

Artificial Intelligence in Healthcare from a Patient's Perspective

Report

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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.

The project has been supported by the European AI Fund, a collaborative initiative of the Network of European Foundations (NEF). The sole responsibility for the project lies with the organiser(s) and the content may not necessarily reflect the positions of European AI Fund, NEF or European AI Fund's Partner Foundations'.

Executive summary

Four findings include:

1. Most participants felt hope about AI's potential. Some had concerns about lofty, unsubstantiated AI promises diverting funds away from health system improvements.
2. Most patients and AI deployment actors lack a strong understanding of AI and its potential. They desire examples that positively impact patients and from other sectors.
3. Participants with more expertise in AI had stronger concerns about policymakers' and politicians' understanding of AI and their ability to ensure patient protections.
4. Many patient representatives were unaware of how bias, poor data, or badly designed AI can lead to negative consequences to patient outcomes and experiences such as misdiagnosis, ineffective treatment or unequal access to care.
5. Greater advocacy is needed to ensure early and full participation by all patient groups in AI development and policy making, despite the high cost to ensure meaningful involvement.

The findings are a starting point for future AI research, policy and action rooted in the views of people who stand to benefit. Four recommendations, based on the findings, include:

1. Monitor changing patient attitudes towards AI. As AI develops and spreads, opinions will continue to change. Further research should examine factors impacting on diverse patient AI priorities and interests. Patients should not be treated as a homogenous group.
2. Build AI expertise amongst patients and frontline health workers so that they can ensure AI development meets patient needs, participate in innovation and safeguard patients from the potential harms of AI.
3. Support AI developers and researchers to access data in ways that uphold patients' rights, by connecting up actors who can learn from one another about how to do it and advocating for unbiased datasets which will ensure more representative AI.

4. Advocate for patient involvement from the early stages in AI development and for resources to support meaningful involvement. Track involvement to ensure representation across disease conditions and inclusion categories such as age, race, gender and ethnicity.

EPF and its members can play a powerful role in shaping the AI field as advocates, patient representatives, conveners and brokers of knowledge. The insights from this report, alongside actionable next steps, pave critical and exciting pathways forward.

INTRODUCTION

Artificial intelligence (AI) in the health sector has been attracting enormous investment and attention in recent years. There are expectations and promises that it will “make the hunt for new pharmaceuticals quicker, cheaper and more effective”,¹ and “save billions of lives by improving the quality of healthcare, reducing costs, increasing accessibility of healthcare, and anticipating health emergency threats.”² Some of these promises are being realised in areas such as drug discovery,³ radiology and ophthalmology.

But these promises, and the way AI is depicted in the media,⁴ have led to hype, misinformation and misunderstandings about AI’s value and potential. A 2019 study found that 40% of European start-ups or ‘AI businesses’ used no AI at all;⁵ the ‘AI’ label was used to attract attention and funding. In recent years, stories⁶ of AI tools using hundreds of low paid human workers have emerged. Some AI tools that claimed they would ‘revolutionise’ healthcare⁷ turned out to be ‘limited’, ‘struggling’ and ‘underdeveloped’.

There have been tremendous successes: AI was instrumental in the fight against COVID-19,⁸ with AI-powered tools supporting the rapid development of treatments and identifying patients at most risk. But there has also been considerable debate about whether false confidence in AI led to AI tools being rushed into clinical use during the pandemic before proper testing,⁹ exposing patients to risk. The quality of AI solutions are also in question. One review of machine learning algorithms that detect COVID-19 in chest images¹⁰ found that none are of “potential clinical use due to methodological flaws and/or underlying biases.”

Unsurprisingly, this uncertainty has impacted public understanding of AI. Studies consistently find that people who claim to understand AI are unable to describe its capabilities or identify whether they use AI products or not.¹¹ Furthermore, for patients to trust AI, they have to understand it.¹² A repeated finding in the research to be presented in this report was that patients and patient representatives overwhelmingly feel confused, underinformed, and concerned about the capabilities of all stakeholders to understand the technology, effectively engage in developing it and trust it when implemented. In this context, it can be difficult to identify exactly how AI is actually impacting patients.

Very few initiatives or research studies examine patient perceptions of AI. Notable exceptions include a study of patient apprehensions about the use of AI in healthcare¹³ and patients' views of wearable devices and AI in healthcare.¹⁴ There seems to be an upward trend of AI design teams rooting their work in patient needs. Yet, the industry is still far away from a deep understanding of how to make effective, impactful use of patient input.

This report presents findings from explorative research sponsored by the European Patients' Forum (EPF) to understand the opportunities and challenges of deploying AI in the health sector from a patient perspective. It seeks to document experiences and understandings of AI amongst patients, patient representatives as well as health professionals, technologists, researchers and policymakers who work with them, or AI 'deployment actors.' It does not claim to offer a complete picture, but a window into a complex landscape, and future recommendations.

Through engagements with eighteen AI deployment actors, the research surfaced representative views from across European and national levels as well as across a range of conditions and advocacy priorities. Deployment actors included patients, patient representatives, technologists, researchers and AI policy experts. Engagements involved two webinars, organised by EPF, and a micro survey informing topics discussed in an in-depth interview. Webinars asked people to share their hopes and concerns about AI and how it is, and could, change patients' care and experiences. While analysing the insights, we paid attention to where there was excitement, interest, agreement and disagreement across the spread of opinions. A detailed description of the method is included in Appendix 1.

Recommended actions for EPF and the stakeholder groups we studied, are presented in the final section of the report. Though the low number of participants makes it difficult to draw firm and generalisable conclusions, the findings are a starting point for future AI research, policy and action. We hope that people deploying new AI technologies across health systems will find the insights and recommendations useful to grounding future AI development and policy efforts in the views of people who stand to benefit.

Research findings

In the webinars and interviews, research participants reflected on their experiences, feelings, concerns and aspirations about deploying AI in the health sector. When taken together and analysed, their perspectives and deliberations centered around four main topics:

1. Experiencing AI
2. Understanding AI
3. Patient involvement in AI
4. AI deployment challenges

The sections that follow present each topic through the perspectives of research participants, interpreted and discussed through the domain expertise of the report authors.

EXPERIENCING AI

Many of us experience AI directly as part of our everyday lives - perhaps finding a route using Google Maps or talking to a customer service AI on an automated phone line. We may also be indirectly affected by AI if it is used to determine how our environment is designed or public services are funded. For example, AI is used by brands to determine where they should open new branches of shops, and by public transport systems deciding where to invest in new routes.

Encountering AI in healthcare can also be direct or indirect. We could directly use a chatbot to schedule a general practitioner (GP) appointment, or be affected indirectly when AI is used to decide the number of staff who will be at hospital when we visit. Most of the people we spoke with have participated in conversations about AI in their professional work with some having contributed to AI development projects. This section explores experiences of AI, and the factors which appear to be influencing different experiences.

HOPEFUL FEELINGS ABOUT AI

Many participants described concerns in their interviews but an overwhelming majority of the 18 survey respondents answered that their primary feeling about AI was “hope” (Figure 1).

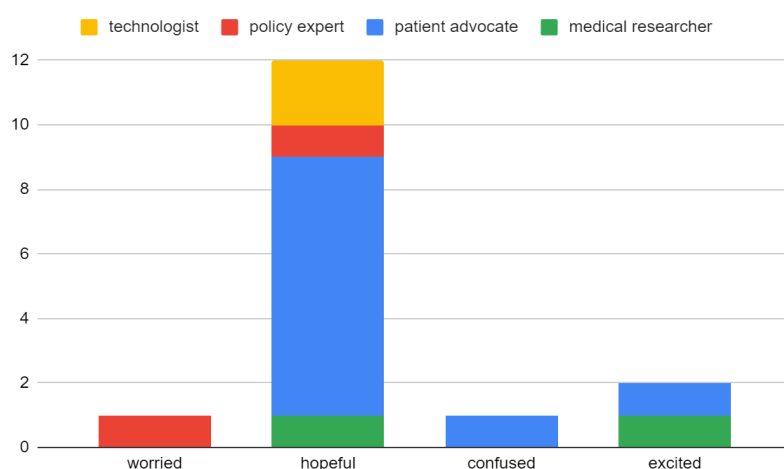


Figure 1: How survey respondents feel about AI

For some who have encountered AI directly, this hope was based on real results of experiencing the results of AI in practice. One interview participant told us *“I don’t just have ‘hope’. [My belief AI will help] is substantiated in the sense that it is happening already.”*

Others hold hopes about the future such as that AI will help patients and medical staff better manage data. An irritable bowel syndrome (IBS) patient spoke with despair about how he sees AI as *“the only defense against the data we’re drowning in.”* He is using AI to make sense of a biobank of 200,000 samples to identify potential drug side effects for IBS patients. An multiple sclerosis (MS) patient saw the potential for AI to *“future proof us against ourselves.”* In other words, she hopes that AI can help people predict their potential future health problems more accurately and make decisions about their health earlier on in their lives to avoid and prevent ill health and unpleasant symptoms in the future.

When this feeling of hope is mixed with a lack of AI understanding there is a risk of unsubstantiated promises being used to influence or justify concerning policy decisions. An example is a 2020 speech delivered by the UK minister for health and social care,¹⁵ where he linked poorly defined hopes with a recommendation for relaxing privacy regulations, and allowing private interests more influence over state healthcare: *"It is about making sure that we have an open door to the NHS to all of those who want to come in and use the capabilities of the NHS in order to save lives and improve treatment."*

Our research participants raised concerns about AI not living up to such promises, and research participants cautioned against spending money on technologies that promise much but deliver little, worrying that the technologies could negatively impact on patients and health systems in the short term. Participants noted actual scenarios where AI technologies were launched prematurely without proper testing - where misplaced enthusiasm encouraged inappropriate uses of AI - and where financial resources were diverted from urgently needed health system improvements to fund ambitious AI projects that may not meet the needs of patients.

AI INTERESTS SHAPED BY DISEASE EXPERIENCE

What patients and patient representatives care about with regards to AI is shaped by their past experiences. In particular, the diseases people have or represent can lead to diverse concerns and priorities.

For instance, people affected by life limiting rare diseases were most often concerned with accelerating advancements in treatments and cures. The slow pace of technology development can be deeply frustrating when lives are at stake. One interviewee told us *"I can't emphasise enough, around rare diseases, the importance of urgency. The lives of people depend on how fast we move."* Patient representatives concerned with these diseases were often familiar with life saving treatments developed using AI;¹⁶ their experiences influenced their concern with speeding up AI progress. Some representatives felt that the potential damage to privacy, or even issues of bias, were not comparable to the tradeoffs or harms caused by conditions going without treatment; one told us *"Can AI do harm? No, I don't think so. Harms from not using AI; yes, I can describe those."*

In contrast, patient representatives focused on conditions impacted by marginalisation or stigma such as mental illness tended to be most concerned with AI's potential harms. These representatives were familiar with examples of people being harmed by AI such as AI algorithms in the UK which 'target' disabled people in hunt for benefit fraud.¹⁷ They were less likely to trust promises that AI could improve outcomes, instead raising concerns about harms caused by data sharing *"Why would you want to be involved in a process that hasn't helped you in the past - or even caused harm? It can be logical to say no."*

These experiences shaped patients' and patient representatives' responses to AI developments, and illustrate the need to target and adapt responses, and to make sure a diverse range of patients and patient representatives are included in research and action moving forwards.

Key points

1. Most patients and patient representatives feel hopeful about AI benefiting patients, despite some concerns.
2. While hope that AI will improve patient experiences can be positive, if it is accompanied by a poor understanding of AI, it may be leveraged to justify policy decisions that do not align with patients' best interests.
3. Features of conditions, such as being life limiting, influence patient and patient representative advocacy interests, goals and attitudes.
4. How people relate to AI can be highly influenced by past experience.

UNDERSTANDING AI

Research participants revealed a sense that deployment actors in the health sector lack a strong understanding of AI. One participant said, *"If you have an intelligent, highly trained, well-supported... audience of clinicians and academics who are struggling with the basic concepts of AI... you can only*

imagine what that's like translated to the patient or public level." In this section, we explore sources of contention or concern around how people understand AI in the health sector as well as some opportunities to improve deployment actor understanding.

FALSE CONFIDENCE COVERING UP CONFUSION ABOUT AI

AI experts we spoke to in the interviews stated that news and popular media coverage of AI is *"dangerous"* as it leaves people feeling confident they understand AI while actually being poorly informed. Several experts reported an AI innovation culture that discouraged questioning as well as a policy culture of policy experts repeating what they hear from others due to lack of confidence. *"I notice there is a lot of parroting... people are repeating each other when they aren't really acquainted with AI or how it works. I wish we could sometimes push an alarm button and be like stop! Everyone! Make it clear what you mean!"* Another expert stressed the need to create a culture which allows people to admit uncertainty, request clarifications and *"admit that we don't know everything."*

Confidence in decision-makers' understanding of AI

Research participants with more experience of working with AI often had less confidence in the power of AI, and in the capability of decision-makers to understand it. There was real concern that key decision-makers do not understand the technology, its risks and weaknesses. The majority of our survey respondents disagree that *"regulators, policymakers and law enforcers are protecting patients effectively from the harms of AI"* (Figure 2), and thought that educating them would be costly and high effort. This lack of confidence in stakeholder understanding may erode trust in relevant policy decisions.

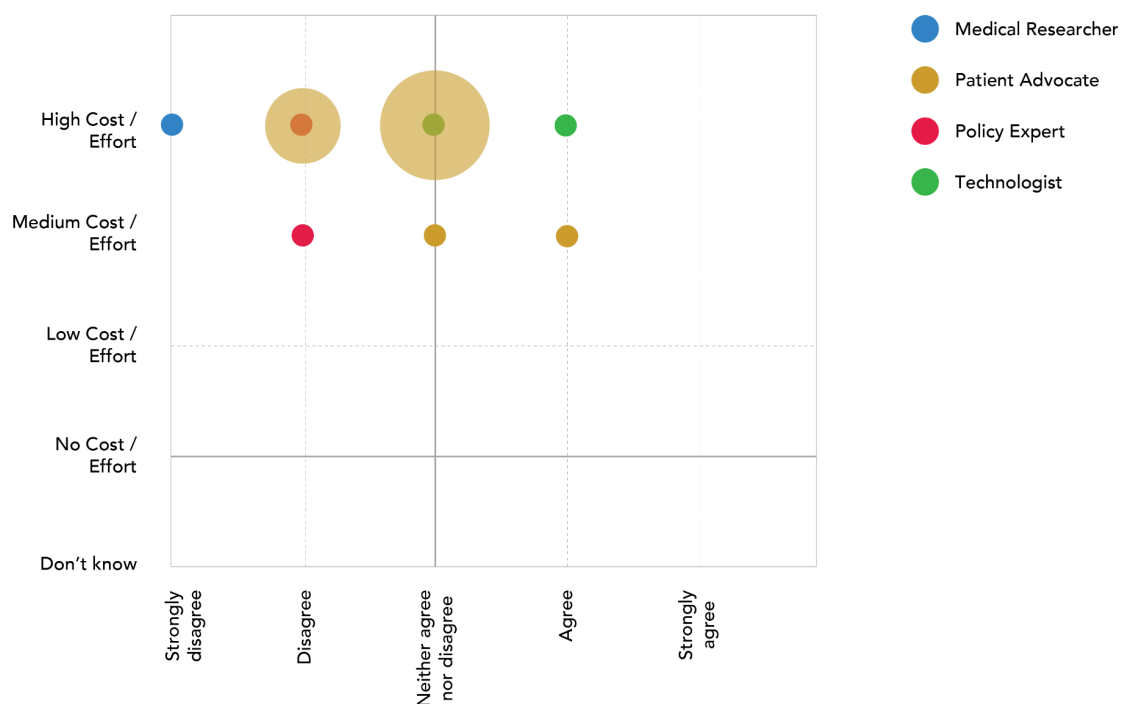


Figure 2: Responses to survey statement - "I feel that regulators, policymakers, and law enforcers are protecting patients effectively from the potential harms of AI such as prejudice, bias, or inequality in algorithms"

WHAT CAN THIS TECHNOLOGY DO, AND DO FOR US?

Participants generally expressed a desire to understand AI more, including what it is and how it works as well as what it can do for patients, medical staff and health systems. Currently, how AI works, and could work, can feel opaque with one participant comparing AI to a black box: "You might as well stand in the middle of your GP surgery with a cardboard box painted black... throwing patient notes into it... and expect... a cancer treatment to fall out... there is no connection between the output of the AI... and the data it stands on." Some technology companies are keen to solve this black box problem for clinicians and patients.¹⁸ Heightening the mystery and myths around AI is people consuming inaccurate news about AI or news which is not open about its realities. For example, many European technology companies claim to utilise AI when in reality, humans are pretending to do the work and misleading

people, such as humans posing as chatbots ¹⁹ Sometimes, developers are even incentivised to over-hype, or fake, their technologies' capabilities.

Most participants were unable to cite examples of AI in the health sector with positive outcomes, particularly examples that benefit patients. According to one participant, there are few occasions where you hear, *"This is done by artificial intelligence... and this is the outcome for patients."* Participants generally desire these use cases and feel that positive use cases of AI, both inside and outside of the health sector, would help them better understand what AI can do, and for whom, as well as better communicate its potential to their colleagues.

Dire implications of poor understanding of AI

Patient representatives felt that a poor understanding of AI amongst health system actors can have negative consequences for patient care and patient experience. One gave the example that *"If you don't understand [AI]... enough to be able to interrogate what's going on... you could end up with racial bias cooked into your facial recognition."* Patient representatives with relatively little exposure to AI believed that it can offer more accurate or personalised diagnoses and treatments without patients needing to more deeply understand AI. They were unaware of the ways that bias, poor data, or badly designed systems can lead to misdiagnosis, ineffective treatment, unequal access to care, or the poor management of limited healthcare resources.

Key points

1. A culture of false confidence undermines attempts to improve AI understanding.
2. AI experts are concerned that key decision makers don't understand AI, which means they can lack faith in those decisions.
3. Patients and patient representatives know too few positive, well documented and explained use cases of AI.

PATIENT INVOLVEMENT IN AI DEVELOPMENT

There has been significant investment and interest amongst researchers to involve patients and the general public in research regarding AI in health. The BMJ recently started requiring researchers to report how patients and the public are involved in AI research.²⁰ Despite these advancements, patient representatives in our research consistently expressed concern that they were not being meaningfully involved in the development of either AI systems or relevant policy.

It appears that there are specific features of AI in healthcare - including the complexity of the technology and the variety of settings within which it can be deployed - that make designing effective patient involvement difficult; too often involvement felt like it occurred too late in the process or was a 'tick box' exercise without impact. Research participants also highlighted challenges of involving patients such as the high costs of informing patients enough for meaningful participation and navigating different country requirements for patient involvement.

LACK OF PATIENT INVOLVEMENT IN AI DEVELOPMENT

A majority of the patient representatives we spoke with have never been involved in an AI development, research or policy initiative. Those that had been involved felt underrepresented in the groups they were participating in. One person commented that, *"I've been in a couple of projects or meetings where... there was ... no patient... the most important people."* One person talked about his uphill battle and efforts to get more patients involved in meetings related to AI and data-driven development. He described false promises to involve patients at a future date, with meeting organisers saying, *"Next time we will invite them, yes..."* He replied, *"...but this is next time."* *"Sometimes you'll see that 'Oh, the project is already on... we forgot patients...'"*

Our survey respondents expressed strong agreement that it is important for patients to be meaningfully involved in the development of AI technology and policies that affect them (Figure 3) but in interviews they often expressed concern about the cost and difficulty of patients and patient representatives engaging on a complex topic they felt they did not understand.

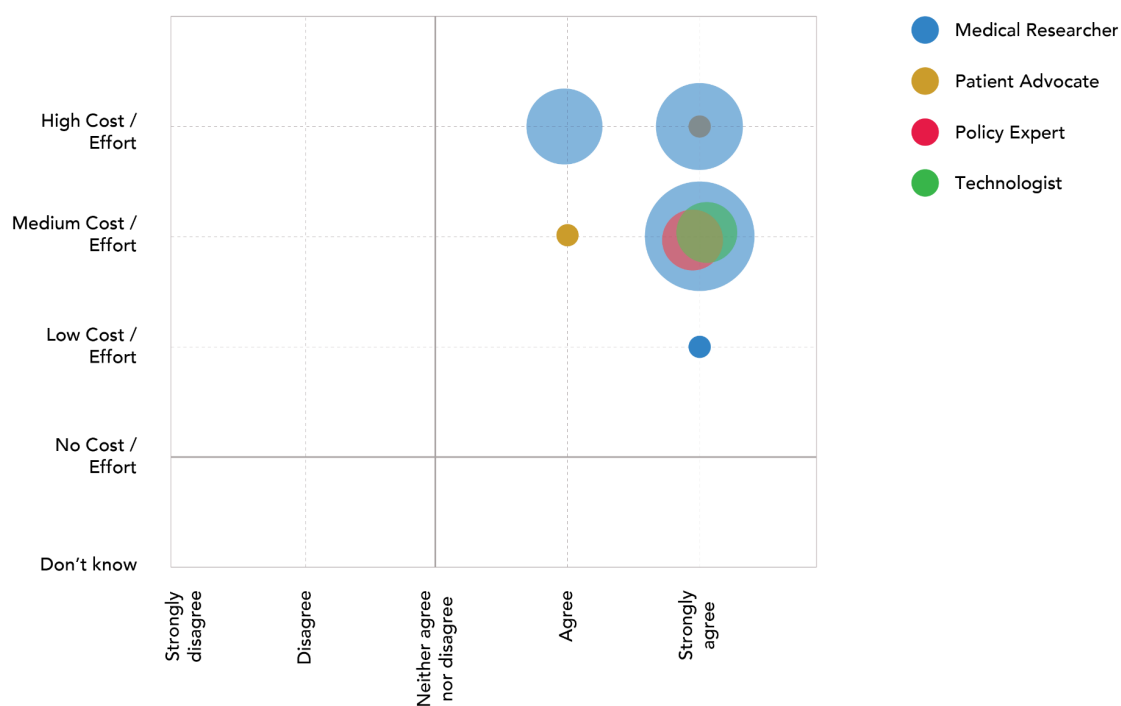


Figure 3: "It is important for patients to be meaningfully involved in the development of AI technology and policies that affect them"

Different approaches to patient involvement

Patient representatives feel that they approach patient involvement differently to technologists and developers. One patient representative perceives developers to believe that “involving” patients means asking patients to comment on the user friendliness of digital interfaces, rather than discussing whether the tool actually meets their needs and is deployed ethically. Representatives were adamant that involving patients should involve creating space for them to express what matters to them.

The piece of advice we heard most often from participants about involving patients in AI development projects was to involve them from the conception stages so that their needs and perspectives are baked

into research and design requirements as well as the broader project scope and vision. *“We have to have them at the table before we start the project... you have to start thinking of them in the beginning.”*

NEGATIVE CARE IMPLICATIONS OF NOT INVOLVING PATIENTS IN AI

Not involving patients in developing AI applications intended to benefit them can have dire consequences. One patient representative described an AI solution, developed without patient involvement, that was inaccessible to significant numbers of patients that it was intended to help. Once a poor design has been implemented it is not always possible, or technically feasible, to spend further resources on developing fixes or alternate solutions. This leaves patient representatives needing to overcome not only the challenge, but the unsuitable solution - a situation one interviewee described as having to do “double work.”

WHO PRINCIPLES FOR AI DESIGN AND USE

In 2021, the WHO issued a global report on six guiding principles for AI design and use in health.²¹ One of these principles includes *“Ensuring transparency, explainability and intelligibility”* which requires that *“sufficient information be published or documented before the design or deployment of an AI technology. Such information must be easily accessible and facilitate meaningful public consultation and debate on how the technology is designed and how it should or should not be used.”* One interviewee talked about how he struggles with these guiding principles as they feel *“very abstract,”* lacking *“practical impact”* and usability.

WHEN IS INVOLVEMENT APPROPRIATE?

Whether to involve patients in a particular AI project is also an area of contention that another patient representative was unclear on, citing the lack of rules or guidance around this issue. She explained that there are some projects that do not require patient involvement, such as triage on the ICU (Intensive Care Unit): *“I don't think that as a patient, you will really notice”* because people not admitted to ICU don't think about it often, and people who are admitted are in the midst of medical crisis. However, even in these situations involvement is important; the system could be designed with the input of people

who have previously been in ICU, or families, so that they understand and can input on relevant ethical decisions, and explain factors that mattered to them.

Difficulties mobilising diverse stakeholders

It can be difficult to bring diverse stakeholders - such as data scientists, clinicians and patients with diverse and strong motivating interests and ways of approaching problems - together to develop AI applications. One researcher told us she originally thought that bringing these stakeholders together would be a straightforward process but *“now I know that this is a very difficult topic... will take many more years before we can get this running.”*

Key points

1. Greater advocacy is needed to ensure patient and staff involvement in AI development, research, and policy projects that address the needs of these groups.
2. Stakeholders could use clearer and more practical guidance about whether, when and how to involve patients, and other health system stakeholders as well as how to mobilize the appropriate stakeholders to guide and implement the project.
3. Training patients and staff in AI principles is not a standard practice currently and there is a need for expert guidance on the curriculum that would be most helpful to specific projects.
4. Involving patients early in AI development projects is critical to ensuring the projects' vision, scope and requirements are rooted in the needs and perspectives of the people intended to benefit from, and use them.

AI DEPLOYMENT CHALLENGES

Survey participants voiced a number of challenges they have personally experienced with deploying AI technologies in healthcare, including data quality and access issues, ensuring representative datasets,

lack of trust in AI algorithm outputs, the cost of developing AI applications, unsuitable eligibility criteria for deploying AI technologies and regulation challenges surrounding AI.

DATA QUALITY AND ACCESS ISSUES

Securing high-quality data is one of the biggest hurdles to developing AI algorithms, alongside the high cost of meeting regulatory regulations such as Conformité Européenne (CE) Mark, noted one participant. CE Mark indicates that a product has been manufactured to European Economic Area (EEA) health, safety and environmental protection standards and can be sold anywhere in the EEA.

Several participants noted that most readily available data is not *“sufficient to create algorithms”* or *“good quality prediction models.”* Sometimes, there is just not enough data. An experienced AI technologist described how AI could actually result in *“people being diagnosed with a condition incorrectly just because... your database wasn't big enough to train the AI to distinguish between two very similar conditions.”* Other times, the nature of available data might not support algorithm development. For instance, in hospitals, *“There's a lot of data about patients who were treated... but... not much data about patients who were not treated”* explained one participant. In developing AI algorithms, not having data about patients who were not treated limits comparisons between these two groups. Comparisons between these two groups is useful when *“what you would like to predict is the difference between being treated or not [such as the impact of treatment on lifespan]... we can only say something about all patients who were treated... and what the results are.”* One implication of a lack of good or quality data is AI resulting in poor quality decisions such as misdiagnoses.

Most respondents agreed in the survey that we would see *rapid* and *significant* advances in healthcare if researchers could access the health data they need (Figure 4) but in the interviews, many struggled to imagine specific improvements that AI can offer in the short term. It is possible that patient representative views would change given a greater understanding of AI’s potential uses and impacts. The data expert who strongly disagreed that we would see rapid and significant advances in healthcare if researchers could access the health data they need clarified in an interview that according to her, change would come *slowly* due to additional barriers such as the need to clean data or the cost and scarcity of data analysts.

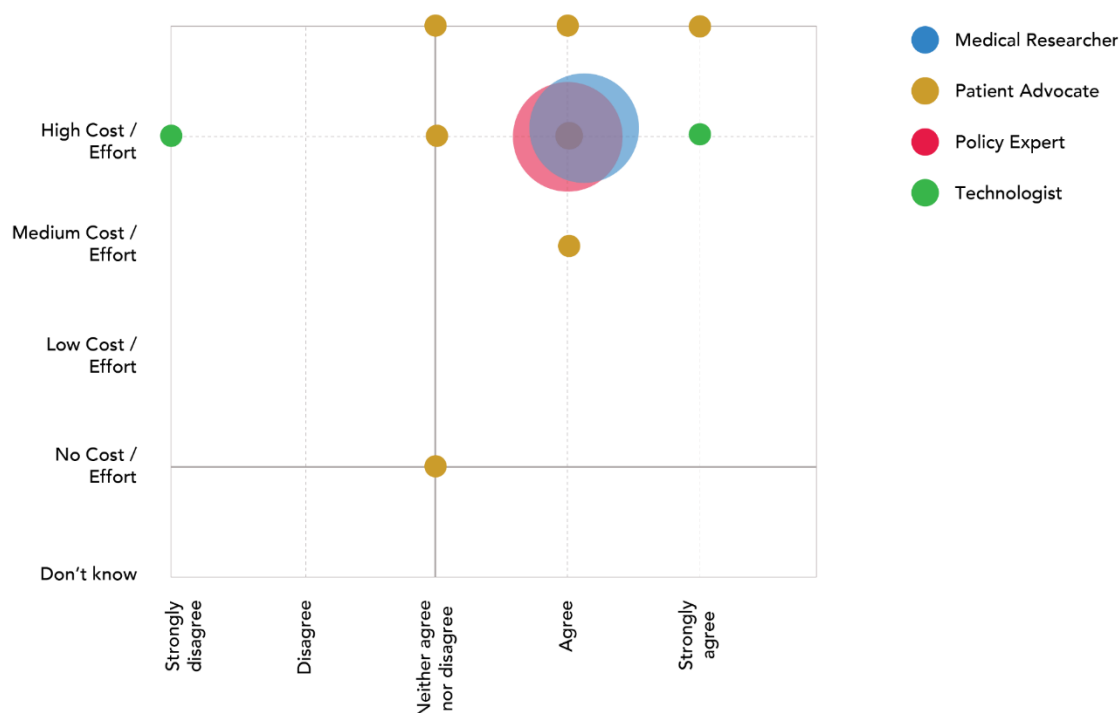


Figure 4: "For patients like me or for the people/sector I represent, I believe that: If researchers could access the health data they needed easily and cheaply (with patient privacy protected) healthcare would improve significantly and rapidly"

REINFORCING EXISTING BIASES AND PREJUDICES

Participants were concerned about AI reinforcing existing biases and prejudices. It can be incredibly difficult to ensure AI algorithms are trained on datasets representing everyone in a predefined

population such as a population that needs to represent all disease conditions, for instance, or all diversity, equity and inclusion categories such as race, ethnicity and gender. Representative datasets can also be about making sure a particular solution is as applicable to everyone as possible. A researcher from the Netherlands described how her group successfully secured access to a national-level patient database which immediately made their tool useful to all hospitals across the nation. “Usually,” the researcher said, “...you have a dataset from like one hospital, and then you have to validate it... it gets... complicated really quickly.”

TRUSTING THE OUTPUTS OF AI ALGORITHMS

Clinicians often feel “insecure about the quality of the decision of [AI] algorithms.” Yet, clinicians do not see AI algorithms as a substitute for their judgment, necessarily, as patients might believe. According to Robbie Freeman, Vice President (VP) of clinical innovation at Mount Sinai, AI algorithms are often intended to be a “conversation starter” (Fierce). Medical staff might make observations that need to be taken into account to diagnose a patient, for instance, because “robots operate logically, as opposed to empathetically.”

COST OF ENTRY OF DEVELOPING AI APPLICATIONS

Developing AI applications can require “too much money to begin with,” according to one participant; the shortage of AI development skills across Europe can make it difficult to commit to developing the technology in-house. He continued that it can be easier “to hire a person... to... implement it.” This brings with it the concern raised in earlier EPF policy briefings - that such partnerships can “inadvertently lead to an embedding of corporate actors.”²²

UNSUITABLE ELIGIBILITY CRITERIA FOR DEPLOYING TECHNOLOGIES

Healthcare systems often impose strict criteria for deploying technologies. When the criteria do not reflect patient interests, patients can miss out on treatments that benefit them. We spoke with several patient representatives and a technologist regarding one example relating to Cystic Fibrosis (CF). Several health systems across the EU use a single lung function measure to determine whether a new and very

expensive CF treatment is working and will stop that treatment if the measure is not improving. Patient representatives feel this measure is too simplistic and does not reflect the range of improvements patients experience, and that the treatment is being withdrawn without justification due to its cost. [Cystic Fibrosis Europe](#) supports an AI project that collects multiple measurements from CF patients, intending to build a more nuanced picture of how the treatment affects patients. They hope to identify a single, simple score that more accurately reflects this more fair, nuanced picture.

AI can support the design of more sophisticated criteria for patient access to new technologies. Yet, health systems should proceed with caution. In less regulated healthcare systems this is already a reality, with one system in the USA to determine eligibility for care described by activists as 'wildly irrational' and 'cruel' and blamed for multiple deaths.²³ Involving patients in criteria development, and enforcing requirements for transparency in algorithmic decisions, may mitigate this risk.

REGULATION CHALLENGES

Current regulatory developments are discussed in a second [policy report](#); here we discuss perceptions and experiences of regulation amongst patients, patient representatives and technologists who work closely with regulators.

One patient told us that *"there are lots of separate laws"* about regulating AI - hinting at confusion about how different regulations interact. Technologists we interviewed felt that AI developers need to know about the law but this is a challenge as *"lawyers and tech people really don't communicate."* According to one technologist, developers have a mentality that, *"the sky's the limit... we're just gonna develop all these amazing things... and the company lawyer will... tell us... when we go too far."* Yet, the communication needed usually does not happen.

It is also important for clinicians to understand AI regulation. *"If doctors don't understand AI regulation... and it's hard to explain [how AI works] to patients... patients won't be able to give informed consent"* but the depth to which they need to understand AI is not clear as *"most patients don't really understand... MRI scanners."* It was unclear to some participants how AI technologies should change existing

approaches to informed consent where patients are currently not required to understand exactly how other technologies work.

A respondent felt that AI regulation is more about protecting innovation and regulating the economy than about protecting human rights where *“fundamental rights is more of a ‘plus’ or even a thing to do to make more sales.”*

Another participant was worried about large commercial players snatching up data collected with poor consent policies. In fact, he felt that these players do not develop an app *“to make your health better... just... gather as much data as possible... you have GDPR [General Data Protection Regulation] to keep that a little bit in check.... but it doesn't change the fact that, well, if you give informed consent, then they can take anything and it's fine.”*

Key points

1. There is a need for greater understanding amongst patients and AI deployment actors of the specific improvements that AI can offer, especially in the short term.
2. Clinicians do not necessarily see AI algorithms as a substitute for their judgment, as some patients believed.
3. Involving patients in the development of criteria to determine patient access to new AI technologies may mitigate risk to patients.
4. It is important for developers and clinicians to understand AI regulation to effectively scope projects and mitigate risk.

Recommended actions

There is tremendous potential for AI to positively impact patients and health systems. This research points to actions that patients, patient representatives and AI deployment actors can take. This section presents each action, why it is important and who stands to benefit.

1. Monitor changing patient attitudes towards AI. Realising the full potential of AI will depend on AI deployment actors staying attuned to patient attitudes towards AI; and to how those attitudes change while the technology, and its place in society, evolves. Patients should not be treated as a homogenous group and further research should examine the factors and experiences which impact on patients' different priorities with respect to AI.
2. Grow AI expertise amongst patients and frontline health workers. Patients and frontline health workers will be directly impacted by the deployment of AI solutions in health. Ensuring these two groups have at least a basic understanding of AI, and AI legislation, will make it easier for them to engage with AI developments and steer policy and practice towards patient needs and interests as well as build trust in AI solutions when appropriate. A basic understanding of AI can also equip clinicians to safeguard patients from the potential harms of AI as well as foster more inclusive innovation by inviting people close to patients to envision AI innovations that can benefit them.
3. Disseminate AI examples that positively impact patients. There is a dearth of clear, well documented AI examples with positive patient outcomes. Producing, disseminating, and discussing these examples could support patients to envision and advocate for the future they want to see. Examples from outside healthcare can illuminate how AI has gained "*attitudinal acceptance*" in other industries and innovations that could be translated into the health sector.

4. Invest in AI expertise for patient representatives. Deep AI expertise amongst some patient representatives, would better equip them to inform how patients can meaningfully be involved in AI development and policy making as well as lead to more trust in AI solutions when appropriate. Training materials and periodic learning sessions could be developed to keep them up-to-date on the latest advancements in AI as well as research about evolving perceptions and concerns of patient groups with regards to AI.
5. Advocate for involving patients in AI development and policy making. In all cases, patients and patient representatives must be given the right resources, skills and information to be involved in AI development and policy making. Research participants felt the following principles are particularly important.
 - a. Involve patients early, ideally at a project's conception, to ensure their interests and concerns are reflected in projects' vision and goals.
 - b. Involve patients in evaluating AI in clinical settings, including identifying criteria for granting patient access to new AI technologies and reflecting their interests in AI metrics. These involvements could mitigate potentially harmful risks and inform decisions about who should get access.
 - c. Involve patient advocacy organisations. These organisations can inform how patients can, and prefer to be, involved in AI development projects in ways that respect their interests and time.
 - d. Research gaps in AI understanding between deployment actors (e.g. clinicians, technologists, data scientists, patients) to aid more effective collaboration.
 - e. Track involvement to ensure diverse representation of patients across disease conditions and diversity, equity and inclusion categories such as age, race, gender and ethnicity.

- f. Motivate people who have experienced harm to get involved in AI development. *“If you’re not involved in the process then data might not reflect you & your experiences correctly, so the AI could make inequalities and inaccuracies worse.”*
6. Support AI developers and researchers to access data easily and cheaply. Securing data from health institutions, with the proper patient privacy protections, is one of the biggest hurdles to developing effective AI algorithms. EPF, and patient representatives, can effectively support these actors to secure this data by connecting up actors who can learn from one another who have successfully done it and ensuring health institutions know how the data will be used. They can also advocate for unbiased data to ensure more representative AI outputs and solutions.

TOWARDS THE FUTURE

This report has illuminated the diverse views about AI in healthcare from patients, patient representatives, health professionals, technologists and developers across European countries. The European Patients’ Forum, and all of its members, have a powerful role to play in shaping the AI field as patient representatives, conveners and brokers of knowledge and information. The insights from this report, alongside actionable next steps, pave a set of critical and exciting pathways forward.

Appendix #1: Methodology

This research adopted a qualitative methodology centered on two webinars, a short survey and sixteen interviews. The webinars contributed to the survey design, and survey questions were used both for ‘at a glance’ maps of participant concerns, and as prompts for deeper discussion within interviews.

The majority of interview participants were patients and patient representatives. Patient representatives were asked to recommend technologists and medical researchers with whom they had worked or with whom they shared goals. Recruiting non-patient interviewees in this way enabled us to contextualize while remaining centered on patient perspective and experience.

The short survey asked participants to what degree they agreed with a statement related to AI policy, and then what they believed the cost would be of implementing a relevant policy. These questions were explored in more depth in interviews, and results are included to provide at-a-glance summaries of key concerns.

The “Big Data and AI” webinar, as was communicated to all European Patients’ Forum (EPF) members, was intended for everyone, not just people already using data or interested in AI. During the webinar, participants were invited to ask questions and share their hopes and concerns around AI and ideas for how it is, and could, change patients’ treatment, outcomes and experiences.

The Members’ Circles took place on October 8th and 21st in 2021. During the sessions, attendees were asked to rate three statements on two scales: 1) Impact to me and my work (or, the people I advocate for) and 2) Difficulty and Cost of Implementation. The statements were:

1. Researchers get easy, secure access to health data for medical research and/or to improve the healthcare system
2. Patients & patient representatives are involved in the development of all AI applications that impact them
3. Involve patients & patient representatives in the development and enforcement of laws regarding AI use

Particular attention was then paid to where there was the most excitement and interest, which topics had the widest spread of opinions, where there was agreement and where experiences were very different between

different conditions, different regions, and different populations. The end of the session was focused on how these three statements connect.

Attendees were also asked whether they would like to participate in a longer interview about their own experiences or opinions as well as if they know anyone doing great work on AI in healthcare who is patient-led or is doing a great job of involving patients. The insights from these sessions are signposted and woven throughout the next section which presents the findings.

Interviews were semi-structured and 45 minutes long. The interview protocol for policy experts focused on understanding the intended and unintended consequences of AI policies discovered in the desk research from Phase 1, as well as examining current policy positions. An interview protocol for EDF patient representatives focused on understanding how each actor understands AI and perceives its benefits, risks and challenges to the healthcare sector as well as advocacy activities.

Ethical considerations: For all interviews conducted during Phases 2 and 3, participants were invited to an interview by email describing the research, requesting consent to conduct the interview and be recorded and sharing that there will be no monetary benefit to participation. At the interview start, the researcher again explained the research and clarified that participant information will be treated with strict confidence (e.g. that their identity will not be passed onto a third party beyond EDF). Interviews were conducted over Zoom, posing no risk to participants beyond day-to-day activities, and transcribed using Otter.ai, ensuring confidentiality and effective capturing of content. Participants were not asked about their diagnoses or medical information, but about their experiences of care and views about AI and relevant technologies and policies. Participants had the option to be quoted anonymously and to review quotes before publication.

Appendix #2: Glossary

Term	Description
Algorithm	A process or set of rules to be followed in calculations or other problem-solving operations by a computer
Artificial Intelligence	The ability of computers to perform tasks typically associated with human intelligence
Big Data	A field that treats ways to analyse, systematically extract information from, or otherwise deal with data sets that are too large or complex to be dealt with by traditional data-processing application software
Black Box	A system which can be viewed in terms of its inputs and outputs without any knowledge of its internal workings
AI Deployment Actors	Actors involved in the deployment of AI (in the health sector, in this context), including health professionals, technologists and researchers
Digital Health	A discipline that includes digital care programs, technologies with health, healthcare, living, and society to enhance the efficiency of healthcare delivery and to make medicine more personalized and precise
Machine learning	The study of computer algorithms that can improve automatically through experience and by the use of data

Appendix #3: Acronyms

AI	Artificial Intelligence
CE	Conformité Européenne (translated as « "European Conformity »)
CF	Cystic Fibrosis
EEA	European Economic Area
EPF	European Patients' Forum
EU	European Union
GDPR	General Data Protection Regulation
GP	General Practitioner
IBS	Irritable Bowel Syndrome
ICU	Intensive Care Unit
MRI	Magnetic Resonance Imaging
MS	Multiple Sclerosis
VP	Vice President
WHO	World Health Organisation

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