CENTER FOR THE GOVERNANCE OF CHANGE

INNOVATION, SUSTAINABILITY AND THE FUTURE OF HEALTHCARE

HOW IS ARTIFICIAL INTELLIGENCE RESHAPING HEALTHCARE IN EUROPE?

EXECUTIVE REPORT
JUNE 2020

IN PARTNERSHIP WITH Lilly

CONTENTS

Programme developed with the support of Lilly
For a full version of the report, including full chapters, references, and case studies, please visit cgc.ie.edu

KEY MESSAGES

The studies included in this report show that the integration of Artificial Intelligence (AI) technologies in the European healthcare setting presents a series of unique challenges that will require large, collaborative and transparent efforts crossing boundaries of profession and geography.

Although the technology is advancing quickly, issues of data sharing, privacy, biases, patients' experiences, training and integration need to be carefully and continually addressed. The COVID-19 crisis has exposed some of the most pressing challenges affecting healthcare, and highlighted the benefits that a robust integration of digital and AI technologies in the healthcare setting may bring:

01

So far, most progress has focused on improving or accelerating specific moments in care using AI, such as the reading of scans or improving diagnostics. However, to address some of the biggest challenges of this century–increasing demand and co-morbidities from an ageing population–, it needs to improve the pathways of healthcare: in other words, how care is delivered to and experienced by patients.

02

The step change in technology in healthcare, which is the main focus of this report, has so far not reached the same level in social and personal care. However, the potential benefits could be just as important, so understanding the status and challenges of AI in this area will also be key to optimizing pathways of care.

03

The technology is exciting, but comes with risks. A concerted European effort is needed for an open, mature conversation about the best possible way to guard against and mitigate possible harms. This conversation must include national and international policymakers, clinicians, digital health and machine learning leads from industry and academia, and representatives from patient communities and the general public.

KEY FINDINGS

Four countries dominate the digital health patent landscape in Europe: Germany, the Netherlands, the United Kingdom, and France, with Sweden following closely behind. In the Netherlands, over 60% of the digital health patents studied are for AI technologies.

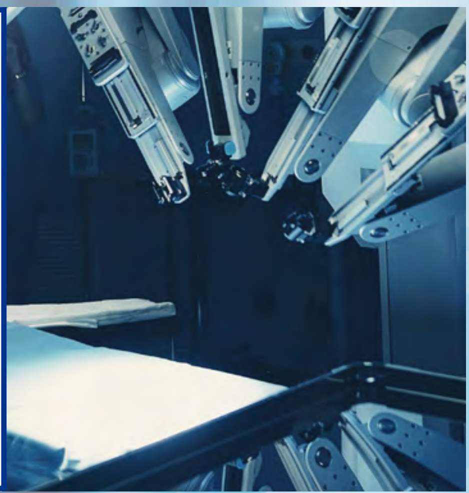
Data sharing, curation, standardization, anonymization and validation remain some of the biggest hurdles for the development of health AI applications in Europe. New initiatives and regulations are moving in the right direction, but they need to be able to adapt quickly and involve cross-disciplinary efforts.

There is little data on how the general public and professional communities perceive the potential benefits and drawbacks of healthcare AI. However, all available studies provide a strong and consistent message that AI innovations should be fully integrated within healthcare systems and should complement healthcare professionals, instead of replacing them.

KEY FINDINGS

A proactive approach to address the education and training of the healthcare workforce is needed to realize the potential of AI. The strategy must take into account the changing nature of the tasks involved, the attractiveness of the career path, and the constant evolution of AI in itself.

The deployment and integration of AI-based technologies with the potential to significantly change the patient care pathway should proceed in a controlled way, with continuous monitoring and adjustment. In addition, funding schemes may need to be re-evaluated to ensure high-quality care for everyone, particularly the most vulnerable.



A series of case studies, ranging from symptom checkers to fertility applications, suggest that rigorous studies of clinical effectiveness are often lacking.


Examination
PostProc
Filming
mGy
µGym²
kV
mA
Measure Field
ms
Time
Cu mm
f/s
Dilatation
Σ A+B
kV
mA
ms
Cu mm
p/s
Heat Unit %
Autotransfer is enabled again
BIPAP ASB
mbar
L/min

PREFACE

This report aims to be a step forward in the necessary discussion around healthcare AI in Europe.

At the time of writing, the COVID-19 pandemic has claimed almost 500,000 lives worldwide, infecting more than 9 million people at an exponential rate. The high number of patients in critical condition has saturated intensive care units in the major outbreak areas, and doctors from all specialties—and, in some cases, even students and retired professionals—have been enlisted to assist. With a few counted exceptions, the response from most countries to the spread of the virus has relied on centuries-old measures including isolation, quarantines and masks. While our powerlessness is humbling and highlights how far we still need to go in our understanding of infectious diseases, the differences with respect to historical precedents are just as important. One of the reasons governments have taken such drastic measures is the confidence that, sooner rather than later, treatments will be improved, immunity tests developed, and a vaccine found. The worldwide scientific community has united in an unprecedented manner, volunteering time, skill and effort to progress to this point as rapidly as possible.

This pandemic—and its associated strain on the healthcare system—is happening at a time of technological optimism and promise. The digitalization of health data, together with the advent of advanced data mining techniques, has brought forward the possibility of automating and even improving the tasks that healthcare professionals have traditionally conducted in a qualitative or semi-quantitative way. In particular, **AI techniques are increasingly being used in a wide variety of applications** involving cognitive tasks, from image-based pattern recognition and data integration models for disease prognosis to triaging chatbots.

The hope is that this new family of tools will alleviate the burden on an overstretched healthcare workforce and also enable new ways for patients to receive care that contribute to the long-term sustainability of the system.

—

However, **although the advances are promising, the associated challenges cannot be underestimated.** AI algorithms must be robust enough to avoid biased learning, which can easily happen when training datasets are too small, too skewed or poorly annotated. This requires cross-disciplinary, international agreements for data sharing, standardization, curation, anonymization, validation and continuous monitoring. Implementing the tools in the clinic also requires a digitally-trained workforce and widespread access to the latest technologies—a challenge compounded by the European Commission anticipating a shortfall of thousands of data scientists by 2020. At the same time, clinicians and patients have to be involved in the design and development process, as ultimately the tools will only be successful if they are comfortable using them. These are just a few examples of the hurdles faced by AI technologies, but they reveal one of the key common features: **the need for a global effort.**

Motivated by the rapid technological advancement in recent years, **this report explores the status of healthcare AI in Europe,** and analyses the challenges, hurdles, opportunities and possible ways forward. The results have become particularly significant, as the current health crisis is triggering an unprecedented surge in the development and demand of digital and AI technologies worldwide.

DIGITAL AND AI-BASED HEALTHCARE FOR COVID-19

When, early on in the pandemic, chest CT scans were found to reveal the extent of lung damage, efforts were established around the world to facilitate data sharing, model training and scan assessment. For example, the Tianhe-1 supercomputer in China was made accessible to anyone in the world in order to provide quick COVID-19 diagnoses based on chest scans. Similarly, in Europe, a collaboration of 30 international partners including the most affected areas in Italy and Spain created *Imaging* COVID-19 AI, which aims to provide an automated diagnosis and quantitative analysis of COVID-19 based on imaging. The initiative is a collaboration between the European Society of Medical Informatics and the companies Robovision and Quibim.

In parallel, AI is being used to mine existing databases of medical information. As early as February 2020, Benevolent AI, a company based in the United Kingdom, had proposed the use of existing drugs for COVID-19 treatment. In March, Kaggle, the world's largest machine learning and data science community, launched a competition to analyse more than 47,000 scholarly articles about COVID-19 and related coronaviruses to learn about its origin, evolution, therapeutic and social implications. Intrepida, a Swiss company, launched Ancora.ai, a web-based AI tool to match patients with relevant clinical trials. Data is also being gathered from multiple contact-tracing apps developed by companies and governments around the world, demonstrating the deep connections between clinical care and other aspects of social life.

Although not always AI based, telemedicine has boomed. NHS England recommended GPs to change face-to-face appointments to telephone or video in March. Some telemedicine platforms made their services available for free, including Kry in Sweden, Doctolib in France, and Adent Health in Denmark. Push Doctor, a company in the United Kingdom that has partnered with the NHS, claimed in March that usage of their product had increased by 70 %. Kry claimed to have doubled their usual number of appointments in two weeks. The need for remote consultations has also laid the ground for virtual tools, some of them AI powered: symptom checkers based on user inputs have been launched by Babylon Health in the United Kingdom, Natural Cycles in Sweden, and Mediktor in Spain.

Regulation is also moving quickly. The French government and German health insurance companies have removed reimbursement restrictions on video consultations. In the United States, Medicare has expanded its coverage to include telemedicine. The British Medicine and Healthcare Products Regulatory Agency authorized fast-track approval of medical devices during the outbreak, and the FDA stated that it did not intend to enforce requirements for "certain lower risk device software functions," including symptom checkers.

In many cases, this rapid, global response is already providing critical and beneficial support. However, even at this relatively early stage there are some warning signs of the risks of this type of rapid development. In April, a review published in the *British Journal of Medicine* systematically evaluated 31 computational predictive models for COVID-19, finding that all of them were at high risk of bias, mostly due to non-representative sample selection. This means that, when tested in a different, more general population, the accuracy of the predictions could decrease significantly. Similar discussions are also happening in other scientific domains, for example for antibody tests, which have been proposed as the basis of "immunity passports". Their performance can only be established confidently after trialling on large population samples; however, so far most test assessments have only been performed on small groups of individuals, according to a recent news article in the journal *Nature*.

In addition, there are concerns that some of the tools, particularly those used for location and contact tracing, may compromise personal privacy.

The European Data Protection Board produced a set of express guidelines in April, emphasizing that such apps "should be used to empower, rather than to control, stigmatise, or repress individuals".

—

UNDERSTANDING THE EUROPEAN HEALTHCARE AI LANDSCAPE

The progress that we have made in regards to AI and digital healthcare in a matter of weeks could have, under normal circumstances, taken years. However, the speed at which we have arrived to this point means that it is even more important than ever to monitor the advances carefully, to ensure that patients receive the best possible care, and to earn the trust of the clinical community and the general public. Avoiding missteps at this time will be critical not just for the management of the pandemic, but also to ensure the credibility and the future of digital AI-powered healthcare.

In this context, the studies presented in this report acquire particular importance and urgency. They display the complexity of AI-based healthcare and highlight the need to develop strategies that carefully consider the multiple dimensions of the integration process. The common theme across all the studies is the need for multi-disciplinary efforts to coordinate, validate and monitor the development and integration of AI tools in the clinic. Moving forward from here, as discussed in the *"What Next?"* section (p. 36), the focus will be on improving care *pathways*—including not just health, but also social care.

The report is complemented by a set of four case studies. They explore issues relevant to the deployment of different types of healthcare AI tools, from validation of clinical effectiveness to communication strategies for positive perception. The case studies span widely different scenarios, from a symptom-checker chatbot to tools used in fertility clinics.

The next sections provide a summary of some of the most important findings from the different chapters of the report. For the full text and references, please refer to the full version of the report, available online. **All chapters and case studies were finalized just before the start of the COVID-19 crisis and were the result of independent research produced by the authors credited in each chapter.**

This report aims to be a step forward in the necessary discussion around healthcare AI in Europe.

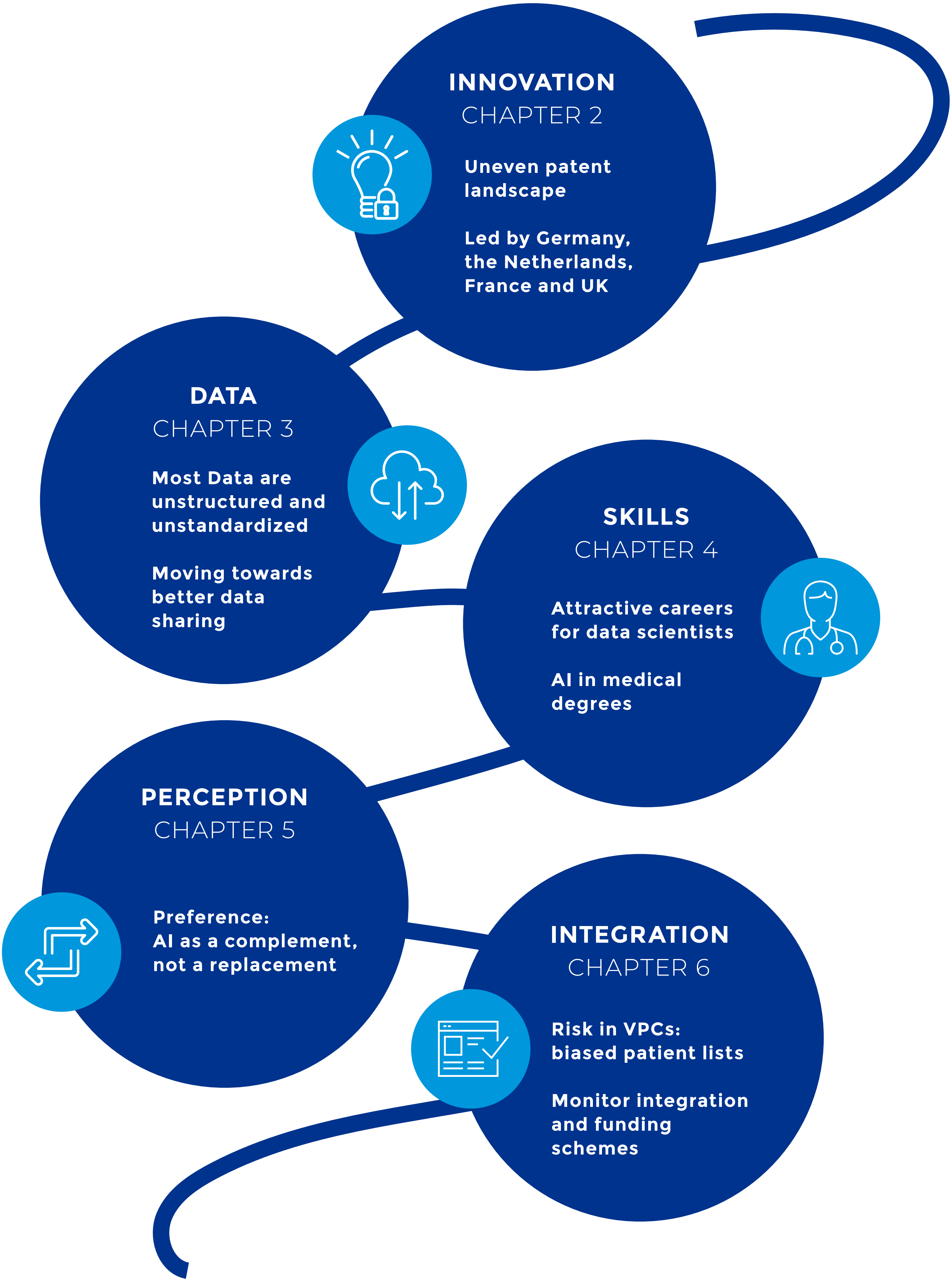


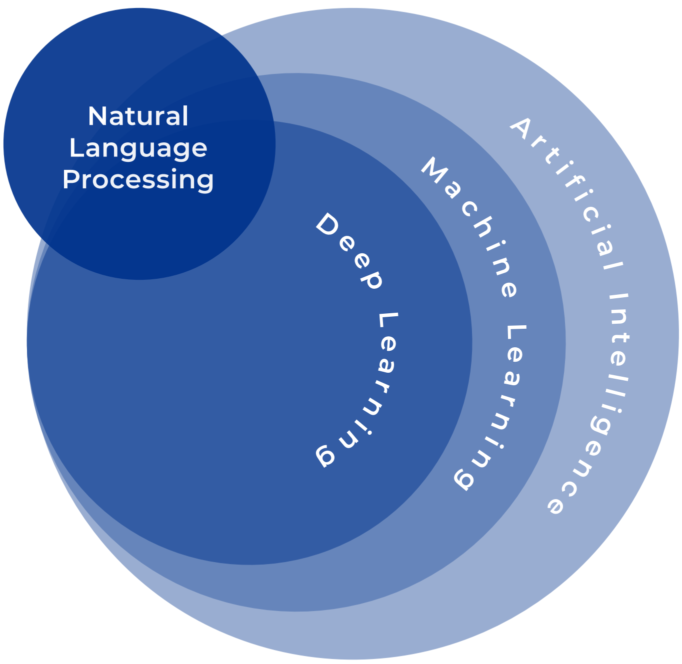
Figure 1. Key ideas from the different chapters in the report

ABOUT ARTIFICIAL INTELLIGENCE (AI)

AI is one of the key technological innovations shaping our modern world. AI is defined as the collection of techniques that confer an artificial entity with the ability to perceive the environment and take actions that maximize a certain goal.

Commonly, however, the term is used as a synecdoche to refer to the learning algorithm only. As **explained in the study led by Dr Gallego et al. (Chapter 1),** most of the algorithms used for medical applications are based on machine learning (ML) techniques. ML refers to programmes that are able to automatically learn rules and discern patterns based on data and experience with the aim to achieve a desired objective.

New-generation algorithms are becoming increasingly competent at extracting complex patterns from large amounts of data and using them to make decisions. This, coupled with their ability to improve the quality of their prediction over several iterations, makes AI algorithms an attractive tool for optimizing medical decisions in healthcare settings.



TYPES OF MACHINE LEARNING

Most ML algorithms used for medical applications are trained in a so-called "supervised" way, which means that there is a set of examples for which the association one wishes the model to discern has been provided **as** a ground truth to learn from. If the dataset is too small, or the number of input features the algorithm can learn from too large, the resulting model may be overly fine-tuned *(overfitted)* and therefore generalize poorly.

Another common distinction is between shallow (or "traditional") ML algorithms and their counterpart, the newer deep learning (DL) algorithms. Traditional ML algorithms are characterized by having a simpler architecture and fewer parameters than DL models. They have the advantage of being generally quicker to train than their deep counterparts, and they remain effective and successful in many domains. Deep learning algorithms are a sub-class of machine learning techniques primarily comprising large and complex neural networks. They are responsible for the most popular successes of AI in recent years. In particular, convolutional neural networks (CNNs) are a subtype of deep neural networks that have attracted a high level of interest due to the fact that they are extremely well-suited to analysing image data, including medical images such as MRI scans, X-rays and histopathologically-stained tissue images. CNNs have achieved notoriety as some studies have claimed that they were able to achieve superior accuracy compared to humans, for example when analysing dermatology images for some specific diagnostic purposes.

Figure 2. Venn diagram showing the different types of AI. ML algorithms can be considered as a sub-group within AI, while deep learning algorithms are a special class of machine learning algorithms.

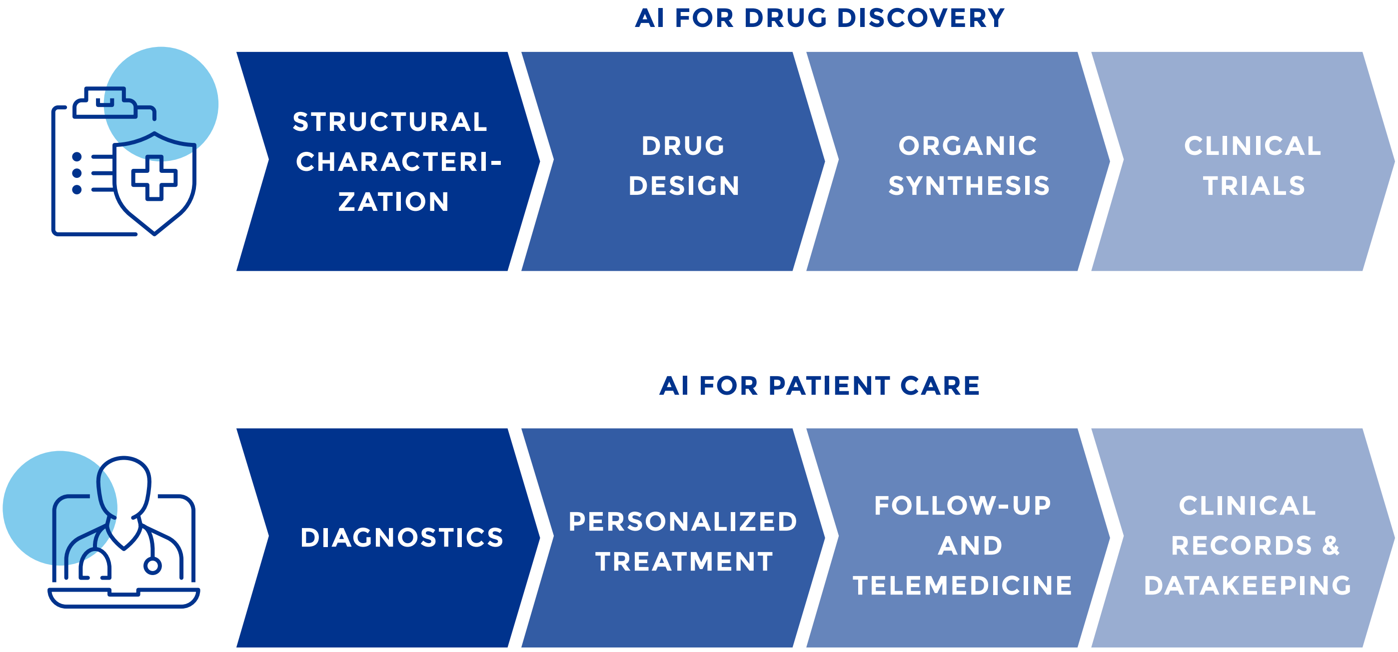


Figure 3. Areas of the drug discovery and patient care pathways that can be assisted by AI

In addition to analysing images, AI applications are being developed to tackle most stages of the process of going from bench to bedside and beyond. Not all of them will have the same disruptive impact. Some may be used as more efficient versions of previously automated technologies, whereas others may have the potential to completely change the patient care pathway.

A number of AI systems have been developed to optimize pre-clinical drug discovery processes, such as DeepBind, by the University of Toronto, DeepSEA, at Princeton, or companies such as BenevolentAI or HealX in the United Kingdom. AI is also being used for diagnostic and non-patient-facing clinical applications. The types of tasks that are most amenable to AI automation are those based on quantitative analysis or perceptual recognition. As such, disciplines such as radiology, pathology or some aspects of cardiology, where physicians' tasks are to a large extent based on assessing data visually, have received more attention. Finally, there are also some AI tools that directly target patients' interaction with human doctors or rely on patients disclosing personal data. A well-known example is that of chatbots used for symptom checking and triaging (see Case Study 1 and 3).

CHALLENGES AND OUTLOOK

Some of the most important aspects to be assessed during the evaluation of an AI tool for practical use will be discussed below. Nevertheless, even on a fundamentally technical level, there are **four key questions** that should always be asked: can the decision process be rationalized? Is the training data representative and relevant, and has the model been extensively validated on large external datasets? Is the performance assessment robust, and are specifications satisfied? And finally, are predictions sensitive to subtle variations in the input data? Addressing these questions is the essential foundation upon which further evaluations of privacy, ethical considerations or biases have to be built.

The use of AI in the clinical setting brings forth a set of technical, logistical, regulatory and ethical challenges. However, it also has the potential to bring a paradigm shift to healthcare, and to assist in the move towards data-driven, prediction-based decision-making—from pre-clinical studies to early diagnosis, treatment monitoring and follow-up. The early successes of AI have motivated a global effort to move towards this vision. However, the amount and pace of the innovations is not uniformly distributed.

FOUR KEY QUESTIONS THAT
SHOULD ALWAYS BE ASKED:

CAN THE DECISION PROCESS BE RATIONALIZED?

IS THE TRAINING DATA REPRESENTATIVE AND RELEVANT, AND HAS THE MODEL BEEN EXTENSIVELY VALIDATED ON LARGE EXTERNAL DATASETS?

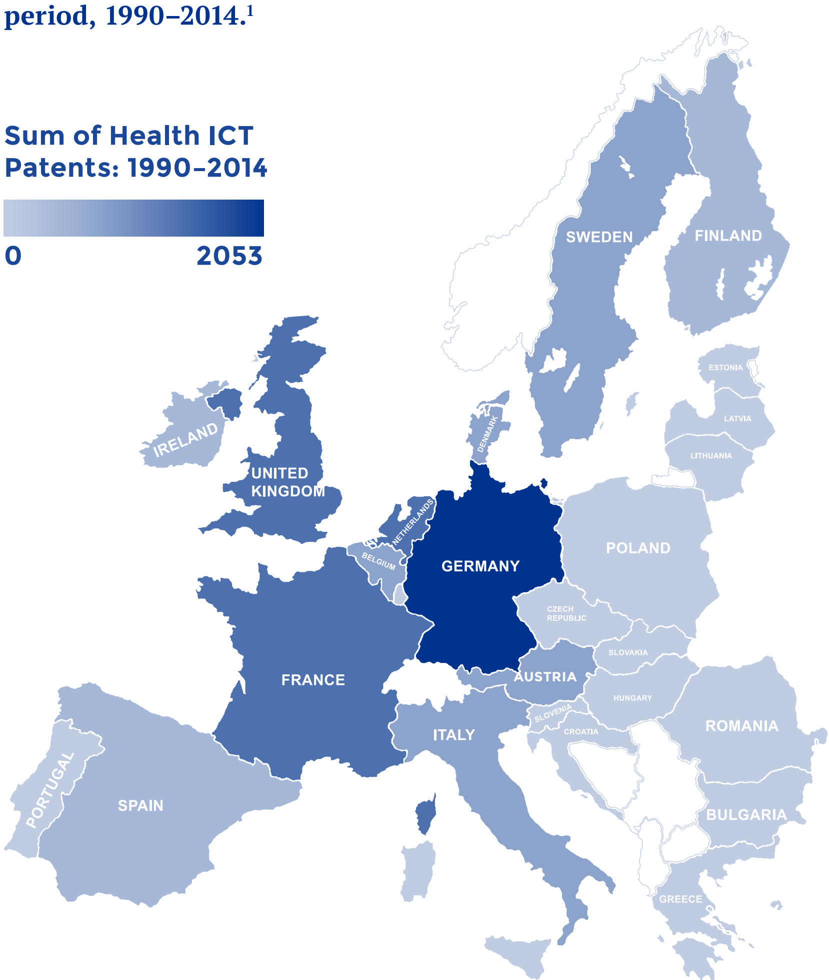
IS THE PERFORMANCE ASSESSMENT ROBUST, AND ARE SPECIFICATIONS SATISFIED?

AND FINALLY, ARE PREDICTIONS SENSITIVE TO SUBTLE VARIATIONS IN THE INPUT DATA?

THE INNOVATION LANDSCAPE

The study led by Jeffrey and Machado (Chapter 2) has unveiled a widely variable landscape of digital health innovation across European countries. To map the variations in digital health innovation, the authors searched the database of the European Patent Office (EPO) for patent applications filed by members of the European Union that belonged to both a health category—biotechnologies, medical technology (MedTech) and pharmaceuticals—and an information technology (ICT) category, which are further classified into big data, AI and Internet of Things (IoT) technologies. They restrict their analysis to patent applications to the EPO filed by members of the European Union in the stated time period, 1990–2014.[1]

MedTech was one of the top technology fields in 2018 in the EPO. Overall, **Germany, the Netherlands, the United Kingdom and France lead the way** in patent filings in digital health, followed closely by Sweden. While in Germany and the United Kingdom big data analytics is the dominant type of patent of the three, in the Netherlands AI leads. The spread between big data analytics and AI is more equal in France and Sweden. Health patents in the Internet of Things are always a minority.



Tier 1 n < 25	Tier 2 25<= n < 500
Luxembourg	Sweden
Poland	Denmark
Greece	Austria
Hungary	Belgium
Czech Republic	Italy
Portugal	Finland
Slovenia	Spain
Romania	Ireland
Malta	
Bulgaria	**Tier 3**
Croatia	**n => 500**
Slovakia	
Cyprus	Germany
Estonia	Netherlands
Lithuania	United Kingdom
Latvia	France

Figure 4. Total number of health patents in the European Union: 1990–2014. *Source: PATSTAT Global 2019 Spring Database*

1 We restrict the data to 2014 as the data for the years following will still be incomplete due to the amount of time it takes for the process to be completed, which may result in an under-reporting of the actual patent activity.

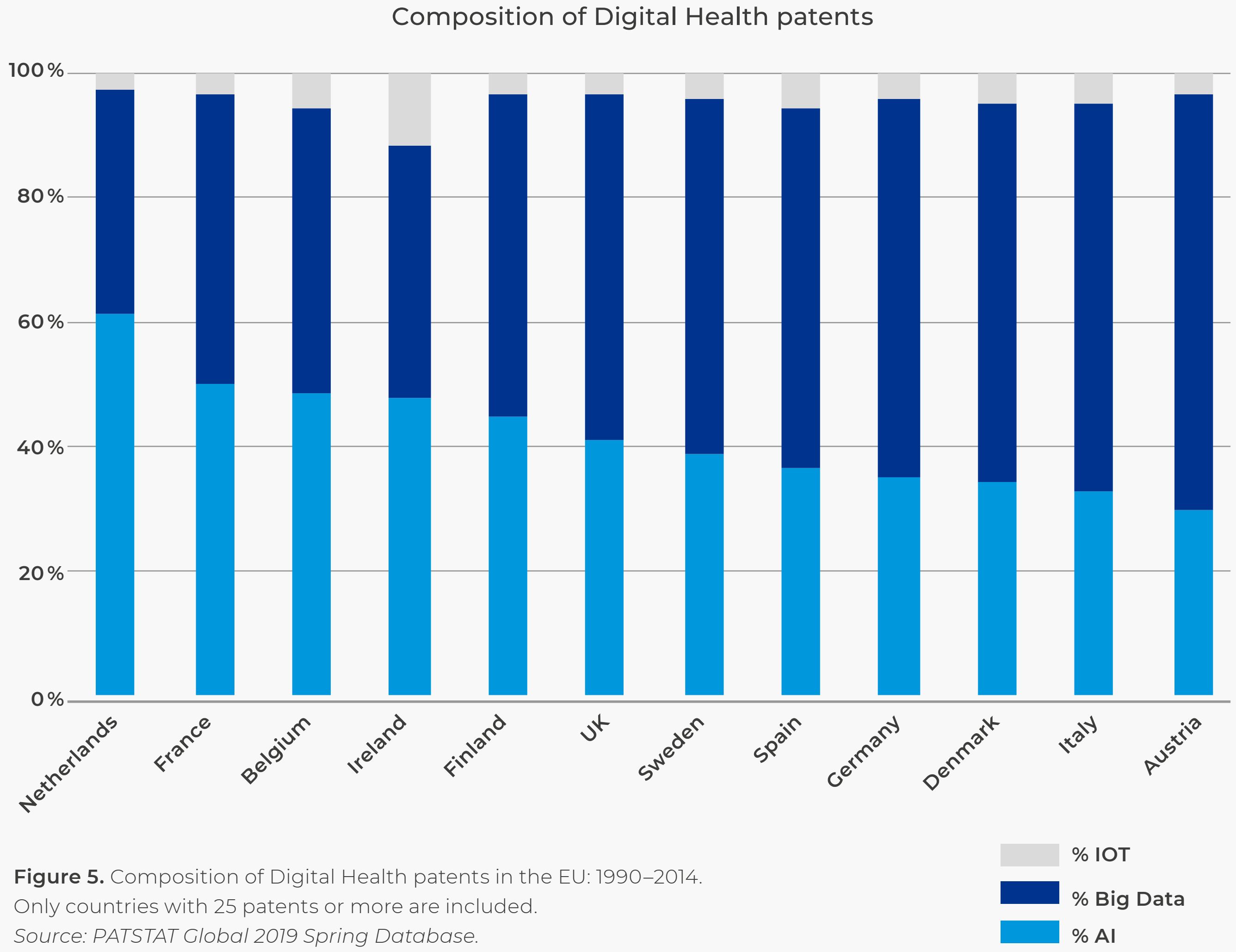


Figure 5. Composition of Digital Health patents in the EU: 1990–2014. Only countries with 25 patents or more are included. *Source: PATSTAT Global 2019 Spring Database.*

If we look at the breakdown by biotechnologies, pharmaceuticals and MedTech, we see that these countries still lead the way except for the Netherlands which does not lead in pharmaceutical patents. **Sweden rises to the top 4 in pharmaceuticals and into the top 5 countries for MedTech research.** With regards to the digital technologies being employed in these patents in these fields, big data analytics leads the way in patents filed in biotechnologies and pharmaceuticals. IoT features only in patents in MedTech, and even so comprises the smallest percentage.

When we look at the breakdown by digital ICT type, Large-Capacity Information Analysis is the most dominant type, totalling 2257 patents in the whole period in these 28 economies, and Cognition and Meaning Understanding is the next most popular with 1347 in this time period, amongst these economies.

Out of the 28 economies studied, only 13 filed digital pharmaceutical patents in the period studied.

The magnitude is also smaller, with no states filing above 200 patents, and only Germany and the United Kingdom filing above 20 patents in this period and sector.

These results indicate that the landscape of technology development varies and is uneven across Europe. The long-term implications of this is that some countries will be quicker to adopt technologies as a result of the more developed ecosystem of innovation linked to their healthcare system. Our results give an indication of trends in the future and allow for a robust evaluation of the policies that have led to this outcome and an indication of the impacts of more recent policy interventions in this space.

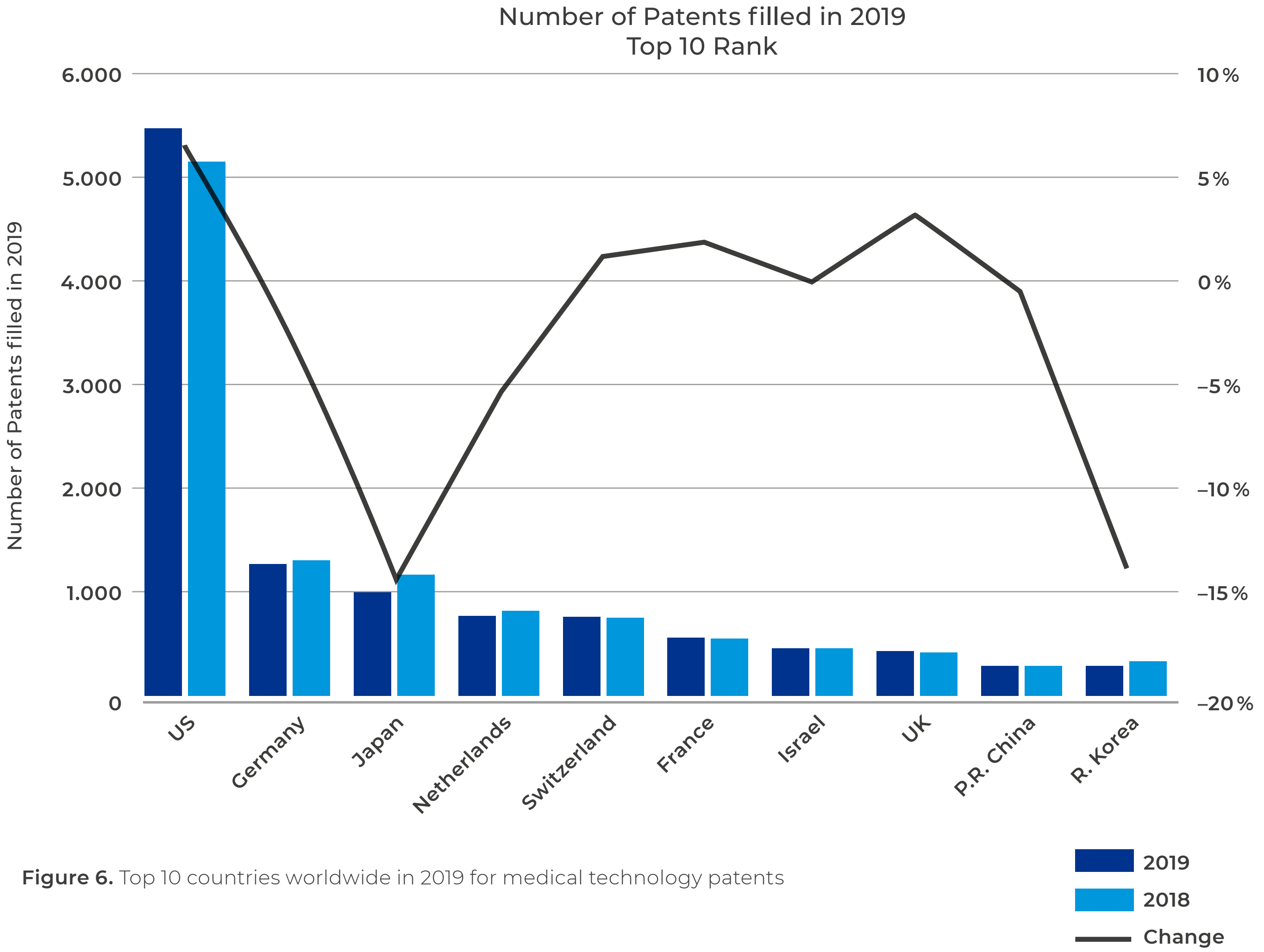


Figure 6. Top 10 countries worldwide in 2019 for medical technology patents

Countries leading the digital health revolution all have policy initiatives prioritizing the interoperability of health data, in particular promoting the personalized medicine sector.

—

For example, the Dutch Venture Initiative funds ICT, clean technologies and medical technologies, with a yearly budget of €100–500 million.

In Germany, several multi-million initiatives provide grants for innovation and the creation of clusters and collaborative platforms. The United Kingdom has similar schemes to support and stimulate healthcare innovation, including the “Industrial Strategy Challenge Fund” set up in 2017 with a budget of £100–£500 million, and the “Innovate UK Funding Competitions” set up in 2016 with an unspecified budget. The establishment of these funds may have contributed to these countries retaining their positions as top innovators worldwide according to 2019 patent data (see Figure 6). Recent initiatives led by the European Union may result in the development of a more uniform landscape across European countries in the coming years. The European Commission has established two working groups and published several documents outlining a strategic approach for European AI, with health being one of the key parts to be funded under the Digital Europe Programme (2021–2027).

The innovation ecosystem is an important step. However, unlocking the power of digital technologies to improve health systems will require large efforts in the standardization and interoperability of the key ingredient for AI tools: data.

THE DATA CHALLENGE

The percentage of health data collected digitally instead of analogically increased dramatically in the past two decades. Current estimations suggest a doubling of the total amount of data in the world every 2–3 years. Since AI-based systems require big training datasets, healthcare, with its abundance of data, is in theory well-poised to benefit from it. However, as shown in the study led by Dr Pesapane (Chapter 3), variable completeness, quality of data entry, and interoperability between different providers remain a problem. Most health-related datasets are unstructured and unstandardized.

DATA SHARING

The lack of appropriately curated large datasets is one of the key obstacles to the introduction of AI systems in healthcare. A set of standards would be necessary to allow for integration between different algorithms and to allow them to be used in different centres, by different users, and on different equipment.

Several **guidelines for prediction model reporting** (including development, validation, model update, impact assessment and implementation reporting studies) are being updated specifically to incorporate standards applicable for AI, including the so-called TRIPOD, PRISMA and CHARMS guidelines. Also with the aim of sharing standards, a multicentre cooperation for gathering and distillation of information is being coordinated by the European Innovation Partnership on Active and Healthy Ageing, covering standards, technical reports and technical specifications, but also guidance documents, industry standards, databases and scientific methodologies and tools.

Although the current healthcare environment still holds little incentive for data sharing, European governments are starting to actively promote it, similarly to what happened in the United States where the National Science and Technology Council Committee on Technology recommended that open data standards for AI should be a key priority for federal agencies. Some have proposed creating anonymized benchmarking datasets with known diagnoses that are updated and calibrated at regular intervals using local data from the implementing institutions, similar to how clinical laboratories maintain a local reference standard for blood-based biomarkers. Including in such approach a **local calibration** (i.e. through a collaboration amongst different institutes across the European Union) is crucial, because DL algorithms may capture local or cultural-specific parameters that may not be generalizable to different populations. Examples of data sharing initiatives that European countries either coordinate or participate in include the Cardiac Atlas Project, the Visual Concept Extraction Challenge in Radiology, the Cancer Imaging Archive, the Cancer Genome Atlas and the UK Biobank.

These applications raise additional questions concerning the standards to which AI systems are held and the procedures and techniques available to ensure those standards are being met.

DEVICE REGULATION

Both the European Union and the United States have their own criteria for identifying healthcare and AI devices; however, not all DL algorithms used in healthcare may be deemed to be medical devices. Indeed, the Food and Drug Administration (FDA) and the Inter-national Medical Device Regulators Forum (IMDRF) have recently recognized that AI technologies are distinct from traditional medical devices. The IMDRF is a voluntary group of medical device regulators including the European Union, United States, Canada, Australia, Brazil, China, Japan, Russia, Singapore and South Korea, working toward harmonizing international medical device regulation. The collaboration between the IMDRF and FDA has defined a new category called Software as Medical Device (SaMD) pointing out the need for an updated regulatory framework which takes into account the fact that AI systems have to face additional safety challenges in the forms of complex environments, or periods of learning (during which the system's behaviour may be unpredictable) which may result in significant

DIRECTIVE 93/42/EEC	MEDDEVS	MDR	IVDR
• Directive on medical devices • Will be replaced by MDR on 26 May 2021	• Non-binding guidelines on legislation related to medical devices	• Regulation on medical devices • Applies from 26 May 2021 • Repeals Directive 93/42/EEC1	• Regulation on in vitro diagnostic medical devices • Applies from 26 May 2022

Table Key:
MDR = Medical Device Regulation;
IVDR = In Vitro Diagnostic Medical Device Regulation;
EEC = European Economic Community

Table 1. Regulatory framework in the European Union on medical devices.

variation in the system's performance. Their guidance recommends a continuous iterative process based on real-world performance data and states that low-risk SaMD may not require independent review.

In the European Union, the regulatory framework is composed of the Medical Devices Regulation (MDR) and the new In Vitro Diagnostic Medical Device Regulation (IVDR) (see Table 1). Both came into force on 25 May 2017; however, the MDR will apply from 26 May 2021 while the IVDR will apply from 26 May 2022. These **updates to the regulatory framework** attempt to address the previous issues through an extended scope for a wider range of products, extended liability in relation to defective products, strengthening of requirements for clinical data and traceability of the devices, more rigorous monitoring of notified bodies, and improved transparency through making information relating to personal data used for developing and training AI algorithms.

As AI and data sharing become the norm, the notions of patient confidentiality and the cybersecurity measures will be increasingly important in the current healthcare systems, as cyber-attacks against hospitals, universities and research centres increase in frequency. Only the collaboration between patients, healthcare operators and decision makers will be able to prevent the risks of inappropriate use of sensitive datasets, inaccurate or inappropriate disclosures, and limitations in de-identification techniques.

OWNERSHIP AND CONTROL OF THE DATA

In the current scenario the worldwide healthcare organizations are the de-facto owners and **guardians of patient data** generated in the healthcare system, although informed consent from patients is formally required. In the last decade, however, the healthcare system has shown a slow movement from a hospital-centric data model to a more patient-centric data model that also includes integration of new information obtained from wearables, devices designed to collect the data of users' personal health and exercise. In addition, **the model of open data is increasingly being advocated** by governments, resulting in huge collections of data mostly available in the cloud and establishing sandbox environments to be used by anyone to train and validate their algorithms. There is a **risk of losing control** of the data and uploading health-related information to a variety of dispersed non-connected and non-standardized cloud solutions.

Therefore, healthcare operators and regulatory bodies are called to closely protect patients' health data, and the development of large patient datasets incorporating wide ranges of clinical, imaging data and pathologic information across multiple institutions for the development of AI algorithms will necessitate a thorough re-examination of issues surrounding patient privacy and informed consent. What type of data is considered personal for an individual patient or participant in a clinical trial, and who owns the data that is produced by an AI algorithm? Will **informed consent** be required only for patient data in the development of deeply annotated AI datasets? How will informed consent be addressed if a patient's data is used in assessing an algorithm in routine clinical practice, and then used to retrain the algorithm?

While there is a critical need to provide high-quality and geographically diverse data to developers for testing and training, patient privacy must be carefully maintained. In the European Union, regulators updated the legislation concerning data protection and cyber-security substituting the European legal framework for data protection as set out by Directive 95/46/EC with the General Data Protection Regulation (GDPR). Accordingly, all data processing and use should be opt-in, and consumer consent for data use should be clear, prohibiting the current data marketing based on third-party non opt-in personal data. GDPR is a more suitable instrument to regulate AI because it has an extended territorial scope and wider rights for data subjects. In the context of the 2020 COVID-19 crisis, the European Data Protection Board published an official statement in March stating explicitly that GDPR "[does] not hinder measures taken in the fight against the coronavirus pandemic", and that "even in these exceptional times, the data controller and processor must ensure the protection of the personal data of the data subjects".

THE NEED FOR PARTNERSHIPS

In conclusion, all the solutions proposed to the challenges posed by AI deployment require a multi-disciplinary team which includes AI developers, health providers, regulators, governments, patients/public and physicians.

Such a community needs to work together with a common, public aim of improving care and trust creating infrastructures that enable the responsible use of patients' health data to facilitate the development of AI tools that will improve population health.

—

Should this fail, data breaches and other data failures could set the industry back decades.

SKILLS AND EXPERTISE FOR AI-BASED MEDICINE

It can be confidently assumed that technological advances in AI technology and efforts to create the necessary cross-disciplinary partnerships will continue. However, how readily and efficiently these advances can be assimilated into the clinic is less clear, as shown in the study led by Dr Ahmad and Dr O'Carrigan (Chapter 4). To maximize the benefits of these technologies, the healthcare ecosystem, and in particular its workforce, must be prepared.

Healthcare professionals and allied health professionals across Europe will require a spectrum of key digital literacy skills to navigate the data-rich environment of a digital healthcare system supported by the AI revolution. The depth and breadth of such skills will vary according to each professional's level of engagement with modes of care transformed by AI, but there are themes common to all, as shown in Table 2.

The introduction of AI in itself has the potential to address some of the current **skill gaps and shortfalls,** in particular critical areas such as staff shortages. In the United Kingdom alone, there are currently 100,000 vacant posts (1 in 11 posts) across the NHS, including 10,000 doctors and 36,000 nurses.

The shortfall continues to worsen, with projections for a staffing shortfall of 250,000 by 2030. Central investment in education and training has fallen from 5% of health spending in 2006/7 to 3% in 2018/19. At the same time, the current workforce is ageing. Across Europe, the share of medical doctors over 55 rose from 27% to 38% from 2011 to 2016. The distribution of healthcare staff also varies across Europe. The number of physicians per 100,000 population is considerably higher in some member states (>480 in Greece, Austria and Portugal) than others (<300 in Ireland, the United Kingdom, Romania and Poland). The number of nurses also varies dramatically, with >1,000 nurses per 100,000 in some member states (Germany, Ireland, Luxembourg, Ireland, Sweden) but <450 in others (Bulgaria, Slovenia, Greece, Croatia, Romania).

The readiness of staff for interacting with AI solutions is also limited. Survey data from across all European Union member states from May 2018, including health facility staff, researchers, governmental health authorities and software developers identified perceived challenges to the adoption of AI solutions, with 13% of survey respondents citing a lack of trust from medical staff and 10% of survey respondents citing insufficient user knowledge.

TYPE OF SKILLS	MEDICAL STAFF	NURSING STAFF
Creation, innovation and research	Assessing diagnostic utility and validity of novel AI diagnostic solutions	Identifying where areas of unmet clinical need can be met by AI to foster innovation
Information, data and content	Curating the structure of data inputs (medical records, clinical notes) to substantially enhance the power of downstream algorithms	Providing guidance to colleagues on data integrity and the use, editing, storage and sharing of data
Teaching, learning and self-development	Using digital tools and technologies to support offline learning (classroom-based, work-based etc)	Using digital tools and technologies to support the education of patients and their carers
Communication, collaboration and participation	Discussing with patients and carers the capacity and limitations of predictive algorithms	Discussing with patients and their carers how to use and monitor novel AI devices (e.g. wearables)

Table 2. Examples of skills and expertise healthcare professionals will need to enable successful integration of new AI-based healthcare approaches (Adapted from Health Education England: A Health and Care Digital Capabilities Framework).

Number of vacant posts in the UK NHS

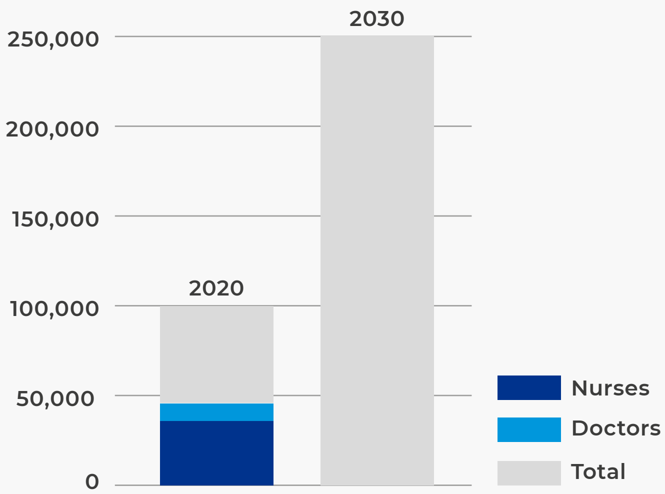


Figure 7. Vacant posts in the United Kingdom's NHS, both in 2020 and the projection for 2030. The 2020 figures include a breakdown in number of nurses, doctors, and other professionals

Physicians per 100,000 people

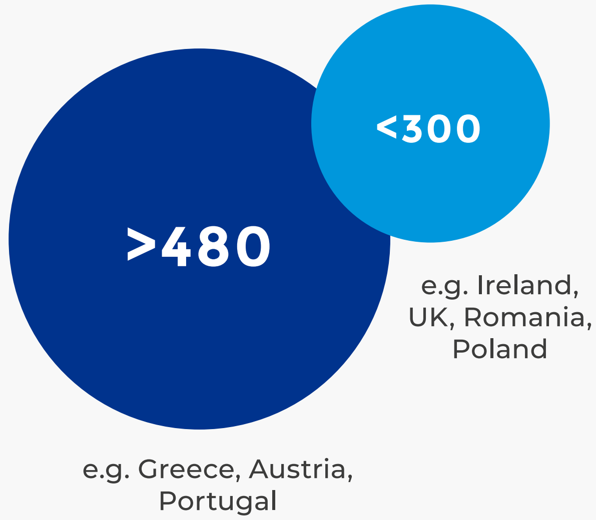


Figure 8. Example of the uneven distribution of healthcare staff across Europe, in terms of the number of physicians per 100,000 inhabitants

MAIN CHALLENGES

The European Commission published a communication in April 2018 focused on "enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society". These efforts are enabling in nature, with policy changes remaining the remit of national policymakers. Traditionally, within any national government organization, different bodies have existed in order to drive policy across finance, health, education and industry. However, all four of these sectors (and likely others) would play a key role in addressing the AI skills gap in healthcare and it is therefore vital that the corresponding bodies work together as seamlessly as possible. European countries are trying to address this issue through the creation of bodies such as the Office for Artificial Intelligence and NHSX in the UK, or the publication of national AI strategies in France or Germany. Although smaller economies will be able to dedicate less resource to these areas, it is notable that many of them are still developing an AI strategy, and, for example, in the case of Lithuania the role of AI in healthcare remains a key area for investment.

There are widespread concerns that, in the longer term, an increasing use of AI may lead to job losses across healthcare, and this may deter individuals from entering or staying within the health sector. However, studies suggest that the issue will be more complex.

In a recent Swiss survey, 79 % of radiologists stated that they chose radiology because of technologies such as AI.

This suggests that the types of people who will go on to choose careers in healthcare in general, and in particular areas with a strong AI focus, may be more engaged with technology adoption. This is likely to increase retention, make training more efficient and thus alleviate workforce issues.

AREA	CHALLENGES	PROPOSED SOLUTIONS
Culture	• Insufficient user knowledge • Lack of trust	• Assign learning time for staff • Develop multi-professional learning approaches
Educator Support	• Lack of clear vision on training for AI related skills • Lack of organizational details on learning AI-related skills	• Develop a leadership team to provide strategic overview • Foster leading educators of the future
Workforce development and education	• Lack of AI training programmes for current professionals	• Support staff to develop digital literacy • Re-design curricula related to professional, statutory and regulatory bodies
Special workforce and teams	• Need thousands of data scientists • Higher attractiveness of AI jobs in other industries	• Develop attractive career pathways for AI-linked specialist roles • Nurture collaborations with industry
Training the future workforce	• De-skilling • Need for continuous learning	• Ensure basic capabilities are always trained • Introduce AI training in of undergraduate curricula • Create joint degrees across health, engineering and computing

Table 3. Recommendations made in "The Topol Review" to develop an educational support framework for the healthcare workforce in the context of the digital and AI transformation

ADDRESSING THE SKILLS GAP

Commissioned by HEE and recently published, "The Topol Review" provides a wide range of broad and tangible insights and recommendations that are generalizable across national healthcare providers. Focusing on AI-readiness, three important themes appear to emerge: **leadership and organization, education and collaboration.**

It is recommended that leadership teams are developed at a national level and healthcare professionals should have strong representation within these to advise on opportunities and challenges. This is already taking place in countries around Europe, with Estonia's approach being a leading example. The Estonian e-Health Foundation Board is made up of multiple stakeholders including representatives from the Estonian Society of Family Doctors and Estonian Hospital Union. The board has been responsible for overseeing the country's e-Health initiative which is regarded as developing one of the leading integrated health information systems within Europe, which has been optimally designed in order to leverage AI-based technologies.

The approach to education must be broad and strategic (see Table 3), developing current and future healthcare professionals comfortable in cross-disciplinary environments. This needs to be linked with the development of **attractive career pathways** and higher specialist training for data scientists. This will need to be leveraged alongside genuine partnerships with industry. Significantly, survey data from 907 data scientists in the United Kingdom highlighted that 56 % of data scientists were considering seeking new roles within 12 months. Although a number of reasons were cited for general job dissatisfaction, over 50 % of managers cited that there was a great challenge in operating in siloed teams. This could potentially be addressed through a healthcare-based alliance and suggests that such collaborations may be attractive in improving job satisfaction for data scientists.

Addressing the skills gap will not be simple, and there is likely to be ongoing disruption to the workforce as AI assumes an increasing role within patient care. However, the potential value for patients and healthcare institutions as a whole is undeniable, and a proactive approach by policymakers with a specific focus addressing educational needs and enablement of multi-stakeholder collaboration will be critical for these benefits to be realized.

PATIENT AND PROFESSIONAL PERCEPTION

Ultimately, beyond the technological advancements, partnerships and technical skills, the success or failure of AI in playing a part in patient care, treatment or management will hinge on patient and professional acceptance of these technologies on a practical level. However, we still have a limited understanding of how these innovations may be perceived by the professionals and patients that will be using them to make important healthcare decisions. The study led by Dr Goldsworthy (Chapter 5) draws together the existing literature to bridge this gap, covering results from multiple surveys and interviews with clinicians across various disciplines, patient populations and the general public.

THE HEALTHCARE PROFESSIONALS' PERSPECTIVE

A recent survey of 791 psychiatrists representing 22 countries across the world, 47 % of which were European, found that 83 % of participants predicted that AI would replace human clinicians in tasks of documentation in the future. Most participants (83 %) believed that AI would not replace the key task of **providing empathy to patients** and 67 % believed that AI would not be able to undertake mental health examinations. Participants were also asked whether they believed the potential benefits outweighed possible risks. Within the European sample, 38 % believed the potential benefits did outweigh the potential risks.

—

Both patients and professionals agree that AI healthcare innovations should be fully integrated within healthcare systems and should complement healthcare professionals

—

A novel interview-based qualitative study of 40 health-care AI specialists in France found that there was a concern that AI innovations in healthcare might become "consumer goods" with little practical utility. This claim highlights the concern that private interests may overrun clinical utility in the development and deployment of AI innovations in the healthcare setting, the cost of which would be felt by the patients. In this study there was an overwhelming consensus that AI should not replace healthcare professionals making clinical decisions but would best serve as an aid in clinical decision making. Clearly, more research is needed on how particular professional communities within national healthcare systems perceive and respond to AI innovations.

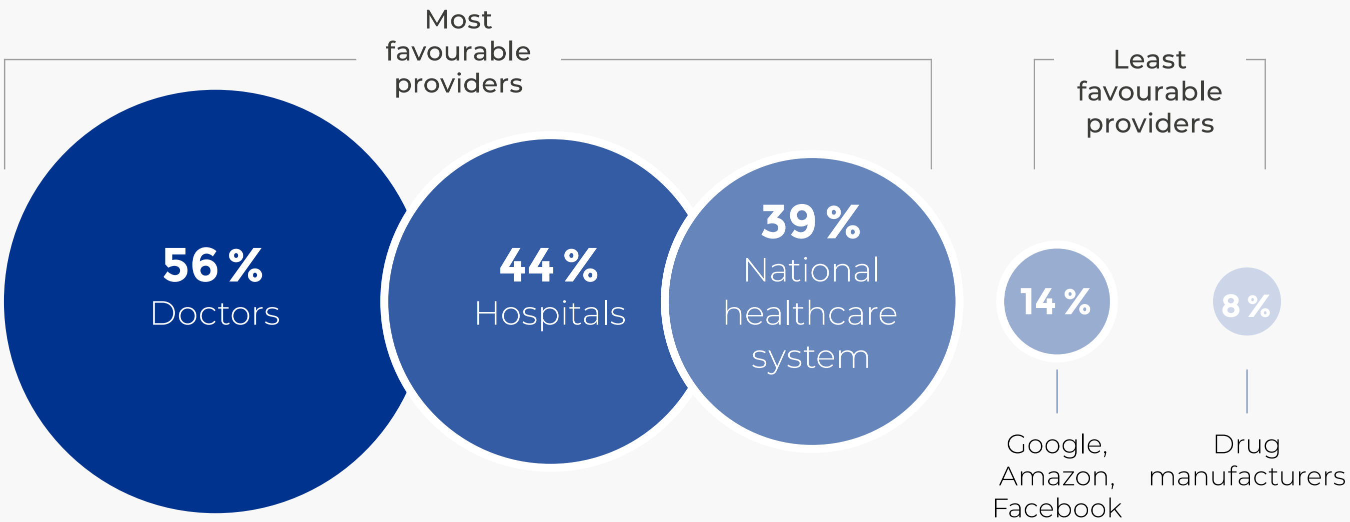


Figure 9. Most and least favourable providers of healthcare AI according to a study run by Syneos Health Care Communications (North Carolina, 2018)

THE PATIENTS' PERSPECTIVE

There is, similarly, insufficient research at the moment about patients' perception of AI in healthcare. While much of the existing literature draws on healthcare professionals, who infer what the interests of patients may be, there is little research representing patients' own views.

A commentary written by patients published in the *British Medicinal Journal* (BMJ) identified key concerns regarding some aspects of the integration of AI innovations within the healthcare context. The first concern relates to the consequences of over-hyped innovations that may be prematurely translated into the healthcare context in which patients may bear the brunt of unmet promises, and the cost of private interests.

Such a concern was also voiced by patients within a Syneos Health Care Communications study of patient perceptions of AI innovation in healthcare.

The most favourable providers of AI in healthcare were agreed by European participants to be doctors (56 %), the hospital (44 %), and the national health-care system (39 %), whereas the least 'trustworthy' providers were drug manufacturers (8 %) and technology companies, such as Google, Amazon and Facebook (14 %).

The BMJ commentary can be summarized with the concern that, while AI has the potential to become a powerful aid in healthcare, it will never replace humans during doctor-patient interactions because AI cannot care in the same way as a human can. Similar ideas were reflected in a large online survey of 12,000 participants across Europe, the Middle East and Africa run by PricewaterhouseCoopers (PwC). While they found that, across all countries in which the study was carried out, participants were more willing than unwilling to use an intelligent healthcare assistant via their mobile phones, tablets or personal computers, when specific scenarios of services were offered, there was no AI service that the majority of participants were willing to receive.

Although the PwC report may be misleading in its presentation of overwhelming public support for AI and robotics in healthcare, the study identifies an interesting set of issues worth further exploration. The data shows that participants were more willing to accept **less**

RISKS/BARRIERS	BENEFITS
• Technology will require an overhaul of the care system • Increasing risk of data misuse • Intruding in patients' lives • Risk of hacking • Reliability issues/risk of errors • Replacing the human in care is unwanted • Impairing patient-caregiver relationships/reducing patients' voice • Negatively impacting patients' health behaviours/false reassurance • May not be accessible to everyone	• Improving access to care • Improving the follow-up of patients • Reducing the burden of treatment/ improving patient responsibility • Improving caregivers' work/improving efficiency and increasing automation of repetitive tasks • Improving communication in care • Facilitating the prediction and prevention of health events • Lowering the risk of medical mistakes/ improved traceability of data • Economic and environmentally friendly • Accelerating research

Table 4. Summary of perceived risks and benefits of AI in healthcare by patients with chronic conditions (Adapted from Tran et al., 2019).

invasive healthcare AI for monitoring, and there was broad support for mobile intelligent healthcare assistants; there was also a clear positive perception for the role of AI in improving the efficiency of, and access to healthcare. However, it is quite clear that there is no support for scenarios in which AI or robotics replace healthcare professionals, and this support lessens as the invasiveness of the medical intervention increases. A similar picture was found in a study with 1183 French participants with chronic conditions published in BMJ Quality & Safety; a summary of the risks and benefits they perceive can be found in Table 4.

The clear message that emerges through the available studies in this subject is that both patients and professionals agree that AI healthcare innovations should be fully integrated within healthcare systems and should complement healthcare professionals, instead of replacing them. These considerations would overcome many of the key risks or fears associated with AI in healthcare as identified by patients, such as the risk of unchecked errors and the fear associated with the consequences of private industrial interests on personal healthcare choices. Moreover, these considerations would ensure that innovation in this field better represents the needs and preferences of their users, such as AI innovations that support administrative clinical tasks, improve the communication between patients and clinicians and increase patient autonomy within shared decision-making models or diagnosis, treatment and chronic condition management. Finally, it is important to recognize the position patients could take in the AI healthcare innovation pathway.

Patients across Europe have a strong sense of their preferences and needs in relation to AI healthcare innovations; integrating this perspective within the development and translation of AI healthcare innovations could circumvent many of the teething issues currently experienced by innovators.

—

THE INTEGRATION PATHWAY

As discussed at the beginning of this report, AI applications that directly affect the patient care pathway and patient-doctor communications have the potential to be particularly disruptive and therefore require special attention.

In addition to the challenges posed by privacy, data biases, data sharing infrastructure and the digital skills gap, there is one more key component for the successful clinical translation of these AI-based technologies: the **practical integration into the healthcare system.** The wrong approach would risk introducing unwanted biases or inequalities, and challenge the long-term sustainability of the system, both socially and financially. The rapid pace at which healthcare AI is developing means that decisions are being taken quickly and sometimes without direct precedents.

GPA at Hand Patient Demographics

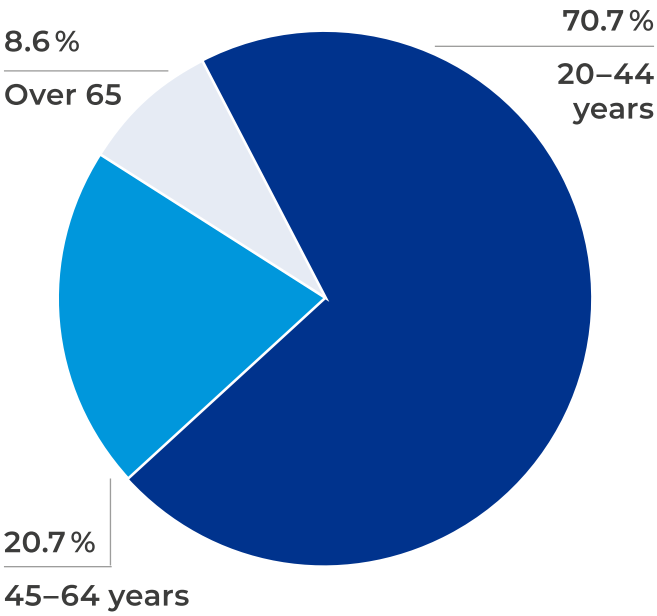


Figure 10. January 2020 demographics of GP at hand (NHS Digital Health England)

The study led by Sissons (Chapter 6) investigates the main challenges involved in the integration process by studying a recent, very closely related example of a disruptive digital healthcare technology: virtual primary care services (VPCs).

VPCs allow patients to consult with a doctor or nurse via email, text message, telephone or video. A majority of these services can be accessed through mobile or desktop technology. VPCs are a rapidly growing healthcare delivery model and are servicing an increasing number of patients. In Sweden, KRY has treated over 6,000 patients and Min Doktor has over 20,000 registered users, while in the United Kingdom, Babylon has 70,000 members enrolled in its service, and is continuing to grow.

VPCs can offer a number of advantages over in-person GP services. For patients these include decreased travel time and convenience, which in theory, can improve access to health services. This can be particularly important for rural patients or those with disabilities.

For health systems, VPCs may prove to be a cost-effective means of delivering services, with less overheads than traditional primary care practices. However, limited to no research has been done on the clinical outcomes, quality of care and cost efficacy of VPCs.

—

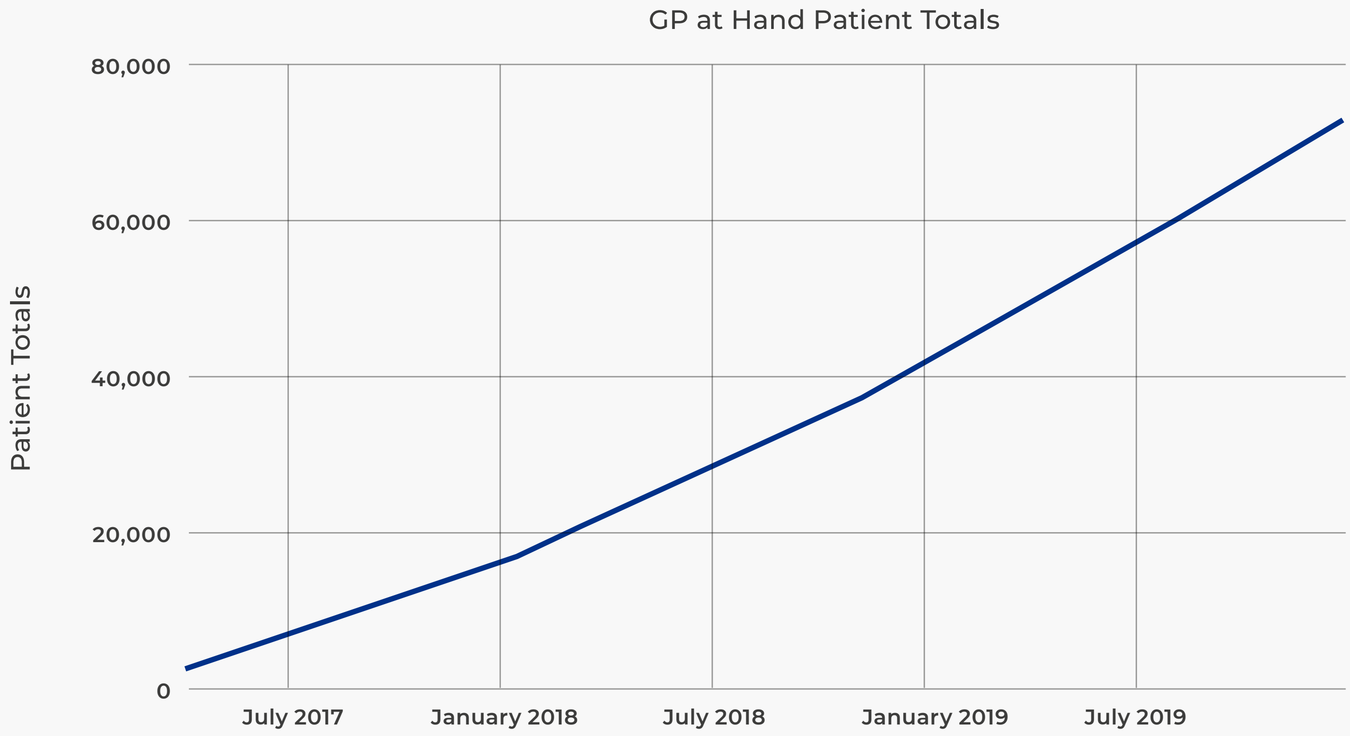


Figure 11. Total patients at VPC GP at hand (Babylon) (NHS digital health data)

At the heart of the issue is that, despite adoption of smartphone technology across demographics, VPCs tend to service specific populations. Recent data from England highlights that 53 % of VPC users are male, 71 % are between the ages of 20 and 44 years, and just 9 % of users are 65 years or older. Similar user demographics are seen in VPCs in Sweden and France, with the majority of VPC users being urban and young, and therefore, statistically, more likely to be healthy.

However, when combined with policy dictating that patients must de-register from their in-person GP to access virtual services, as seen in England, the unintended consequence of risk selection is that brick-and-mortar GPs are left with **increasingly complex patient lists.** The consequences of this can be manifold, including inadequate compensation, burnout and GPs leaving the workforce. In a period where many countries are facing a shortage of primary care providers this could have lasting effects for years to come.

The tendency for younger, healthier patients to opt for VPC services might threaten the financial sustainability of traditional GP practices in a capitated payment scheme. For example, the majority of GPs in England are contracted to provide services via the General Medical Services (GMS) contract. Under GMS, GPs receive a capitated fee—a base payment of £87.92 for each patient registered to them—with additions calculated according the Global Sum Formula, which takes into account sex, age, rurality, deprivation and turnover of patients. However, these formulas are far from perfect and do not capture the many variables of primary care. In England, GPs must cross-subsidize care to ensure adequate remuneration for caring for higher-needs patients with surpluses from those with lesser needs, and thus rely on diverse patient lists with a balance of both.

In addition, it remains to be seen if VPCs lead to cost-shifting in other health services. Indeed, Ipsos Mori (2019) found that despite being healthier than the general population, VPC "patients are historically higher users of NHS 111 and A&E than might be expected, given their age."

The best solution to ensure the benefits of VPCs are garnered for both patients and the health system, might be to create a unified system of physical and virtual primary care services, in which patients can access VPCs through their GP clinic, and the allocation

of funds reflects the actual contribution of providers towards improved health outcomes and population health. Success of this unified model has been seen in Canada which has a similar health system to the United Kingdom, where virtual visits are integrated into rural GP clinics and physicians are remunerated the same for a virtual visit or an in-person visit.

While VPCs are not necessarily AI driven, lessons can be learned from their integration and applied to new health technologies entering into the primary healthcare market. Government and private enterprise should aim to integrate new technologies in a slower and more controlled way with continuous monitoring and adjustment. This will prevent larger scale integration issues and allow for continued improvement. The necessity of a more flexible and adaptable model is outlined in the World Health Organization guidelines on harnessing digital technology to strengthen health systems. In a resource limited environment, careful consideration must be given to how technologies will be funded, and whether this funding will affect other areas of service.

For VPCs, it became clear that the current funding formulas were not made with digital health services in mind and require re-evaluation. This same consideration should be applied to all new health technologies and ensure payment models are adapted prior to integration.

The best solution to ensure the benefits of VPCs are garnered for both patients and the health system, might be to create a unified system of physical and virtual primary care services.

WHAT NEXT?

This report has shown that the integration of AI technologies in the European healthcare setting presents a series of unique challenges that will require large, collaborative and transparent efforts crossing boundaries of profession and geography. Although the technology is advancing quickly, issues of data sharing, privacy, biases, patients' experiences, training and integration need to be carefully and continually addressed.

The current all-encompassing COVID-19 crisis has shown that the field has much to offer, but the conditions experienced during the peak of the outbreak are extraordinary and cannot be generalized. This crisis has exposed some of the most pressing challenges affecting the way we do healthcare as a society: an aged, more susceptible population; the periodical over-burdening of hospitals during seasonal disease peaks; the ever-increasing numbers of chronic illnesses; and a more mobile, but more connected population. The COVID-19 experience has unquestionably highlighted the importance of having a technologically robust and sustainable healthcare system, and our response to this crisis will expedite the development of AI-based technologies. However, a global, comprehensive effort to tackle the challenges discussed here will be essential to turn such potential into long-term benefits for patients, doctors and the healthcare system as a whole.

*Emerging from the key results found in this report are **three ideas** that may guide the next steps of the work of European countries towards a robust integration of AI technologies in healthcare.*

DATA	SKILLS	PERCEPTION	INTEGRATION
✓ **Improve** explainability and transparency ✓ **Avoid** overfitting and biases ✓ **Protect** privacy ✓ **Assess** performance and evaluate clinical outcomes	✓ **Train and recruit** healthcare professionals with AI skills ✓ **Provide** attractive careers for data scientists ✓ **Provide** continuous learning	✓ **Understand** public perception of AI ✓ **Improve** communication ✓ **Include** patients in design process	✓ **Prevent** fragmentation and imbalances ✓ **Develop** adaptable funding strategies that integrate new technologies

Table 5. Key actions from the different specialized areas discussed in this report.

This is a global challenge that requires a concerted European effort.

FIRSTLY,

there is significant potential for AI to revolutionize the way we experience care. With the exception of personalized treatments based on genomic insights, so far most progress is being seen in improving or accelerating specific moments in care, such as the reading of scans or improving diagnostics. **If technology is to help us address the challenges of this century—increasing demand and co-morbidities from an ageing population—then it has to not just improve care but change how it is being delivered and experienced. It needs to change the pathways of care,** for example moving treatment out of hospital into the community or into people's homes. And for this much more collaboration is required across systems and sectors, in terms of data sharing, collaborative ways of working, and a willingness to leave behind decades-old traditions of how care is being delivered. **This perspective should shape the work of policymakers as well as innovators.**

SECONDLY,

the step change in technology in healthcare has so far not reached anywhere near the same level in social and personal care. However, the potential benefits here are no smaller than in healthcare: revolutionizing home care through digital care observations and records, connecting people to their families, upskilling carers to monitor health conditions with mobile aids, and sensor monitoring technology could genuinely make home the first place of care and even treatment. However, only if technology advances in both health *and* social care will we see the full benefits of integrating pathways across the two. This report has focused on the progress and challenges of healthcare AI; a similar exercise must also be done for social care.

FINALLY,

the exciting benefits of technology described in our report come with risks, ranging from difficulties in testing, potential bias, the explainability of solutions, and the perceived threat to professionals and the caring relationship they have with patients. Most importantly, unlike other technology sectors, healthcare does not allow us to "move fast and break things"—people's well-being and lives are not the right subject for agile iteration. But these risks cannot become a reason to not pursue technology's benefits. As discussed across the multiple studies included in this report, what is required is an open, mature conversation between policy makers, professionals, technology developers, patients and the general public about the benefits and risks of this exciting future. The conversation would need to acknowledge that things can go wrong and set out the best possible way to guard against and mitigate such harms, and to make sure we learn from them. **This is a global challenge that requires a concerted European effort.**

Team of Researchers

PROGRAMME DIRECTOR

Dr Mireia Crispin

RESEARCH COORDINATOR

Dr Marcos Gallego

ADVISORY TEAM

— Javier Ellena
— Dr Malte Gerhold
— Prof. Javier Lezaun
— Arantxa Unda

RESEARCHERS

— Dr Saif Ahmad
— Adam Berman
— Stevan Cirkovic
— Dr Christopher Goldsworthy
— Dina Halai
— Genevieve Jeffrey
— Dr Samantha Law
— Diogo Machado
— Dr Brent O'Carrigan
— Dr Filippo Pesapane
— Amanda Sissons

RECOMMENDED CITATION:

CGC, *Innovation, Sustainability and the Future of Healthcare.* Madrid: Center for the Governance of Change, IE University, 2020

CENTER FOR THE GOVERNANCE OF CHANGE

cgc.ie.edu