The Medical Futurist Institute

TMF INSTITUTE

Table of content

Welcome Message

With the spread of social media, digital health and disruptive technologies such as health sensors, artificial intelligence or robotics, a new era has begun in healthcare. The ivory tower of medicine is breaking down; patients are becoming empowered; and technologies have been changing the status quo of the doctor-patient relationship.

Healthcare in the 21st century is facing several challenges such as a growing demand for the management of chronic conditions and the increasing costs of healthcare. Digital technologies provide a pathway by which healthcare becomes sustainable and meets the most important goals: improving health, improving patient satisfaction and reducing costs.

Patients are motivated because of their condition. Physicians derive motivation from the proactivity of their patients. Both patients and caregivers are actively devoted. Companies and start-ups are driven by business needs generated by these changes. This new ecosystem can only thrive if relevant policies are comprehensive and efficient. Before, policy makers had more time to regulate a new technology as pressure only came from lawmakers.

In the 21st century, this has significantly changed as pressure also comes from consumers who can access data, information and technologies. They don't wait anymore for policy makers to make a technology available but turn to new technologies if that helps alleviate pain, better manage their disease or lead to a cure.

The #wearenotwaiting initiative is the perfect example for this kind of pressure. As there was no single device on the market to monitor blood sugar and supply insulin automatically, creative patients invented a DIY version from existing technologies. A movement grew out of the initiative and campaigned for the introduction of such an artificial pancreas on the market for years. One of the leading figures of the movement, Dana Lewis used the device for almost two years before the Food and Drug Administration (FDA) in the United States finally approved it.

Patients are not limited to stay outside the ivory tower but can access almost anything only professionals could access before.

This notion made us write this report. At The Medical Futurist Institute, we feel obliged to help the public adopt digital health safely, efficiently and quickly.

We hope to inspire policy makers worldwide to make the first steps in shaping their regulatory agencies, adopt new technologies or at least acknowledge patient empowerment and the cultural transformation of healthcare.

As digital health is growing fast and generative AI tools like ChatGPT have hundreds of millions of users, new examples will arise soon therefore this report will be updated when needed and your feedback is more than welcome for that.

Let's bring healthcare together to the 21st century.

Dr. Bertalan Meskó

Director of The Medical Futurist Institute

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01

DIGITAL HEALTH TECHNOLOGIES ARE SHAPING HEALTHCARE

Digital health, defined as “the cultural transformation of how disruptive technologies that provide digital and objective data accessible to both caregivers and patients leads to an equal level doctor-patient relationship with shared decision-making and the democratisation of care”, initiated changes in providing care and practicing medicine. As technological innovations become inseparable from healthcare and as healthcare systems worldwide are becoming financially unsustainable, a paradigm shift is imminent.

Since the dawn of medicine, physicians have tried to make informed decisions with a very limited set of tools and a growing amount of experience that could be transmitted to the next generation. Even in the case of the first stethoscope, a hollow wooden tube introduced by Dr. Laennec in France in the early 19th century, it took decades to spread the idea of improving care with an innovation. Since then, healthcare has become dependent on technologies but neither the medical curriculum nor the policies and guidelines could catch up with this development.

By the 2010s, the digitalisation of healthcare became inevitable, the amount of medical knowledge continued to grow rapidly; and patients started to become empowered, while stakeholders were not prepared. Physicians burn out easily under the burden of bearing all the responsibility; patients become frustrated by looking for solutions in a mess of information and decision makers hesitate to change the system.

Digital health has made a range of technologies from genome sequencing to smartphone-connected ECG readily available, although it also carries the risk of dehumanising care. Advances in technology along with widespread access by patients mean that there is a growing demand that policies keep pace with this rapidly changing dynamic in the healthcare environment.

This way, disruptive innovations such as deep learning algorithms, virtual reality, or health sensors could contribute to value-based healthcare, and help make human skills such as clinical judgement, experience or creative problem-solving determine the success of intervention and the doctor-patient relationship.

As digital health makes patients the point-of-care, a new status quo and new roles for both patients and caregivers are approaching. The new, currently forming doctor-patient relationship is based on participation, teamwork and transparency. Patient-generated health data also contribute to practicing medicine.

"All the changes initiated by digital health heavily affect healthcare policies."

Policy makers are expected to make every new technology available quickly, otherwise consumers start using those without regulations. This is an unprecedented time pressure as technologies are becoming available at an increasing rate.

It comes with risks too. Medical technologies including surgical robots, pacemakers and insulin pumps have been shown to be prone to hacking. Health sensors used by patients at home might not be accurate and lack evidence-based background. Patients might find misleading information online that leads to false self-diagnosis. Shared decision-making has an obvious problem too: who is responsible for the individual decisions?

Companies providing direct-to-consumer genetic tests, ECG measurements and other analyses might sell their data to third parties without their users' consent. Digital health technologies can also increase the risk of bioterrorism. These are the challenges we already know about and there are many others we can anticipate.

Soon, chatbots could answer basic medical questions at home; 3D printed biomaterials might be used to replace organ transplantations in certain conditions; drones could deliver blood supplies; Amazon could sell prescription drugs and the ultimate technology, artificial intelligence could take over plenty of repetitive elements, diagnostic decisions and data analytics in a physician's job.

The expected outcome of the work of policy makers in all these is diverse:

- **To help promote the safe use of digital health technologies**
- **To regulate new technologies as fast as possible**
- **To keep healthcare technologies and patients' data safe**

While issues vary over countries, regions and specialties; there are great examples worldwide that could serve as an ammunition for ideas. Not all digital health technology is created equal. A smartphone app for counting calories is not the same as using a direct-to-consumer genetic service.

Regulators are therefore trying to figure out the new paradigm on the go. This report provides a running list of such examples in the coming chapters.

02

BEST PRACTICES OF REGULATING DIGITAL HEALTH

Some of the best practices and important milestones we collected might be specific to a region, healthcare system or technology, but this list was meant to give a clear picture about how policy makers worldwide deal with digital health and hopefully serve as an inspiration that will spark new ideas and even better ways of regulation.

We divided the examples into 4 categories:

A. **Patient Centricity vs. Patient Design**
B. **Regulating Digital Health**
C. **National Policies**
D. **Regulating Artificial Intelligence**

PATIENT CENTRICITY VS. PATIENT DESIGN

Patient design vs patient centricity

A paradigm shift is underway in the patient-clinician relationship, driven by irreversible changes in information access, yet the model under which clinicians are trained, care is conducted, and care delivery is designed has not changed significantly even though we call it “patient centered.” It is increasingly important to understand the crucial difference between the illusory ‘patient-centered’ approach that keeps patients in passive roles and means nothing more than “we might think about you when we make decisions”.

Patient design is a different concept, one that invites patients as active participants – and stakeholders – in the highest levels of decision-making in healthcare. This is called a “co-design” approach and is defined as “a creative practice that can be used to improve customer experience and enhance value”.

To build this new world of practice and workflow, we simply must engage with patients as true partners. To achieve medicine’s new potential, it must be optimised around the wants and priorities of the ultimate stakeholder—the party that has the most at stake in how it all plays out: the patient. Patient design is the approach that can make it happen.

Patients Included badge

Patient-centeredness is really at the heart of digital health, because the patient is assuming a greater role in their care with new technologies. Therefore institutions that incorporate patients into their thinking merit recognition to spur others to do so.

The concept of the “Patients Included” was developed at an innovation hub called the REshape Center of Radboud University Medical Center led by Lucien Engelen in 2010. The Patients Included badge helps identify those medical events where patients are either among the speakers or involved in the organizing committee.

Source: https://patientsincluded.org

Good examples include Stanford Medicine X and Doctors 2.0 and You that even launched e-patient ambassador programs and invited patients to speak. The British Medical Journal was also awarded a special “Patients Included” certificate to acknowledge and encourage their focus on the involvement of patients in the field of medical publishing.

Patient Engagement Advisory Committee

The FDA held the inaugural meeting of the Patient Engagement Advisory Committee, launched in September 2015 and released the names of the nine committee members who all have direct experience as a patient or as a care-partner for a patient. They are experts in the field of patient engagement, and their experience extends beyond their personal disease or condition to the broader patient perspective, which is a critical piece of FDA's work. The meeting's topic was the challenges of clinical trial design, conduct, and reporting identified by patients.

The Committee provides advice on complex issues relating to medical devices, the regulation of devices, and their use by patients. The Committee may consider topics such as: agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes and device-related quality of life or health status issues, and other patient-related topics.

This helps regulators understand patient needs and form legislations accordingly.

Inviting patients to contribute to designing a facility

Prof. Stefaan Berge, head of the Oral and Maxillofacial Surgery Department of Radboud Medical Centre in the Netherlands invited patient feedback while designing a new facility. Based on the feedback, they installed round tables in rooms where patients can discuss their issues with their physician on an equal level highlighting their partnership.

Patients expressed a desire for more partnership with their doctor resulting in discussions taking place around the round table and the exam taking place within a “clinic”, which is bordered by a blue line on the floor.

As patients feel like they are on an equal footing and a valued part of the healthcare team in such a setting, patient satisfaction gets better, which eventually leads to lower stress and demand from their caregivers.

Source: medicalfuturist.com

Providing a digital means for communication between physician and patient

One of the greatest frustrations for patients is the inability to contact their doctor without going through a lengthy phone attempt or going through layers of staff. It's hard to define what kind of communication should take place via emails, therefore it's worth talking about this openly in the in-person visits.

To solve this, it is compulsory for all physicians in the Danish primary care services to offer their patients communication via e-mail. Launched fifteen years ago, the public national health portal (Sundhed.dk) is a successful provider of health information, access to medical records and medication, while providing an overview on Denmark's healthcare system and linking the existing data sources to an easy-to-use, world-leading eHealth portal.

It's important to discuss what and what not should be included in the emails. Such a chance for digital communication helps improve the doctor-patient relationship and avoid unnecessary visits.

Giving clear access to medical records

Sweden's national eHealth vision states that all residents aged 16 or over should have access to all health-related information documented in county-funded health and dental care by 2020. Although the county councils are autonomous and can prioritize which eHealth services to focus on, the national strategy indicates that patients should only have one way to reach healthcare through a national patient portal, '1177.se'.

The patient portal consists of three parts: 1177 on the phone; 1177.se on the web – where citizens can access and search for information about illnesses, symptoms and treatments, as well as finding out about healthcare in their particular region; and 1177.se personal e-services – where individuals gain access to personalised e-services such as adding their primary care centers, sending secure messages to them and accessing their electronic health records (EHR).

While there are still different EHR systems in use across the country, Sweden has implemented a national Health Information Exchange (HIE) platform to facilitate the communication between different health information systems and eHealth services. The national HIE platform enables a single point of connectivity for client applications, making all Swedish EHRs appear as a national, virtual EHR.

Improving patient co-participation in decisions

According to the Health Consumer Powerhouse, The Netherlands is the only country which has consistently been among the top three in the total ranking of any European Index the Health Consumer Powerhouse has published since 2005.

The country is characterized by health insurance providers competing against each other being separate from caregivers and hospitals. They addressed accessibility to care by setting up 160 primary care centres which have open surgeries 24 hours a day, 7 days a week putting an open clinic within easy reach for anybody.

Across Europe, the Dutch system has one of the most structured arrangements for patient organisation participation in healthcare decisions and policy-making. This way, operative decisions in healthcare are taken, to an unusually high degree, by medical professionals with patient co-participation.

Financing agencies, politicians and bureaucrats seem removed from operative healthcare decisions more than in almost any other European country.

REGULATING DIGITAL HEALTH

Approving a digital health sensor

Some emerging technologies are more tricky to regulate than others because these become directly available to consumers too. It was AliveCor's smartphone ECG, available for both Apple and Android phones, that first received FDA clearance in 2014 to be used by patients.

In 2015, AliveCor received an additional FDA 510(k) clearance, this time for an algorithm that allows its smartphone ECG to detect atrial fibrillation - an abnormal heart rhythm that isn't always detectable to the patient, but if left untreated, can lead to stroke or congestive heart failure - with high accuracy. In 2017, the FDA cleared AliveCor’s Kardiaband ECG reader as the first medical device accessory for the Apple Watch. By now there are multiple FDA-approved ECG readers for home use that come with FDA-approved AI algorithms.

It paved the way for other approvals for digital health sensors available to patients.

Source: alivecor.com

Regulating expensive technologies

A motorized exoskeleton designed to help people with lower body paralysis won clearance from the FDA in 2014 to market the device in the US. ReWalk Robotics' device was designed to help people with spinal cord injuries stand upright and walk.

It was followed by many great examples of exoskeleton uses. From stroke to multiple sclerosis, there is quite a wide range of medical use cases. Recently we started seeing non-medical examples as well.

ReWalk uses a fitted, metal brace that supports the legs and parts of the upper body. Motors provide movement at the hips, knees, and ankles. There's also a tilt sensor and a backpack that contains the computer and power supply. The idea is that by getting people out of their wheelchairs, users can lead healthier lives.

Similarly, Germany's national social accident insurance provider, Deutsche Gesetzliche Unfallversicherung ("DGUV"), approved the rental of ReWalk Personal exoskeleton systems for qualified beneficiaries. Additionally, DGUV also approved the supply of exoskeleton systems for qualified beneficiaries on a case-by-case basis. Recently a ruling gave eligible, insured patients with spinal cord injuries (SCIs) a legal basis to use an exoskeleton as an orthopedic aid for direct disability compensation in Germany.

Approving a state-of-the-art technology that shapes pharma

In 2016, the FDA approved the first drug produced on a 3D printer, which is used to treat seizures and has a more porous matrix than the drug manufactured in the traditional way,enabling the drug to dissolve more rapidly in the mouth to work faster. 2023 marked the first 3D printed pediatric medicine trials in Europe that was launched in Spain.

These could prove to be an important step for integrating 3D printing more deeply into the US health systems. Doctors in the US already use a government-sponsored 3D-printing repository to share tool designs to aid in surgeries and treatments; now scientists are working on 3D-printed tracheas and bones, as well as ears, kidneys and skin, which could one day help cover the massive shortage in donor organs.

While the quick-dissolving Spritam tablet is a world away from 3D-printed organs and body parts, its approval shows that the FDA thinks certain 3D-printed materials are safe for human consumption.

Source: 3D printed pills from FabRX

Approving the first digital pill

The FDA approved the first drug in the US with a digital ingestion tracking system. Abilify MyCite has an ingestible sensor embedded in the pill that records that the medication was taken. The product is approved for the treatment of schizophrenia, acute treatment of manic and mixed episodes associated with bipolar disorder and for use as an add-on treatment for depression in adults.

The system works by sending a message from the pill's sensor to a wearable patch. The patch transmits the information to a mobile application so that patients can track the ingestion of the medication on their smartphone. Patients can also permit their caregivers and physician to access the information through a web-based portal.

This was an important milestone as the patient swallows the microchip embedded in the pill too, which makes it an invasive technology. It could help the treatment of patients with mental health conditions and improve compliance with the therapy in general.

Protecting patients by regulating direct-to-consumer genetic tests

When direct-to-consumer (DTC) genetic tests were launched in the 2010s, it seemed those companies claimed more than what they could deliver regarding quality and accuracy. Thus, in 2013, the FDA shut down all DTC genetic services.

There was an expectation that it would soon provide a regulatory framework for such services. In 2017, one of the companies, 23andMe, was allowed to market tests that assess genetic risks for 10 health conditions, including Parkinson's and late-onset Alzheimer's disease.

In 2017, the FDA also proposed to ease the approval process for such tests, saying that the diagnostics can increase consumer engagement in their health. They said the FDA seeks to strike a balance that provides an efficient pathway to bring these tests to consumers without sacrificing the assurances offered by FDA oversight.

As DNA is highly sensitive data, regulating how it can be used is also crucial. The Genetic Information Nondiscrimination Act of 2008 is an Act of Congress in the United States designed to prohibit some types of genetic discrimination. The act bars the use of genetic information in health insurance and employment: it prohibits group health plans and health insurers from denying coverage to a healthy individual or charging that person higher premiums based solely on a genetic predisposition to developing a disease in the future, and it bars employers from using individuals' genetic information when making hiring, firing, job placement, or promotion decisions.

While a new section was introduced which would let employers demand workers' genetic test results, this law provides a good example of how policymakers can help protect patients' sensitive data from profit-oriented companies.

Virtual Wards – Hospital-grade intensive care at home

A virtual ward is a solution that supports patients who would otherwise be in hospital to get acute care, remote monitoring and treatment in their own homes, with the use of digital, remote monitoring health tools relaying real-time data to the hospital. The main difference between ‘full-grown’ virtual wards and the earlier existing solutions is the available data. Virtual wards provide the same data in real-time as would be available if the patient was hospitalised.

The digital health arsenal used is dependent on patients’ condition, but generally measures health parameters such as heart rate, blood pressure, body temperature, and blood oxygen level monitoring besides other, condition-specific metrics. The data is displayed in real-time in the hospital, and the support staff follows it as closely as if the patient was monitored in the intensive care unit.

This is two-way communication. The patient has the option to immediately contact the health team, and real-time data allows healthcare providers to immediately intervene if measurements suggest deterioration in the patient’s condition.

In this model, everything that physically needs a trained professional, like blood tests, wound dressings, intravenous therapy and so on, are carried out by a visiting nurse.

Medical drones

A UNICEF guidance note identifies three basic types of potential use cases for drones in healthcare: 1. delivery and transportation; 2. aerial disinfection, and 3. public space monitoring.

Drone delivery of medical supplies or even vaccines is not quite new, American startup Zipline was delivering such supplies in Rwanda already in 2016. The model proved to be very successful and was recently extended. Zipline for example delivers 75% of Rwanda's blood supply outside Kigali, the capital city. Rwanda is not the only country Zipline is present, they are also active in Japan, Kenya, Ghana, Nigeria, Ivory Coast, and the United States.

Medical drone pilot projects, tests and initiatives are underway in many corners of the globe from India to the US, from the UK to Sweden, delivering medicine, equipment (such as defibrillators for example), blood supplies, lab samples just to name a few use cases.

Digital therapeutics

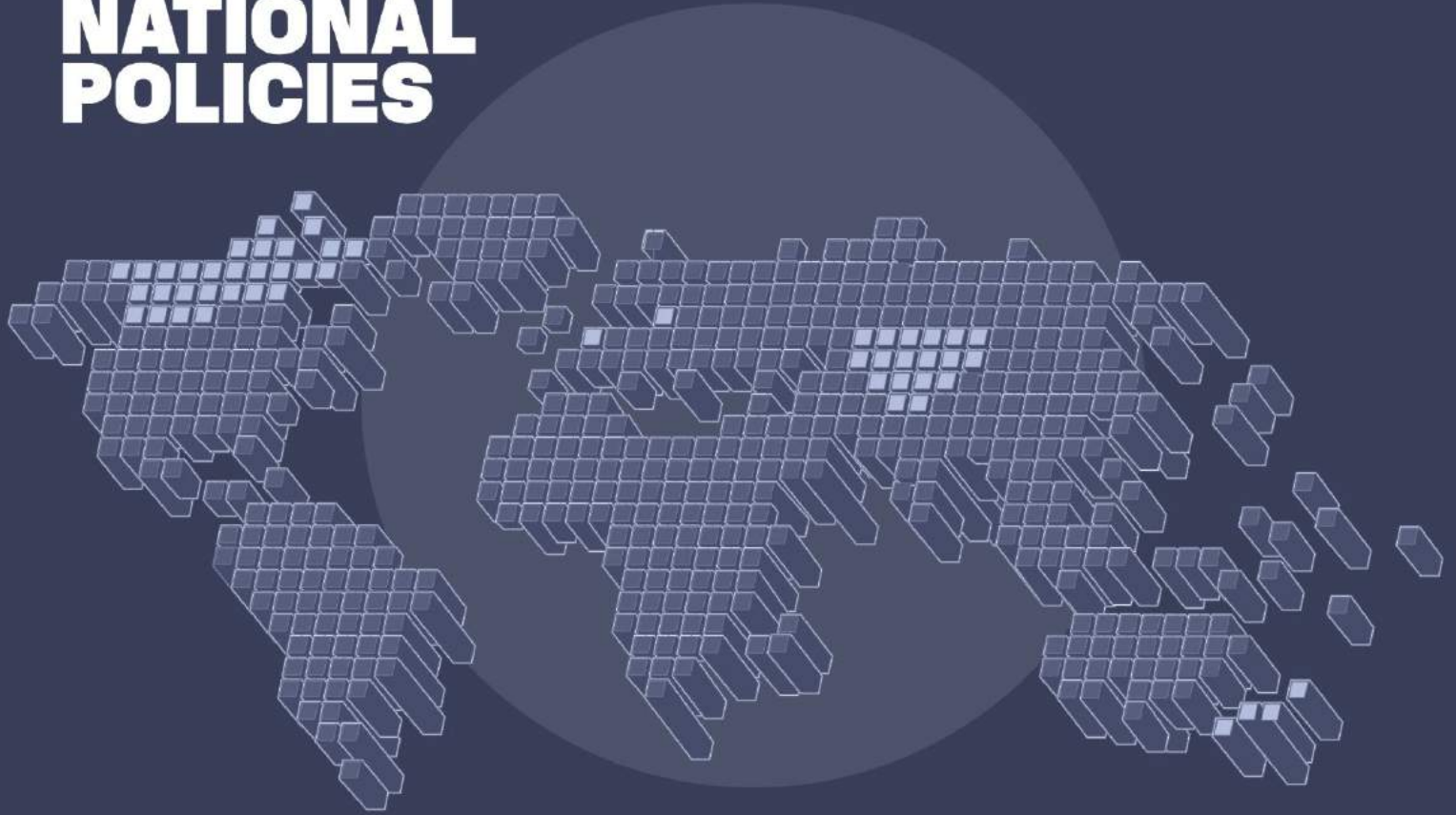
Digital health applications and solutions are increasingly becoming part of our healthcare experience. Partially because they offer fast and convenient solutions for problems arising from capacity shortages of the traditional medical systems (like skin checking apps), or because they enhance the capabilities of doctors, medical personnel, or hospitals (like sepsis watch algorithms or AI diagnostics models).

While these apps are available in a large number of medical specialties, channeling them into state-run healthcare systems to harness the benefits on population-wide scales is challenging. Germany's DiGA (Digital Health Apps) system tackles this issue.

Based on the Digital Healthcare Act, 73 million Germans covered by statutory health insurance (approximately 90% of the total population) are entitled to use DiGAs, provided they have a prescription or an attested diagnosis. This means that digital healthcare has made it into primary care.

Statutory health insurers reimburse the associated DiGA costs, with prices negotiated in advance with the umbrella association of German health insurance companies.

NATIONAL POLICIES



Canada created a venue for expert input into government policy

Responsible governments prepare their citizens for technological changes. They listen to people to shape policy according to real needs.

Canada recognized how massively technology has started to shape healthcare and they want to be in the first row to guide the coming changes. A Canadian Senate Committee invited experts to share their opinion about what the future of medicine would look like.

In this first hearing, they focused on robotics, artificial intelligence and 3D printing. They published a report with actionable steps for the next years.

New Zealand - Getting outside input into government policy

The Government of New Zealand has a public health strategy, a health technology strategy and they invited people to give feedback on the upcoming digital health strategy too. They create the report with the digital health sector through literature review, briefings to sector groups, face to face workshops and online collaboration.

Their opinions will be incorporated into the final report and will be published under a Creative Commons license meaning that anyone can freely access them.

The Strategy is not meant to be a detailed plan, nor a document to sit on a bookshelf, but aspirational goals and enabling strategies, priorities, frameworks, guidelines and resources that will evolve and change over time in response to the changing digital world that New Zealanders live in.

They also expect continual revision of the Strategy as the digital future emerges, which is an excellent approach to address the changing needs of patients.

Denmark - social safety net based on data

The Danish digital health strategy is one of the most forward-looking examples of a government-supported objective to adjust the medical arena to the 21st century. The initiative emphasizes the importance of the cooperation of each and every healthcare actor through the easiest and fastest way, technology, with a clear purpose: to build an integrated network focusing on patients and looking at the person as a whole, not just at the individual diagnosis.

The Nordic countries as excellent examples of the social welfare state have been providing a social safety net to their citizens based on their data for decades – so they have been front-runners in the collection of information on births, deaths, disease and its control through the centralized state.

In the Danish healthcare system, all residents are entitled to public healthcare benefits, have free and equal access to general and specialised practitioner services, and digitization is at a high level. Everyone gets access to the Sundhed.dk patient portal, which allows any patient to access their own health data, make appointments with doctors or look up their complete patient history. But that's only one type of data registry: medical professionals, researchers or institutions get access to a wide range of clinical databases, biobanks, lab- or imaging systems – with high-quality data.

Estonia – making the most of a highly digitalized democracy

Estonia started to build their digital health system 25 years ago, and the Baltic country already started to reap the benefits of a transparent, blockchain-based, digital health system hooked on genetic data. During the last approximately twenty-five years, project e-Estonia has wired up the entire nation, including their healthcare.

The Estonian e-Health vision 2025 sums up the efforts in a rather short but powerful four-word sentence: “Better information – more health”. The country is striving to collect high-quality data in a secure and transparent way about the past, present and genetically predictable future health state of patients in a highly personalised way by staying in close proximity.

Estonia is a great example of steadily working for a set goal: In 2008, they launched the national EHR, two years later added digital prescriptions, in another two years came e-consultations. In 2015, e-ambulances were introduced, and a drug interaction decision support system was launched in 2017.

Of course, even in a highly digitised democracy, it takes time and effort to find the most efficient ways to counter the problems of doctor shortages, brain-drain and remote practices, but such conscious planning makes their efforts efficient.

Kazakhstan – remote solutions for large territory & low population density

Being a relatively new republic and with its widespread inhabitants - the country has one of the lowest population densities worldwide -, Kazakhstan poses as an adequate hub for digital health to expand.

The healthcare system (medical service providers) in the country is mainly state-owned, and the government's push to provide universal health coverage aims to reduce out-of-pocket expenses. To achieve this, one of the aspects that the Ministry of Healthcare is betting on is the digitisation of the healthcare landscape.

The country launched the "personalised medicine" 2020-2023 program in 2019. This ambitious project aims to analyse all possible data inside data centers of the Ministry of Healthcare, as well as over 300 terabytes worth of data from other sources related to disease trends so as to be able to forecast disease prognosis on a national scale.

The main goal of the 2020-2025 healthcare development plan will focus on shifting from hospital-oriented medical care to patient-oriented medical care. This will bring in patient involvement through smartphones and wearables, which will be able to feed data paramount to projects like the above-mentioned "personalised medicine" program.

REGULATING ARTIFICIAL INTELLIGENCE

Creating a regulatory pathway with input from the industry

In 2017, the FDA launched a first-of-its kind pilot program that will help revolutionise digital health regulation in the US. The digital health software precertification pilot program (FDA Pre-cert) is intended to inform a tailored approach toward digital health technology by looking at the software developer or digital health technology developer, rather than primarily at the product.

The goal of this approach is for the FDA to, after reviewing systems for software design, validation and maintenance, determine whether the company meets quality standards and if so, to precertify the company. Precertified companies could potentially submit less information to the FDA than is currently required before marketing a new digital health tool as part of a formal program. The FDA is also considering, as part of the pilot program, whether and how precertified companies may not have to submit a product for premarket review in some cases.

Participants, chosen from more than a 100 submissions, include Apple, Fitbit, Johnson & Johnson, Pear Therapeutics, Phosphorus, Roche, Samsung, Tidepool and Verily. The FDA took the approach here of building a bicycle as they try to ride it.

Integrating AI applications into national healthcare systems

Skin-checking apps were one of the earliest examples of how AI-backed systems can assist wide populations in receiving faster/better/cheaper healthcare services. AIP Labs and Semmelweis University (Hungary's largest medical university) developed a skin checking application which was launched to work integrated with the national healthcare system and offer full-scope dermatology services including diagnostics, treatment plans and cloud-based drug subscriptions.

According to currently available data, processing speeds have improved by 5-10 times compared to the traditional care model.

AIP Derm detects 700+ pathologies, covering some 95% of skin diseases. The submitted images and the diagnosis created by the AI are always reviewed by a doctor. Once an image comes in, the system pre-evaluates it, tells the dermatologist team which pathologies it believes are likely to be involved, and then sorts them by chronological order or severity.

In the pilot, 10 doctors of the Semmelweis University Clinic of Dermatology, Venereology and Dermatooncology worked to evaluate the uploaded cases, they were able to go through 40-80 images per hour. These clinicians provided the treatment suggestions, issued the cloud-based drug subscriptions and suggested in-person consultation if necessary.

Regulating AI in medicine

Regulatory authorities such as the U.S. Food & Drug Administration (FDA) and the European Medicine Agency (EMA) are heavily regulating the medical landscape when it comes to artificial intelligence (AI)-based solutions. The FDA took the lead, having issued a specific framework for AI-based algorithms.

While novel, AI-based medical devices show promise in enhancing medicine, they are inevitably high-risk in nature. There are several unknown consequences of using AI in medical decision-making and data analysis.

However, even this leading authority did not provide a comprehensive database of these tools that it had approved for many years. In 2020, we found ourselves inadvertently stepping into the shoes of the FDA, compiling data on exactly how many AI-based technologies have been approved and their respective specialties. Just one year later, in 2021, the FDA released their own database, citing us as a source.

Regulators face the next level of these challenges these days, as they must come up with a safe but suitably flexible framework for large language models like GPT-4 and Bard, and adaptive – constantly changing, self-learning – algorithms.

Regulation of Large Language Models like ChatGPT

The rapid progress in the field of artificial intelligence (AI) has given rise to advanced large language models (LLMs) like GPT-4 and Bard. These LLMs have already gained significant interest in the realm of healthcare due to their wide-ranging use cases such as aiding in clinical documentation, expediting insurance pre-authorization, summarising scientific studies, and functioning as chatbots to respond to patient inquiries about their personal data and worries.

Despite their immense transformative potential, it's crucial to approach LLMs with caution. Their training methodology differs from other AI-powered medical technologies that have already undergone regulation, a distinction that becomes particularly significant in the sensitive arena of patient care.

The latest iteration, GPT-4, introduced in March 2023, escalates the potentials and risks of this technology in supporting various medical tasks. Alongside the inherent risks of misinterpreting its outputs due to inconsistent reliability, GPT-4 showcases advanced capabilities such as interpreting text within images and analysing their context.

The task of regulating GPT-4 and other generative AI in the healthcare sector without stifling their revolutionary potential is a pressing and critical challenge. This is necessary to ensure patient safety, uphold ethical standards, and safeguard patient privacy. We propose that regulatory supervision should reassure medical professionals and patients of the safe use of LLMs, without jeopardizing their data or privacy.

03

WHERE IS DIGITAL HEALTH GOING?

Digital health only emerged in the 2010s, thus it's still forming. So are the challenges that come with it. The ethical issues and regulatory burdens we aimed to identify in this report represent current trends. As digital health evolves, new challenges will arise we have not even thought of before. It means it's impossible to address those challenges now while we cannot comprehend what the massive use of technologies will lead to.

In order to help keep up with the changes, we collected a list of reliable and quality resources that discuss important issues and report relevant developments about where digital health is heading, see the next slide.

We remain confident that there is a better chance of preparing for whatever is coming next by showing best practices of how regulators tackle the challenges of today.

From here, you will be the ones finding the solutions and providing best practice examples. We, at The Medical Futurist Institute, wish you strength and good luck with it!

List of online resources that help keep track of changes and developments of digital health technologies.

Online resource	Topics it covers
http://www.3dprintingindustry.com	**3D printing**
http://www.medicalfuturist.com	**Digital health**
http://www.futurity.org	**Research news**
http://www.bbc.com/future	**Technologies' impact on society**
http://www.reddit.com/r/futurology	**All disruptive technologies**
http:///futureoflife.org	**Technologies' impact on society**
http://www.therobotreport.com	**Robotics**
http:///www.mobihealthnews.com	**Mobile health and telemedicine**
http://www.genomeweb.com	**Genomics**
http://www.medgadget.com	**Wearable health trackers**

The Medical Futurist Institute

http://tmfinstitute.org

contact@tmfinstitute.org