The EU Policy and Legislative Framework on Artificial Intelligence

Report

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The Authors

This report is part of our capacity building work on AI, as part of the 'AI Knowledge Hub' resource point. EPF aims to present complex technical content in an understandable and engaging way to equip the European patient community with the necessary know-how to shape and present the patient perspective on the new and increasingly important AI policy topics that are becoming an important field of policy discussions, both at European and national level.

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Executive summary

This report presents findings from research commissioned by the European Patients' Forum (EPF) to understand the current state of European policy and legislation as it pertains to artificial intelligence (AI) in healthcare. The research involved in-depth interviews with AI policy experts and deployment actors in healthcare, webinars with patient advocates organised by EPF, and a micro survey informing the interviews.

- Though experiments and small-scale pilots get a lot of media coverage, AI deployments in medical care remain rare. However, other uses that impact patients, such as medical research or checking citizens' eligibility for state benefits, are becoming more common.
- Europe lags behind China & the USA in AI development, investment and skills.
  - Some experts believe that existing strong regulation is slowing AI progress and thus harming Europe's ability to compete in international AI markets.
  - Other experts believe strong regulation ensures quality, protects rights, and positions Europe as a leader in 'human-centric', trustworthy, high-quality AI.
  - Current AI policy is shaped by the tension between the desire to accelerate progress and to ensure high quality AI which protects people.
- Recent EU AI policy proposals demonstrate the intention to compete in global AI on Europe's strengths, institutions, and size, rather than compete purely on development speed.
  - The AI Act represents a compromise; 'high-risk' AI applications have clear requirements and obligations, whereas 'low-risk' AI applications have much lighter burdens. Some high-profile uses like 'social scoring' for trustworthiness are banned.
  - The European Health Data Space seeks to align policy and infrastructure to enable data sharing and support AI applications to scale across the European market; making a strength of Europe's scale and diversity.
- Many AI bans seem to contain significant loopholes. Documentation such as the 'conformity assessment' required of 'high-risk' AI applications, are actually intended for internal use, not public

scrutiny. The onus is on campaigners to prove systems cause harm, and much language is open to interpretation, such as 'exploiting vulnerabilities.'

- The AI Act does not address healthcare as a general sector; instead it categorises all products and services which are already subject to the Medical Device Regulation (MDR) and the In Vitro Device Regulation (IVDR) as 'high-risk'. This fails to cover many systems which impact patients' experience, outcomes, and rights that are not purely medical.
- Aligning AI policy and infrastructure to realise the European Health Data Space will be long and politically and technically complex. The effects of the AI Act will depend on regulatory action in the future.
- The current situation leaves enormous scope for influence over the development and deployment of policy. A shortage of AI technical skills drives the public sector to seek expert support from external sources.
    - At the moment, much of this expertise is within the commercial sector, which risks embedding commercial interests in key decisions.
    - Despite the complexity and expense, it is vital that patients and patient advocates are closely involved in the whole AI development process.
- In order to develop necessary expertise and take positions of influence, patients and patient advocates will need to pool resources, build, and sustain relationships with regulators and policymakers, make effective use of a variety of policy levers, including GDPR, MDR, and IVDR, and deflect pressure for those tools to be weakened and protections loosened.

Introduction

Artificial intelligence (AI) in healthcare is increasingly transforming our present experiences of healthcare, and the ways we imagine healthcare's future. The transformation it is igniting is leading to new and complex policy questions: Can AI systems deliver efficiencies and cost savings for European healthcare systems coping with funding challenges, ageing populations, and shortages of qualified staff? How can regulatory systems and policy infrastructure protect patients' rights while supporting innovation and technological advancements? How can patients remain involved, and their interests be defended when issues require understanding of new and complicatedly interconnected technical systems, business models, medical practices, and research methods?

Commercial interests and state actors that do not centre patient interests have much to gain from the advance of AI in healthcare. Large tech companies including Google and IBM have invested billions of dollars into AI health products, with the expectation that enormous profits are to follow. There are serious concerns about the impact on patients now and in the future. Some products are extremely expensive but produce low-quality results: IBM Watson for Cancer, marketed around the world as a revolution in oncology, was found to be recommending "unsafe and incorrect"[1] treatments with developers who had called it "the future of knowing" finding themselves "frustrated by the complexity, messiness and gaps in the genetic data."[2] As discussed in the case study *Developing AI to Detect Kidney Injury in the UK* (see page 44 of this report), data has been inappropriately collected by AI companies in order to train their systems. Over the long term, there are concerns about private companies embedding "their own interests and agendas"[3] in public health systems through public-private partnerships, investments, and selling products both to healthcare systems, and directly to patients and consumers.

The COVID-19 pandemic rushed many of these complex questions to the forefront of policy debates. AI solutions were deployed rapidly and often used patient health data. Some of these solutions appeared to offer valuable benefits to patients and health systems, such as improving diagnostics[4] and accelerating gene sequencing[5]. These efforts to rapidly deploy AI led some stakeholders to dub data

protection regulations as 'highly problematic'[6] because they slowed down this valuable progress, and to call for them to be loosened. At the same time, human rights advocates have raised concerns that AI used to tackle the pandemic has enabled surveillance, inequality and human right abuses both globally[7] and within the EU.[8]

The same data and AI technology that can be used to track infections and so improve public health can also be used to surveil marginalised populations or political protesters; it can be used to identify people with stigmatised health conditions, can judge (potentially inaccurately) whether they are eligible for life-saving treatments or vital state benefits. When commercial interests have access to this data, they could invest in innovations that improve patient experience and outcomes – or they could profit unreasonably, make treatments expensive and inaccessible, provide unequal or unfair services, or produce low-quality products which fail to deliver promised improvements.

This report presents findings from research commissioned by the European Patients' Forum to understand the current state of European policy and legislation as it pertains to AI. Alongside policy analysis, the research involved in-depth interviews with AI policy experts and deployment actors in healthcare. It also involved two webinars with patient advocates, organised by EPF, and a micro survey informing topics discussed in the interviews.

As reported in more depth in this report's partner document focused on patients' experience, our research confirmed that many patients and advocates are hopeful about the future of AI but that they do not trust that policymakers are well-informed about the technology and its consequences and believe that some uses of AI could lead to bias and injustice.[9]

Developing legislation and policy that patients trust will require policymakers with a fundamental level of knowledge and information about AI. Policymakers will also need to navigate the patient interests, experiences, and expectations regarding AI in healthcare that vary enormously according to factors such as disease and are continuously changing as the technology itself evolves.

Legislating and regulating AI is complicated further by the interlocking political, economic, and digital infrastructures that make up the European Union (EU), European Economic Area (EEA), and United Kingdom (UK). Legal scholars have commented that while "Overseeing and enforcing EU law is always complex… the scheme devised for artificial intelligence is particularly baroque."[10] This lack of clarity is reflected in the findings of a survey of patients' perceptions of AI in healthcare conducted by EPF in 2020. When asked 'who regulates AI in Europe'? almost a third of survey respondents chose 'there is no active regulator in Europe' and 22% answered 'a combination of the EU, member states and industry.' Each of these groups is both wrong and right; currently there is very little direct, explicit regulation of AI. The new EU AI Act is expected to be adopted and come into force in late 2022 or early 2023, after which a period of transition period of perhaps up to two years will be needed before it becomes applicable. At the same time, a combination of the EU, member states and industry all implement regulations that affect AI, mostly indirectly, by affecting how data can be collected, stored and processed.

The health policy landscape adds a further dimension of complexity for regulating and developing policies for AI. While some facets of healthcare – most notably medical devices – are regulated under EU legislation, the provision of health and social care is the responsibility of member states, and there is enormous variety in how it is organised, funded, and regulated across countries. These factors contribute to very different environments, barriers, and incentives for AI development, and thus, different markets and practices. These differences contribute to patients and advocates in different geographic regions expressing different hopes, concerns, and policy priorities regarding AI.

This report does not claim to cover all contexts within which AI policy is developing and impacting patients, health institutions and health systems. Instead, it offers an introductory view of the policy context and policies related to AI in healthcare in the EU, EEA and UK and shines a light on the diverse experiences and issues arising in four select countries and case studies.

AI PRIMER

Advocating on AI European policy on behalf of patients and patient advocates requires understanding how AI systems are developed and implemented as well as the economic, social and scientific contexts within which these systems are built and used. This section serves as a brief AI primer as context for this report.

Artificial intelligence refers to any system which can process information about its environment and make decisions or take actions to achieve specific goals. Within healthcare, researchers often provide systems with enormous amounts of data and test the capacity of AI to achieve specific goals. As examples, they might ask AI to:

- Answer a question: *Given thousands of records from patients admitted to and discharged from hospital, which demographic features (e.g., age, sex, socioeconomic status) predict whether a person will be readmitted to hospital within 30 days?*
- Label images based on prefixed labels: *Given thousands of images of chest x-rays labelled by human radiographers as cancerous or non-cancerous, can the AI predict the likelihood that a new image is cancerous?*
- Cluster information into related topics, or to identify similarities and connections across information: *Given thousands of scientific papers about medicines, and databases of protein structures, what medicines could be repurposed to treat a rare condition that has similarities to other, treatable common conditions?*

AI can learn from and respond to information. This means AI products interact with and change the systems by which humans collect and use information. The quality of the result that AI delivers relies on many technical, practical and political decisions made by humans, such as:

- What data should be collected and who should that data represent?
- How should organisations be convinced to make data available?

- What kinds of data should be prioritised?
- How can the data be held and shared safely?
- If data is labelled, how should it be labelled?
- Which data should be offered to the AI?
- How should an AI's goal be designed?
- What kinds of decisions or recommended actions by AI are acceptable or useful? How should these recommended actions be used?
- How should people be trained to understand and use AI products?

The ways we might answer these questions are intrinsically linked to policy decisions.

USE OF AI IN HEALTHCARE AT PRESENT

Despite the frequent reference to AI in healthcare in the media, the number of patients directly affected by AI systems remains low. Many systems are in development, and more are being used in the back-office functions of public services including healthcare, but very few AI systems are being used in direct patient care. Two key reasons for this discrepancy are regulatory complexity, which new policy solutions seek to streamline, and the fact that it is difficult to replicate the headline-grabbing performance of AI systems in research settings in the complex, busy setting of real-world healthcare.

As an example, AI is extremely well developed in image recognition, with demonstrations of AI detecting cancer in scans "better than human doctors."[11] But these results do not necessarily translate into improved experiences for patients, as explained below.

The idea that AI will replace radiologists and that algorithms will diagnose faster than humans, hits the news frequently. But developers describe complex interactions post-deployment that can lead to unexpected outcomes and poor results that could impact patient care negatively.

"When we collect data from Stanford Hospital, then we train and test on data from the same hospital, indeed, we can publish papers showing [the algorithms] are comparable to human radiologists in spotting certain conditions. It turns out [that when] you take that same model, that same AI system, to an older hospital down the street, with an older machine, and the technician uses a slightly different imaging protocol, that data drifts to cause the performance of AI systems to degrade significantly."

- Andrew Ng quoted in *AI Promised to Revolutionize Radiology But So Far It's Failing*[12]

Some systems have successfully been introduced to hospital settings, such as Aidance[13], which monitors the growth of lung nodules in chest scans; the product's documentation stresses seamless integration into human workflow, and its role as a 'second'[14] reader; a support for human decisions, not a replacement.

More often, at present, AI impacts patients indirectly; it may be used as part of analysis that impacts resource allocation by modelling population growth or predicting the incidence of different illnesses over time. It is also used in research, both in the modelling and analytics of large datasets within specific research projects, and in even more indirect ways such as determining how funding is allocated or determining how publishers rank and recommend scientific papers.

AI is also present in patients' lives in ways indirectly related to their health. For instance, many patients will turn to the internet to search for health information; the results of their searches are determined by AI systems. Public services not directly linked to health have been quicker to take up AI as part of decisions; as discussed in our case study *Identifying Fraudulent Child Benefits Claims in the Netherlands* (see page 41 of the report). Because patients and their families are more likely than those without medical needs to access state benefits, these uses impact them and their rights.

THE EUROPEAN SKILLS AND INVESTMENT SHORTAGE

The AI field is characterised by high investment and substantial skills shortage, leading to intense competition for skilled developers. The impact on patients and the future of AI in healthcare is significant: countries, populations and organisations that cannot access the necessary skills and expertise will struggle to develop AI systems, to understand AI systems that affect them, and to be meaningfully involved in the development of relevant infrastructure and policy.

Analysis of the AI skills gap shows that the EU27 lags behind the UK, which in turn lags behind the US and China in its number of computer science and AI graduates, and in its capacity to attract graduates.[15] Competition to attract people with AI skills is high, with organisations offering candidates high salaries and media-friendly, interesting projects. This in turn makes it harder to attract skilled people to roles in policymaking bodies, regulatory bodies, or to organisations that represent and support patients.

The European AI policy context

This section offers a brief overview of the factors influencing policy relating to AI in healthcare in the EU, EEA and UK. While not exhaustive, it hopes to provide patient advocates and stakeholders with information about the motivations of the many stakeholders in AI policy, some understanding of the context within which these policies are being designed, developed, and implemented, and thus support effective advocacy.

European AI policy is heavily influenced by a desire to compete effectively in the global AI race and the potential for AI to address practical challenges of European healthcare systems such as staffing and funding crises. This creates a complex and shifting landscape, in which policies can be designed as value statements while their implementations are, in practice, serving different objectives.

COMPETING IN THE GLOBAL AI RACE

Many stakeholders are concerned that the EU AI development lags behind that of America and China, and that this will negatively impact economic growth, national security, labour markets, and overall competitiveness. Using 2020 data, the Information Technology and Innovation Foundation analysed AI development drawing on over 30 metrics including human talent, research activity and investment. The USA scored 44.6 points, China 32 and the EU 23.3.[16] The risk of 'losing the AI race' to the US or Asia is frequently referenced in popular media, such as in the 2018 book '*AI Superpowers: China, Silicon Valley, and the New World Order*', or in 2019 research on the distribution of AI patents,[17] which resulted in headlines like 'Europe is losing the AI race.'[18]

Rather than compete with the US and China directly through scale of investment, the EU has focused its ambition on becoming 'the global hub for trustworthy Artificial Intelligence (AI).'[19] This will be a model of 'human-centric' AI that 'works for people and protects fundamental rights.' It intends to draw on the strength of EU institutions and infrastructure to support high-quality AI development and competitive products that extend the EU's influence over the development of AI internationally.[20]

The simple narrative of an 'AI race', creates a pressure to accelerate development in order to 'get ahead', and so best suits those who might benefit from lighter regulation. This could be commercial actors who are concerned that regulations lead to higher costs, large consulting firms that want to open markets to their AI consulting offers, or state actors who wish to attract attention and investment through flashy applications of AI.

But the simple model of a 'race' does not account for the complexity of the AI tools or of the society within which those tools will be used. Racing to 'beat' others in this 'race' by rapidly implementing AI services increases the risk that those services will be of poor quality, built on unreliable infrastructure and untrustworthy data sources, without the staff, skills, and culture to maintain and use them well.

One tool that attracted many headlines and was implemented around the world, but was later found to deliver "unsafe and incorrect" medical advice, was IBM's Watson for Cancer, discussed earlier. Such tools can also perpetuate injustice, as discussed in our case study *Identifying Fraudulent Child Benefits Claims in the Netherlands* (see page 41 of this report).

For organisations seeking to influence AI policy and practice, it is important to understand the tensions between the EU's stated goal of strongly regulated, human-centric AI, and the pressure to loosen regulations. This pressure arises from a narrative that strong regulations "slow" or "choke" AI development and thus lead to Europe falling yet further behind in the AI race.[21, 22] The tension between regulation supporting strong rights versus AI development is already evident in discussions on the future of the EU General Data Protection Regulation (GDPR).

"There were discussions recently to loosen up GDPR when it concerns health AI.[23] GDPR is a really strong patients' rights instrument; protecting confidentiality and making it clear what you can and cannot do. It's only been here a few years and they want to loosen it up already. That often happens; there is a pressure to be the leader in economic field or a new technology and rights are in the way, so someone suggests 'let's just open it up a little.'"

- Hannah van Kolfschooten, Researcher and Lecturer in EU Health Rights Law

The narrative of an AI 'race' often contains reference to international relations; to national security issues of intelligence and weaponry, trade imbalances due to superior AI products, 'brain drain' to areas with more advanced research.

CAN AI HELP EUROPEAN HEALTHCARE SYSTEMS TACKLE THEIR CHALLENGES?

European healthcare systems are facing a number of practical challenges, such as a staffing and funding, which are influencing how AI policy is interpreted and implemented. Both of these challenges are expected to worsen as the continent's population gets older. Staffing shortages were a concern long before COVID-19: in 2010, the European Health Forum Gastein predicted a shortfall of 2 million staff by 2020,[24] a grim target that the EU Public Service Union claimed in 2022 had been exceeded.[25] This shortfall is predicted to continue to grow, reaching 4.2 million by 2030.[26]

Both state and private actors have hope that AI can help tackle these complex policy challenges. One joint report from McKinsey and the European Institute of Innovation and Technology's health network concluded that AI "can increase productivity and the efficiency of care delivery and allow healthcare systems to provide more and better care to more people" and could "help improve the experience of healthcare practitioners, enabling them to spend more time in direct patient care and reducing burnout."[27]

This challenge is also of interest to patients and advocates. In the EPF 2020 survey of 77 patients and patient advocates, 48% indicated interest in supporting healthcare professionals in providing personalised care and 33% indicated interest in supporting healthcare system efficiency. When asked to select three options from a list of possible possibilities for AI that they felt were the most interesting and positive, 48% chose 'support healthcare professionals in delivering more personalised care to patients', and 33% chose 'support health system efficiency and improve organisation and delivery of care.' However, there were concerns about AI being used to replace humans, rather than support them. When asked what their concerns were, the most common answer, at 55% was 'Less human interactions with healthcare professionals.'

Stakeholders can be attracted by the benefits of AI funding opportunities. Corporate investment in AI systems in health continues to grow; by some estimates "from USD 6.9 billion in 2021 to USD 67.4 billion by 2027."[28] This investment is attractive to state healthcare systems and institutions facing funding challenges. Private investment in health AI also promises highly paid, skilled jobs. Corporate investment and partnerships can support AI-ready infrastructure, such as high-quality accessible digital health records, and lead to greater investment in the future.

All these factors contribute to a complex European policy landscape of hopes, concerns, opportunities, and challenges, within which it is too easy for the needs, interests, and rights of patients themselves to be overlooked. Understanding the narratives, and the possible motivations behind different stakeholders' actions, including patients, may help advocates strategise and adapt accordingly.

European AI policy timeline

An in-depth analysis of relevant AI policy up to 2020 can be found in EPF's 2020 policy briefing *Big Data and Artificial Intelligence.*[29] Here we present a timeline of policy related to AI as context for shaping arguments and a starting point for gathering further information.

2017 MEDICAL DEVICE REGULATION (MDR)

Under the EU AI Act, AI applications which fall under the Medical Device Regulation are automatically categorised as 'high-risk.' In the MDR, medical devices are defined as "products or equipment intended for a medical purpose" with products or equipment including "any instrument, apparatus, appliance, software, implant." Medical purposes include diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.[30] EU medical device legislation has been evolving and consolidating for over twenty years. The 2017 Medical Device Regulation is the most recent major iteration and was applied on 26 May 2021 after a four-year transition period. [31]

Unlike medicines, medical devices are not regulated centrally at EU level, but they are required to undergo a 'conformity assessment' by Notified Bodies – third-party bodies accredited by the European authorities to audit medical device companies and products – to demonstrate they meet legal requirements. The process is regulated by member states, and once successful, devices can apply a CE (Conformité Européenne) mark and be marketed across the EU.

2017 IN VITRO DIAGNOSTIC MEDICAL DEVICES REGULATION (IVDR)

Similarly, to MDR, IVDR[32] does not explicitly mention AI, but because all products which fall under the IVDR's definition of *in vitro* devices will be classified as high-risk, it is pertinent to understanding how the AI Act could shape the development of AI technology. *In vitro* devices are defined as the 'subset of medical devices primarily used for to testing human fluids such as blood, tissue or urine in a test tube.' Under IVDR, devices are classified into classes A, B, C and D, with D being the highest risk. Devices of all classes require implementing a quality management system. While the lowest risk class, A, can self-certify, devices of class B, C and D must have their technical documentation audited

by a Notified Body. This legislation became applicable on 26 May 2022 with a progressive roll-out for some requirements of certain medical devices.

2018 GENERAL DATA PROTECTION REGULATION (GDPR)

The 2018 General Data Protection Regulation (GDPR) regulates how data is collected, stored and used, which in turn impacts the data that is available for AI systems to train and make decisions on. It also gave EU citizens the right to object solely automated decisions, and to 'meaningful information' about automated systems which impacted them significantly. The impact of this critical piece of legislation on healthcare specifically is detailed in more depth in the 'key legislation' section of this report.

APRIL 2018 'DECLARATION OF COOPERATION ON AI'

In this relatively short declaration, member states made commitments to coordinate on:

- Boosting Europe's technology and industrial capacity and uptake of AI, including better access to public sector data
- Addressing socio-economic challenges, such as the transformation of labour markets and modernising Europe's education and training systems, including upskilling & reskilling EU citizens;
- Ensuring an adequate legal and ethical framework, building on EU fundamental rights and values, including privacy and protection of personal data, as well as principles such as transparency and accountability.

Critically, they also promised to review and update national policies in order to better 'work towards a comprehensive and integrated European approach on AI to increase the EU's competitiveness, attractiveness and excellence in R&D in AI. This emphasis on coordination of policy and the interconnected goals of pursuing quality, 'boosting' speed and protecting rights set the tone for future policy development.[33]

APRIL 2018 COMMUNICATION ON ENABLING THE DIGITAL TRANSFORMATION OF HEALTH AND CARE IN THE DIGITAL SINGLE MARKET

The 2018 European Commission communication[34] highlighted key common challenges facing health systems across Europe including ageing populations, growing prevalence of multi-morbidity and non-communicable diseases, workforce shortages and rising costs. It stresses the need for shared infrastructure projects to overcome these challenges, to enable "continuity of care across borders" and to advance research. While AI is not mentioned in the document, the infrastructure projects it proposes, which would later be developed further into the European Health Data Space, would support sharing, pooling, and repurposing of data in a manner that supports AI research.

APRIL 2018 ARTIFICIAL INTELLIGENCE FOR EUROPE

This Commission communication[35] outlined a European strategy for AI, focused on improving Europe's technology and industrial capacity, preparing for socioeconomic changes, and ensuring strong, appropriate regulation. It stressed the positives of AI and highlights examples of AI in health, including its possible application in "treating chronic diseases" and begins with a real use case: "AI is helping save lives by allowing emergency services to diagnose cardiac arrests or other conditions based on the sound of a caller's voice."

To make the most of these positives, and guard against potential negatives, it encourages a coordinated approach, setting out an aim to attract €20 billion of public and private investment by 2020 and to share (referred to as 'unlock') data to make it more accessible to AI. It also launched a High-Level Expert Group on Artificial Intelligence (AI HLEG) which would go on to publish its *Ethics guidelines for Trustworthy Artificial Intelligence* in 2019.[36]

DECEMBER 2018 COORDINATED PLAN ON AI

The Commission published a coordinated plan[37] in 2018 that built on preceding communications and proposes joint actions across four priorities: "increasing investment, making more data available, fostering talent and ensuring trust". It set out concrete plans for joint AI efforts across

sectors, promised funding for AI through Horizon 2020, and encouraged states to develop their own AI strategies.

FEBRUARY 2020 WHITE PAPER ON ARTIFICIAL INTELLIGENCE

This paper follows on from the Commission's priorities for 2019-2024 to build an excellent, trustworthy AI by "combining] its technological and industrial strengths with a high-quality digital infrastructure and a regulatory framework based on its fundamental values." To achieve this, it set out plans for creating an 'ecosystem of excellence' to steer and accelerate AI development and an 'ecosystem of trust' to ensure quality, confidence, and respect for fundamental rights. Referencing the European data strategy[38] and European industrial strategy,[39] it also nodded to AI's contribution to European economic growth goals.

APRIL 2021 REVIEW OF THE COORDINATED PLAN ON AI

This review summarises progress of the 2018 coordinated plan and sets out future actions. It celebrates that "most member states have adopted national AI strategies and started to implement them; investments in AI have increased and the EU was able to mobilise a critical resources pool to support those processes," but stresses the need to 'accelerate, act, and align' to make an 'EU global leadership on trustworthy AI.'[40] Future objectives are to:

- Accelerate investments in AI technologies to drive resilient economic and social recovery facilitated by the uptake of new digital solutions.
- Act on AI strategies and programmes by implementing them fully and in a timely manner to ensure that the EU reaps the full benefits of first-mover adopter advantages.
- Align AI policy to remove fragmentation and address global challenges.

APRIL 2021 THE EU AI ACT

The proposal for an EU law on artificial intelligence, or 'AI Act' emerges from proposals in the 2020 White Paper on Artificial Intelligence for a coordinated European regulatory framework. It seeks to enshrine in EU law a technology-neutral definition of AI systems and to categorise them into unacceptable, high-, limited- and low-risk applications. Each category of applications will be subject

to different rules. While healthcare as a sector is not mentioned, AI systems which fall under MDR and the IVDR are automatically categorised as high-risk.

In November 2021 a progress report (draft compromise) detailed the Council of the EU's discussions of the proposal to date. Suggested changes included the exclusion of significant areas from the regulation's scope, such as military uses and scientific research, and the addition of AI systems that "control emissions and pollution" to the list of high-risk applications. Notably, it did not add general healthcare uses, or address concerns regarding duplication and discrepancies between the MDR and AI Act. The AI Act is expected to face a final vote in November 2022 and come into force in late 2022 or in 2023.

NOVEMBER 2021 ARTIFICIAL INTELLIGENCE IN HEALTHCARE REPORT AND COUNTRY FACTSHEETS

This report commissioned by the European Commission[41] outlines the development, adoption and use of AI technologies and applications in the healthcare sector across member states. It identifies potential barriers to AI adoption to support EU policymakers in overcoming them.

For instance, the report found that while most member states with national AI strategies identified healthcare as a priority area, "there are no policies within those strategies targeting healthcare in particular." There are, however, policies relating to the management of healthcare data, which will be critical to the development of AI.

Furthermore, across the EU, adoption of AI was found to be hindered by a lack of trust and "issues around the integration of new technologies into current practices." Member states need funding and support to turn research into intellectual property and translation into practice.

The report proposes six future areas of work to overcome these barriers, including:

1. policy and legal framework supporting the further development and adoption of AI aimed at the healthcare sector in particular;
2. initiatives supporting further investment in the area;
3. actions and initiatives that will enable the access, use and exchange of healthcare data with a view to using AI;

4. initiatives to upskill healthcare professionals and to educate AI developers on current clinical practices and needs;
5. actions addressing culture issues and building trust in the use of AI in the healthcare sector;
6. policies supporting the translation of research into clinical practice.

The report also contains detailed country factsheets covering legislation and policy frameworks, start-up ecosystems, public awareness of AI, as well as comparable data on number of published scientific papers and of patents and statistics on research collaborations.

2022 THE EUROPEAN HEALTH DATA SPACE (EHDS)

On 3 May 2022, the European Commission put forward a legislative proposal for a European Health Data Space (EHDS). This initiative aims to provide a common framework across Member States for the sharing and exchange of health data to support healthcare delivery (primary use) and facilitate health research policymaking, and legislation (secondary use). It follows the principles in Commission President Ursula von der Leyen's mission letter to Health Commissioner Stella Kyriakides, asking that she create a space to "promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes." It is envisioned as an early part of the process to build a "European Health Union".

According to the Commission, the European Health Data Space will:

- promote safe exchange of patients' data (including when they travel abroad) and citizens' control over their health data;
- support research on treatments, medicines, medical devices and outcomes;
- encourage the access to and use of health data for research, policymaking and regulation, with a trusted governance framework and upholding data-protection rules;
- support digital health services.

The proposal foresees that minimum categories of health data will be integrated into the EHDS, such as patient summaries, electronic prescriptions and laboratory results. Patients will have the right to add data, to object to the processing of health data, to request rectification of data as well as the

right to obtain information on the healthcare professionals and providers who have accessed the electronic health data.

In addition, the draft regulation contains provisions on the interoperability of certain health-related datasets and further outlines specific requirements for the Electronic Health Record systems, the software used to store and share health records. Cross-border infrastructures will also be reinforced to support and facilitate electronic health data exchange between Member States.

Some shared services are already being rolled out, including ePrescription (and eDispensation) which allows EU patients to pick up prescriptions in EU countries other than their country of residence, and Digital Patient Summary exchange, which provides doctors with a patient's essential health information.

The EHDS also aims to facilitate the reuse of health data for research, innovation, policymaking and regulatory purposes by defining a set of data types that can be reused for defined purposes. Regarding AI, health data can be reused to train, test and evaluate algorithms to contribute to public health or social security or ensure high levels of quality and safety of health care, medicinal products or medical devices.

Key Legislation Relevant to AI

GDPR

GDPR regulates data protection and privacy in the European Union (EU) and the European Economic Area (EEA). It remains the most impactful legislation regarding access to health data, and patients' rights regarding automated decisions, and is therefore one of the most powerful tools for advocates working in AI.

AI requires large amounts of data. Personal data is regulated under GDPR and is defined as information that relates to an *identifiable* individual over time. Because of improvements in technologies that enable individuals to be re-identified from anonymised data, increasing amounts of data that was once considered anonymised or pseudonymised are considered 'personal data' and thus fall under the purview of GDPR.

Article 6 of GDPR (and UK-GDPR) outlines six lawful bases for processing personal data, the most relevant of which for training data in AI health and health research are consent and public interest.[42]

AI applications often require large amounts of data to be trained and for their accuracy to be tested, so it is rarely cost effective to collect data for the sole purpose of training AIs. Instead, training is often a *secondary use* of data collected for other purposes.

GDPR requires that member states obtain meaningful consent from data subjects, but what this means differs between states. Article 9(4) explicitly provides that with regard to the processing of genetic, biometric or health data, member states may maintain or introduce further conditions, including limitations. This may mean that in health the GDPR will not be applied in the same manner in each member state.

Differences are also significant regarding the secondary use of health data which is used under the legal basis of 'public interest' because public interest is defined very differently across member states. A key concern for AI in health in the EU is that several portions of GDPR relevant to health data grant member states significant leeway in interpretation and implementation, and some countries use different definitions of consent. As noted in the 2020 *Guidelines on the processing of*

data concerning health or the purpose of scientific research in the context of the COVID-19 outbreak, the conditions and the extent for such processing vary depending on the enacted laws of the particular member state.[43]

Aside from legislative issues, the technological infrastructure, governance structures, availability of skills and resources necessary for effective and compliant secondary use vary significantly. Aligning EU and member state legislation, technological infrastructures and governance structures in such a way as to effectively permit secondary use of health data for AI training while upholding GDPR is a complex topic, addressed at length in the Open Data Institute's 2021 report Secondary use of health data in Europe.[44]

In addition to drawing on existing secondary data, AI systems can also request explicit consent for secondary use of personal data from users of AI applications and ultimately generate new datasets. AI applications which collect health data as part of their functioning – such as private services like the American *23andMe*, product ecosystems such as the French *Withings*, or diet & fitness apps like the Austrian *Runtastic* – can request or require users to consent to secondary uses of their data. Whilst collecting the data and consent requires significant initial investment, the value of these datasets and the AI systems trained on them can be enormous – so much so that offering the initial products for free or at a loss can make financial sense.

GDPR AND AI DEPLOYMENT

GDPR continues to provide protections once AI is deployed and used in the real world.

Firstly, human data subjects have the right to object to a "decision based solely on automated processing, including profiling" which "legally or otherwise significantly" affects them. Secondly, they have the right to "meaningful information" about "the logic involved" in automated decisions. For example, this might mean a significant medical decision, or a decision about eligibility for a treatment or benefit. Patients can, for example, ask for information about why AI flagged them as at risk of kidney injury, or why they were found ineligible for an expensive medication. Both rights have influenced the development and implementation of AI in the EU, but the specific wording in both cases has faced scrutiny.

For instance, the right to object to a "decision based *solely* on automated processing" has prompted those implementing AI to find ways to keep humans 'in the loop' of a decision so that the decision is not 'solely' automated, and thus cannot be objected to. But having a human 'in the loop' does not necessarily mean that human has the opportunity or the right to refuse or reverse an automated decision. They might face pressure to accept the AI's decision, they might be overworked or poorly trained, as we will show later in this report.

The right to "meaningful information" is often described as a 'right to explanation', but the complexity of cutting-edge AI systems is such that "meaningful information" is hard to define.

Scholars have concluded that GDPR's language encourages mathematical and logical explanations, when what people want is the understanding and opportunity to uphold their rights and prevent injustice.[45] For example an AI that advises on cancer treatment programmes might make hundreds of decisions based on thousands of data points; having access to the complete mathematical model behind the decisions is unlikely to help a patient truly understand the risks or benefits of using such a system. It is also unlikely to help patient advocates who are trying to see whether such AI cancer treatment programmes have better or worse outcomes for different regions, and different ethnic groups.

These two rights focus on the individual human data subject, but some of the most concerning potential impacts of AI are systemic injustices and harms to marginalised populations. For advocates concerned with systemic issues, GDPR also provides valuable tools - such as the right to erasure, the right to data portability, the requirement to complete Data Protection Impact Assessments (required for 'novel technologies' such as AI but also for other use cases), all of which encourage transparency and justice in the design of AI systems.

IS GDPR SLOWING OR STRENGTHENING AI?

Some believe that GDPR has slowed down AI progress within the EU by adding costs and practical barriers to early AI development. Other commentators have opined that GDPR stymied innovation within the EU, hinting that it hindered attempts to combat the COVID-19 pandemic.

> *"Despite all of its efforts, the EU is not yet ready to make full use of AI because its stringent data protection rules… restricting the collection, use, and sharing of data… are slowing down the bloc's ability to address the spread of the disease."*
>
> - E Chivot, *Center for Data Innovation*[46]

But the balance of costs and benefits of GDPR is complicated. Personal data collected and shared in service of addressing the pandemic has been misused by some governments prompting statements from Amnesty international and other human rights organisations and underlining the value of GDPR's protections.[47,48] Many of the key successful use cases of AI in addressing COVID-19, such as genome sequencing variants or modelling the impact of different policies on future infections and hospitalisations,[49] did not involve personal data so were unaffected by GDPR.

The need to align contact tracing with the requirements of GDPR led to innovation in the field of privacy protecting contact tracing apps, such as the Pan-European Privacy-Preserving Proximity Tracing protocol (PEPP) and the Decentralised Privacy-Preserving Proximity Tracing (DP-3T). These two tracing apps then formed the basis of contact tracing tools used within and beyond the EU. Protecting privacy meant systems were more trustworthy for vulnerable and marginalised populations, and thus were potentially more widely used and more effective in protecting public health.

THE EU AI ACT

The AI Act intends to support appropriate, targeted, regulatory responses to AI applications based on level of risk. Specifically, it classifies AI systems into four risk categories: minimal/no risk, limited risk, high risk, and 'unacceptable risk.' Applications in each of these categories are subject to different rules.

While entire sectors such as justice and education are deemed 'high-risk,' healthcare is "conspicuous in its absence" in the AI Act.[50] Healthcare technologies that fall under existing legislation regarding

product safety, including the Medical Device Regulation (MDR), are categorised as 'high-risk.' As explained earlier, medical devices are defined broadly as "products or equipment intended for a medical purpose" so covers many, but not all, AI applications related to healthcare. Concerns have been raised that the MDR and AI Act contain 'duplications and discrepancies,'[51] which will complicate and slow AI development.

AI applications that impact healthcare may be also categorised as 'high-risk' under other rules – for instance, any application that impacts hospital staffing might fall under the definition of employment. This leads to potential inconsistency in protection; some applications that impact healthcare will fall under multiple regulations, some will only be regulated as 'high-risk' due to other features – for instance if they impact employment – but others will be categorised as 'limited' or 'no' risk and therefore be very lightly regulated. As one patient advocate who was interviewed in this project stated: the focus has been on "tools that have direct impact on patients… but AI can also be used on how many beds are free, what equipment should we buy?"[52] Such indirect effects could impact patients' outcomes, experiences, and rights.

The AI Act does not require member states to create new, specialised AI regulatory authorities; existing regulators can take on the additional duties. Those regulators will have the power to investigate concerns regarding health and safety as well as fundamental human rights, and then enforce companies to fix errors or remove AI applications from the market. Although existing regulators will have "access to all information, documentation and data necessary to enforce the law, including access to source code if needed,"[53] there are concerns about whether regulators and subjects who wish to seek redress for harms have access to the appropriate skills and information they need to understand and enforce it, given existing skill shortages and the complexity of the systems they will need to regulate.

The AI Act will define and regulate the different risk levels as follows:

Unacceptable risk

Uses of unacceptable risk include:

- Subliminal, manipulative, or exploitative systems that cause harm. This includes "exploiting vulnerabilities" of a "specific group of persons due to their age, physical or mental disability."
- Real-time, remote biometric identification systems used in public spaces for law enforcement.
- All forms of social scoring, such as AI or other technologies that evaluate an individual's trustworthiness based on social behaviour or predicted personality traits.

Uses that constitute 'unacceptable risk' are banned across the EU under the AI Act, but there are significant exemptions and exceptions that may be of relevance to patient advocates. For instance, 'general' social scoring is banned but it is "unclear" whether this ban would deter scoring systems that "are more limited in scope", such as identifying fraudulent benefit claims. Human Rights Watch has noted that systems scoring according to these narrow scopes "can still have devastating human rights consequences."[54] Such uses have the potential to impact the rights of patients who face eligibility tests for support services and access to treatment.

High risk

The full list of high-risk uses is listed in Annex III of the AI Act.[55] Most relevant to healthcare is the inclusion of Medical Devices and In Vitro Medical Devices but other uses of particular relevance are:

- 'Employment, employee management and access to self-employment' This includes recruitment, task allocation, monitoring, evaluating performance and more. Because many healthcare providers are motivated to invest in and adopt AI in hopes it can help address the staffing crisis, it is likely this will include many AI applications which impact patients - such as optimising staff rotas, arranging appointments, automating staff evaluation and training, and organising care.
- 'Access to and enjoyment of essential private services and public services and benefits' Many patients and their families are eligible for state benefits as a result of disability, chronic illness, and care responsibilities. Human Rights Watch is concerned that protections for this use, including the ban on 'score' citizens regarding their eligibility for benefits, are not strong enough.[56]

- Law enforcement and Migration, Asylum and Border Control are also 'high-risk' which may significantly impact some patient rights; for instance, the UK Home Office has previously used hospital data to track the movements of migrants, a situation which the UK Patient Association CEO worried 'could undermine the core principles of our health service' and was associated with a rise in cases of tuberculosis because people feared seeking treatment.[57]

AI applications judged 'high-risk' are subject to a series of additional requirements which include establishing risk management and quality management systems, maintaining up-to-date technical documentation and registering in a publicly accessible EU-wide database. They must also use high quality datasets, which are "relevant, representative, free of errors and complete" and be transparent, enabling users to understand how the application works as well as interpret and use its output. Finally, they must be supervised with supervisors needing to be able to "fully understand the capacities and limitations of the AI system."

The AI Act also requires robustness, accuracy, and cybersecurity, which means an 'appropriate level of accuracy' and 'resilience against errors' as well as 'attempts by unauthorised third parties to alter the system'.

High-risk AI applications will be required to perform a 'conformity assessment' before they are used or introduced to the EU market, demonstrating conformity to all the requirements above. But it is important to note that this assessment would be an internal document, not available for review by the public. Regulators will need to specifically request to view the document, rather than being proactively required to review it.

Amongst the suggested changes published in the 2021 Progress Report was the suggestion that the 'High-risk' categories are reviewed and potentially updated every two years, offering the possibility of influence over future categories.

Limited risk

AI applications will be categorised as limited risk if they interact with humans, are used to detect emotions, are used to "determine association with (social) categories based on biometric data" or generate or manipulate content. Examples of chatbots in healthcare might be a chatbot that helps

arrange appointments or provide information about a medical issue (though not diagnosis). Example uses of AI to detect emotion, or to categorise patients, are less well known, but might include systems that alert hospital security if people become agitated while waiting for treatment.

The only requirement for applications of limited risk is that "users should be aware that they are interacting with a machine so they can take an informed decision to continue or step back." They are also encouraged to adhere to voluntary codes of conduct.

No Risk

AI uses not classified as 'unacceptable risk', 'high risk', or 'limited risk' are not regulated under the AI Act, although they are encouraged to adhere to voluntary codes of conduct. Many 'no-risk' AI systems will be part of products or tools that are not directly related to consumers, or to medical purposes, but it is possible that systems which impact health indirectly might be affected, especially if they affect accessibility options, resource allocation, may fall in this unregulated category.

THE FUNCTIONING OF THE AI ACT

The AI Act places most responsibilities on manufacturers or developers ('providers') when AI is ready to go to market. AI systems may be purchased by a 'user' where a user is "an entity or person under whose authority the AI system is operated, except where the AI system is used in the course of a personal non-professional activity … for example, if Company A implements a chatbot on its website developed by Company B, Company A is the user and Company B is the provider. The visitor to the website who chats with the chatbot is not considered a user under the Draft AI Regulation."[58]

The Act also covers providers and users located outside the EU "where the output produced by the system is used in the Union." This means the regulation impacts companies that use AI to process data outside the Union, if it includes data about EU citizens, or if any decisions that are made by the system impact EU citizens. This division of roles and responsibilities may lead to some complex legal situations:

"Let's imagine applying this principle to regulating 'general purpose' AI systems such as Open AI's large language model GPT3[59], which, some studies have shown, can produce biased outcomes. Because reviews carried out before the AI system is brought to market cannot fully predict unintended consequences, providers may claim they cannot anticipate how these systems will be used in future deployments. Yet downstream deployers ('users' in the terminology of the AI Act) will be able to see actual uses and impacts, but may have neither the legal nor practical resources to make these systems compliant with human rights."[60]

The AI Act is inspired by product safety legislation.[61] It treats its developers like manufacturers, and AI systems like products, like a TV or toaster. This approach places significant weight on providers to get AI 'right' before deployment; after deployment, the burden is on citizens and regulators to provide evidence of harm.

But AI systems have significant differences from physical products; After deployment they interact dynamically with the environment they operate in, creating feedback loops and unexpected outcomes. The complexity of getting an AI that is supposedly ready for deployment to actually work well when deployed in the real world is suggested by an MIT Sloan study that reports that "A good rule of thumb is that you should estimate that for every $1 you spend developing an algorithm, you must spend $100 to deploy and support it."[62] These complex interactions will change over time and will be different in different contexts, with different users, and different populations.

Much of the power of the AI Act will rest on national regulatory bodies' choices. The Act does not require that documentation, quality and risk management systems are made available for review by people who might be affected. Instead, this documentation is available on request to regulatory bodies. The specifics of implementation are likely to vary between countries, and this may potentially create situations in which documentation that could be helpful in proving and understanding harms is not available to patients and their advocates until *after* they have shown evidence of harm to a regulator. Much of the wording is open to interpretation, which again gives national regulators scope for decision-making. For instance, commenters have highlighted that "an

enforcing agency will have to determine when a system is exploitative or manipulative,"[63] but exploitation and manipulation are not discussed in further detail. Future regulatory action will determine the scope and power of these instruments, and interpretation and action may differ between countries and sectors.

The European Health Data Space

The impact of the EHDS on the development of AI in healthcare is likely to be significant. Technical, practical and political decisions about how exactly data should be standardised and shared will impact the data that is available for use for developing AI systems and the ways that developers and researchers can use that data. Efforts to clarify the safety and liability of the use of AI in health will involve complex technical, practical and political compromises as member states with very different healthcare infrastructures seek to align policy and practice.

It is important that patients and patient advocates are aware of and involved in these efforts to align and integrate systems from the early stages. The complexity and obscurity of AI-enabled decisions, and the shortage of relevant technical skills, make infrastructure design a prime site for commercial actors to become involved and to advance their interests.

Decisions at early stages about how policies will be shaped, the technologies that might be used in digitising and standardising records, and where data is stored may seem far removed from patient care; but in fact they will define the environments within which new research, treatments, and healthcare practices are developed and thus will shape patient experience significantly. As discussed in our case study *'Protecting Citizen Health Data in France'* (see page 42 of this report), decisions about where and how to host data, taken long before AI applications are even developed let alone implemented, are critical to protecting patient rights.

Examples from European countries

EU-level legislation – MDR, GDPR and the proposed AI Act – aims to align AI policy across the EU. Yet EU member states have been encouraged to create their own national strategies on AI, and each has different regulatory bodies, different technology ecosystems, and varying infrastructure for data, health, and innovation.

Here we highlight the AI policy contexts of three member states – the Netherlands, Italy, and Greece. These countries were selected to represent a range of digital infrastructures and policy readiness, as measured across several scoring and index tools, including:

- Open Data Institute (ODI)'s Secondary Use of Health Data policy readiness score, which identifies 22 policy components for an open and trustworthy data ecosystem for secondary use of health data and gives each policy component a score for 'policy activity' and 'policy implementation stage'. These scores are added together for the EU27, the UK, Israel, and the European Commission as a whole. The UK (81.8) and Finland (81.3) scored the highest and Bulgaria (23.9) and Greece (20.5) scored the lowest. The European Commission itself scored (64.2).[64]
- Digital Economy and Society Index 2020 ranking, which summarises key indicators of digital performance in EU countries. These indicators are Human capital, Connectivity, Integration of digital technology, Digital public services, Research & Development in ICT. After scores are calculated, EU countries are ranked, with the highest being 1.[65]
- Bertelsmann Stiftung's Digital Health Index, which scored seven EU and three OECD countries by Policy Activity, Digital Readiness, and Actual Use of Data, and then averaged the three scores. The highest scorers were Estonia (81.92) and Canada (74.73), the lowest scorers were Germany (30.02) and Poland (28.52).[66]

Patient advocates who want to explore information relevant to their own countries can read our key sources for this information: the Country Factsheets appended to the 2021 *Artificial Intelligence in Healthcare Report*,[67] the Open Data Institute's *Secondary Use of Health Data* project, in particular

its interactive comparison tool and policy summary, and the Bertelsmann Stiftung's cross-national study on health digitisation strategies and AI Watch.[68] In the three highlighted countries, information from these sources has been supplemented by interviews with patients, patient advocates, policy experts and technologists.

NETHERLANDS

ODI Secondary Use of Health Data country policy readiness score	50.6%
Digital Economy and Society Index 2020 ranking	4
Digital Health Europe Digitalisation score	66.1

The Netherlands has a strong start-up ecosystem and significant state investment in data infrastructure including data standardisation programmes. Key examples are the "Basic Data Set for Care (Basisgegevensset Zorg, BGZ365) by Nictiz, and the Registration at the Source (Registratie aan de Bron366).

The Netherlands is engaging with private partners to deliver programmes that are impacting healthcare such as Health Outcomes Observatory (H2O), an effort to build a health observatory for inflammatory bowel disease, cancer, and diabetic care. As part of BeNeLuxA (a consortium of Belgium, Netherlands, Luxembourg, and Austria), it is participating to standardise the pricing of new medicines through shared negotiation, shared information in patient registries, horizon scanning, health technology assessments, as well as standardising data registries and data models. These standardised datasets will be capable of supporting high-quality future AI projects and potentially enabling more effective scaling of solutions. The Netherlands also recently appointed a Chief Information Officer in the Ministry of Health, which will give clear lines of accountability and support future AI developments.

The Netherlands is advancing AI specifically through the AI Coalition (NL AIC), a public-private partnership consisting of more than 400 participants which aims to accelerate the development and

application of AI. One of the partners is the Netherlands Patient Federation, who manage the team for patient and citizen participation in AI, managing dialogue sessions with patients and caregivers and programmers where they can ask questions about bias, privacy, and other issues. The partners all received a share of EUR 276 million to fund the first phase of its project on AI, called the AiNEd Programme (Netherlands, 2021).

Involvement in the Netherlands AI Coalition has exposed Dutch patient advocates to a large number of case studies. But while this has led to greater understanding of policy and practice, it has also led to concerns. They worry that there is "a huge gap" of understanding between technologists, and patients and doctors. While they are happy that the Netherlands has an advanced AI strategy, they are concerned that the principles "are very abstract" and will thus require significant work to turn into practical frameworks. They are also very aware that for many policy stakeholders "economic benefit is very important" and that advocates need to keep this in mind.

ITALY

ODI Secondary Use of Health Data country policy readiness score	61.4
Digital Economy and Society Index 2020 ranking	24
Digital Health Europe Digitalisation score	55.8

Italian progress in building coordinated, AI-ready digital infrastructure in health is complicated by the fact that its 20 regions have legislative autonomy, and the healthcare system falls under exclusive regional competence. The Italian central government has some power over implementation, but not in regulating healthcare. Therefore, it is difficult to achieve cohesion across electronic health record collection, management and interoperability; management of biobanks and other registry databases; and initiatives aimed at building data infrastructure. One consequence is that Italian organisations and individuals have engaged enthusiastically in international

programmes; there are high numbers of Italian patient registries and biobanks on the EU's Orphanet relative to other EU member states.

Italy's AI strategy has gone through many rounds of revision with input from several task forces.

- A white paper on AI in public service claiming to be a world first (2018)
- The Italy's Ministry of Economic Development (MISE) published a first draft of its proposal for a National Strategy on AI (2019)
- A National AI strategy for public consultation (Sept 2020).
- A strategic programme on AI 2022-2024 which is notable for its deep integration and allegiance with the EU coordinated plan on AI (2021). 'Health and wellbeing' is listed as one of 11 priority areas.
-

Much of the available AI funding and policy work is directed at supporting AI researchers, building public-private capital support for national centres of excellence, and encouraging AI professionals to return to Italy, reversing a perceived 'brain drain' of AI experts to other nations. These activities are already having effects. Interviewees in our patient perspective report[69] who were developing AI tools for patients in Italy said they felt well supported by Italian institutions and policies. Italy ranks first among the EU-27 for the number of scientific papers published on AI (considering the share of authorship on most relevant papers published), and seventh among EU member states for the number of AI patents. A relatively high number of AI start-ups are spinning out of research universities, demonstrating effective support for turning this research strength into practice and societal value.

In the future, Italy's National AI strategy seeks to draw on the strength of its AI research capabilities to address its fragmented healthcare data infrastructure.

GREECE

ODI Secondary Use of Health Data country policy readiness score	20.5 (lowest in EU)
Digital Economy and Society Index 2020 ranking	25

Digital Health Europe Digitalisation score	Not ranked

Greece originally aimed to publish its AI Strategy by the end of 2021, but it has not yet happened. Its five-year digital growth plan 2020-2025[70] has been rolled out, as well as The Digital Transformation Bible (DTB), which includes AI in its "strategic intervention axes." New 'Strategic Actions' from the National Health System of Greece include the use of data-driven decision support systems, and the use of Big Data in healthcare using machine learning and AI.

Despite the relatively slow progress on AI policy readiness and infrastructure development, positive stories of AI supporting the battle against the COVID-19 pandemic have emerged from Greece. For instance, a joint project between the Greek government, data scientists from the University of Pennsylvania and the University of Southern California, and AgentRisk used AI to predict the risk of spreading COVID-19 by travellers visiting Greece and to identify high-risk travellers to test on arrival at the border in Greece. This tool "enabled Greece to re-open its borders" without seeing a spike in COVID-19 cases.[71]

The European Institute of Innovation and Technology's health programme (EIT Health) has reported positively on the life sciences, digital health and MedTech sectors of the Greek start-up economy. Georgios Megas, coordinator of the EIT Health Hub, noted that due to the recession students and professionals "had two options: either move abroad or start their own business", and that start-ups "are increasingly focusing on resolving health issues and challenges." Megas believes that policy solutions are required: "More flexible regulations regarding pre-commercial procurement and public procurement of innovation" because public hospitals represent a large group of early testers of digital health technologies.[72] As Greece is in the early stages of developing its digital health infrastructure, these kinds of interventions are required to develop the foundations from which AI readiness can develop.

Focus on AI in healthcare cases

AI is used in health and related public services in Europe in diverse ways. In the UK a business is using AI to find existing medicines that can be repurposed to treat rare diseases.[73] In Belgium a company is using AI for blood analysis and predicting heart attacks.[74] A French pharmaceutical company is using AI to speed up analysis of research.[75] There are hopes that AI can be integrated into the planning, design and delivery of services to improve the effectiveness, efficiency and experience of healthcare in research, treatment and prevention.

Yet, as the following three case studies illuminate, the use of AI sometimes risks causing harm to citizens. Advocates have needed to understand and use regulatory tools to defend their rights and interests.

IDENTIFYING FRAUDULENT CHILD BENEFITS CLAIMS IN THE NETHERLANDS

In 2021, an AI scandal in the Netherlands forced the Dutch government to resign. A 'self-learning' or 'risk-classification' system designed to identify fraudulent child benefits claims incorrectly labelled over 20,000 families as fraudsters, barring them from entitled benefits. Immigrant families were disproportionately affected. Families had no right under GDPR to object to this process as a 'solely automated decision' because the process was designed to keep humans 'in the loop' on decision-making. The AI flagged families as 'high-risk' but let officials review those who were flagged and make the final decision about confirming fraud and barring them. However, because of the speed at which people were required to work, they tended to quickly agree with the AI assessment, rather than investigate.

"The risk-classification model served as a first filter; officials then scrutinised the claims with the highest risk label. As it turns out, certain claims by parents with double citizenship were systematically identified by the algorithm as high-risk, and officials then hastily marked those claims as fraudulent."[76]

Prime Minister Mark Rutte responded: “Mistakes were made at every level of the state, with the result that terrible injustice was done to thousands of parents.”[77] After investigating the case, Amnesty International concluded that it served as an “urgent wake-up call” about the use of AI in public service and that “governments around the world are rushing to automate the delivery of public services, but it is the most marginalised in society that are paying the highest price.”[78]

The scandal highlighted several challenges in implementing AI in public services. When AI is used as part of complex processes affecting large populations, it can take a long time, or many thousands of uses, to gather evidence that the results are unfair or systemically unjust. It can also be difficult to identify why this happens; the exact reason in this case has still not been identified. While regulations such as GDPR can require that humans be involved in decisions, it is very difficult to ensure that this human involvement is meaningful. The new AI Act requires that supervisors of high-risk systems “fully understand the capacities and limitations of the AI system” but it does not require that supervisors have the time and capacity to meaningfully consider each decision.

PROTECTING CITIZENS’ HEALTH DATA IN FRANCE

In 2018, the President of France named health a priority sector in the development of AI. Shortly afterwards, the Health Data Project was launched to assemble a national health data platform from existing health databases, including the national health insurance system, some hospitals and healthcare organisations. The centralised database was intended to facilitate research by public and private groups, including research on AI. Without consulting with qualified French organisations, the French administration contracted Microsoft to host the platform, in a deal that would involve hosting the data on US servers, potentially opening French citizens’ health data to US surveillance authorities who could presumably make requests for personal data.

Santhenaton, a French patient advocate collective and union of open-source software providers and associations,[79] including the National Free Software Council (CNLL), The Federal Union of Doctors, Engineers, Executives, Technicians (UFMICT-CGT), and patient associations like The French Association of Haemophiliacs (AFH) took legal action to suspend the contract, stating that it represented a “breach of public procurement rules,” an “offence of favouritism in the criminal

sense" and form of "passive corruption." Santhenaton's legal action explicitly links the development of the Health Data Project with the expansion of AI in public services; they see its development within the context of the French President's 2018 call for the health sector to be one of the priority areas of AI development in France.

In 2020, France's data protection authority (CNIL) reviewed the contract between the French administration and Microsoft to offer arguments to the French Supreme Court (Counseil d'Etat), concluding that "the safeguards to protect the data against US surveillance law were not sufficient."[80]

The case against the Microsoft contract rests on the fact that requests by US authorities would represent unauthorised disclosures of health data under Article 48 of GDPR because the requests are "not made pursuant to an international treaty (e.g., mutual legal assistance treaty) and cannot be justified by any other lawful grounds." However, arguments against this have also been brought under GDPR: the Conseil d'Etat stated that there is significant public interest in allowing the use of health data on the platform, stating in particular "the needs of the COVID-19 ('Coronavirus') epidemic."[81]

The CNIL recommended using hosting services that are not subject to US surveillance laws, or preferably that worked exclusively under EU jurisdiction to avoid this risk and recommended several viable options. However, in October 2020, the Conseil d'Etat published its decision to not suspend the Health Data Hub hosting by Microsoft, despite the CNIL's position.[82]

This case study illustrates the complexity and strategic nature of advocacy regarding health data and AI. While AI may not be specifically in use, the infrastructure to support it is being designed and implemented, and advocates have taken active roles in attempting to shape those conditions. It also illuminates the important role that patient advocacy groups can have in protecting future AI infrastructure as well as the ongoing negotiation of GDPR law interpretation.

DEVELOPING AI TO DETECT KIDNEY INJURY IN THE UK

In 2017, the UK's Information Commissioner's Office (ICO) ruled that the Royal Free Hospital failed to comply with the Data Protection Act when it gave the personal data of 1.6 million patients to

Google subsidiary DeepMind to develop AI tools to detect kidney injury. The Data Protection Act includes the UK's implementation of GDPR.

The public narrative about the deal drew on familiar promises about the capabilities of AI: "We're building an infrastructure that will help drive innovation across the NHS [National Health Service], ultimately allowing clinicians, patients and other developers to more easily create, integrate and use a broad range of new services."[83] The legal justification for the data transfer was improved treatment for kidney injury, citing that a 'direct care' relationship with patients is grounds for the transfer and use of data without direct consent. An enormous quantity of patients' data was transferred, with some patients at no risk of developing kidney injury, belying this direct care relationship.

The ICO's ruling of the case was largely based on the broad scope of the data transfer, insufficient evidence of informed consent or of procedures removing the need to obtain informed consent (such as anonymisation), and the fact that an AI application was actually tested with real patient data.

> *"A patient presenting at accident and emergency within the last five years to receive treatment or a person who engages with radiology services and who has had little or no prior engagement with the Trust would not reasonably expect their data to be accessible to a third party for the testing of a new mobile application, however positive the aims of that application may be."*
>
> - Elizabeth Denahm, Information Commissioner in ruling RFA0627721 regarding provision of patient data to DeepMind[84]

In this case, lawyers used GDPR to deem the transfer of personal health data illegal and seek damages. But legal scholars cautioned that "from the perspective of patient autonomy, public value, and long-term competitive innovation, existing institutional and regulatory responses are insufficiently robust and agile to properly respond to the challenges presented by data politics and

the rise of algorithmic tools in healthcare."[85] It appears that as the technology develops, it will be necessary for advocates to use new regulatory tools like the AI Act in defence of their rights.

Challenges and opportunities for patient advocates

POLICY TOOLS FOR INFRASTRUCTURE INFLUENCE

AI is shaped by the data used in its development and which it uses to make decisions. The infrastructure that supports the collection, use, and protection of that data will be critical in determining the impact future AI will have on patients and patients' rights. Influencing future AI systems requires involvement in shaping these infrastructure projects long before any AI is actually developed; if possible, influencing the regulations and policies that govern the design of those infrastructure projects.

Patient organisations need to push hard for the EU and member states to involve patients and patient organisations in the governance of infrastructure at all levels. Where possible, it should be a requirement that representatives of those affected by an infrastructure project, and representatives of those people whose data will be collected and used are involved at board level or in advisory capacities. It is concerning that the European Digital and Health Data Board foreseen by the EHDS does not include patient organisations in its governance.

USING POLICY LEVERS TO SCRUTINISE AND CHALLENGE

GDPR may continue to be the most powerful policy tool for patient advocates to protect patients' privacy, patients' rights affected by 'solely' automated decisions, and to intervene in projects that might make EU citizens' data subject to US or other foreign law. Patient organisations need to be aware of GDPR's strengths and challenge efforts to weaken it. Some patient organisations perceive data protection as a problem, slowing efforts to find cures; care should be taken to find solutions that allow for necessary exchange of data while maintaining strong protections, as the GP3T project[59] did.

While not always successful, efforts bring attention and scrutiny to infrastructure projects, such as the Health Data Project in France, should continue. The specifics of projects will differ between states, regions, and disease areas, but patient organisations should support one another, sharing

resources and tactics in their efforts to hold infrastructure projects to high standards and maintain strong protections.

The AI Act will provide new tools for scrutiny and challenge. The specifics of how it can be leveraged will only be clear through implementation and regulatory action. Language regarding "high-quality datasets" that are "relevant, representative, free of errors and complete" is likely to be a powerful tool for patient advocates who seek to build strong foundations for future AI work. This will be particularly for patient populations marginalised or underrepresented in decisions, and those advocates interested in unequal or unjust decision-making.

SUPPORTING AND INFLUENCING THE AI ACT

There are multiple points at which patients and patient advocates might intervene in the development of the AI Act. At this late stage it is unlikely that 'healthcare' as a sector will be added to the list of high-risk categories, but patients and patient advocates can support the suggestion that the list of high-risk categories be regularly reviewed and amended, as laid out in the 2021 Progress Report. It is likely to be in the interests of patients' rights that this suggestion is upheld; much as the scope of GDPR has changed due to new technology enabling 'anonymised' data to be 're-identified', the areas of AI impact which are considered pertinent to patients' rights may change as well.

The AI Act, in its current form, contains significant scope for interpretation by different member states and their regulatory bodies. Much like GDPR, its power and impact will be determined over time through regulatory action. Patients and patient advocates have an opportunity to be involved in the early stages of adoption into law in member states, and in designing infrastructure for regulatory oversight.

While in its current form the AI Act only requires that conformity assessments and other documents are held as internal documents, patients and patient representatives can pressure member states to require that documentation, quality and risk management systems are available for review by those potentially affected.

The skills shortage in AI leaves member states and regulatory bodies open to potential influence from commercial interests, or other more powerful bodies, who can afford to retain skilled experts.

Patient representatives need to be actively supporting and advising regulatory bodies as they establish their approach to AI in healthcare, providing useful, accessible information, and well-structured opportunities to engage with patients and patient advocates.

BUILDING AND SHARING EXPERTISE

Aligning policies related to health data and AI across the EU will involve a period of complex, technical, legal, and political decision-making and compromise. The AI skills shortage may drive policymakers to turn to commercial actors for expert advice. This risks embedding commercial agendas in the policy and infrastructure which will determine development for years to come. The same skills shortage makes it difficult for patient organisations to access the necessary skills and expertise to participate in these decision-making processes.

In the immediate term, patient advocates may find it valuable to enter into partnerships and consortia alongside other stakeholders in healthcare - such as healthcare practitioners and researchers - in order to access the technical, legal, and political expertise necessary to contribute effectively to these dialogues and decisions. As discussed in *Protecting Citizen Health Data in France* this intervention may need to happen early in the development of AI infrastructure projects, pre-empting actual AI development.

In the medium term, patients and patient advocates need to invest in developing and sharing relevant expertise. This will need to involve training for patients and member organisations, developing structures that support participation at a varying level of understanding and expertise.

In the long term it will be necessary to support specialist research and fellowships and support cross-disciplinary work that connects technology with deeper understanding of patient rights, experience and outcomes. Patients and patient representatives should take every opportunity to engage with educational institutions that are training the next generation of AI developers and AI businesses, exposing them to patient experiences, offering case studies and project ideas.

Appendix: Acronyms

AFH	The French Association of Haemophiliacs
AI	Artificial Intelligence
AI HLEG	High-Level Expert Group on Artificial Intelligence
CEF	Connecting Europe Facility
CNLL	National Free Software Council
DTB	Digital Transformation Bible
EHDS	European Health Data Space
eHDSI	eHealth Digital Service Infrastructure
EEA	European Economic Area
EIT	European Institute of Innovation and Technology
EMR	Electronic Medical Record
EPF	European Patients' Forum
EU	European Union
GDPR	General Data Protection Regulation
ICO	Information Commissioner's Office
IBS	Irritable Bowel Syndrome
IVDR	In Vitro Device Regulation
ODI	Open Data Institute
OECD	Organisation for Economic Co-operation and Development
MDR	Medical Device Regulation
MISE	Ministry of Economic Development
PEPP	Pan-European Privacy-Preserving Proximity Tracing protocol
DP-3T	Decentralised Privacy-Preserving Proximity Tracing
UK	United Kingdom
US	United States

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