DIGITAL HEALTH

THE SHIFT IS HAPPENING, CREATING VALUE AND EMPOWERING PEOPLE
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$536BN
digital health investments by 2025

2,314BN
gigabytes of healthcare data generated by 2020

80%
of health data is still invisible

29%
expected compound annual growth for global mobile health market

$134BN
projected global Augmented Reality market for healthcare by 2021

90%
of companies worldwide recognize not being sufficiently protected against cyberattacks
**Introduction**

Technology is rapidly evolving and reshaping our world in one of its most exciting and dramatic moments of transformation ever. Digitalization is a reality today and there is no way to avoid it.

The Healthcare ecosystem is changing, influenced by major innovations. Big Data & Advanced Analytics, Artificial Intelligence, Virtual Reality and the Internet of Things are not futuristic science fiction but part of our reality. Within two to five years, a significant proportion of pharmaceuticals will create value through more than just drugs and medicinal products by integrating a digital ecosystem, generating “beyond the pill” complex solutions while shaping interactions among all stakeholders [1].

While some might consider that this may place people at a distance, healthcare players are using this opportunity to refine more human-centered business models, where patients are empowered by information, generating health insights so they can act directly as decision makers for their own health and well-being. These factors will facilitate the implementation of concepts such as health democratization [2] and P4 Medicine (Predictive, Preventive, Personalized and Participatory Medicine) [3]. Essentially, individuals will live longer and in better health, enabled to manage their healthcare concerns while putting less strain on healthcare systems, lowering context costs and improving public health overall [3].

This panorama will also put pressure on manufacturers, because cost-to-market is expected to increase while sales volumes are likely to decrease. However, global revenue from health management software and services is projected to increase from US$8.92 billion in 2016 to US$50.35 billion by 2025 [4]. This is evidence that digital health may be the best solution to insure a strong competitive position in the market.

Tech giants, highly practiced in the use of consumerization and gamification tools, are moving into the healthcare ecosystem. A good illustration is that between 2013 and 2017 alone, Alphabet, Microsoft, and Apple collectively filed more than 300 healthcare patents, mostly for developments related to data storage and processing, as well as wearable technologies [2]. New partnership and investment models are necessary between tech and health companies to speed up innovation.

From the consumer’s point of view, as other industries are reinventing and personalizing the consumer experience through digitalization and the use of multi-channel / continuous reach, the healthcare system must adapt from the traditional, sporadic, point-to-point, doctor-to-patient relationship to a patient-centric, networked, holistic model.
Regulators are also facing challenges due to the absence of clear regulation to keep pace with the digital revolution and increasing pressure to make every new technology available. The use of unregulated or poorly regulated technologies by consumers may have an impact on their safety and health, creating a cause for concern. A good example regarding the need for increasing regulatory agility is the FDA’s creation of a unit dedicated specifically to Digital Health, focused on areas such as Digital Therapeutics, Software as a Medical Device (SaMD) and Cybersecurity [5]. There is no doubt as to how beneficial and disruptive digital health might be for everyone, but making this happen is not that straightforward, and determining its intrinsic value is still a challenge.
Knowing more with Big Data

With 7.5 billion connected objects in 2017 and between US$20 billion and US$50 billion expected in 2020, the impact of the Internet of Things (IoT) on the economy could reach US$11.1 trillion by 2025 [6]. By 2020, approximately 2.314 billion gigabytes of healthcare data will be generated from electronic medical records (EMR) to IoT [7].

This ecosystem will help improve healthcare outcomes by tailoring therapies to real world necessities, where data supports end-to-end conditions decision-making systems and enables healthcare professionals to remotely monitor patients' conditions and adherence to therapies [1]. Big data and analytics are integrating individual and collective data on chronic diseases, costly acute events and uncertain outcomes, which then might be extrapolated to public health policies [8].

Advanced data analytics that are obtained from electronic medical records, including diagnostic results, epidemiology, medication history, genomic, proteomic and gene-expression data will help to identify optimal therapies and to predict how individual patients will respond to therapy.

By combining IoT with telemedicine, the Internet of Medical Things (IoMT) has emerged. The variety of wearables capable of monitoring biophysical signals such as heart rate, skin temperature, glucose levels, voice profiling and blood pressure could provide significant data to patients, caregivers and healthcare professionals in order to predict, diagnose and monitor both chronic and acute diseases. Combining these with other connectable devices storing data about patients as they go about their daily lives – nutritional information collected by a smart refrigerator, exercise information from smart gym weights, sleeping habits or even digestible sensors combined with pills to track therapeutic adherence – will allow real-time monitoring and health state prediction [1].

Data can also be used to improve efficiency in the organization of healthcare systems - patients who are at heightened risk for re-admission may, for example, be treated for longer periods during their initial admission in order to improve long-term care and reduce re-admissions rates [9].

However, there is still no central, shared database consolidating all, or even the majority, of healthcare data on a specific disease or patient. It is thus estimated that 80% of health data is invisible to current systems because it is unstructured [10]. This limits the quality of care that
physicians can deliver to their patients, as some of the most essential data points may be hidden behind virtual walls or stuck in slow-moving processes, as the transition from paper to digital is still underway [2]. To unleash this potential, data must be placed in more efficient, centralized, standardized, robust, uncorrupted and scalable models. To do this, partnerships with technology companies must be seen as a key enabler.

Moving faster with Artificial Intelligence

The growth and spread of data have generated more information than any single person could possibly interpret. Fortunately, artificial intelligence (AI), with algorithms fed by data, is evolving quickly to meet this challenge - the more data AI has, the further it can go.

The AI and machine learning market is immense and growing fast. AI in the healthcare market is expected to reach US$6.6 billion in 2021 [11]. In fact, 15% to 20% of the healthcare market may be impacted by AI, making it one of the most affected sectors [12].

AI enables faster and more accurate diagnoses of both acute and chronic diseases, identifying early stages of diseases, suggesting personalized and “right first time” therapies, reducing the uncertainty and stress of misdiagnosis and leveraging long-term management of well-being [10]. AI will also optimize medical imaging; help in predicting chemical and biological interactions; provide support in clinical trials; simulate epidemiological studies; optimize salesforces and improve interactions between health stakeholders. Consequently, it permits cost savings, speeding up pipelines and increasing cost-effective strategies, as patterns and trends in this data flow can help develop hypotheses and provide new insights at a much faster rate [13].

By ensuring that the right care is given at the right time and in the right setting, advances in AI can significantly slow the onset of chronic disease for a given population and prevent some forms of disease altogether. Even small improvements could result in large economic savings for all stakeholders in the healthcare system [2]. Smart algorithms and platforms could assist medical professionals in designing treatment plans and finding the best-suited methods for every patient. Together with robotic companions, professionals can “delegate” repetitive and monotonous tasks, so they are more available to focus on human care [14].

Through greater accuracy and reduced time compared to methods relying only on humans, analytics and AI also play a major role in supporting...
decision-making with life-saving consequences. AI is used for multifactor screening of individual risk factors for cancer. These factors include genetics, age, and family history and lead to better prediction compared to the screening of single genes, as risk is related not only to genetics, but also to behavior and environment. The capacity to link, integrate and analyze all existing data together enables a better understanding of health, with more impactful health outcomes.

However, people still do not fully trust AI to make decisions if something unexpected is found (e.g. during surgery) since it is perceived as impersonal and inhuman, hence ethics and morals related to patients’ sensibilities appear as almost impracticable by AI. Approximately 30% of people do not understand this kind of technology well enough to predict if it might be beneficial or dangerous to healthcare [10].

To revolutionize healthcare, AI systems and companies must engender trust as their priority.
Payers and governments have an ever-sharper focus on managing costs while delivering improved patient outcomes. This puts even greater onus on pharmaceutical companies to demonstrate the value of their medicinal products in the real world—not just in randomized controlled trials—if they are to maintain market access and premium pricing.

Targeted online recruitment and remote-monitoring technologies such as sensors, connected devices and apps will increasingly enable clinical trials to take place in "real world" settings so that participants can go about their lives with minor changes in their habits. Yet, optimizing these sensors and wearables with the precision and robustness to meet clinical trial-level requirements and outcomes is still a challenge [15].

Increased connectivity and automation in trial-management processes will also enable advanced trial design and monitoring approaches. For example, sites and sponsors can be connected in order to support the data management and analytics required for adaptive trial designs. With these tools, companies can recruit patients more efficiently and precisely, create personalized trial participation experiences, define patients’ profiles for future trials or trial phases and support drug awareness and educational campaigns. In the end, this will speed up pipelines, reduce costs and improve global health.

By integrating Big Data, AI and medical expertise, we can simulate living organisms that could be tested and repeated as many times as necessary. We can thus carry out clinical trials more safely in less time and with more affordable cost models, thereby still obtaining amazing results. This silicon trial method, in which an individualized computer simulation is used in the development or regulatory evaluation of a medicinal product, device or process of intervention, is expected to bring major benefits over current in vivo clinical trials, as soon as we become fluent with the technology and have a better understanding of biology [16].

Soon, centralized “virtual control rooms” could provide real-time insights and predictions for continuous improvement in a data-driven R&D operation, including site-less virtual clinical trials. Nevertheless, these innovations in clinical trials still must be based on the power of randomization and the double-blindness of clinical trials which enable us deal with the extreme complexity of human biology.
Seeing farther with Virtual and Augmented Reality

What if hospitalized patients could spend their time enjoying immersive virtual interactive scenarios, allowing for relief from the stress and monotony of hospitals? What if we could optimize physiotherapy using neural stimulation through virtual reality? Imagine a doctor performing a surgery wearing glasses that provide additional information about the patient.

The arrival of virtual (VR) and augmented (AR) reality solutions has led to significant advances in healthcare technologies. Advances that could only be dreamed of a decade ago are now implemented and provide revolutionary solutions for cases where conventional methods fail. By 2020, the global market for VR in healthcare is projected to reach US$3.8 billion [17] and the global AR market is expected to reach approximately US$133.78 billion by 2021 [18].

Concerning mental health and psychological therapies, VR allows the creation of powerful simulations in which psychological difficulties occur for in situ coaching without leaving the consulting room or home and provide the possibility of repeating and reinforcing them as many times as necessary [19]. Autism therapies for children might be facilitated with VR, enabling the child to interact with virtual characters at home instead of spending time with doctors’ simulations using toys on a table. This would also allow for the reduction of trips to the doctor, making the child more comfortable [19].

VR has been shown to alleviate brain processing of pain, making patients less exposed to “pain-induced” stress, thus speeding recovery. This is true for both acute and chronic pain management, with special interest in countries in which opioid abuse is problematic.

Regarding physiotherapy rehabilitation, VR is being used as a co-adjuvant, allowing patients to be immersed in scenarios in which they are able to freely move damaged body parts (e.g. legs, neck, spine, etc.) in order to neurostimulate the muscles.

In terms of disease awareness, VR and AV allow for the simulation of migraines, Parkinson’s disease, psychiatric illnesses or even aging, thus enhancing the caregivers’ empathy towards their patients as well as their knowledge of symptoms, perception, constraints and limitations. For example, a 30-year-old doctor could “feel” like his 80-year-old patients, knowing more about their physical and mental limitations.
In terms of medical education and support, VR and VA can see the human body in very diverse perspectives and levels of detail – practitioners can explore, simulate surgeries and perform surgeries supported by readily available data on the patient’s status or combine data from 3D computed tomography during a visual analysis of a patient.

Engaging People in Healthcare

In a digital age, patients are much less dependent on their doctors for advice, and increasingly able and willing to take greater control of their own health – consumers have come to expect access to their health information at their fingertips.

They feel empowered by the vast amount of health information and digital therapeutics solutions available, such as telemedicine and the array of health and fitness wearables, making them want to be included as equal partners in the healthcare ecosystem.

The digitalization of health is now reshaping the former one-to-one relationship between expert and patient and creating a multiplicity of information-sharing relationships – one-to-many, many-to-one and many-to-
any [2]. This has a fundamental impact on rural or isolated areas, where it can be the difference between having expert input in a given case or not an. Virtual and mobile care now serve as a primary health resource for many patients, making it possible for them to have their own healthcare specialist available at any time, on any device. In fact, over the next five years, the global mobile health market is expected to have a compound annual growth rate of 29% [2]. In 2017, the British National Health Service (NHS) rolled out a program that encourages physicians to prescribe apps for their patients with chronic conditions such as chronic obstructive pulmonary disease (COPD) or gestational diabetes [20].

This allows hospitals to reduce readmission rates by providing real-time monitoring and support to patients outside the office. Furthermore, sending “connected patients” home to recover will be more frequent, reducing the possibility of hospital-acquired infections and leaving more hospital beds available for critical cases.

In the future, patients might not firstly contact health professionals for each and every one of their health questions but Chatbots supported by AI, making it possible to address easily diagnosed problems, allowing professionals to focus on matters requiring the full attention of a physician and empowering patients as concerns their health [14]. In any event, attention must be paid to some of the risks - automated systems should not be seen as replacements for the opinions of experts, especially when the risks include threats to patients.

Chatbots may also be beneficial for practices dealing with older patients. A character can be created to serve as an assistant to provide friendly reminders or introduce gamification concepts to involve the patients, thus promoting better health literacy and healthcare commitment.

Allied with telemedicine, biotelemetry will enable doctors to monitor their patients remotely, 24/7, in the comfort of their home. This will improve health long-term monitoring and decrease the number of people in waiting lines in hospitals and healthcare services, making them more efficient and available.

Digital-engagement technologies open up a completely new world - a new two-edged model grew out of this: connected health. Since connected health appears as a unique opportunity for those who embrace it and a mortal danger for those who do not, understanding how to find value in this new world is the essential question for this entire activity.
Strengthening Cybersecurity

While this “connectedness” can add tremendous clinical value, it also makes healthcare more vulnerable to cyber threats. Innovations driving rapid growth create complex cyber risks, with 600 million new malware identified every quarter - and they are growing more sophisticated [6].

According to the World Economic Forum Global Risks report published in January 2016, 90% of companies worldwide recognize they are not sufficiently prepared to protect themselves against cyberattacks [21] and cybersecurity threats to the healthcare sector, as they have become more frequent, more severe and more clinically impactful.
Every year, the financial impact of security breaches to life sciences organizations increases with significant physical impacts and added liabilities, through cyberattacks from malware, phishing and social engineering (SE), web-based attacks or malicious code. In the healthcare arena, there is a critical difference, as cybercrimes could potentially threaten not just the integrity of personal data, but patient safety and integrity as well.

Patient privacy and safety are cornerstones of healthcare. Consumers tend to be wary of sharing their personal data despite a growing desire for more personalized experiences. From a healthcare standpoint, consumers might feel comfortable sharing their data from their health app with their own specialist but are reluctant to share it with pharmaceutical companies or non-traditional healthcare actors [13]. Despite being the creators of such technologies, tech companies are less trusted to provide virtual healthcare than are doctors and hospitals [2].

The privacy concept must be prioritized, as digitalization will require access to considerable amounts of information about the patients and, if protection is eroded, society will not place enough trust in these systems.

One of the tools in trial to increase data protection is blockchain, which is a shared, immutable record of peer-to-peer transactions built from linked transaction blocks stored in a digital ledger. The blockchain allows each patient data source to be a “block” of a complete, unalterable patient data profile that can then be shared securely with healthcare providers or organizations. In the future, blockchain solutions from different companies or even industries will be able to communicate and share digital assets with each other seamlessly [13].

Big Data and AI can also have unintended consequences. Algorithmic bias is becoming a major concern in this critical moment in the evolution of intelligent computing. If biases built into healthcare algorithms (or those that evolve within the program naturally) go unchecked, they could jeopardize the quality of care, and even patient safety [2].

The future is in the implementation of security-by-design, incorporating cybersecurity practices in the product development life cycle, not only for the new products in the development stage, but also for existing ones.
The digital shift is happening in healthcare. The public now has access to medical data, both personal and general, as never before. Patients can access and interact with their health data and obtain health counseling and services, thus leveling the doctor-patient relationship.

To seize this opportunity, stakeholders must consider how their businesses might be affected by the digital changes underway, and then chart their course accordingly. Companies must identify their core activities, build cross-functional organizations supported by evidence-based decision models, continue to seek new partnerships with start-ups and tech companies, and trial Everything-as-a-Service (XaaS) for business and operational models – transversality and collaboration are fundamental.

The roles and context in healthcare will change, requiring new and different professional skills – an understanding of technology will be imperative. Educational in the life sciences will include programming and data analytics on par with anatomy. Many organizations will add the Chief Data Officer to the C-suite.

This change will not reduce the doctor’s key role in healthcare. Instead, it will empower healthcare professionals affording more time to focus on the patient, with emphasis on keeping patients healthier longer. In fact, healthcare professionals will spend less time performing mechanical and repetitive tasks (e.g. inserting data in a computer) and will be able to apply their knowledge to human actions, wherein they provide the most value and find the most satisfaction [2].

Regulators must set and harmonize regulations and standard procedures to keep pace with the widening use of digital products in healthcare, preserving the commitment to helping patients maintain access to innovative therapies designed by value-based outcomes. Actors in healthcare will need to engage directly with key regulatory bodies to clarify compliance requirements. Following the example of US and EU regulatory agencies, it will be possible to aggregate more regulations across the globe.

With all of these new concepts, trends and innovations, it is easy to have unrealistic expectations, with the idea in mind that one health app or algorithm could clarify the entire picture. In fact, the countries, societies and places where care is given are not yet prepared to unleash the potential of digital healthcare. Expertise, time, dedication and persistency will be crucial to making this transformation happen, making it real for every single life.

Conclusion

The digital shift is happening in healthcare. The public now has access to medical data, both personal and general, as never before. Patients can access and interact with their health data and obtain health counseling and services, thus leveling the doctor-patient relationship.

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The author would like to thank Filipa Delicado and Inês Ferreira for their support in reviewing this paper.
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