Medicine for the European Citizen* (ESF 2012), alongside Stephen Holgate and Aarno Palotie. These explorations and experiences have steered me toward the most interesting, puzzling, and problematic aspects of visions of personalized medicine. On some occasions I will draw upon interviews that I have carried out myself, or that I was involved in analyzing (for example, Harvey et al. 2012). On other occasions I employed interpretive methods to analyze data that are publicly available, such as the content of online platforms, policy documents, or marketing materials. I also often use materials from studies by other colleagues to illustrate my arguments. Empirical studies on "patient work" in the era of personalized medicine are still relatively scarce, as the field is still young, but their number is growing (e.g. Juengst et al. 2016; Noury and Lopez 2016).

My methodological approach is interpretive, focusing on the exploration of what Hendrik Wagenaar called "discursive meaning" (Wagenaar 2011). I look at how actors understand certain terms, developments, and events. In other words, practices of meaning making, and the larger shared and institutionally enacted understandings that are outside of the domain of singular individuals and actors, are the main subject of my analysis. Theoretically I am grounded in critical

approaches used in Science and Technology Studies (STS) and policy studies. Like so many others in STS I consider science, technology, and societal order as practices that emerge in connection and interaction with each other (Jasanoff 2004). From critical policy studies—and my training in political science and political theory more broadly—I take a commitment to look at the workings of power—not only when power is exercised in a situation of open conflict but also when it works in more silent ways. Last but not least, and reflected also in my methodological approach, I am inspired by epistemology and hermeneutic traditions that give an important place to meaning in the lives of people, and that are interested in understanding how meaning is made at personal and collective levels.

2

The Patient Researcher

What's New? "Activated Patients" as Data Contributors

All visions of personalized medicine, no matter how they are labeled, envisage an active role for patients. As noted in the previous chapter, former President Barack Obama, the initiator of the U.S. Precision Medicine Initiative, was very clear that it can only succeed if patients participate actively. Policy makers in the European Union have been equally explicit about the need for people to contribute time, data, and effort towards the personalization of health care (see, for example, European Commission 2014: 42–43). Mark Britnell, a previous high-level manager within the English National Health Service (NHS) and recent author of a book on health care systems around the world, put it most bluntly: "I do not know of a health system in the world that will not need greater patient activation if it is to become—or remain—sustainable" (Britnell 2015: 216; see also Lupton 2014).

The key message of such statements is not only that personalized medicine specifically requires the active participation of patients to realize its goals but also that health care systems on the whole will only be able to survive if patients become more "activated." But what are "activated patients"? When Anselm Strauss and colleagues coined the term "patient work" in the early 1980s, they focused on the participation of patients in their own care (Strauss et al. 1982; 1997; see also Kerr, Cunningham-Burley, and Amos 1998; M. Stacey 1984). After carrying out extensive fieldwork in hospitals, Strauss and colleagues concluded that:

> Among the people who perform work in

> [hospitals], contributing directly or indirectly to the care of patients, there is one class of workers which is not so easily recognized. These workers (the patients) have no occupational titles; the tasks which they perform are often unnoted—although paradoxically often assumed and even expected—but their work is certainly not paid for by the hospital. In fact, much of it is quite invisible to the staff [. . .] either because not seen or not defined as work (Strauss et al. 1982: 977).

This diagnosis still holds true today. Health care continues to rely on the unpaid work of patients and caregivers—most of the latter are women (Levitsky 2014; M. Stacey 1984). But in the context of contemporary personalized medicine, patient work includes a much broader range of activities. Patients and nonpatients alike are expected to monitor themselves by collecting data on tablets, smartphones, or wearable sensors. They are asked to help to fill the "data gap" between doctor's visits to establish baselines of their physiological functioning, or for other purposes of prevention: People at risk for skin cancer, for example, can wear sensor patches to detect high levels of UV radiation (Gruessner 2015).

Is this a good development? Some authors and practitioners answer with an unqualified yes. They see every instance of data transfer from a patient to a doctor, a health care provider, or even a web-based platform that will analyze patient data as making medicine more democratic. For some, the fact that people can access previously inaccessible information online, organize themselves on patient platforms, and contribute to scientific research in novel ways amounts to a participatory turn in medicine and science (Prainsack 2011b). Others see participatory practices and initiatives in the domain of medicine as unduly romanticizing patient "empowerment." They believe that the strong emphasis on patient participation conceals some of the other purposes that these initiatives serve, such as shifting tasks that are too expensive or too onerous for

corporate actors to do to patients. For the most disenchanted of observers, the current emphasis on patient empowerment is mostly about cutting costs.

In this chapter, I will discuss the factors that have led to the understanding that there is a participatory turn in medicine, including the emergence of so-called lean forward digital technologies. These technologies give information to users but also require that users give information back, thus turning patients into research contributors. This development, in turn, has consequences on who is empowered and disempowered by these new forms of participation, and it gives rise to new patterns of exclusion. What happens to those who cannot be, or refuse to be, “activated”?

What Is the Participatory Turn in Medicine?

Next to the notion of patient work (Strauss et al. 1982), the concept of self-care is relevant in this context. In the widest sense of the term, “self-care” refers to things that people do to protect or promote their health without formal medical supervision (Dean 1989; DeFriese et al., 1989). In the scholarly literature, self-care often refers to situations where patients decide how they want to manage their own health, free from constraints of institutionalized healthcare. At least in principle, while patient work takes place under the constant presence of the medical gaze, self-care takes any form that people choose. As such, it takes place beyond the boundaries of the clinic, and is as old as humankind.

What, then, is the difference between these older forms of self-care and participation and the kind of patient “activation” and empowerment that is appealed to today? The answer to this question consists of several parts. One is related to the advancement and rapid spread of digital tools. Digital tools and social media have broadened the range of tasks that people can do without the personal guidance of health care professionals. One of the most impactful changes in the doctor-patient relationship has been the ability of patients to access

information that was previously inaccessible to most. Even two decades ago, patients searching for medical information had to go to a library and retrieve articles from medical journals. Nowadays, much of this information is available at the click of a mouse.

But this is not the whole story. The participation of patients has also become more visible because it has become individualized. In many regions and contexts it is considered the prime responsibility of individual patients—or their families, if patients cannot do it on their own—to stay healthy or manage their illness (Levitsky 2014; Petersen 1996; Petersen and Bunton 2002; Petersen and Lupton 1996). This focus on the individual is not self-evident. In systems with publicly funded universal health care, for example, patients are part of a collective: They pay into a system and take services out when they need them. They rely on others to pay for services they cannot afford, and collective actors decide what services patients will have access to. In this sense, patients are a group before they are individuals. Absent such solidaristic arrangements, in systems where individual patients must choose what insurance to buy and what preventive measures to spend their money and time on, patients are first and foremost individual actors who are expected to assume responsibility for their supposedly free and autonomous choices. If we see patients in such a way, we will see both their self-care and their patient work as an individual choice too: They decide to be good patients or not, or to be good citizens or not. Such a framing, of course, moves out of sight collective factors such as the social determinants of health (Marmot 2015): Social and economic factors including housing, access to clean water and food, labor rights, income equality, and gender or racial discrimination have been found to be fundamentally important to people's health and disease. Their importance is reflected in the fact that health outcomes do not differ only between high- and low-income countries, but also within one single society or country. Social determinants also shape who *can* participate in their own health care in the first place. They make it easier for some people to "choose" a healthy lifestyle, to "decide" to comply with their

doctor's orders, or to agree to participate by contributing data.

Patients as Research Contributors

Easier access for a greater number of people to wider ranges of information, and better ways to make themselves heard, are clearly positive developments. But when we take a closer look at how people participate in supposedly participatory platforms and groups in the health domain we do not only see empowerment. Sometimes, participatory practices can also make patients more vulnerable. An example of the latter in the offline world is the cooptation of patient groups by pharmaceutical companies, where funding from the latter compromises or even hijacks the agendas of the former (see, for example, Jones 2008). In the online world people can become more vulnerable when their data and information are used for purposes that go against their interests. For example, when a person discloses health information through surveys or website registrations, this information is not protected by the rules that apply to health data in the clinic. It can be sold by the owners of online platforms to data brokers or credit bureaus that provide health care providers or insurance companies with risk scores for individual patients (see Dixon and Gellman 2014: 15). And patients can also be disempowered collectively if, for example, an entire district is redlined on the basis of particular indicators suggesting that people in that area are poorer or sicker or otherwise less desirable clients and consumers. And although discrimination on the basis of racial or ethnic categories is often illegal, online platforms can bypass this prohibition by using proxy information. The social media platform Facebook, for example, has used "ethnic affinity" labels that they calculated on the basis of users' postings and preferences to enable advertisers to exclude certain groups. This has allowed them to use ethnicity as a category without asking users about it, and without technically breaking the law (Hern 2016).

Regardless of whether people are empowered or

disempowered by the use of participatory platforms and initiatives, a particular characteristic of online services in the health domain is that they make the difference between patients and research contributors practically obsolete. Personalized online services tailored to serve patient needs, such as PatientsLikeMe (patientslikeme.com), Cure Together (curetogether.com), or online symptom checkers (for example, symptoms.webmd.com), use patient data for medical, marketing, and other research (Merchant 2015). Patients who share information on dedicated online platforms may do this to receive information and support. At the same time, the data of these "empowered" patients are turned into valuable assets for research and profit making by these very platforms and their corporate customers (Kallinikos and Tempini 2014; Tempini 2015). And even those of us who do not use health-specific platforms but use generic search engines or social media or disclose seemingly innocuous information when registering for services can end up having our data used for health-related purposes.

In the following section I will argue that, due to developments such as the proliferation of web-based tools, the roles of patients and contributors to research are converging. I will discuss how the role of the Internet in the health domain has changed since its Bronze Age years of the early 2000s. Using two of the aforementioned online platforms, PatientsLikeMe and CureTogether, I will illustrate how some services that present themselves as support systems for patients are data-collection enterprises at the back end. I will also take a closer look at the notion of participation: What forms of participation do people engage in when using online symptom checkers to self-diagnose health problems, for example (see also Jutel and Lupton 2015; Lupton and Jutel 2015)?

From Leaning Back to Leaning Forward: The Changing Role of the Internet in the Medical Domain

In 2010, Apple launched a tablet computer, the iPad. It made a

splash in the consumer tech market, and other companies soon followed with competitor products. Tablet computers, with their touch screens and their small size, marked a new era in personal computing. Many wondered how the particular characteristics of iPads would affect user behavior. Would tablet computers become another tool for people to passively consume media, or would they be used more actively to search for information, or to upload and edit photos? In other words, would tablet users "lean forward" more when using them, instead of mostly "leaning back"?[1]

Lean-back and lean-forward technologies are two ideal types that should not be seen as denoting a clear dichotomy or reflecting a linear historical development. They overlap in practice. But in a nutshell, lean-back technologies are those that operate without continuous and active input from users. After a person has chosen a clip to watch or a page to read, she can literally lean back. Lean-forward technologies, in contrast, require users to communicate actively through the device and thus continuously input data. Until the second half of the 2000s, online services that targeted patients were providers of information: after typing in search terms or questions, patients were expected to "lean back" and absorb the information. This was not necessarily the case because patients were hesitant to participate more actively, but because these early online health tools did not offer anything different. Social media were not yet widely available, and if patients went online it was presumed to be for the sake of seeking information (see also Cline and Haynes 2001). This also explains why ethical and regulatory debates at that time focused on how users could be protected from incorrect or misleading information, and not yet on other aspects such as privacy (see also Fuchs et al. 2012). At that time, online health resources were seen as competitors to medical professionals, who had until that time been the only group able to provide trustworthy health information.

This situation changed when digital social media entered the scene. What sets digital social media apart from earlier generations of digital media is that they are built for the

exchange of user-generated content.[2] File- and photo-sharing sites such as Flickr, social networks such as Facebook, or blogs, including the microblogging service Twitter, are some of the best-known examples of social media. Another important feature of social media is that it is users who both produce and consume content; the medium merely provides the technical infrastructure to do this. This phenomenon is often called "prosuming," a composite of the terms "producing" and "consuming" (Toffler 1980; see also Benkler 2006; Rheingold 2002; Shirky 2008).

Materials that users post on these sites range from the intimate to the trivial to the political. And all of the most successful social media platforms are also heavily used for health-related purposes. Many users of Facebook, for example, discuss health-related issues ranging from diets to the side effects of prescription drugs to the discussion of the most intimate of problems (see, for example, Hawn 2009). Clinical trial participants are recruited via Facebook, and postings on Twitter are mined to discern disease outbreaks: When many people in a certain area tweet about being ill with fever and a sore throat, for example, this can be an advance warning of a flu outbreak in that region. Moreover, sensors on smartphones or smart watches can turn these devices into diagnostic tools (Topol 2015). Although many web-based platforms and services in the health domain still see themselves as information providers, they now do a lot more: They are designed in such a way that users lean forward most of the time. Users are prosumers of health information, sometimes consciously, willingly and happily, and sometimes without being aware what will happen to the data they disclose in this manner. Sometimes they are not even aware that they are contributing data in the first place.

Web-based platforms such as PatientsLikeMe or CureTogether represent archetypical lean forward services. Both platforms integrate the functions of information provision and data collection. They encourage people to contribute data and information about themselves in the process of learning

about and from others. This resembles other, offline interactions where people are likely to share and receive information in an iterative manner, such as during a conversation with a colleague or friend over coffee. One key difference between the online and the offline world here, however, is that web-based platforms log and analyze data that are uploaded, and these data can, in principle, also be accessed by or sold to third parties. This does not normally happen in the offline world.

As noted in chapter 1, Viktor Mayer-Schönberger and Kenneth Cukier (2013) use the term “datafication” to signify the representation of ever more aspects of our lives into computable formats, so that these data can be mined for associations. In the context of participatory medicine, the notion of datafication also refers to information previously considered irrelevant for medical purposes that is now being seen as useful. Information on virtually anything that plays a role in people’s lives could potentially aid research or medical decision making, such as lifestyle, diet, mood changes, or similar (see also Kish and Topol 2015).

Leaning Forward for Health

PatientsLikeMe: Sharing More of You(r Data)

The for-profit company PatientsLikeMe is probably the world’s best-known online network for patients. It was founded in Cambridge, Massachusetts, in mid-2002 by three engineers whose brother and friend had been diagnosed with motor neuron disease (also known as amyotrophic lateral sclerosis, ALS, or Lou Gehrig’s disease). At the time of writing this book, the network had more than 500,000 users. This is a small number in light of the total numbers of patients in the world, or even those with Internet access. But it is a sizable figure considering that the platform is limited to English-speaking users, and that it is still relatively young.

PatientsLikeMe initially set out to facilitate the sharing of information about their users’ experiences with their illnesses

and diseases. Members could exchange information about relevant new research, clinical trials, personal experiences, and give and receive support. Via messaging functions, members of the network can contact each other on the basis of any personal characteristics that they are happy to share; most members use nicknames, but they can also use their real name if they prefer. In a way, PatientsLikeMe started out as a platform seeking to simplify what patients have always been doing, namely looking for others who have relevant information or expertise, and pooling knowledge. In the offline world, self-help groups have existed for a long time, and some patients were among the first to use newly emerging technologies for this purpose, such as e-mail lists. From this perspective, PatientsLikeMe did not enable its members to do anything categorically new. Instead it supported them in doing things they were already doing more easily and more effectively. Members could now reach thousands of other patients simultaneously, with only minimal or no marginal cost.

For PatientsLikeMe, it was only a small step from facilitating the sharing of users' experiences and information to using these data for research purposes. In this light, PatientsLikeMe could appear to be a textbook case of successful crowd sourcing of data-collection (Nielsen 2011). If we examine more closely the work that the people running the PatientsLikeMe platform do, however, we see that it amounts to more than merely collecting data from a large number of patients. One of the main tasks for the company is to turn the unstructured conversations and data entries of its members into structured data that can be analyzed and mined (Kallinikos and Tempini 2014). This is also how PatientsLikeMe makes money: It sells data shared by patients to drug companies, device manufacturers, insurers, and medical service providers (PatientsLikeMe 2014). Getting patients to "talk" on its platform is thus one of its key tasks: Users are continuously encouraged to share information on their diseases and lives. In the words of James Heywood, one of the founders of PatientsLikeMe: "Our job is to allow a conversation with the computer that will match a conversation between two patients. [. . .] then we capture that dialogue and turn it into useful, clean

data" (quoted in Goetz 2008).

Apart from selling patient data to companies, PatientsLikeMe also carries out its own studies. In one famous instance, users of PatientsLikeMe who suffered from motor neuron disease took lithium carbonate—a substance typically used as a mood stabilizer—and recorded dosage, any functional changes, and other relevant metrics in a self-organized study. The study had been initiated by members of PatientsLikeMe after a clinical study had suggested that lithium carbonate could slow down the progression of the disease (Fornai et al. 2008). The patient-led study could, unfortunately, not confirm that lithium carbonate slows down the progression of the disease. But the fact that patients on the platform had organized their own self-experimentation study was seen as a new way of doing disease research (see, for example, Swan 2012), and the platform has since been involved in numerous further studies. It is yet another reason why PatientsLikeMe encourages their users to "lean forward." By participating in the network, users also contribute to experimental groups and studies.

CureTogether: Quantifying Similarity

CureTogether was founded by two pioneers of the self-tracking movement, Alexandra Carmichael and Daniel Reda, in 2008.[3] At first sight, CureTogether may look very similar to PatientsLikeMe: As with PatientsLikeMe, CureTogether encourages users to quantify and share information about the nature and severity of symptoms, as well as different treatments they have tried. Both platforms aggregate and analyze data generated by users. But in contrast to PatientsLikeMe, CureTogether focuses exclusively on collecting structured, quantified, anonymized data. This means that users are required to enter data in predetermined and computable formats, rather than sharing unstructured narratives. At the same time, the diseases that both platforms include emerge "bottom up" in the sense that users can add conditions that are not yet included. At the time of writing this book, the site had more than thirty thousand registered users.

Users of CureTogether can identify what treatments work for other users who are similar to them: A filter feature on the site allows them to limit comparisons to other users who have similar combinations of symptoms, comorbidities, or demographic characteristics that they do. Once similar users have been found, their data can be used to draw conclusions for one's own situation: For example, if a particular treatment has worked well for women of roughly the same age as my age, who also suffer from migraines and have a combination of symptoms similar to mine, I may be tempted to try this treatment as well. If, in contrast, it turns out that for users very similar to myself a new drug that I have just been prescribed has caused very bad side effects, I may not want to try it, despite my doctor's advice. In countries where access to clinical care is easily accessible for patients, sites such as CureTogether may be used primarily to complement or double-check information that patients receive from their doctors. Patients may consult the website to see what works for other users who are similar to them before they speak to their doctor about possible treatments, or may use the service to replace a clinical second opinion. In countries where access to clinical care is difficult or expensive (or both), sites such as CureTogether may be places that patients turn to *instead of* consulting their doctors. For chronic health problems, and especially in connection with conditions that do not require invasive procedures, such as surgery or chemotherapy, people may feel that learning what kinds of treatments worked for others who are similar to them is all they need to know. Many of the treatments assessed on the CureTogether site are not drug treatments but other remedies and measures such as exercise, or the consumption of specific foods. And even where a treatment with a particular drug is reported as being the most effective remedy, this drug can be bought over the counter or online, in some cases illegally. It is for this reason that concerns have been raised about the potential harm stemming from sites that tempt patients to take medical decision making into their own hands (for example, Vicdan and Dholakia 2013; Haig 2007). In sum, CureTogether turns patients who use the platform not only into contributors to

research, but also into data sources for decisions that other patients may make.

In 2012, CureTogether was acquired by the personal genome testing service 23andMe, a California-based genetics company that we will revisit a few more times in this book. For a while after this acquisition, CureTogether encouraged its users to upload their genetic profiles. When sufficient numbers of users have done so, the platform suggested, genetic similarities could become an additional reference point in potential searches for "similar" users. This plan was later dismissed; at the time of writing this book, CureTogether users are merely encouraged to order genetic testing from *23andMe,* not to upload their DNA data.

The acquisition of a nonprofit platform created by self-tracking activists by a powerful commercial player requires further comment: Commercial players often acquire platforms or initiatives that were started by people without profit motives in mind. The new commercial owners sometimes keep the basic services free of charge, as happened also in the case of CureTogether, where users are still not charged anything for signing up or participating. But the sale of user data is now part of the business plan. Many platforms do this without telling users how they make money with their data; PatientsLikeMe is a laudable exception. And most of them retain the rhetoric about participation, democracy, and empowerment. By participating in such platforms, users are given the impression that they not only obtain useful information regarding their own health but also help to make medicine more participatory and democratic.

But do they? In the next section of this chapter I will unpack the notion of participation in more detail. I will explore what forms of participation web-based platforms encourage or require from their users, and against what criteria the "democratic value" of these kinds of participation can be assessed.

Patient and Public Participation—In What? Categories of Participation in Medicine and Science

Among initiatives that claim the participatory label for themselves, there is great variation in terms of how and what patients and other lay people contribute. So-called citizen scientists—people without professional training in a subject area—can participate by providing funding or participating in data collection and generation, analysis, interpretation, application, dissemination, or evaluation. There are, however, considerable differences in terms of how much influence these nonprofessional participants have. Some initiatives are led by patients or activists in every respect, whereas in others, nonprofessionally trained participants have no decision-making power with regard to core strategies. Instead they merely contribute as data collectors—which often requires expertise, but this expertise does not translate in decision making power about what data will be collected or what will be done with them—or even just as funders. The schema presented in box 2.1 allows us to obtain a better understanding of the type of participation that different projects involve, and the influence that patients or "citizen scientists" have.[4] Taking the aforementioned PatientsLikeMe study on the effect of lithium carbonate as an example, we would first ask about *coordination:* Who was involved in agenda setting, in determining the execution of the main idea, and the procedural aspects of this study? Who decided, and how? What should count as results, and who decided what "good" results were, and what should be done with them? Who decided on intellectual property-related questions?

So, who coordinated PatientsLikeMe's lithium study? According to the authors of the study, the initial idea came from patients registered on the site. The development of the data collection tool was initiated by patients and some friends and family members, and was then developed further by the platform. Data analysis was led by PatientsLikeMe (Wicks et al. 2011). This means that agenda setting was shared between users and employees of the platform. The fact that PatientsLikeMe is a commercial company illustrates the entanglement of health activism and commercial interest that is characteristic of many participatory projects in the medical

domain at present (for a more detailed discussion of this aspect see chapter 5).

Box 2.1. Criteria for the categorization of participatory initiatives and projects (Adapted from Prainsack 2014a)

Coordination: Who has influence in:

1. Agenda setting
2. Determining the terms of the execution of the idea/procedural aspects
3. Deciding what results are (and what "good" results are)
4. Deciding what will be done with results
5. Deciding on intellectual property questions

Participation:

6. Who participates (demographic and social parameters of those who participate)? Why, and how do they participate?
7. How much, and what kind of, training, skill, or expertise is required to participate in this project?
8. Are there cultural, institutional, or other differences in perception and framing of core issues and stakes?

Community:

9. What forms of community precede this project or initiative, if any? Which new communities does the project or initiative facilitate or give rise to? What is the constitutive factor for the feeling of belonging on the side of the participants?

Evaluation:

10. Who decides what good outcomes are? How?
11. What happens to the results of these evaluations?

Openness:

12. Do participants have access to the core data sets?
13. Can participants edit or modify the core data sets?
14. Is the contribution of participants adequately acknowledged in published materials?
15. Are data sets made publicly accessible (open source/open access)?
16. Are main findings made publicly accessible (open source/open access)?

Entrepreneurship:

17. How is the project funded?
18. What is the role of for-profit entities in this project? Are these small, medium-size, or large entities, and where are they located?
19. How are for-profit and other interests aligned in this project (and/or do they conflict, and where?)

The second set of questions in box 2.1 focuses on the practices and modes of *participation:* Who are the participants of an initiative or project, and what characteristics do they have? Why and how do they participate? What are the requirements for participation in terms of technical or language skills, or geographical location? How much and what kind of training, expertise, experience, and skill, and what talents and capabilities, are required to participate in the project? Are there cultural, institutional, or other differences in the perceptions and framings of core issues and stakes among actors at various levels? In our example, the most obvious requirements were

that participants in the study had to be registered with the platform, be able to enter data in a sustained and structured manner over a period of several months, have been diagnosed with motor neuron disease, and be able to get hold of lithium carbonate. As data had to be entered by patients—or by family members or caregivers respectively—some level of computer literacy, the ability to read and write in English, and a considerable time investment, were also required. Ironically, one of the very features that makes some web-based studies so successful, namely that they do not require participants to meet face-to-face with researchers, may also contribute to the high drop-out rates.[5] In PatientsLikeMe's lithium carbonate study, of the 348 diagnosed motor neuron disease sufferers who provided sufficient base-line data to be included in the study, only 78 were included in the final analysis. Important reasons for "attrition" were that many patients were unable to take lithium for the full twelve months of the study, and that some patients died during that year.[6]

Notions of *community* are the focus for the third set of questions in box 2.1. Questions to be asked here include: What forms of community preceded a particular project, if any? What do people in these communities have in common? Which new communities does the project facilitate or give rise to? In our example, answers to these questions are relatively straightforward, because the study emerged out of one platform and focused on one relatively specific patient group. If there was a community that preexisted the study, it was a community of patients, family members, and friends around motor neuron disease who contributed time and effort to this trial, hoping that the results would inform their own treatment, or the treatment of others after them. In other projects, however, the question about preexisting communities could be much more difficult to answer, because of the dearth of evidence available on the collective identities and motivations of members of participatory projects in medicine and health (for exceptions, see Hobbs and White 2010; Raddick et al. 2010; Reed et al. 2013).

The fourth set of questions in the box concerns *evaluation:*

Who decides what "good" outcomes are, and how is this decision made? Who decides, in turn, what will happen with the outcomes of the evaluation? Outcomes are not the same as results; outcomes include wider societal, educational, and economic impacts, including any unintended consequences. Results are typically the findings of the project or study in the context of the research question or mission. In our example, the people who decided what good outcomes were and how they would be used were the owners of PatientsLikeMe, who led the study, in collaboration with some particularly active patients. There is nothing to suggest that the study was formally evaluated after its conclusion (although PatientsLikeMe says that its projects are regularly evaluated internally).

Openness is another relevant aspect in our assessment of participatory projects. It refers to the absence of technical or financial barriers to access. Such barriers include proprietary data that are not available to users at all, or data locked behind pay walls (Suber 2012). When thinking about how open a particular project or initiative is, questions we need to ask include: Do participants have access to core data sets? Can they edit the core data sets? Is the contribution of participants adequately acknowledged in published materials? Are data sets made publicly accessible (open source/open access)? Are the main findings made publicly accessible (open source/open access)? In practice, strongly participatory projects will always entail a certain level of openness, because otherwise active participation by a wide range of nonprofessional contributors would be practically impossible. However, openness is never a *sufficient* condition for a project to be participatory. It is possible, in theory, for a project that publishes all data sets, protocols and other materials online to be run by only one person who makes all decisions by herself. Such a project may meet the criteria for "open science" projects, but it would not be considered participatory. But the openness of such a project would take the edge off autocratic governance here, because if all data collected and generated by this project were available online, anybody could use them for their own purposes. Our example, the lithium study organized by PatientsLikeMe, scores relatively

highly in terms of openness. For data protection reasons, however, it would be neither possible nor desirable to make all data sets publicly available. But many useful data sets were published online (see “supplementary data,” Wicks et al. 2011).

The sixth and final dimension to be assessed is *entrepreneurship.* Questions to be asked here include: How is the project funded? What is the role of for-profit entities in this project? Are these small, medium-size, or large entities, and where are they located? Finally, how are for-profit, communal, and other interests and stakes aligned in this project? Do they conflict, and if so, where? Answers to these questions may be different for various stages of the project or initiative. This becomes apparent also in the case of PatientsLikeMe, which started out as a patient-led self-help network and is now a powerful commercial player. Although neither the lithium carbonate study nor the platform that hosted it changed their mission significantly during the course of that particular study, other projects may change their mission after a few weeks, months, or years. Reasons for this can be related to the internal organization of the project, or external factors such as new scientific advances, new technical opportunities, change of leadership, or being acquired by another entity. When analyzing a particular project or initiative with the help of box 2.1, questions in every category should be considered separately for every stage of the project, as answers may vary.

In summary, how much influence “lay” participants have over the aim, design, and utilization of results in a project tells us something about the disruptive—in the sense of challenging dominant scientific institutions and practices—potential of a project or initiative. This disruptive potential of a project does not prejudice, however, how successful it will be in terms of the standards and metrics of traditional medical practice and science. For some projects, an assessment according to the standards of established professional practice may be ill fitting. In those participatory projects that aim at reducing treatment burden for individuals, for example, traditional metrics such as median survival rates may not be adequate. The best metrics

here would be the subjectively perceived decrease of pain and burden, in a wide sense, and an improvement of happiness of the person concerned. The growing field of patient-reported outcomes research is developing excellent instruments and measurements in this respect (see Nelson et al. 2015).

Political and Economic Dimensions of Participatory Projects in the Medical Domain

Commentators have been both enthusiastic and also concerned about the emergence of participatory projects and practices in the domain of health and medicine. There are concerns about replacing the expertise of professionally trained experts, such as clinicians and medical researchers, by that of "amateurs"–such as the participants in the lithium carbonate study organized via PatientsLikeMe. Sometimes these worries stem from a genuine concern about quality control: Because amateurs are not trained in scientific methodologies, it is feared that they cannot record or analyze data correctly and thus compromise the quality of science. Indeed, Tempini (2015; see also Kallinikos and Tempini 2014) found that data quality at the point of data entry is one of the most notorious challenges for PatientsLikeMe. But quality control is not the only concern: Riesch and colleagues (2013) found that some professional scientists also worry that the unpaid labor of citizen scientists could make some of their own, paid labor redundant.

Some participatory practices in citizen science projects bear strong resemblances with the participation required from users in Web 2.0 enterprises.[7] Google, for example, famously combined its focus on user experience with reliance on user-generated information: Google's algorithms draw on how many times users access particular websites (Auletta 2009). The assumption is often that those who contribute to participatory projects in the medical domain where they have little influence on what happens with the results, and where corporations profit from their participation, cannot knowingly and willingly be doing so; their participation must thus be driven by some kind of false

consciousness. As I have argued elsewhere (Prainsack 2014a), this assumption is problematic. For many people, being part of something that they consider useful, being acknowledged publicly in publications, or learning about the scientific area in question is a strong incentive to participate. For them this is a sufficient reward. Research with early adopters of online genetic testing services has shown that at least within this group, motivations and perceived benefits included good entertainment value, playful engagement with information, unspecified curiosity, and the desire to contribute to something meaningful (McGowan, Fishman, and Lambrix 2010; Vayena et al. 2012). But this does not mean that there is no issue here. When participatory projects, platforms, and websites—and in fact everything and everybody that collects information from patients—are not transparent, in a proactive way, about how they make money, and about who is likely to benefit from participants' contributions, then participants cannot make these decisions in an informed and meaningful manner. The need for proactive transparency in this respect cannot be emphasized enough.

New Patterns of Exclusion? The Digital Health Divide, and the E-Health Filter Bubble

In recent years, many services similar to PatientsLikeMe or CureTogether have become available in many more languages.[8] Doctors and patients in growing economies such as China seem to be at the forefront of the early adoption of social media, despite the little attention that these developments receive in English-speaking media (see, for example, Chiu, Ip, and Silverman 2013). A common objection against predictions that web-based platforms and services will play an essential role in routine clinical care so far has been that these web-based tools attract only particularly well-educated, computer-savvy, or wealthy individuals. Therefore, the argument continues, web-based platforms are of negligible importance in today's world and will remain marginal in the foreseeable future. While this view may have held true for early phases of Internet use in the domain of health and medicine, several

developments in the last few years have changed the landscape. The availability of portable devices equipped with touch screens, for one, has lowered the threshold for use: people no longer need to start up computers or use keyboards in the traditional way. This opens up the possibility of Internet use to groups who had been excluded from its use before, such as many elderly people who may never have learned how to operate a desktop computer. For many people, a large icon that can be tapped with a finger, rather than clicked upon with a cursor, is easier to operate. For all of these reasons, efforts to develop remote monitoring tools, applications to report side effects or functional changes following new medications or treatments, or other web-based devices targeted at elderly patients prefer tablet computers (for example, Fanning and McAuley 2014; Goyal, Bhaskar, and Singh 2012; Greysen et al. 2014; K. Morrison 2012).

Similarly, the widespread use of inexpensive battery-powered devices increases the range of Internet users in countries where stable power supply is an issue. The prohibitive costs of desktop computers have been a longtime obstacle to Internet use in the developing world, and in any case they are of little use without a stable supply of electricity. Consequently, the uptake of cell phones in low-income countries has been much faster than the uptake of personal computers, due to lower cost and the use of batteries; with the emergence of smartphones, Internet use has come within reach for new groups of people. Research supported by the Rockefeller Foundation reports a growth rate of 700 percent in mobile/smartphone/PC/tablet use between 2007 and 2012 (Hatt et al. 2013; see also Kirkpatrick 2013). The World Bank (2015) reports a 433 percent growth in Internet users in low- and middle-income countries between 2005 (6.9 percent) and 2015 (36.8 percent). If calculated for low-income countries alone, the growth rate of Internet users for the same period is 956 percent (from 0.9 percent to 9.5 percent). Although exact data on the proportion of people accessing the Internet via handheld and portable devices are not available, we can assume that this proportion is considerable: The proportion of cell phone subscriptions in low-

income countries has risen from 4 to 60 percent between 2005 and 2015.

This rapid growth rate in mobile smartphone use in the developing world—which is, of course, also due to the low market saturation at baseline—has led authors to refer to the phenomenon as “mobile leapfrogging” (for a critical discussion of this issue, see Napoli and Obar 2013). An additional explanation for the greater popularity of portable devices, in both high- and low-income countries, is that they can be used in the privacy of people’s homes. This is relevant for many Internet users, whether they have a specific reason for keeping their searches private or not. Most of us prefer to conduct our Internet searches and check our e-mail without being monitored. In societies where public media are seen to expose people to allegedly indecent content, any Internet use, especially by women, could be discouraged (see, for example, Armfield and Holbert 2003; Crompton, Ellison, and Stevenson 2002; Hakkarainen 2012; Oudshoorn and Pinch 2003; Wheeler 2001, 2003). Portable devices such as laptops, but especially inexpensive types of smartphones and tablet computers, provide women and men in such societies with a means to use the Internet without being exposed to familial or communal scrutiny. Such devices also make Internet access available whenever people need it, not only during particular limited hours of the day. For all these reasons, for an increasing proportion of Internet users worldwide, mobile-based access is the primary form of Internet use (Napoli and Obar 2014). And this, in turn, makes it easier for people to access health information online too (Ziebland and Wyke 2012).

In high-income countries, an important reason for people using the Internet for health-related purposes has been found to be the presence of chronic health problems. In 2010, the Pew Internet national survey of three thousand U.S. residents found that a quarter reported going online to interact with others who suffered from similar health-related problems (S. Fox 2011). Four years later, a survey by the same organization found that 72 percent reported having looked for health information online

in the previous year. Eighteen percent had gone online specifically to find others with similar health conditions, with chronic disease sufferers being overrepresented (Pew Research Center 2015). Although most people seem to use the Internet in addition to consulting medical professionals, and not instead of it, when it comes to managing chronic diseases, many patients seem to trust other patients more than their doctors (Schaffer, Kuczynski, and Skinner 2008; Ziebland and Wyke 2012: 221).

In low-income countries, health-related Internet use is expanding. But partly due to the unaffordability of airtime and bandwidth in many places, those who use the Internet in the health care context tend to do so to obtain information, and not to upload content.

Within the group of non-users both in high- and low-income regions, the reasons for non-use are diverse. A major factor associated with nonuse remains education; in low-income countries, poor education corresponds with lower Internet access and less possibility to contribute content (Brake 2014). But in high-income countries such as the United States, too, Internet use in general, and web use for health purposes in particular, are unevenly distributed, and education is an important factor. Women, non-Hispanic whites, younger people, and those with higher levels of education use the Internet more, and they look for health information online more frequently (Pew Research Center 2011; see also Blum 2015). Those with lower levels of formal education are less likely to use the Internet (38 percent). And they are much less likely to seek health information online; only two-thirds of people with Internet access and lower levels of education do so (note that this does not apply to people with chronic illnesses. In this group, those with lower levels of education who have Internet access are equally as likely to use it for health-related purposes as everybody else does). By comparison, 90 percent of people with college degrees had Internet access, and almost all of them (89 percent) used it to obtain health information online.

In low-income countries, women are underrepresented

among Internet users (Hilbert 2011). They are also underrepresented among content producers (Schradie 2015), meaning that many women are primarily passive information consumers (Olesen and Lewin 1985: 10; Riska 2010). The reasons for this are complex; they include the aforementioned stigmatization of Internet use by women in some cultures, due to the alleged risk of compromising their moral purity. Low literacy rates among women and the higher burdens of work and caring responsibilities carried by women in some countries also contribute to this situation. When it comes to the underrepresentation of women in content creation, not only lower digital literacy skills but also difficulties in getting past male gatekeepers have been found to hinder the participation of women and girls (Stephens 2013). Moreover, the overrepresentation of women among those who access health information in the United States needs to be seen in conjunction with the fact that most respondents reported searching for health information on behalf of somebody else, not themselves. Many women are going online in their capacity as mothers, wives, and caregivers.

Media studies scholars Philip Napoli and Jonathan Obar (2015) also make an interesting argument regarding the supposed “re-passification” of online audiences by mobile web-based services. They argue that people are less likely to lean forward when using mobile devices today than had been the case during the time when social media were used mostly on desktop personal computers. One of the reasons for this process of repassification, according to Napoli and Obar, is the aforementioned problem of unequal access to bandwidth. Limited bandwidth makes it difficult to upload content. Smartphone users in rich countries experience this when trying to send files while travelling on data-roaming plans abroad; in countries and places where good broadband is not available, however, this is the default state of Internet use. Such users cannot do much more than browse sites and passively consume information; they cannot create, play, and upload (see also Haklay 2009). Another reason for the repassification of Internet use is the popularity of smartphones, which are, as argued by

Internet governance expert Lisa Horner, on average much more difficult to program for a wider variety of uses than personal computers (Horner 2011: 13).

Some media studies scholars have concluded that in times when (often inexpensive) mobile devices have become the primary means of online access for many people around the world, the most meaningful means of describing the digital divide is no longer by separating people into users and nonusers. Instead, the divide is between those who use the Internet mostly in passive and basic ways, and those who engage with it in more creative and deeper ways. This distinction is independent from how much time people spend online on a daily basis (see, for example, van Deursen and van Dijk 2014; Robinson et al. 2015; Wei 2012). People with poorer education and lower socioeconomic status—among whom women and ethnic minorities are overrepresented—tend to be in the passive group, although the relationship between these factors is far from linear. The picture is complicated further by the fact that lack of Internet access is not the only reason for nonuse. Some people deliberately decide to remain offline because of what media and technology expert David Brake calls "motivational" access barriers (Brake 2014): People feel that the Internet does not have anything worthwhile to offer, or they are concerned about privacy. Is the time or effort spent worth what we get out of it? Will my data be safe? In a review conducted by information studies scholars Stacey Morrison and Ricardo Gomez, the emotional cost of Internet use was identified as the single most important factor for people to limit or even opt out of information and communication technology use (Morrison and Gomez 2014). Among those who did use the Internet and decided to stop using it, or to use it less, the observation that Internet use made them feel worse, or disconnected from what mattered most in their lives (such as spending time with their families or friends), emerged as the most frequent motivation for this decision.

Where Internet Nonuse Is a Problem: The E-Health Filter

Bubble

In a world where medicine is increasingly driven by digital data, and where "activated" patients are expected to play a major role in contributing such data, any barrier that prevents people from using the Internet could be seen as a problem. It could be a problem because people who cannot or will not contribute data to the personalization of their health care forego the benefits of prevention, diagnosis, and treatment being tailored to their specific characteristics and circumstances (see also Lerman 2013). It could be an issue also because, as the previous section has shown, many barriers affect people with lower socioeconomic status more severely than others. Some access barriers are particularly problematic for ethnic minorities or women. Especially in areas where more and more medical and health-related services are offered online it seems troubling that some people who would want access do not have it. In high-income countries, tasks and services that are moving from the offline to the online domain include checking symptoms, making clinical appointments, and filling prescriptions; in low-income countries, it is often access to basic health information that is at stake when people do not have access to the Internet. And there is another reason why we should be concerned about unequal access: The use of data that people upload to social media, symptom checkers, and platforms such as PatientsLikeMe and CureTogether set new standards and reference points for how we understand our own health data (Prainsack 2015a). In clinical medicine, clinical reference values are typically derived from aggregate data at population level. They often draw upon subgroup analyses, for example, between patients suffering from specific diseases and healthy controls, different age groups, or pregnant women and others (Siest et al. 2013). For a long time, the categories used for sub-group analysis have been relatively generic, such as gender and age; only in the last two decades, categories such as ethnicity and genetic variation have been considered more systematically (e.g. Horn and Pesce 2002; Shirts, Wilson and Jackson 2011).

The data collected and processed in web-based tools such as symptom checkers or participatory patient platforms are of a very different kind than information and data collected in the clinic. At first sight, the algorithms that compare our data to the data of other people in web-based health platforms do the same as "traditional" epidemiological analyses have done: They map our characteristics against those of other patients so that our health data or test results are compared with the most relevant (that is, most similar in a relevant respect) group of people. The difference between clinical reference values on the one hand, and online health services on the other, however, is that people who do not use a specific online platform are not included in the population we compare ourselves to. A patient using CureTogether, for example, to see what treatments work for other patients who are similar to her, will only see data from a very specific group: a selected subset of an already heavily biased subset of the population, namely those who use CureTogether in the first place. Here, the "filter bubble"—the phenomenon that information from our activities is used to "personalize" what we see (Pariser 2012)—enters medicine. It reinforces existing inequalities and lines of segregation in much more silent ways than in the case of explicit stratification for socioeconomic status or race. If the only difference that we see between ourselves and others lies in the severity and combination of our migraine symptoms, or in our genetic predisposition to respond well to blood thinners, then we may fail to notice that 80 percent of the people we compare ourselves to hold a university degree.

In this way we move farther and farther away from approaches that look at the whole population. The new normal is not what is most common in our state or our entire nation, but what is most common among people who are similar to us. Here, social inequalities are made worse by moving poor people, members of minority popuations, or women out of sight: They become, quite literally, "missing bodies" (Casper and Moore 2009). Furthermore, channeling public funding into privately held biobanks (Reuters 2014), within which white and wealthy people are starkly overrepresented and which are not

accountable to the public regarding this problem, exacerbates old patterns of exclusion (Aicardi et al. 2016).

Taken together, these developments increase old patterns of exclusion and give rise to new ones. Adele Clarke and colleagues' notion of "exclusionary disciplining" is helpful here: The notion captures the simultaneous exclusionary actions of biomedicine "that erect barriers to access to medical institutions and resources that target and affect particular individuals and segments of populations" (Clarke et al. 2010c: 61). Although Clarke and colleagues' analysis focuses on the United States, it applies to global patterns of exclusion as well: Especially in low-income countries, where access to clinical services can be very difficult, people are targeted as information consumers online. They become the data sources for algorithms and services put to use for the benefit of people in the rich world.

The Blessings of Internet Abstinence? The Downsides of Being a Patient Researcher

So far I have discussed the ways in which not participating in web-based communication and data collection can disadvantage people. But can abstaining from these things also be an advantage? Is it desirable to be below the "digital radar"? To answer this question, it is again important to consider that data from activities that patients engage in—from looking up symptoms online to technologically facilitated interactions with health professionals—can be harnessed for research purposes. The two web-based platforms discussed in this chapter, PatientsLikeMe and CureTogether, are cases in point: In both cases, data curation for medical decision making and research are intertwined. Somebody who uploads data on changes in her mood and well-being when starting to take a new antidepressant, for example, could be contributing to research without even being aware of it (see also Purtova 2015).

Although some platforms, including PatientsLikeMe, place great emphasis on being transparent about how they use data and information that users share on their website

(PatientsLikeMe 2014a), in the case of many other services, it is not immediately apparent to users how their data are processed and utilized by others. Not all users are conscious of the fact that by using these platforms, they are creating value for others, often for commercial enterprises. Part of the reason for this is that online platforms and services often make heavy use of language around community and sharing, leading users to believe that they are doing this for the common good when in fact they are also creating tangible financial benefits for the platform. When the latter becomes apparent to users, irritation is often the result. When the personal-genome-testing company 23andMe, which acquired CureTogether, was granted a patent for gamete donor selection in 2012, for example, many users were displeased. The patent was granted for a technology that enables prospective parents to select egg or sperm donors who would be more likely to pass on desirable traits to their offspring, developed on the basis of the DNA and phenotypic information provided to the company by their paying customers (Rimmer 2012; Sterckx and Cockbain 2014). The problem was not that the company had applied for patents; it is a commercial company after all. The issue was that it had done it behind its customers' backs. The company's self-portrayal as the spearhead of a movement that made medicine more democratic, as the driver of a revolution in disease research that wriggled power out of the hands of established experts and gave it to regular people, was at odds with the company's old school approach to intellectual property protection and their hiding of information on it in the small print of the terms of service (Prainsack 2014a; see also Sterckx et al. 2013).

The Darker Side of Data-Driven Medicine: Three "H"s of Digital Surveillance

Digital data collection and use in our societies is characterized by what I called the three "H"s of digital surveillance (Prainsack 2015b). The first "H" stands for *hypercollection.* It refers to situations where just because institutions can collect information about customers or citizens, they do. CCTV cameras, company

loyalty cards, or the retention of geolocation data by telephone companies are all based on the principle of "collect first, use later." And although many data-protection laws provide that no more data than strictly necessary for a specific purpose should be collected and processed, if people give their consent for their personal data to be collected or used for wider purposes, this is perfectly legal. Very often, this consent is given by ticking a box or clicking on "I agree" buttons online, which many people do without giving any consideration to what they are agreeing to. Such data collection takes place in the name of possible future benefits: CCTV cameras collect data that could, eventually, be useful for criminal investigation and crime control. Retail companies collect data on people's shopping patterns and behaviors because they can offer people discounts that match products of their interest—digital home assistants such as Google Home or Amazon's Echo, which switch on your heating, send your emails for you, or look for a song that you like, are but the most extreme example. Home-assistant devices are relatively cheap—because you are "paying" the company by giving them access to information about what music you listen to, what movies you watch, and when the light goes on and off in your house. Geolocation data collected by mobile phone providers ensures that they get vouchers or discount offers on their cell phones exactly at the time they are entering the shopping mall. In some cases, people can also trade personal data for cheaper drugs, or for access to other products that they would otherwise not be able to afford (Greenhalgh 2015; Robbins 2015). In other words, greater "personalization" of services is often portrayed as the boon of hypercollection. But the flip side of the benefits of personalization is that data can be used to discern patterns that can then be applied back to make probabilistic statements about individuals. As a result, as Helga Nowotny put it, people have become "more exposed to the laws of chance in the form of probabilities" (Nowotny 2016: 63).

This brings me to the second "H" of digital surveillance, which stands for *harm.* Despite the positive rhetoric about the benefits of data-driven personalization, many corporative actors do not collect data to help people, but to do other things, such as

increasing revenue and profits. Although some of these goals overlap with public goods—crime control is an example—they can inflict considerable harm on individuals who, on the basis of an algorithm, have a mortgage or insurance application declined or become the subject of an investigation. This can happen to anybody, even the most upright, hardworking and law-abiding person. Taken individually, most pieces of information used for predictive analytics in this manner look entirely innocent and unable to hurt the person they pertain to. Who could do anything bad with the information that I regularly buy orange juice and like to go skiing? This is what makes today's digital surveillance so hard to see: It is not my drinking orange juice, going skiing, or accessing particular types of websites that make me suspicious, but the combination of these factors in conjunction with the insight that the same combination has been found in other people who display a particular characteristic. If predictive analytics suggests that I am a particularly "risky" or a particularly desirable customer, I may be charged less, or more, for the same service. Or I may be excluded from being offered certain services altogether.

No type of information is exempt from this dynamic. Experts suggest, for example, that hospitals and doctors should use predictive analytics to identify patients who, after a surgical intervention, have a particularly high risk of complications, and offer them extra care (King 2015; Shams, Ajorlou, and Yang 2015). It is not hard to imagine what the flip side of such extra care would look like: Risky patients are also costly patients, and costly patients are unwelcome "customers" in the health care system and elsewhere. Also, some visions of personalized medicine include the integration of wide ranges of information about people—including credit card purchases, social media activity, and even criminal records—together with their health records into the "tapestry of health data" (Weber, Mandl, and Kohane 2014). In the context of predictive analytics, it has become impossible to separate "health data" from nonhealth data, because any type of information can be mined and analyzed to draw conclusions for any particular trait.

The third “H” indeed stands for *humiliation.* People feel humiliated when their status or dignity is diminished. One of the archetypical examples of humiliation is when people have to participate in harming others or themselves. In the context of digital surveillance, people are regularly humiliated by having to trade their privacy for something that they cannot otherwise afford. I already mentioned patients who “agree” to pharmaceutical companies using their personal information in return for access to more affordable drugs (Hiltzik 2015). Other examples include “risky” borrowers who are pushed into consenting to having sensors installed in their cars. These sensors allow banks to know where they are, and to remotely shut down the engine if borrowers default on their repayment (Corkery and Silver-Greenberg 2014). A further example are people in low-income countries who are encouraged to download apps on their cell phones that monitor their communication patterns and online behavior in exchange for microcredits. “For example, are the majority of someone’s calls longer than four minutes? Good: They may have stronger relationships and be a better credit risk” (Lidsky 2015).

The company that invented this model of asking poor people to trade information on their online and mobile communication for access to loans has been celebrated as empowering people who would otherwise not get credit to obtain one. None of these celebratory accounts considers it a possibility that the core problem to be solved is that these people live in poverty in the first place. Moreover, none of these accounts mentions the humiliation involved in a person having to agree to a company monitoring and assessing the quality of her relationships. Such practices have been normalized; they are part of what people are supposed to experience when they do not have enough resources to buy a car or get a loan. It is part of the governance regime of our societies, and it has been for a long time; with predictive analytics it is now also entering digital health.

Does this mean that the safest thing to do is to refrain from participating in health-related online activities altogether, and to limit the information about ourselves that we give consent to

health care providers to use? Or is there another solution? There is a clear need for public actors here to regulate not only how personal information can be used by commercial and public entities, but also what kind of information can be collected about people in the first place. Moreover, as I will argue in the second part of this book, enhancing harm-mitigation instruments is a crucial step to start addressing the power asymmetries that exist between those whose data are used, and those who use data. But regulation is not the only answer: Laws and regulations are often toothless when it comes to large multinational companies. The latter can evade regulation, or influence the very rules that were designed to control them. Moreover, public authorities are in the seemingly paradoxical position of having the responsibility to protect its citizens from harm from digital surveillance while at the same time benefitting from it. The solution must thus also come also from us, the citizens: from citizens who resist surveillance from both "Big Brother and Company Man," as the American legal scholar Jerry Kang and colleagues (2012) called it; from citizens who demand to know what kind of information is held about them in public and private repositories (Lunshof, Church, and Prainsack 2014); and from citizens who donate data to "information commons" that use data strictly for public benefit, instead of signing them over to those who monitor us for their own profit.

Conclusion

Although some authors and practitioners celebrate every instance of data transfer from a patient to a web-based platform as an instance of the democratization of medicine or science, others blame participatory practices and initiatives in the domain of medicine of unduly romanticizing patient "empowerment." Indeed, merely labeling an initiative as participatory or empowering does not mean that power relationships change. In order to see how power relations change, we need to take a close look at exactly how patients or others participate in certain

tasks, and what they contribute. And we need to look at the wider political and economic landscape that these practices are embedded in.

Patient activist Gilles Frydman (2013) famously defined "participatory medicine" as "a movement in which networked patients shift from being mere passengers to responsible drivers of their health, and in which providers encourage and value them as full partners" (see also Hughes, Joshi, and Wareham 2008). In this view, the primary agency still lies, ironically, with health care providers, who "encourage and value" patients as "full partners"; this means that for patients to be fully "empowered," they need to be encouraged and valued by others first. Here, the metaphor of the car is useful: It is true that drivers are the ones in charge of operating the car, but they are not always the ones deciding where to go. They can also only operate the car if they have enough money to obtain a car in the first place, and to pay for fuel and maintenance costs. A more desirable picture of genuinely participatory medicine—one where the agency of people to make decisions that are meaningful to them and their significant others—would be a system of roads that allows drivers of different vehicles to go wherever they wanted in any vehicle they chose, whether it be a bike, a bus, or a high-end sports car, while allowing others to ditch these forms of transport altogether and choose to walk. People would decide what vehicle to use, if any; whether to build it themselves, rent, or share it. The fact that people's freedom to make these decisions is inevitably limited by the means and resources available to them is an issue that merits a discussion in its own right. The key point here, however, is that genuine empowerment of people in the domain of health and medicine requires (a) the provision of publicly funded infrastructures that de facto enable choice (to continue the car metaphor, this would be the provision of a road system and good public transportation), and (b) recognition that it can be the expression of a person's autonomy to decide *not* to drive a car. The opportunity to participate must not become a duty.

It is *not* a requirement for genuinely participatory medicine

that medical professionals encourage and value this participation. While ethicists, clinicians, and regulatory agencies in many countries are still deliberating whether or not particular forms of patient participation are worthy of their support, and discussing how patients can be protected in areas where they are considered not to be competent enough to understand what they are doing, patients are voting with their feet—and with their computers. PatientsLikeMe and CureTogether, the two platforms discussed in this chapter, are but two examples. They illustrate how lean-forward online technologies in particular, by collecting data and information from users, turn everybody into a data source. This, as I argued, blurs the boundary between patients and research contributors. And this dynamic can turn patients into tools for cost cutting. Here, the empowerment rhetoric helps to conceal this fact. Many initiatives that call themselves "participant-led" are not actually led by participants but by the people owning and running the platforms, or by organizations that facilitate these participatory practices (see also McGowan et al. 2017). Moreover, the fact that many of these platforms and organizations are for-profit is an unintended consequence of neglect on the side of public and governmental actors: While public actors are discussing how to limit the alleged risks of online platforms for patients, they leave the creation of digital infrastructures and other health innovation to commercial actors. The acquisition of CureTogether by the personal genomics testing company 23andMe is a case in point (see also Masum 2012; Trevena 2011). Such developments contribute to an even stronger concentration of power and expertise among commercial actors, rendering—quite ironically—the very participatory practices that are often celebrated as democratizing medicine a tool to increase commercial revenue and power.

And to increase commercial revenue and power, it is necessary that patients remain engaged in participatory practices on a continuous basis. As I will argue in the next chapter, online platforms and devices turn patients into permanent contributors of data, information, time, and effort. Participatory patients need to be permanently "on."