Digital Health 2020
A practical cross-border insight into digital health law
First Edition

Featuring contributions from:

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- Astolfi e Associati, Studio Legale
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Digital Health 2020
First Edition

Contributing Editor:
William A. Tanenbaum
Polsinelli PC

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<tr>
<td>Germany</td>
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<td>Kenya</td>
<td>TripleOKLaw LLP Advocates: John M. Ohaga, Stephen Mallowah, Catherine Kariuki &amp; Janet Othero</td>
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<td>LEΓA: Victoria Montero &amp; Carlos García Soto, Hoet Pelaez Castillo &amp; Duque: Joaquín Nuñez</td>
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This growth is driven by both established initiatives to create, apply, and evaluate metrics, as well as to establish resources such as a Digital Apps Library – a resource that contains a register of apps that have proven to be reliable, usable, and safe. Such efforts will be instrumental to improving transparency and grounding technology on the needs of consumers. However, cost evaluation will remain difficult in the foreseeable future and will require a more comprehensive approach to evaluate outcomes.

The use and adoption of digital health is likely to completely transform care delivery as we know it today. While uptake by patients and healthcare providers can benefit that segment of the population, concerns such as supply-induced demand and spillover effects exist. Increasing access to care and lowering the cost has the potential to encourage use and may lead to higher levels of low value healthcare utilisation. Uptake of offerings such as Telehealth by some providers may shift the patient mix served by providers in a particular region and may lead to cream-skimming whereby providers attract lower cost patients and increase the profitability of their practice, while other competing practices suffer.

Introduction

Digital health refers to the intersection of information and communications technology (ICT) with healthcare. By leveraging the technological advancements of the Digital Revolution, digital health has the potential to increase access to high quality care and reduce inefficiencies associated with healthcare delivery. Digital health broadly includes mobile health (mHealth), telehealth and telemedicine, with its scope is constantly evolving in response to new technology (particularly in the realm of data collection, storage and analysis). Recent digital health offerings comprise of an array of products and services that include online medical booking, genetics tests, and even gamified mobile apps designed to incentivise healthy activity. Each of these technologies has the benefit of being oriented toward individual consumers, responding to their needs and offering the potential of personalising outcomes. Ultimately, these technologies will bring disruptive changes to the healthcare framework that will fundamentally alter the roles of patients, providers, payers, industry, and regulators.

Digital health has experienced strong investment trends with the potential for immense financial gains in the coming future. Its financial growth has been just as remarkable as the technological advancements that drive it, with a current value at $86.4 billion and expectations of further astronomical growth: some firms estimate compound annual growth rates (CAGR) over 27% over the next decade and a market value of more than $500 billion by 2025. This growth is driven by both established firms and startups with the latter raising more than $8.1 billion in funding in 2018 alone and more than half of all deals were made for seed and series A rounds. If these trends continue, digital health will have more than quintupled in size by 2025, with even more diverse offerings for consumers and providers.

While there has been tremendous technological and financial growth in this space, attention is often centred on the promise of these technologies with relatively little concern focused on potential inherent risks. These risks include issues relating to equity, effectiveness, value, and use. Digital health can expand access to care and, through AI and Machine Learning, may lead to more effective and efficient care delivery. However, these gains may not be distributed evenly across the population. Without well-informed and meaningful intent, digital health apps and related services may alienate some segments of the population. Machine Learning that is informed by data and samples not representative of the population may decrease quality of care and outcomes from those underrepresented in the data. Those that are underrepresented are often the most vulnerable, further compounding the issue.

The rapid proliferation of digital health has occurred in an environment with few checks and balances. There currently exists no reliable regulatory framework for evaluating the effectiveness or validity of digital health applications, and the lack of formal standards could prove detrimental to the digital health market due to the proliferation of ineffective technologies. This can already be seen in the mobile health market, where a study of 280 diabetes monitoring applications found that only five applications had adequate health outcomes supporting the effectiveness of the product. The study also noted that current literature on mHealth effectiveness is methodologically inconsistent and that it is difficult to design reliable control groups that distinguish the internal and external effects of app use. Since the burden of establishing effectiveness falls on consumers, this exacerbates the difficulties in gauging effectiveness due to the inherent variability of preferences and technological literacy.

To overcome these difficulties, groups such as the NHS have established initiatives to create, apply, and evaluate metrics, as well as to establish resources such as a Digital Apps Library – a resource that contains a register of apps that have proven to be reliable, usable, and safe. Such efforts will be instrumental to improving transparency and grounding technology on the needs of consumers. However, cost evaluation will remain difficult in the foreseeable future and will require a more comprehensive approach to evaluate outcomes.

The use and adoption of digital health is likely to completely transform care delivery as we know it today. While uptake by patients and healthcare providers can benefit that segment of the population, concerns such as supply-induced demand and spillover effects exist. Increasing access to care and lowering the cost has the potential to encourage use and may lead to higher levels of low value healthcare utilisation. Uptake of offerings such as Telehealth by some providers may shift the patient mix served by providers in a particular region and may lead to cream-skimming whereby providers attract lower cost patients and increase the profitability of their practice, while other competing practices suffer.
Digital health will undoubtedly play a critical role in healthcare moving forward. The enormous financial and technological growth underpinning digital health is indicative of a vibrant industry that will continue to grow over the coming decade. The development of effective regulations and quality measures will require full engagement from consumers, providers, and developers to ensure that technology is properly regulated, and researchers will need to develop a framework for evaluation with a consensus on methodology. Despite these concerns, digital health promises a future focused on the consumer, and along with that, the possibility of an evolutionary leap in healthcare.

**Equity**

Striking inequalities exist within healthcare and these inequalities can profoundly influence wellness, health outcomes, and longevity. In the United States, there exist differences in healthcare utilisation, access, and insurance coverage by race and socio-economic status. Although efforts through the Affordable Care Act in the US and NHS/PHE in the UK have narrowed the gap, significant disparities remain. One striking example is found in maternal mortality. In the US, the pregnancy-related death rate for black women is over three times higher than that of white women. This difference is driven in large part by community factors (e.g. housing), factors related to receipt of care in a facility, and patient risk factors. Disease prevalence also varies among racial, geographic, and socioeconomic groups. Diabetes prevalence among black adults during 2013-2015 was estimated to be just over 12% compared to a prevalence of 7.4% for non-Hispanic whites and 8 percent for Asians.

Many of these inequalities can be traced to social determinants of health, a set of factors that encompass the environment in which people live, work and age. Specifically, social determinants of health (SDOH) include: socioeconomic status, neighbourhood and built environment, health and healthcare, food, social and community context, and education. While health outcomes are driven in part by certain immutable factors such as genetics, the realisation that much of health and wellbeing is influenced by SDOH has spurred action toward addressing these factors. In this context, digital health holds much promise, particularly related to education and healthcare utilisation. However, the proliferation of digital health should not be viewed as a panacea as many disparities are rooted in long standing, deeply rooted inequities. Without due care, digital health technologies may even further increase existing inequities.

In earlier years, differences in access to the Internet and technology presented an obstacle to the access and use of digital health resources. Individuals without financial means to own a cell phone or obtain internet access were necessarily precluded from utilising these resources. However, with current cell phone ownership estimated to be at or above 94% in the US and 93% in advanced economies, this is becoming much less of a concern. Focus is now centered more on differences across the population in their use of such technologies and how these differences impact outcomes.

Digital health technologies are often offered under a “one-size fits all approach”. This is problematic and will limit the potential associated with these technologies. At the extreme, it may even cause harm. How a user interacts with a platform and how they respond to messaging is influenced by his or her own demographic and socioeconomic characteristics. In light of this, care must be taken to account for an individual’s background, and messaging and material design should be culturally appropriate. An individual’s level of education will also impact how they use digital health technology.

Education can have a profound influence on health. It is well-known that individuals with greater educational attainment experience higher levels of health and wellbeing than their less educated peers. This difference, in turn, further contributes to health disparities. While some of the impact of education is related to the ability to process complex information and perform strategic decision making, it also influences an individual’s health literacy. Health literacy is defined as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.” Health literacy is correlated with both health outcomes and health system costs, with low literacy leading to reduced health outcomes and higher costs.

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2018, telehealth use between a provider and a patient unrelated to a hospitalisation increased over 1,000%. Both the level of overall utilisation and growth are highest in provider-to-patient telehealth occurring outside a hospital setting. Discharge-related telehealth showed the second highest growth rate, and provider-to-provider had the lowest rate of growth.

While the potential for enhanced access exists, it may not be realised if certain segments of the population are less likely to utilise this technology. A recent J.D. Power survey found that only 9.6% of Americans reported ever having used telehealth services. A staggering number – 74.3% of those surveyed – indicated that they were unaware or unable to access telehealth. Awareness was particularly low in rural areas, which are generally medically underserved regions that can benefit greatly from improved healthcare access made possible through telehealth.

Use of these services also varies by patient age. Those reporting that they had used telehealth were more likely to be young. Individuals in the 18–24 age group report the highest use (13.1%), but adults in the 35–44 age group report the second highest use (11.8%). Seniors report the lowest use (5.3%). Geographic location also matters. Use is highest among patients located in the western region of the US (11.1%) and lowest in the northeast region (5.7%). Individuals also differ in their views regarding the cost of telehealth. One half of Americans believe that provider visits utilising telehealth costs less than a traditional doctor’s visit, but the other half believe it costs the same or more. As cost is a constraint that leads to individuals foregoing or delaying medical care, inaccurate assumptions regarding the cost related to telehealth may impede uptake. While differences in beliefs about the value of telehealth exist, the potential to expand access to care will be constrained.

Using artificial intelligence (AI) to provide both higher quality and more efficient care is a burgeoning area in the digital health space. Machine learning can be used to process tremendous amounts of data to identify patterns and produce insight that will impact the way healthcare providers deliver care. AI is being used to optimise administrative workflows, aid in diagnostics, wellness, and to improve operational technologies.

AI-assisted robotic surgery can produce superior outcomes by reducing complications. In this context, a patient’s pre-op medical records are analysed to guide the surgeon’s instrument. A study by Harvard Business Review found that AI-assisted robotic surgery has the potential to significantly reduce patient post-operative length of stay and could save billions annually in healthcare costs. AI can also be used to improve efficiency in imaging analysis. One study investigating the time it took to identify specific lung nodules found that automated analysis resulted in more efficient identification. AI could match and identify a nodule as much as 97% faster than that achieved by radiologists. At the very least, this has important implications for radiology workflow and could significantly reduce the time to diagnosis – adding both physician and patient value.

Another promising area falls in the clinical judgment and diagnosis space. Diagnoses can vary from one medical provider to another, and this is especially true when it comes to rare diseases. But because AI can consume and process tremendous amounts of information, it may be used to identify diseases more quickly – and more accurately – than using more conventional means. While this area holds much promise, the very reliance on data to inform machine learning presents tremendous equity concerns. It is well-noted that clinical trials have far too little racial and ethnic diversity among their study population. If data that informs AI is based on homogenous samples, that may lead to bias in the understanding of factors that impact a disease state or medical outcome. In the most harmful sense, it could lead to sub-optimal care for racial and ethnic minorities.

Recent research highlights this concern. Health systems and payers routinely use technology to identify patients for “high-risk case management”. These are patients with complex care needs that will benefit from care coordination and greater resources. To identify the correct target population, health systems and payers rely on commercial risk-prediction tools. These tools are based on proprietary algorithms to create a risk score for each patient. Since the algorithm is proprietary, the process lacks transparency, reducing the user’s ability to “look under the hood” and ensure the process is fair and equitable.

In an effort to test for bias in these scores, a team of researchers worked with a large academic medical centre to review patients enrolled in risk-based contracts from 2013–2015. They reviewed medical records and patient information, as well as the risk score generated for each patient. Their findings showed that the algorithm was indeed biased. While a black and a white patient might have received the same risk score, the black patient was sicker, on average. This means that risk scores for black patients were skewed downward. The effect of this bias reduced the percentage of black patients enrolled in the programme under study and effectively reduced the probability that that same patient would receive extra care that should have been offered.

Cost-Effectiveness

One of the key benefits of telehealth is that it can theoretically reduce travel and patient costs while increasing access to care. These factors are important when considering treatment for chronic (long term) conditions, such as diabetes or chronic obstructive pulmonary disease – conditions with high prevalence rates in both the United States and United Kingdom. Recent studies have shown that approximately 60% of American adults suffer from at least one chronic condition and collectively cost $1.1 trillion in healthcare costs, not including losses in productivity. In the UK, 15 million Britons have at least one chronic condition and account for as much as two-thirds of all NHS spending. These grim statistics motivate the potential that technology and policy can play in keeping care affordable and accessible.

While the use of telehealth can hold promise in treating patients with chronic conditions, it is not a “silver bullet”, singularly able to moderate high healthcare spending. Some telehealth services may have a strong positive impact on the patient’s health and wellness, while others may be less effective. As patients and payers look to sort through the massive amounts of offerings to identify those services that provide true value, information on cost-effectiveness and willingness to pay becomes crucial. Cost-effectiveness analysis is used to examine the costs and health outcomes of an intervention by comparing it against another intervention (or the status quo) to estimate the costs it takes to gain a unit of some positive outcome. An example of cost-effectiveness analysis would be to compare the cost required to generate one unit of health from a school lunch program (relative to the status quo), where lower net costs indicate greater savings. Both cost-effectiveness and willingness-to-pay analyses can be used to empirically evaluate the effects of telehealth programs and to develop objective benchmarks to gauge worthwhile programs and services.

Studies have used these types of analyses to demonstrate that outcomes can be substantially different from the use of digital health as a care substitute versus a supplement, where the latter can result in enormous costs compared with small benefits. It must be noted that most of these studies are on telehealth,
with few existing for other digital health technologies. Even for telemedicine evaluations, there are limitations in evaluating economic impact due to a lack of randomised control trials, small sample sizes, and the absence of quality data and appropriate measures. Nevertheless, numerous studies have been conducted to evaluate the quality and cost-effectiveness of telehealth – some of which have gone as far as developing metrics against which to gauge effectiveness.

An important cost-effectiveness study conducted by Henderson, et al. (2013), compared the cost and cost-effectiveness of telehealth services with those of standard support and treatment alone in the United Kingdom. Using funding and sites provided by the United Kingdom’s Whole Systems Demonstrator (WSD) program, the authors examined the effect of telehealth on primary, secondary, and social care for individuals with chronic obstructive pulmonary disease (COPD), heart failure, or diabetes. The sample was randomised between usual care or a telehealth intervention in addition to standard care in a trial that recruited 3,230 participants between May 2008 and December 2009. 1,573 patients completed a questionnaire used to evaluate outcomes, effectiveness and patient perspective on the telehealth supplement. Of these participants, 728 were randomised to usual care and 845 to the telehealth intervention: 965 patients had both outcomes and cost data at both the baseline and a 12-month follow-up.

The telehealth interventions included both monitoring equipment that collected and transmitted data to create risk-related alerts and the ability for patients to communicate with health professionals who could provide health education information. The outcome measure was incremental cost per quality adjusted life year (QALY). While the costs of the telehealth group were lower than those of the usual excluding intervention costs (12% difference between groups), they were higher when intervention costs were included (10% difference between groups). At the £30,000 WTP threshold recommended by the National Institute for Care and Excellence (NICE), the program was not cost-effective. Most importantly, even with assumed reductions, the probability of cost-effectiveness was only 61% at the £30,000 level, which indicates that telehealth, in this particular scenario, was not cost-effective as a supplement to standard care.

A study from Eckman (2018) compared the cost of a primary care focused digital model with a traditional care model in Sweden. The author used the 2015 national mean of costs per care contact in primary care to measure the direct and indirect costs of both models. The author assumed that the direct costs for a traditional model would include staff renumeration, lab costs and diagnostic services; the indirect costs were assumed to include administration and support, management, office and equipment rents, and investment write-offs. The direct and indirect digital costs for the digital plan were obtained from a Swedish digital care provider company. Captured patient costs included user fees, time, and travel costs. The findings showed that traditional care is less expensive for patients, costing the equivalent of $21 USD versus $29 USD. However, digital treatment took less time than traditional care at 15 minutes per patient on average, versus 24 minutes for traditional treatment. The results of this analysis were used to determine cost-effectiveness, simulating substitution rates ranging between 10% and 50%. Total societal costs were lower for digital care at $222 USD per unit cost compared to $380 USD for traditional care: a difference of 40%. This can be attributed to the lower user costs for digital care, which creates a 51% cost difference due to time costs for the consultation. At a 10% rate of substitution, $229 million USD would be saved annually; savings jump to $565 million USD at a 50% rate of substitution. This study suggests that telehealth can be quite cost-effective as a substitute for traditional care in this context, when considering the monetary costs associated with healthcare.

It is important to note that the prior study suggests not only significant monetary savings, but time savings as well. While these two factors often go together, they are not mutually exclusive, and other studies suggest that telehealth can provide time savings, even in the absence of cost savings. A study from Egede, et al. (2017), compared telehealth treatment with in-room treatment for older veterans. The results demonstrate that there is no difference in cost of care and both modalities were found to provide effective care. While the article does not discuss time and travel costs, these would likely result in savings if brought into consideration. A study by Pyne, et al. (2015), found that participants receiving care via telemedicine had more depression free days, but treatment costs were higher overall. The increase in cost could be attributed to the increase in volume/ utilisation.

As telemedicine interventions in the mental health sphere are commonly used to combat the dearth of mental health resources, this modality of care can represent an effective, and cost-effective, means to provide treatment. This is especially so when patient costs (transportation costs) are taken into account.

The rural health sector is a sphere where telehealth can provide the most compelling net benefits. Due to long travel times and physician scarcity, particularly related to specialists, residents in rural communities often struggle to receive the care they need. A study by Kessler, et al. (2016), examined whether telehealth would be effective in countering problems related to the travel time patients often face when seeing pediatric rheumatologists; rural patients often undertake long-distance travel due to the scarcity of doctors in this specialty. The authors found that telemedicine can reduce the time burden associated with care, especially missed school days. An article by Yang, et al. (2015), studied the provision of video and telephone consultations to children in rural emergency departments (EDs) and how these two separate modalities of care related to total treatment cost and probability of being transferred to another location. Results showed that children receiving a video consultation were less likely to be transferred to another ED and were less costly than those receiving a telephone consultation. These studies suggest that there are notable cost and social benefits to introducing telehealth initiatives to rural communities.

Telehealth benefits can also be realised in older adults. In a study by Uptasing, et al. (2015), the authors examined the cost-effectiveness of supplemental telemedicine care for older adults. The results showed that participants receiving telehealth care had lower variability of care and lower 30-day readmission costs, but there were no significant differences in total cost of care compared with the control group. However, when considering the social benefits and impact on wellbeing associated with achieving lower readmission rates, telehealth, in this context, may still be beneficial.

The foregoing studies demonstrate that when considering cost-effectiveness, it is important to weigh the full set of costs and benefits – including factors such as productivity gains, wellness, and even other externalities that may result from the use of telehealth solutions.

Utilisation

Consumption of healthcare services is generally patient initiated. If an individual is ill or in seeking healthcare advice, he or she will contact a physician, initiating a healthcare-based relationship. This relationship and any associated receipt of healthcare services will generally continue until the patient’s needs are met. Supply-induced demand is when the medical treatment...
the patient receives exceeds his or her actual needs. The reason this may occur is because physicians are economic agents and, as with all economic agents, may be guided in part by their own financial interests. When physician compensation is impacted by the quantity of care they supply, this may lead to supply-induced demand. The net effect of this phenomena is to raise utilisation levels unnecessarily, such that they exceed what they would be if guided entirely by patient requirements.

The propensity for digital health to lead to supply-induced demand varies based on the funding scheme for healthcare services. Accordingly, supply-induced demand is more likely to occur when a physician is compensated for each service rendered than under capitation, where the provided receives a set amount to provide care for the patient, regardless of volume.

As mentioned already, digital health, and telehealth in particular, has the potential to increase access to care. Therefore, there is some expectation that healthcare utilisation will increase. What is challenging, however, is disaggregating changes in care utilisation stemming from suppressed demand from those relating to supply-induced demand.

To see this issue, consider an innovative primary care provider that offers patients the ability to interact digitally with healthcare providers and bypass the wait times generally required for traditional visits offered at traditional brick and mortar locations. While more immediate access to care is surely an attractive feature to registered patients, there are other important, related factors, to consider. For example, use of this “disruptive” technology may increase utilisation of care above optimal levels and have spillover effects that impact traditional providers.

Transaction costs are part of the costs an individual incurs when receiving healthcare services. A prime example is the transportation time required to go from the patient’s home or workplace to their doctor’s office. Because this represents a real cost to the patient, he or she will weigh the value they place on seeing a healthcare provider with the cost they incur from the visit. If the benefit of the visit outweighs the cost, he or she will see their healthcare provider. If not, care will be deferred until such time when the benefit outweighs the cost.

When costs are low, as would be the case with telehealth where the patient can interact with the healthcare provider digitally using his or her smartphone, there is little incentive to defer care. While a patient experiencing a cough may have the incentive to wait a week or two to see if the issue resolves on its own, the absence of transaction costs, that individual may opt to see a healthcare provider earlier on.

A review of utilisation of care from GP at Hand, an innovative digital healthcare provider in North West London, seems to suggest that easing access to care may result in increased utilisation. A recent article noted that GP at Hand’s patients, individuals that have access to AI triage and video visits with healthcare providers, utilised more care than that of a similar demographic patient cohort.41 However, the fact that utilisation is higher among GP at Hand’s patients does not necessarily signal a change in health-seeking behaviour or supply-induced demand: it could benignly be the result of improving access to care and reducing possible pent up demand.

Where telehealth is used by only some providers, there may be negative spillover effects. The types of patients attracted to digital care may differ from the general patient population. The same article noted that 94% of GP at Hand’s patients are under the age of 45 and two-thirds live in affluent geographic locations.42 These patients may be healthier and have less complex health needs than the general population. And since the UK adopted the Patient Choice Scheme in 2015 which allows patients to register outside their traditional catchment areas, the “healthy” patients may self-select providers that offer digital care. In doing so, it can leave the patient mix in the traditional place-of-service GP practices leaning toward those with more complex care needs. Some of the potential impact of this concern is alleviated by the funding formula used to compensate the GP for patients that require a higher workload. However, skewing the patient mix toward those requiring more complex care could increase physician burnout and still reduce the GP’s financial outcomes if the funding formula is not precise enough to capture differences in the workload associated with the characteristics of a particular patient population.

At present, it is difficult to disentangle the effects of suppressed demand from potential supply-induced demand. This is, however, sure to be an area of study. As use of telehealth services grow, this will provide a larger sample and a longer time frame over which to study the issue and inform the debate.

Conclusion

Digital health offers tremendous promise, with much potential to increase access to care, quality of care, and to transform the efficiency of care delivery. Telehealth can be used to improve health literacy which can lead to improved health outcomes and reduce some of the disparities that currently exist in healthcare delivery. Patients in geographically remote locations can benefit from using telehealth to connect with healthcare providers they would otherwise require lengthy travel to see. Even in urban areas where provider scarcity is not an issue, patients can benefit from reduced wait times and ease of access.

However, uptake and the full potential of telehealth will not be realised until stakeholders are able to address the important issues of equity, cost-effectiveness and use. Concerns about data used in machine learning may make users weary about the risk they face in relying on AI too heavily in the healthcare domain. The user interface and communication design may lead to disparities in use and limit the effectiveness of these technologies. Payers will be hesitant to cover services and associated technology if questions regarding the effectiveness go unanswered. If payers, providers, and regulators worry that digitised healthcare will be used to cherry-pick patients, use will be suppressed. The solution to these problems is two-fold. The first speaks to the importance of awareness. As long as those that design and produce these technologies are aware of these issues, steps can be taken to ameliorate the harm that may result from the approach that assumes all people interact with data and messaging the same way. The second key is time and study. As more time goes by and data accumulates, leveraging real world data (such as claims data) will result in a much more comprehensive knowledge base than could ever be generated from case control studies. In fact, the use of real-world data is an increasingly important tool that providers of digital health technology rely on to promote their products and gain reimbursement. As this trend continues, it will be possible to create well-informed guidelines and resources to help users and stakeholders sort through the dizzying array of “solutions” in the space, to identify those that provide the most value.

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Endnotes

1. There are many definitions of digital health; this definition reflects the general scope of the digital health sector.


22. Ibid.


Jen Maki, Ph.D., is a Managing Director in the Center for Healthcare Economics and Policy at FTI Consulting. Her work includes the analysis and modelling of factors that drive demand for healthcare products and services and assessment of trends in the delivery of healthcare. Dr. Maki regularly works with IMS data, commercial claims data and Medicare data to assess demand for healthcare products, price variation, and evaluate treatment patterns. She often works on litigation matters addressing liability and quantifying damages. Dr. Maki has also served as a testifying expert in litigation proceedings. Dr. Maki is an active researcher and has written on topics including the effects of informational interventions on individual decision-making and on tobacco policies and their effect on smoking cessation. Her research articles have been published in peer-reviewed journals, including the Southern Economic Journal and the International Journal of Drug Policy.

FTI Consulting
Two North Central
Suite 1200
Phoenix AZ 85004
USA
Tel: +1 602 744 7157
Email: jen.maki@fticonsulting.com
URL: www.fticonsulting.com

Susan Manning is the Chief Operating Officer and Senior Managing Director of FTI’s Center for Healthcare Economics and Policy. She has over 30 years of economics and litigation consulting experience, including extensive expertise in antitrust and competition issues, mergers and acquisitions, and regulatory policy analysis. She has provided economic analyses of healthcare related mergers and acquisitions before the US DOJ and US FTC, focusing on competitive effects and consumer welfare benefits of proposed transactions. Dr. Manning has focused on assessing and modelling the impact of healthcare reform and structural change in meeting a population’s present and future healthcare needs. This includes determining the most cost-efficient and best quality of care delivery structure for delivering healthcare within a community in light of the changing and broader mission of healthcare providers. Dr. Manning also has worked extensively in the UK on healthcare issues involving transformational change in the delivery of care.

FTI Consulting
555 12th Street NW
Suite 700
Washington DC 20004
USA
Tel: +1 202 589 3458
Email: susan.manning@fticonsulting.com
URL: www.fticonsulting.com

John Maruyama is a Consultant at FTI Consulting’s Center for Healthcare Economics and Policy. He emphasises the use of data-driven methods through programs such as Python and Stata in conjunction with an innovative, holistic research strategy to inform policy decisions. Prior to joining FTI, he was a Research Assistant at Vanderbilt University where he examined the relationship between the history and policy of Medicare and Medicaid. Working under a grant from the NBER, he developed protocol for locating and synthesising hospital data that could be interpreted through STATA. He was also a Research Assistant at the University of Colorado Boulder where his focus was on the economic history of European capital and financial markets. His work included the documentation of data and development of methodology to filter and extract information from historical databases. His output is critical to an ongoing project that builds upon the existing literature in the field.

FTI Consulting
555 12th Street NW
Suite 700
Washington DC 20004
USA
Tel: +1 202 728 8726
Email: john.maruyama@fticonsulting.com
URL: www.fticonsulting.com

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