DIGITAL HEALTH BEST PRACTICES FOR POLICY MAKERS

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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, 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

Acknowledgements

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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 democratization 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 digitalization 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 dehumanizing 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:

1) **To help promote the safe use of digital health technologies**
2) **To regulate new technologies as fast as possible**
3) **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

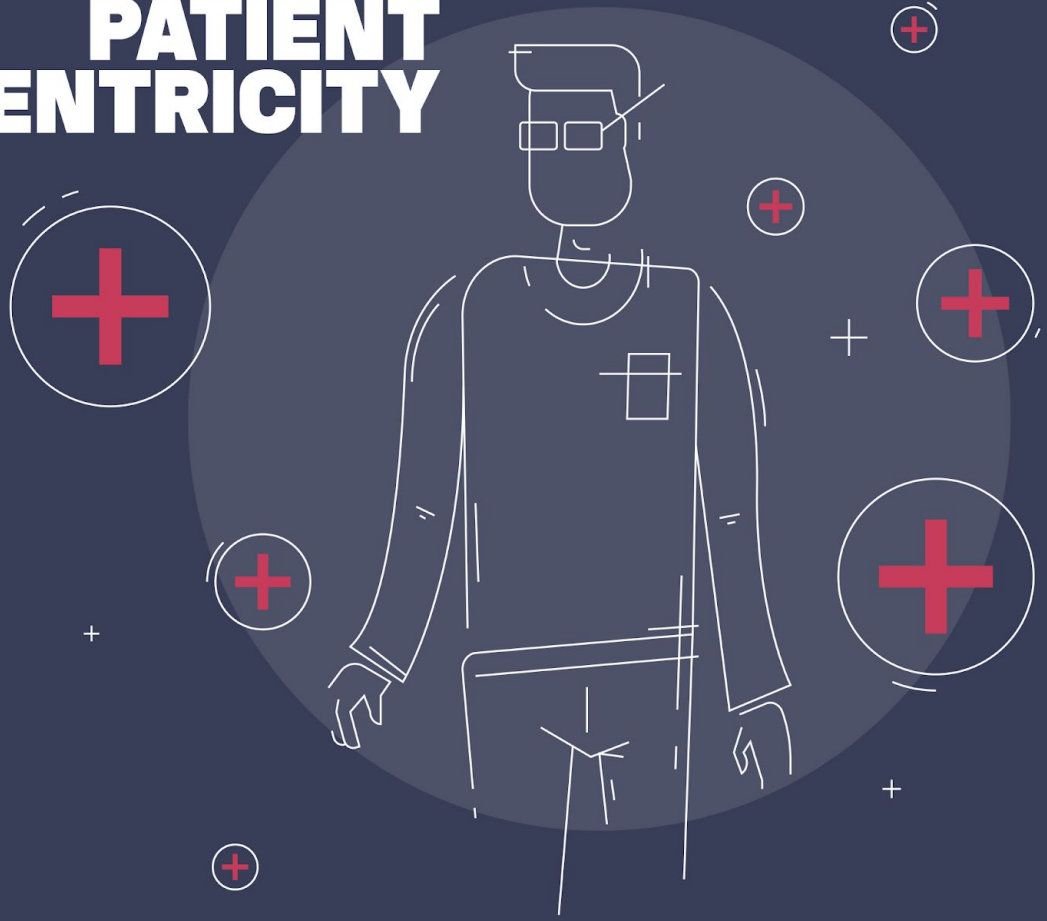
BEST PRACTICES OF REGULATING DIGITAL HEALTH

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:

1) **Patient Centricity**
2) **Regulating Disruptive Technologies**
3) **Preventing Ethical Challenges**
4) **Promoting The Use Of Digital Health**

PATIENT CENTRICITY



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 invite 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 personalized 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

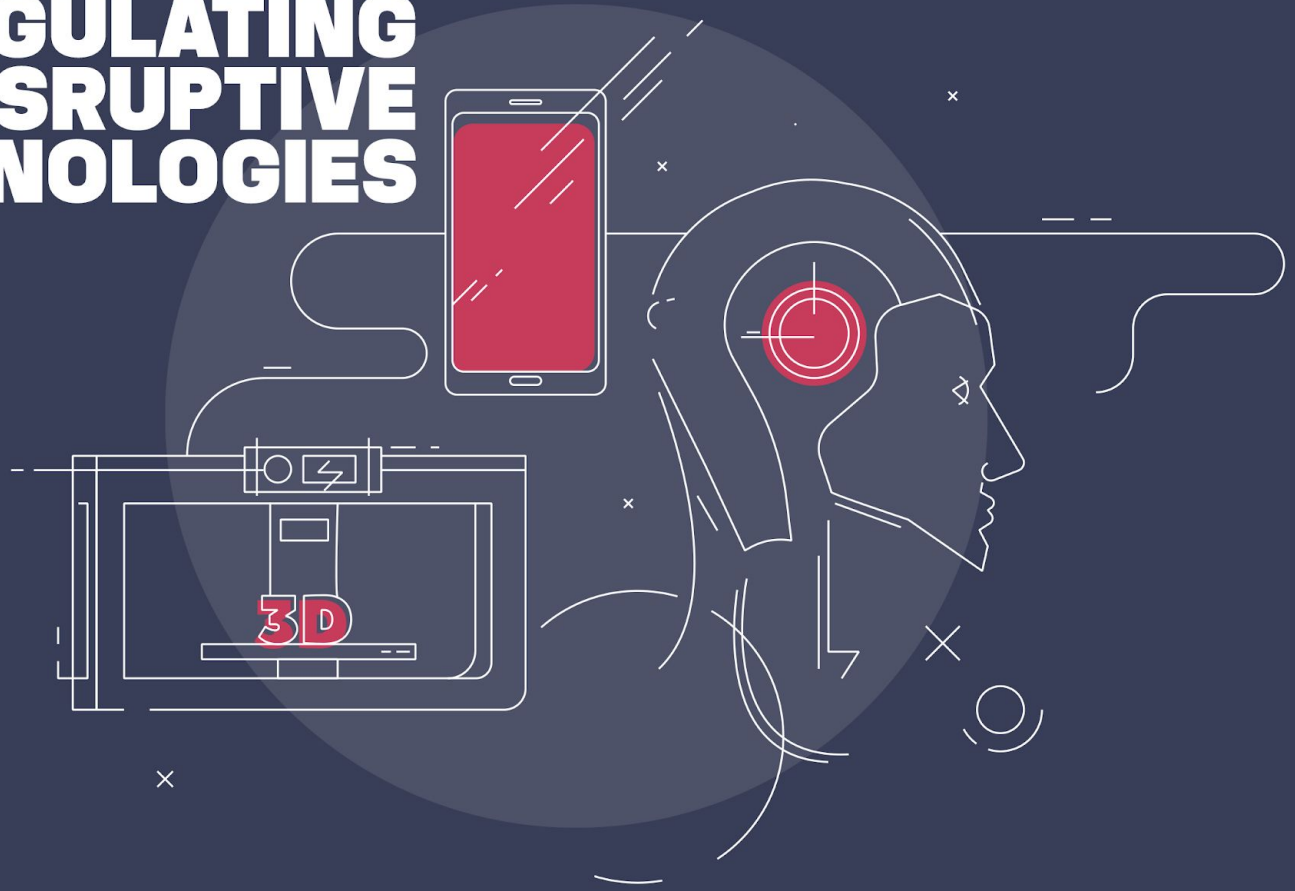
According to the Health Consumer Powerhouse, The Netherlands is the only country which has consistently been among the top three in the total ranking of any European Index the Health Consumer Powerhouse has published since 2005.

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 DISRUPTIVE TECHNOLOGIES



Preparing for 3D printing

Too often, emerging technologies are held back by a lack of regulatory guidance or framework. The FDA was the first in the world to provide a comprehensive technical framework to advise manufacturers creating medical products on 3D printers. They reviewed more than 100 devices such as knee replacements and implants for facial reconstruction that were manufactured on 3D printers.

They issued a guidance to help advise device manufacturers on technical aspects of 3D printing, referred to as additive manufacturing, which clarifies what the FDA recommends manufacturers include in the submissions for 3D-printed medical devices. It includes device design, testing of products for function and durability, and quality system requirements.

It is meant to help manufacturers bring their innovations to market more efficiently by providing a transparent process for future submissions and making sure our regulatory approach is properly tailored to the unique opportunities and challenges posed by this promising new technology.

Approving a digital health sensor

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

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.

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

Source: alivecor.com

Preparing a technology before it's commercially available

Bioprinting human tissues with 3D printers raises ethical concerns and biotechnological challenges. One of the leaders of this field, the US company Organovo, has promising results. Pre-clinical trial data shows that 3D bioprinted liver tissue has been successfully planted into lab-bred mice. The human liver-cell tissue shows regular functionality and, at this stage, is being explored as a suitable patch for the organ.

The liver tissue was studied in-vivo for over a month, detecting function through the presence of 3 human proteins in mice blood plasma within one week of the implant surgery.

As the company plans to launch a commercial product in 2019, the FDA started discussions with them to understand how the technology works in details. This way, they could provide fine regulations by the time the product is ready for the market.

Creating the right regulations depends on companies and policy makers being open to such preliminary discussions.

Regulating expensive technologies

A motorized exoskeleton designed to help people with lower body paralysis won clearance from the FDA to market the device in the US, according to a company and FDA's statement. ReWalk Robotics' device is designed to help people with spinal cord injuries stand upright and walk.

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.

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.

This could prove to be an important step for integrating 3D printing more deeply into the US health system. 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 to the therapy in general.

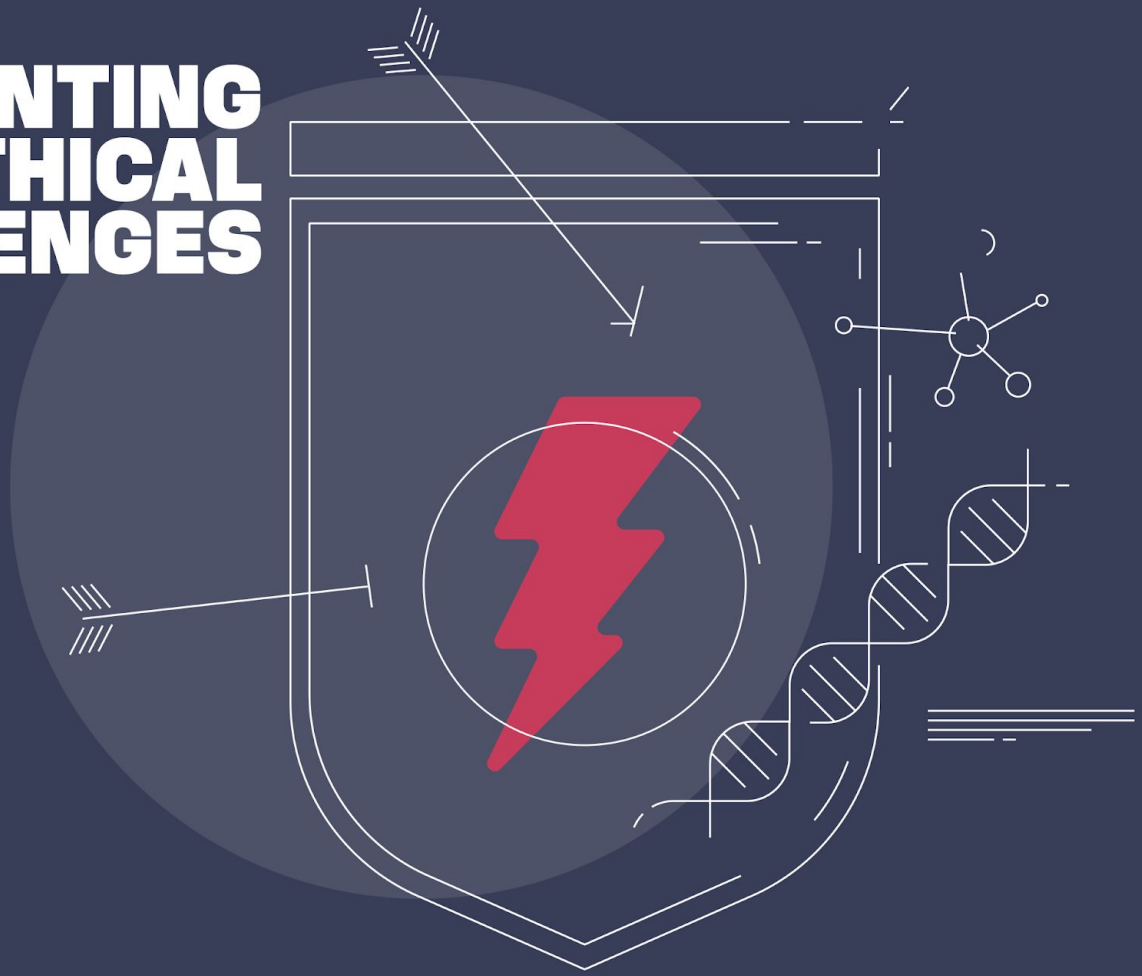
Using deep learning to create a medical software

Artificial intelligence and related methods from deep learning to machine learning are being used massively to tackle healthcare's big data problems. Drug development in pharmaceutical companies; the analysis of data sets in hospitals by providers; and new diagnostic softwares that analyze millions of data points all include some form of artificial intelligence.

The US company Arterys has received 510(k) clearance from the FDA to market its application that leverages cloud computing and deep learning in a clinical setting. It automates time-consuming analyses and tasks that are performed manually by clinicians today.

The software can process a radiology scan in just seconds, compared to manual contouring performed by clinicians who can still edit the automated contours if desired. This way there is manual control over the procedure.

PREVENTING ETHICAL CHALLENGES



Warning biohackers about the dangers

Gene therapies offer the potential to treat diseases or conditions for which no or few treatments exist. These are regulated by the FDA's Center for Biologics Evaluation and Research. Clinical studies of gene therapy in humans require the submission of an investigational new drug application prior to their initiation in the United States, and marketing of a gene therapy product requires submission and approval of a biologics license application. The FDA has already approved certain gene therapy products.

As do-it-yourself gene therapies and efforts to modify one's biological/genomic materials are on the rise, the FDA made clear that it is aware that gene therapy products intended for self-administration and "do it yourself" kits to produce gene therapies for self-administration are being made available to the public.

The sale of these products is against the law. The FDA is concerned about the safety risks involved. Consumers are cautioned to make sure that any gene therapy they are considering has either been approved by the FDA or is being studied under appropriate regulatory oversight.

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.

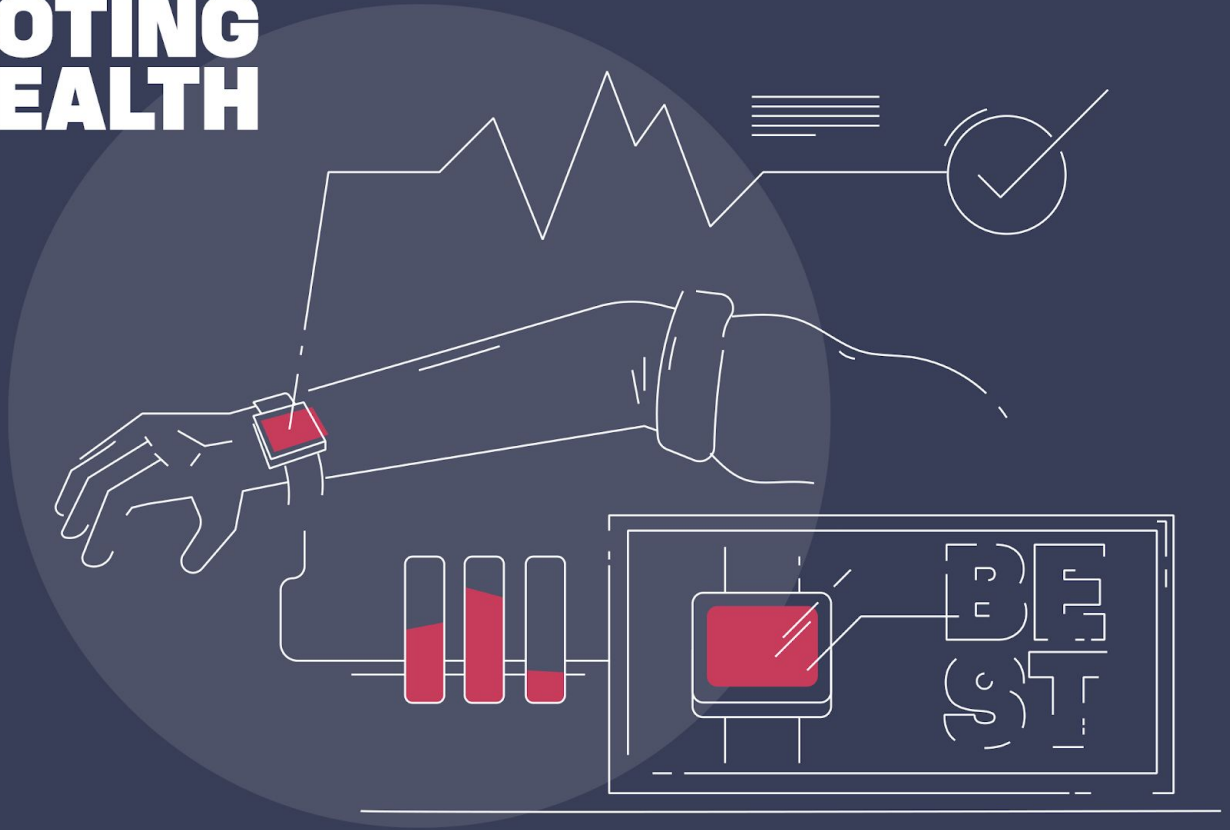
In 2017, the FDA also proposed to ease the approval process for such tests, saying that the diagnostics can increase consumer engagement in their health. They said the FDA seeks to strike a balance that provides an efficient pathway to bring these tests to consumers without sacrificing the assurances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

Keeping patients’ data private

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, in 2017, a new section was introduced which would let employers demand workers' genetic test results, this law provides a good example of how policy makers can help protect patients’ sensitive data from profit-oriented companies.

PROMOTING DIGITAL HEALTH



Encouraging the use of smartphone apps

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. The apps can transmit patient data from a tablet or smartphone directly to clinicians.

A two-year trial at the Royal Berkshire NHS Foundation Trust found that the system reduced the number of patient visits by 25 per cent.

Andrew Lansley, the Health Secretary, has compiled a list of hundreds of apps and online tools which will be recommended by the NHS after a public appeal for the best new ideas and existing mobile phone apps.

Primary care physicians then will be asked to recommend apps that are free or cheap to their patients to use, in an attempt to give patients more power and reduce visits to doctors.

Creating a regulatory pathway with input from the industry

In 2017, the FDA launched a first-of-its kind pilot program that will help revolutionize 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.

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 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.

Source: http://bit.ly/2lDlGpF

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.

A new division dedicated to digital health and artificial intelligence

In 2017, the FDA created a new unit dedicated strictly to digital health. Its leader, Bakul Patel, who started as a policy advisor in 2008, hired engineers, software developers, artificial intelligence and cloud computing experts to prepare the agency to regulate a future in which healthcare is increasingly mediated by machines.

They are also working on the path that would take machines and algorithms to regulatory approval.

They realized that instead of shifting current regulations to cover digital technologies too, they need to start with a clean sheet of paper. Rather than reviewing each line of code in a software or every feature of a medical device, they envision a model similar to TSA security checks at the airport. New developers or manufacturers with a messy track record would still go through the scanner. But trusted companies that demonstrated quality and excellence could get their products to the market faster.

It’s very rare that a leading regulatory agency has such clear visions about dealing with digital health on the long-term.

Guideline for developing smartphone apps for medical purposes

While there are millions of medical applications for smartphones available, it’s hard for consumers to choose the ones that are reliable and of quality.

To solve this, the mHealth Technical Evidence Review Group of the World Health Organization developed a checklist and evidence-based guidelines for reporting health interventions using mobile phones. The checklist aims to identify a minimum set of information needed to define what the mobile health intervention is (its content), where it is being implemented (its context), and how it is implemented (its technical features), to support the replication of the intervention.

Only such guidelines can help standardize the evidence-based practice and improve the quality of mobile health interventions.

03

WHERE IS DIGITAL HEALTH GOING?

Digital health only emerged in the 2010s, thus it’s still forming. So do 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, here we propose a list of technologies that we consider to fall under the umbrella of digital health (Table 1.); as well as a list of reliable and quality resources that discuss important issues and report relevant developments about where digital health is heading (Table 2.).

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!

Table 1.

List of innovative medical technologies that belong to digital health.

Technology
3D Printing
Artificial Intelligence
Augmented Reality
Blockchain
Brain-computer interfaces
DIY Biotechnology
Gamification
Genomics and Personalized Medicine
Health Sensors & Trackers
Medical Robots
mHealth
Nanotechnology
Portable Diagnostics
Telemedicine
Virtual Reality

Table 2.

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://io9.gizmodo.com	Bioethical considerations
http://www.medicalfuturist.com	Digital health
http://www.kurzweilai.net	Artificial intelligence and biotechnology
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.popsci.com	Research news
http:///www.mobihealthnews.com	Mobile health and telemedicine
http://www.genomeweb.com	Genomics
http://www.wearables.com	Wearable health trackers

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