UNIVERSITY OF TURKU
Faculty of Law

The Fundamental Right to Healthcare in the Age of Predictive Health AI systems

Legality and Protections under EU Law

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Master's thesis

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Abstract

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Predictive AI systems are increasingly being adopted by healthcare providers in the European Union (EU) to assess patient's eligibility for healthcare services. These systems typically identify "risk profiles" from large volumes of patient data. Based on this analysis, patients receive targeted notifications suggesting tailored healthcare interventions. However, there is a risk that these systems may reinforce existing barriers to access, caused by, for example, old age, lack of ID, or immigrant background.

This thesis assesses whether predictive AI systems are legal under EU regulation, and how the prevailing EU regulation succeeds in protecting equal access to healthcare. In terms of legality, I focus on the rules of the General Data Protection Regulation (GDPR) on automated decision-making and the Artificial Intelligence Act (AIA) provisions on high-risk AI systems. As for the legal protections, I examine the right to healthcare under the Charter of Fundamental Rights of the EU (CFR) and the Fundamental Rights Impact Assessment put forward by the AIA. This thesis draws on a combination of methods, including legal doctrinal analysis, literature review, and comparative analysis.

The main result of this thesis is that EU regulation does not adequately protect vulnerable patient groups from risks posed by predictive AI systems. The legality of predictive AI remains uncertain due to differing interpretations between the Union legislator and the Court of Justice of the EU. The right to healthcare under CFR lacks justiciability and the AIA's provision on the impact assessment falls short by not ensuring sector-specific safeguards, effective oversight or remedies.

Key words: right to health, right to healthcare, health law, predictive healthcare, Artificial Intelligence Act, high-risk AI system, automated decision-making

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Abstract

Tutkielma

Oppiaine: Oikeus ja eriarvoisuus
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Ennakoivia tekoälyjärjestelmiä otetaan yhä useammin käyttöön terveydenhuollon palveluntarjoajien toimesta Euroopan unionissa (EU). Näitä järjestelmiä käytetään potilaiden hoitoon pääsyn arvioinnissa tunnistamalla niin kutsuttuja ”riskiprofiileja” suurista määristä potilastietoja. Järjestelmän suorittaman analyysin perusteella potilaille ehdotetaan räätälöityjä terveydenhuollon toimenpiteitä. Vaikka järjestelmiin liittyy monia hyötyjä, voivat ne kuitenkin vahvistaa jo olemassa olevia terveydenhuollon pääsyn esteitä. Tällä hetkellä esteitä aiheutuu esimerkiksi korkeasta iästä, henkilöllisyystodistuksen puuttumisesta tai maahanmuuttajataustasta.

Tässä tutkielmassa arvioidaan, ovatko ennakoivat tekoälyjärjestelmät EU:n lainsäädännön valossa laillisia, ja miten unionin voimassa oleva sääntely onnistuu turvaamaan terveydenhuollon yhdenvertaisen saatavuuden. Laillisuuden osalta keskityn yleisen tietosuoja-asetuksen säännöksiin automaattisesta päätöksenteosta sekä tekoälyasetuksen säännöksiin korkean riskin tekoälyjärjestelmistä. Oikeusturvan osalta tarkastelen EU:n perusoikeuskirjan sisältämää oikeutta terveydenhuoltoon sekä tekoälyasetuksen sääntöjä perusoikeusvaikutusten arvioinnista. Tutkielman metodina on lainoppi, kirjallisuuskatsaus sekä vertaileva analyysi.

Tutkielman keskeinen johtopäätös on se, että EU:n lainsäädäntö ei onnistu suojelemaan haavoittuvassa asemassa olevia potilasryhmiä ennakoivien tekoälyjärjestelmien aiheuttamilta riskeiltä. On kyseenalaista, ovatko nämä järjestelmät laillisia, sillä unionin lainsäätäjän ja EU:n tuomioistuimen tulkinnat laillisuudesta eroavat merkittävällä tavalla toisistaan. Lisäksi tuomioistuimessa ei voi nostaa kannetta sillä perusteella, että perusoikeuskirjan oikeutta terveydenhuoltoon on loukattu. Tekoälyasetuksen säännökset vaikutustenarvioinnista ovat niin ikään puutteellisia, sillä ne eivät takaa tehokasta valvontaa tai oikeussuojakeinoja, eivätkä ota riittävällä tarkkuudella huomioon alakohtaisia erityispiirteitä.

Avainsanat: oikeus terveyteen, oikeus terveydenhuoltoon, terveysoikeus, ennakoiva terveydenhuolto, tekoälyasetus, korkean riskin tekoälyjärjestelmä, automaattinen päätöksenteko

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List of Abbreviations

AG	Advocate General
AI	Artificial Intelligence
AIA	Artificial Intelligence Act (EU) 2024/1689
CFR	Charter of Fundamental Rights of the European Union
CJEU	Court of Justice of the European Union
DPA	Data Protection Authority
DPIA	Data Protection Impact Assessment
EDPB	European Data Protection Board
ESC	European Social Charter
EU	European Union
FRA	European Union Agency for Fundamental Rights
FRIA	Fundamental Rights Impact Assessment
GDPR	General Data Protection Regulation (EU) 2016/679
HRIA	Human Rights Impact Assessment
ICESCR	International Covenant on Economic, Social and Cultural Rights
MDR	Medical Device Regulation (EU) 2017/745
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union

Appendices

Figure 1. Vulnerability and limited access to justice.

1 Introduction

1.1 Thematical background

Imagine a healthcare system where services are distributed based on intelligent alerts from AI technologies—like smartwatches that detect irregular heart rhythms or algorithms that analyse electronic health records. Now, imagine a 62-year-old woman with an immigrant background, who owns no wearable device and has had little contact with healthcare professionals. She hasn't seen a doctor in years, largely due to language barriers and long wait times. When she is eventually referred for a routine cancer screening, the system's new AI-driven triage tool quietly flags her as low-priority. Her screening is delayed—and by the time the cancer is detected, it is already in an advanced stage.

Healthcare providers in the European Union (EU) and all over the world are increasingly advancing the adoption of Artificial Intelligence (AI) systems in assessing whether a patient is eligible for healthcare services. To describe these AI systems on a general level, they usually detect so-called "risk profiles" from a large amount of patient data. Based on this assessment made by AI, targeted notifications will be sent to patients who may benefit from specific healthcare interventions based on their medical history, lifestyle, or risk factors.[1] These systems are normally used in the context of interrupting the progression of a disease or preventing complications or other physical consequences of an already symptomatic disease. In this thesis, I refer to these systems as "predictive AI systems".

These so-called predictive AI systems are mentioned in both Union level programmes and national health strategies of several EU Member States. On the Union level, the EU-funded Digital Europe Programme mentions data-driven solutions to enable risk stratifications and to develop targeted and more effective treatments.[2] On the national level, for example Germany's national digital health strategy mentions "utilizing data and AI to detect health risks and automatic notification of […] their general practitioner with a recommendation to see a doctor"[3]. Similarly, a report that focuses on Spanish digital health laws and new

*AI-based language tools were utilized in this thesis in a restricted manner in enhancing linguistic clarity and style when necessary. The use of AI-based language tools is disclosed in accordance with the University of Turku's guidelines on AI in teaching and studying (3/2023).

[1] Dogheim and Hussain 2023, pp. 94–96.

[2] DIGITAL EUROPE, Executive Council for Health's recommendations for EU digital health policy 2024-2029, p. 2.

[3] Germany's Digitalisation Strategy for Health and Care 2023 p. 21.

innovations in the field of digital healthcare, mentions the use of predictive AI. The report mentions "telemedicine applications that use AI to predict possible medical relapses". This is done through analyzing real-time personal health data in conjunction with historical trends from similar patients.[4]

Predictive AI systems may appear lucrative to state governments since they can be used to improve the cost-efficiency of a public healthcare system. Through using massive amounts of data, these systems can be used to enhance the efficiency and accuracy of diagnosing, treatment and management of diseases.[5] However, this cost-effective market-based approach to the distribution of healthcare services will not necessarily safeguard the health of society's most vulnerable, especially those marginalized due to, for instance, poverty, race, ethnicity, nationality, age, or disabilities. These disadvantaged populations experience barriers in accessing healthcare[6], which is why they may be underrepresented in the data that a predictive AI system can access. Thus, despite the fact that disadvantaged populations may have greater relative need for healthcare, it is possible that they are disregarded by predictive AI systems. Consequently, already existing disparities in access to health services may become amplified if AI is used to distribute health services.[7]

As predictive AI systems become more common in efforts to make healthcare more cost-efficient, it is essential to strengthen the protection of the fundamental right to healthcare within the EU's legal framework and to ensure that those deploying such systems comply with this fundamental right.

1.2 Research questions, originality and limitations

The aim of this thesis is to assess whether predictive AI systems are legal under EU regulation and how the prevailing EU regulation succeeds in protecting equal access to healthcare. In terms of legality, I focus on the rules laid out in the General Data Protection Regulation (EU) 2016/679 (GDPR) regarding automated decision-making. In addition, I assess the legality of predictive AI systems based on the provisions concerning high-risk AI systems in the Artificial Intelligence Act (EU) 2024/1689 (AIA). As regards to legal protections, I focus on

[4] ICLG Report on Digital Health Laws and Regulations 2024, Spain.
[5] Gerybaite et al. 2022, p. 385.
[6] For instance, according to a work paper published by the OECD, in every Member State of the EU, people with the lowest incomes are significantly more likely to experience unmet medical needs compared to those with the highest income (OECD 2024).
[7] Roberts and Salib 2024, p. 95.

two specific EU law provisions that may prove useful in the protection of patients against the potential discrimination by predictive AI systems. Firstly, I focus on the fundamental right to healthcare (Article 35) under the Charter of Fundamental Rights of the European Union (CFR). Secondly, I examine the obligations deriving from the Fundamental Rights Impact Assessment (FRIA) (Article 27) of the AIA. My main research question is formulated in the following manner:

- Are predictive AI systems legal under EU regulation and what are the shortcomings in the prevailing regulation (particularly Article 35 CFR and Article 27 AIA) to strengthen the potential of EU law to warrant equal access to healthcare?

In order to answer to the main research question, I use two sub questions:

- Is the right to healthcare under CFR enforceable in court proceedings?
- Is the legislation on Fundamental Rights Impact Assessment sufficient in ensuring compliance with fundamental right to healthcare in the context of predictive AI systems?

While there is some emerging scholarship on the implications of the AIA and the GDPR in the context of health AI systems, Minssen et al. have specifically called out for more research on the intersection of these two regulations in the field of health law.[8] To date, the legality of predictive AI systems has not been thoroughly assessed through the combined lens of the GDPR’s automated decision-making rules and the AIA’s high-risk AI system provisions.[9] Furthermore, FRIA remains an obscure research topic, especially from a health AI point of view, since it was only introduced by the Commission in June 2023. In this thesis, I assess the legal obligations of the FRIA in view of those arising from the Data Protection Impact Assessment (DPIA), which is the GDPR’s equivalent for assessing the threats to fundamental rights. To the best of my knowledge, this comparative approach has not yet been applied by legal scholars, making it an original contribution to the field.

This thesis is limited in the following manner. Firstly, it is important to note that my thesis strictly focuses on predictive AI systems that are used in a healthcare context. Thus, the usage of these systems in a social care context is outside the scope of this thesis.

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[8] Minssen et al. 2024, p. 325.

[9] For example, van Kolfschooten has recognized that Article 22 GDPR may offer protection for patients who are being subject to automated decision-making (van Kolfschooten 2024).

Secondly, out of all the health-related provisions of the CFR, I primarily focus on Article 35 since it is the most crucial provision when it comes to equality threats[10] posed by predictive AI systems in healthcare. The first sentence of Article 35 CFR explicitly recognizes the right to access preventive healthcare and the right to benefit from medical treatment, making the provision directly applicable in cases where predictive AI systems are used in distributing health services. In addition to Article 35, CFR includes many health-related provisions, which I do not cover in my analysis, for example, the right to dignity (Article 1), right to life (Article 2), right to integrity (Article 3), right to privacy and protection of personal data (Articles 7 and 8), freedom of medical research (Article 13), and right to equality (Article 20).[11] The right to non-discrimination (Article 21), however, is also central in addressing the disparity threats posed by predictive AI systems in healthcare. Of course, it does not directly refer to the right to receive healthcare but it could provide an additional safeguard if interpreted together with the right to healthcare. Consequently, in this thesis, I assess the right to healthcare in light of the non-discrimination provision of Article 21 CFR.

Thirdly, this thesis does not cover sectoral regulation. Medical Device Regulation (EU) 2017/745 (MDR) is, thus, outside the scope of this thesis. Although it is likely that a predictive AI system would be categorized a medical device under the MDR, my thesis focuses solely on horizontal regulation (AIA and GDPR). One of the reasons behind focusing on horizontal regulation is that Annex III of the AIA explicitly lists AI systems used for healthcare eligibility assessments as a separate category, in addition to mentioning medical devices under the MDR. So, AIA specifically distinguishes AI systems used for healthcare eligibility assessments from other medical devices under the MDR. Additionally, the MDR does not explicitly address the themes of algorithmic fairness or discrimination, whereas AIA and Article 22 GDPR focus on individual's rights when subject to automated decision-making. Namely, van Kolfschooten has noted how the MDR "mainly sets technical rules with regard to the protection of the physical safety and health of patients, and is less focused on the

[10] In my assessment, I focus only on threats to equal access to healthcare that might originate from the deployment of predictive AI systems in healthcare. That is not to say that there are also other threats in the deployment of these AI systems. Medical and legal scholars have discussed, among other threats, threats to transparency, accountability, and patient autonomy. Mourby et al. have argued that because of the "black-box" nature of algorithmic decision-making, the transparency requirements of the GDPR, that currently apply to fully automated decisions, should also apply to partly automated medical decisions (Mourby et al. 2021). Accountability is also widely discussed in accordance with medical AI. Naik et al. have pointed out how it is not seamless to identify the operator who is legally accountable for damage caused by medical AI systems (Naik et al. 2022). Many scholars have also argued that, in order to practice patient autonomy, patients should have the right to withdraw from medical automated decision-making (e.g. van Kolfschooten 2024, and Ploug and Holm 2020).

[11] Hervey 2003, pp. 202–203, and de Federico 2017, p. 235.

protection of patients' rights"[12]. Accordingly, this thesis takes a broader approach focusing on the horizontal legal requirements, which apply to a wide range of predictive AI-systems, including – but not limited to – those classified as medical devices under the MDR.

Fourthly, my main focus is inequalities stemming from real-world data. With this focus in mind, I do not separately assess the consequences that can occur when the training data is unrepresentative. For example, Article 10 AIA is specifically focused on making sure that training, validation and testing data sets are sufficiently representative. My thesis does not focus on the legal safeguards that ensure the representativity of training data. Instead, I examine how disparities in healthcare access across EU can lead to unrepresentative real-world data. I assess how biased real-world data can impact predictive AI systems and how the Union's regulation succeeds in protecting patients from this type of discrimination. On the same note, my analysis covers only the processing of health data for primary use, and not for secondary use.

Lastly, this thesis focuses solely on the legal framework of the EU. Thus, I do not focus on any national provisions of Member States that would potentially safeguard the patient's right to contest discriminatory decisions of predictive AI systems. I am aware that domestic legislation of the Member States may provide useful safeguards when it comes to predictive AI systems. Yet, I consider it of ultimate importance that EU law should provide for these safeguards since the legislation that applies to predictive AI systems is largely based on legislative acts of the Union.

1.3 Method

This research adopts primarily a legal doctrinal approach, focusing on a detailed analysis of the interpretation of relevant EU provisions and case law. My main focus is in analysing the fundamental right to healthcare under the CFR and the Fundamental Rights Impact Assessment (FRIA) of the AIA. This approach will involve interpreting the scope and limitations of these provisions. In addition to the doctrinal approach, I also draw on literature review and comparative analysis.

In the chapter, which focuses on the thematical background of predictive AI systems, I use literature review to assess the functioning and the popularity of predictive AI systems.

[12] Kolfschooten 2022, p. 22.

Literature review is also utilized when I delve into research conducted the existing disparities in healthcare access in the EU and analyse these findings in view of the shortcomings of the prevailing legislation.

In assessing the features and possible shortcomings of the FRIA, as I previously mentioned, I utilize comparative analysis to draw conclusions of the differences between the FRIA and the Data Protection Impact Assessment (DPIA) of the GDPR. DPIA is a suitable framework for comparison because DPIAs need to be conducted when automated decision-making is used to automatically evaluate aspects related to an individual and important decisions in light of the rights of the individual are made based on this evaluation.[13] In other words, both impact assessment models are activated in situations where automated processes pose a risk to fundamental rights. This type of comparative analysis allows a critical evaluation of the FRIA's scope, effectiveness, as well as identifying its potential gaps.

1.4 Structure of the research

In order to answer my research question, the chapters of my master's thesis cover the following topics. First, I focus on defining predictive AI systems as well as other central concepts. I also showcase a practical example of this type of AI system. Next, I turn my focus onto the fundamental right to healthcare under the CFR. I assess whether this provision, either on its own or in conjunction with the right to non-discrimination, can serve as a legal basis in court proceedings. After this, I focus on the specific threats to equal access to healthcare posed by predictive AI systems. Subsequently, I examine the legality of predictive AI systems in view of the applicable provisions of the GDPR and the AIA. Thereafter, I focus on the Fundamental Rights Impact Assessment of Article 27 AIA. I examine the potential weaknesses that the FRIA might have when applied in the context of predictive AI systems in healthcare. In the discussion Chapter, I interpret and analyse the results of my thesis by contextualizing them to the wider academic discussion and access to justice theory. Namely, I assess EU regulation in light of research conducted on the existing disparities in healthcare access across different societal groups. Moreover, I briefly delve into how the EU legislation should be revised in order to adequately safeguard patients from the algorithmic discrimination occurring in the healthcare context. Lastly, in the conclusion Chapter, I summarize the thesis and highlight its importance.

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[13] Recital 71, GDPR.

2 Predictive AI systems in healthcare

The objective of this Chapter is to provide the reader with a description of the predictive AI-systems that are being adopted and used in healthcare. For instance, defining the level of autonomy of these systems is necessary to identify the legal provisions that apply to them. Additionally, in this Chapter, I present a national example of a predictive AI system from one of the Member States of the EU.

2.1 Defining the central concepts

2.1.1 AI system

Before moving onto the concept of predictive health AI systems it is necessary to briefly look at the concept of an AI system. According to Article 3(1) AIA, "AI system" refers to a "machine-based system that is designed to operate with varying levels of autonomy". AI system may "exhibit adaptiveness after deployment", and it may generate "predictions, content, recommendations, or decisions" from different inputs. It is no surprise that legal scholars have stated that this concept of an AI system, adopted in the AIA, is broad.[14] Because of the loose criteria, it is likely that predictive AI systems used in assessing patient's eligibility for healthcare services, fall into the scope of an AI system under the AIA. This is also why I use the term AI system, and not only e.g. machine learning, when referring to predictive systems that are used in healthcare.

2.1.2 Predictive AI system

Predictive health AI systems have been discussed amongst medical scholars in the past few years. More specifically, there has been a discourse about the emergence of predictive models and intelligent alerts that enable advanced data-driven insights in healthcare. According to medical literature, through analysing large amounts of demographic, clinical and genetic data, these models can form predictive risk profiles for patients. This way healthcare professionals can detect patients at a high risk of developing a specific disease and who, thus, would possibly benefit the most from medical intervention. So, the aim of these models is to make healthcare more proactive and optimize resource allocation.[15]

[14] See e.g. Minssen et al. 2024, p. 315, and Niemiec et al. 2024, p. 5.
[15] Dogheim and Hussain 2023, pp. 94–96.

There has also been a reference to these predictive AI systems in the Union's legislative acts. The AIA refers to "AI systems intended to be used [--] to evaluate the eligibility of natural persons for essential public assistance benefits and services, including healthcare services" (Annex III Paragraph 5a). In the writings of medical scholars, these applications are not necessary called "AI for healthcare eligibility assessment" but they are rather described more unambiguously as "predictive AI models".

In order to describe the function of predictive AI systems, it is crucial to categorize them based on their level of autonomy. In the context of health AI, systems are generally divided into three categories: assisting AI, fully automated AI, and a category that is located between these two: partially automated AI.[16] Assisting AI-systems provide alternative solutions for healthcare professionals. Hence, the healthcare professional has a choice whether to comply with the provided suggestions or not. In contrast, in fully automated AI-systems the choice is made entirely on the basis of the AI without any human intervention.

In partially automated AI systems, on the other hand, the decision-making is not entirely automated: human input is required at some point during the decision-making process. An example of partially automated AI, according to van Kolfschooten, is AI for clinical trial selection, where patients eligible for a specific clinical trial[17] are found by scanning through large amounts of patient data. In these systems, the final decision of contacting is still in the hands of the medical professional. Predictive AI systems function in a similar manner, but the aim is to find patients that would benefit from, not only medical testing, but also health services. Hence, it seems appropriate to classify predictive AI system to the category of partially automated AI systems.[18]

The sources of patient data that are used to calculate the health risk of a specific patient also vary. Patient data can be derived from, for instance, clinical data that has been collected from

[16] Van Kolfschooten 2024, p. 376.

[17] According to WHO, "clinical trials are a type of research that studies new tests and treatments and evaluates their effects on human health outcomes" (WHO, Clinical Trials).

[18] However, there is a fine line between the different levels of autonomy. The Finnish DPA has stated that the patients who are deemed healthy, and thus not selected for closer examination by the AI, are subject to solely automated decision-making (Finnish Data Protection Authority 6482/186/2020 and 3895/83/22). Additionally, Germany's digital health strategy seems to refer to solely automated decision-making when it comes to predictive AI systems, because it mentions "automatic notifications" (Germany's Digitalisation Strategy for Health and Care 2023). Hence, it is not ambiguous that AI for healthcare eligibility assessment necessarily belongs to the category of partially automated AI-systems, because these systems can also function entirely automatically, without any human intervention.

the patient by the healthcare provider (medical records).[19] It is also possible to form the risk assessment based on demographic or genetic data.[20] Health risks can also be detected through the use of wearable health devices, such as smart watches and rings.

Lastly, it is important to note that predictive AI systems are a part of preventive medicine. The discipline of preventive medicine has traditionally been divided into primary, secondary and tertiary prevention. Primary prevention focuses on the elimination of causes of disease through, for example, lifestyle and diet promotion. Secondary prevention centers on early detection of disease. In other words, the aim is to interrupt the progression of the disease as early as possible, at the presymptomatic phase. Examples of secondary prevention include mammography and blood pressure screening. Lastly, tertiary prevention concerns preventing complications and other physical consequences of a symptomatic disease. The goal is to prevent disability or premature death caused by the disease. An example of tertiary prevention is measures that aim to prevent a coronary heart disease patient from possible heart failure.[21]

In its current form of usage, predictive AI systems are predetermined to be used in secondary or tertiary prevention. In other words, predictive AI systems are used in early detection of disease or in the prevention of disability or premature death. At the moment, predictive AI systems are not used in primary prevention to improve public health but this type of usage may come popular in the future as AI models progress more and more.

2.1.3 Different healthcare actors

In this thesis, healthcare provider refers to any organization—public or private—that delivers healthcare services. Healthcare professional, on the other hand, in my thesis, refers to the person providing healthcare services to a patient. These professionals include doctors, nurses and other trained caregivers. Lastly, the deployer of a predictive AI system is defined as the public or private entity responsible for using an AI system under its authority.[22]

[19] Medical records was the source for patient data in the two opinions given by the Finnish DPA (Finnish Data Protection Authority 6482/186/2020 and 3895/83/22).
[20] Dogheim and Hussain 2023.
[21] Katz and Ali 2009, pp. 3–6.
[22] Article 3(4) AIA.

2.2 Case example: Finland

In the Introduction, I pinpointed how multiple EU-level national health strategies indirectly refer to the deployment of predictive AI systems in the healthcare context. In the following, I provide a deeper analysis of one predictive AI system that has emerged in Finland.

In Finland, the introduction of predictive AI systems in the context of healthcare is advanced by the current government and the national legislators. The current government programme (Finnish: *hallitusohjelma*) of Finland mentions an objective according to which "information will be used to anticipate clients' needs for services and for early intervention[23]". Additionally, the government programme refers to "the use of artificial intelligence in healthcare and social welfare [--] in prevention" while "safeguarding fundamental rights".[24] Currently, the Finnish Ministry of Social Affairs and Health is preparing legislation to facilitate the use of technology to analyse patient data for the anticipation of service needs and early prevention.[25]

Predictive AI systems have emerged on the Finnish market already a few years ago. In this thesis, I focus on the Health Benefit Analysis tool (originally "*Terveyshyötyarvio*" in Finnish) that has been introduced by The Finnish Medical Society Duodecim, the largest scientific association in Finland.[26]

The aim of the Health Benefit Analysis tool is to support the assessment and monitoring of the population's overall health. This tool helps in identifying key health trends and grouping patient populations based on their specific healthcare needs, enabling better targeted interventions.[27] Through processing health data, the Health Benefit Analysis tool can identify patients who are at high risk and would benefit from treatment.[28] Currently, this tool is in permanent use in one region in Central Finland, while in Helsinki, it has been developed and tested.[29]

The functioning of the tool can be described in the following manner. The patient data is obtained from the patient information system and it is pseudonymized before it is transferred

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[23] Finnish Government Programme (2023), point 2.5 Digital services and knowledge management p. 43.
[24] Finnish Government Programme (2023), point 2.5 Digital services and knowledge management p. 44.
[25] Draft Proposal of the Finnish Ministry of Social Affairs and Health.
[26] Duodecim, frontpage.
[27] Duodecim, Health Benefit Analysis.
[28] This is how the function of the Health Benefit Analysis Tool is described in the opinion of the Finnish DPA (6482/186/2020). It is based on the statements that the data controller has submitted.
[29] Niskasaari et al. 2025.

to the tool. The tool makes various analyses and reports which will help in measuring the effectivity of the patient's current treatment. If the treatment is deemed ineffective or a significant health risk is detected, the patient can be identified in the patient information system. Healthcare professional then assesses the situation and can contact the patient if necessary.[30] Because Health Benefit Analysis tool is machine-based and generates predictions and recommendations, it is likely to fall into the scope of an AI system under the AIA.

However, advancing the deployment of these type of predictive AI systems assessing healthcare eligibility has proved challenging because the Finnish Data Protection Authority (DPA) (Tietosuojavaltuutettu) has issued two opinions deeming the Health Benefit Analysis tool unlawful under Article 22 GDPR.[31] I focus on these opinions more closely in Chapter 4 where I assess the legality of predictive AI systems.

[30] Finnish Data Protection Authority 6482/186/2020.
[31] Finnish Data Protection Authority 6482/186/2020 and 3895/83/22.

3 The fundamental right to healthcare

This Chapter centres on the fundamental right to healthcare, especially under the Charter of Fundamental Rights of the European Union (CFR). I focus on the degree of protection that this provision can provide to a patient. More specifically, I assess the justiciability and legal strength of the right to healthcare under the CFR, examining whether a patient can invoke court proceedings to enforce this right.

3.1 The rationale behind the right to healthcare

Before moving onto discussing the right to healthcare under Article 35 CFR, it is necessary to shortly focus on what is considered to be the raison d'être behind this fundamental right. In other words, what does the fundamental right to healthcare generally convey in a legal doctrinal context and what is its core aim?

Primarily, it is important to recognize that the right to healthcare is considered a second-generation human right. This implies that the right to healthcare generates a positive claim on the state. In other words, it constitutes a positive obligation to the state to take proactive measures to guarantee that this right is fulfilled. According to Hervey, these so-called proactive measures can include, for example, taking legislative measures to ensure equal access to healthcare, adopting a national health policy, or allocating sufficient state funds to healthcare. [32]

However, the positive nature of the right to healthcare is not unambiguous. Hervey has stated that the right to healthcare could also have a negative dimension. To put it differently, it can be characterized as having a negative obligation to the state not to interfere with the fulfilment of this right.[33] Namely, states cannot operate in ways that would possibly jeopardize the fulfilment of the right to healthcare. According to my assessment, this notion made by Hervey illustrates how the right to healthcare is closely connected to the right to non-discrimination. States need to ensure that they do not, when operating in the field of healthcare, create barriers that would hinder the access to healthcare of the most vulnerable.

Furthermore, Hervey has stated that it is not enough that states do not hamper the fulfilment of the rights of the most vulnerable. Their rights should be protected by states because,

[32] Hervey 2003, pp. 194–195, 199.
[33] Hervey 2003, pp. 194–195, 199.

according to Hervey, the right to healthcare generally involves safeguarding the equal treatment and access to health of society's most vulnerable, especially those marginalized due to poverty, race, ethnicity, nationality, gender, age, or mental and physical disabilities. This is why Hervey also comes to the conclusion that cost effectiveness or market-based approach can never be the sole key objective in healthcare.[34]

In conclusion, the fulfilment of the right to healthcare, firstly, requires states to take an active and engaged role. Secondly, states are not allowed to interfere with this right in ways that would jeopardize its fulfilment. Specifically, states need to ensure that their measures do not interfere with the equal access to health of the society’s most vulnerable.

3.2 The right to healthcare under the CFR

The Union’s commitment to respecting human rights is codified in the Treaty on European Union (TEU). According to Article 2 TEU, “the Union is founded on the values of [--] respect for human rights, including the rights of persons belonging to minorities”. The primary instrument in the Union’s mission in the protection of fundamental rights is the CFR. The Union took remarkable steps in its human rights agenda with the ratification of the CFR in 2000.[35] Eventually, the CFR came into force with the Treaty of Lisbon in year 2009. Article 6 TEU grants the CFR the same legal value as the founding Treaties, making it a source of primary EU law. The CFR contains many provisions that are related to the protection of health, most remarkably the right to healthcare under Article 35.

Before discussing the right to healthcare under the CFR, it needs to be noted that the Union has, under Article 3(1) TEU committed to the promotion of the “well-being of its peoples”. This commitment to the promotion of well-being proves how the Union is not just an economic or political entity but a protector of social welfare. The CFR further specifies this commitment since it contains more detailed provisions aimed to guarantee the well-being and right to health of its peoples.

Article 35 CFR guarantees everyone the right to healthcare. Firstly, Article 35 CFR ensures everyone the right to access preventive healthcare. Thus, this right applies in situations where the purpose is in preventing diseases. Secondly, according to Article 35 CFR, everyone has the right to benefit from medical treatment. Hence, this right governs situations where a

[34] Hervey 2003, p. 196.
[35] McHale in Baeten et al. 2010, p. 295.

patient already has a disease and wishes to receive treatment.[36] Consequently, the right to healthcare under Article 35 CFR seems to apply in, at least, secondary prevention (early detection of diseases) and tertiary prevention (preventions of complications and premature death). However, both the right to preventive healthcare and to medical treatment are not absolute; they are subject to "conditions established by national laws and practices".

In addition to these two rights, the Article establishes a principle, according to which a high level of human health protection shall be ensured. Here, I focus on the protection provided by the two rights mentioned in Article 35 CFR: right to access preventive healthcare and right to benefit from medical treatment, as these two rights have more potential in being interpreted as individually justiciable rights. The "high level of human health protection" principle is clearly meant to serve as a standard for policies that are enacted on a general level in a Member State – it is not a right that is possible to invoke in court proceedings.

Some readers might also question why I chose Article 35 CFR as a legal source for the fundamental right to healthcare since there is an active discussion amongst legal scholars about the lack of competence of the Union in the field of human rights.[37] Namely, the Union generally has no right to intervene in situations where the fundamental rights matter falls solely within the scope of national jurisdiction. The reasoning behind this is that the CFR is only directly applicable when a matter falls within the scope of EU law.[38]

In other words, Article 35 CFR only applies when Member States enact or enforce national laws that implement an EU directive or when authorities functioning in Member States apply EU regulations directly.[39] However, this limitation is irrelevant in the context of predictive health AI. The deployers of predictive AI systems in healthcare are following the rules of the GDPR and the AIA which are both directly applicable regulations. Accordingly, it is clear that predictive AI systems fall under the scope of Article 35 CFR. Consequently, in theory, Article 35 CFR could be used in legal cases to challenge or assess the actions of EU Member States when those actions are taken in the context of implementing law concerning predictive AI systems. This positions the CFR as a suitable and relevant framework for my research.

It is also important to recognize that CFR is not the only statute in the Union's legal framework that refers to the "right to healthcare". EU is a party to the International Covenant

[36] Lock 2019.
[37] See e.g. Beijer 2017.
[38] Article 51 CFR.
[39] When does the Charter apply, Website of the European Commission.

on Economic, Social, and Cultural Rights (ICESCR). Article 12 of the ICESCR recognizes the "right of everyone to the enjoyment of the highest attainable standard of physical and mental health" and "prevention, treatment and control of [--] diseases". Similarly, Article 11 of the European Social Charter (ESC) is titled "the right to protection of health". This provision mentions "ensuring the effective exercise of the right to protection of health" as well as prevention of possible diseases.

However, the enforceability of the above-mentioned provisions is weak compared to Article 35 CFR. Both ICESCR and ESC are more programmatic obligations to the Member States of these Conventions rather than enforceable individual rights. Additionally, neither the ICESCR nor the ESC is a primary source of EU law. Furthermore, it has been pointed out by Lougarre that the CJEU has never referred to either Article 12 ICESCR or Article 11 ESC while it regularly refers to the provisions of the CFR.[40] This makes the right to healthcare under the CFR best suited for my analysis.

3.3 Non-justiciability of the right to healthcare

3.3.1 Principle, not a right

A strict textual interpretation of Article 35 CFR seems to grant everyone the right to access preventive healthcare and to benefit from medical treatment. The textual format that refers to the word "right" seems to clearly indicate that this provision should be treated as such. However, a more profound interpretation of Article 35 CFR seems to suggest that it constitutes a principle rather than a right, which means that Article 35 CFR has no direct effect.

In EU law, rights have direct effect while principles lack direct effect. According to Article 51(1) CFR, rights shall be respected while principles shall be observed. However, the CFR does not specify which provisions are to be considered rights and which provisions should be considered principles. Furthermore, principles may be "implemented by legislative and executive acts" and they shall be "judicially cognisable only in the interpretation of such acts and in the ruling on their legality".[41] This means that individuals cannot invoke principles of the CFR before a national or a European court. Proceedings can only be brought if these

[40] Lougarre 2023.
[41] Article 52(5) CFR.

principles have been further specified in Union legislation or domestic legislation of the respective Member State.

The CJEU has also considered the effectiveness of a CFR principle in its case law. In 2014, the CJEU ruled that for a principle "to be fully effective, it must be given more specific expression in European Union or national law". In other words, for individuals to rely on a principle in court, there has to be a separate legal measure that concretely implements that principle.[42]

Like mentioned above, according to Article 35 CFR, right to access preventative healthcare and right to benefit from medical treatment are subject to "conditions established by national laws and practices". So, the provision is defined through national laws and practices rather than international human rights standards.[43] Hence, in reality, the right to access healthcare is defined through the legislation of the Member State. This illustrates how this provision of CFR is more likely to confer a principle rather than a right. Michalowski has stated how the subjectivity to national laws and practices gives the right to healthcare under the CFR a rather "programmatic nature"[44]. In other words, this subjectivity to national laws and practices makes the right rather general. Namely, it renders the provision to a mere policy guideline. This subjectivity has also lead to many scholars arguing that fundamental right to healthcare is currently lacking from the fundamental right framework of the EU.[45]

For example, imagine a patient who invokes legal proceedings in Finland after being unequally denied healthcare services by a predictive AI system. While they might base their claim on Article 35 CFR, the fundamental right to healthcare would not stem directly from the CFR itself. Instead, it would likely derive its substance from the Finnish Constitution, which guarantees patients the right to access adequate healthcare services.[46] This highlights the role of national legislation in shaping the practical application of Article 35 CFR.[47]

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[42] Judgment 15.1.2014, *AMS v Minister for Justice and Equality*, C-176/12, ECLI:EU:C:2014:2, paragraph 45.
[43] Lougarre 2023.
[44] Michalowski 2004, p. 291.
[45] Suorsa 2021 and Lougarre 2023.
[46] Constitution of Finland (731/1999), Section 19 (3).
[47] Generally, the rights of patients are regulated on a national level while the Union's legal framework provides a mere minimum standard of patients' rights (van Kolfschooten 2022, p. 5). Most Member States protect patient's rights in their national legislation. These rights can be mentioned, for example, in the national constitution, specific patients' rights laws or civil code. For example, constitutions of 21 out of 27 EU Member States explicitly recognize the right to healthcare. In many Member States this right has been added to the constitution within the last 30 years (Constitute Project).

Why have the Union legislators then adopted this wording for Article 35 CFR? Primarily, the subjectivity of Article 35 CFR to "conditions established by national laws and practices" is the result of EU's limited competence in the field of healthcare.[48] There are two provisions in the founding treaties of the Union that specifically underline the lack of competence of the Union in healthcare matters. Firstly, according to Article 168(7) of the Treaty on the Functioning of the European Union (TFEU), the Union shall respect the responsibilities of the Member States in their health policy, delivery of health services, medical care as well as the allocation of resources. Secondly, Article 6(a) TFEU states that the Union has supporting competence in the "protection and improvement of human health". Thus, issues related to healthcare and health policies are mostly regulated on national level in each Member State.[49]

In other words, health is still predominantly a field where Member States' national law plays a primary role. It is crucial to highlight that the unification of health rights and health policy were indisputably not the raison d'être behind the formation of the Union. Although human rights have been recognised as general principles in EU law since the 1960s, many legal scholars argue that health rights and health policy as well as the broader theme of human rights became a discussed topic in the EU only in the 1990s.[50]

In conclusion, although the Union is tied to respecting human rights and promoting the well-being of its peoples in its founding Treaties, it has limited competence in public healthcare matters, which weakens its competence to tackle human rights issues in the field of healthcare. This is the reason why the right to healthcare under Article 35 CFR, in practice, confers a principle rather than a right. Ultimately, although Article 35 CFR could, in theory, be used to judicially review Member States' acts and policies when they are implementing Union law, the limited competence of the EU in the field of healthcare and health policies weakens this ability.[51]

3.3.2 Lack of case law references

The weak justiciability of the right to healthcare under Article 35 CFR is also detectable in the CJEU's case law. In the following, I examine the case law database of the European Union Agency for Fundamental Rights (FRA) concerning the right to healthcare under Article 35

[48] Suorsa 2021, p. 145.
[49] Kolfschooten 2022, p. 5.
[50] Lougarre 2023 and McHale in Baeten et al. 2010, p. 282.
[51] De Rujiter 2019 p. 32.

CFR. Namely, I pay close attention to the amount and nature of references the CJEU has made to the right to healthcare.

Before moving further in my analysis, I would like to highlight a finding made by legal scholars on how the Union and the CJEU have followed a rather passive approach to protecting positive second-generation fundamental rights.[52] For instance, McHale has stated that "they [fundamental rights] do not provide positive entitlements against national authorities, which remain the main bodies that might infringe an individual's human rights in healthcare settings or elsewhere".[53] However, recent CJEU case law seems to have granted some second generation CFR rights direct effect. In *Bauer*, the CJEU ruled that a second-generation social right (right to a period of paid annual leave) has direct effect if it is mandatory and unconditional, and the matter falls within the scope of EU law.[54] Consequently, in theory, it would be possible for the Union and the CJEU to give judicial meaning to a positive second-generation fundamental right.

However, practice proves otherwise. The CJEU has never, in its case law, granted the right to healthcare under Article 35 CFR direct effect. In fact, one could argue that Article 35 has limited presence in CJEU case law. Lougarre has noted that the CJEU has rarely referred to the "right to health" or Article 35 CFR in its rulings. My analysis establishes a similar finding: In the CJEU's case law, there is hardly any citations of Article 35 CFR.[55] According to FRA's case law database, as of March 2025, CJEU has referred to Article 35 CFR, specifically, only 12 times.[56] These references to Article 35 CFR consist of six judgments, one order, and five Advocate General (AG) opinions.

Lougarre has noted how it is usually the AG that refers to Article 35, and not the Court itself.[57] The role of the AGs is to assist the Court in its decision-making.[58] They provide

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[52] See e.g. Frantziou 2019 and McHale in Baeten et al. 2010.
[53] McHale in Baeten et al. 2010, p. 294.
[54] Judgment 6.11.2018, *Bauer*, Joined Cases C-569/16 and C-570/16, ECLI:EU:C:2018:871, paragraph 85.
[55] Hervey and McHale 2021, p. 1012.
[56] Judgment 25.6.2024, *Ilva and Others* C-626/22, ECLI:EU:C:2024:542; Judgment 22.3.2023, *Commission v. Hungary* C-823/21, ECLI:EU:C:2023:504; Judgment 22.11.2018, *Swedish Match AB v Secretary of State for Health* C-151/17, ECLI:EU:C:2018:938; Advocate General Opinion 12.4.2018 *Swedish Match AB v Secretary of State for Health* C-151/17, ECLI:EU:C:2018:241; Judgment 4.5.2016, *Philip Morris Brands and Others* C-547/14, ECLI:EU:C:2016:325; Judgment 29.4.2015, *Lèger* C-528/13, ECLI:EU:C:2015:288; Advocate General Opinion 17.7.2014, *Lèger* C-528/13, ECLI:EU:C:2014:2112; Judgment 6.9.2012, *Deutsches Weintor* C-544/10, EU:C:2012:526; Order 23.5.2011, *Rossius and Collard,* Joined Cases *C*-267/10 and C-268/10; Advocate General Opinion 6.5.2010, *Afton Chemical* C-343/09; Advocate General Opinion 30.9.2009, *Pérez and Gómez,* Joined cases C 570/07 and C 571/07; Opinion 11.1.2007, *Stametelaki v NPDD* C-444/05, ECLI:EU:C:2007:24.
[57] Lougarre 2023.
[58] Article 252 TFEU.

independent and impartial legal opinions which are advisory, not binding. Consequently, half of the references to Article 35 CFR are not even done in actual binding decisions, but in advisory legal opinions.

Analysis of the FRA's case law database on Article 35 CFR also shows how the context where this provision was raised was often connected to tobacco control in the context of public health.[59] In recent years, Article 35 CFR has also been referred to in the context of immigration and environment.[60] It is, of course, no coincidence that Article 35 activates in the specific above-mentioned contexts. In all three contexts, tobacco, environment and cross-border healthcare, there is also secondary EU legislation. In other words, all of these fields clearly fall into the scope of EU law which is required for the activation of Article 35 CFR. Furthermore, the prevalence of the provision in the context of immigration illustrates how the relevance of the provision is usually emphasized in situations where healthcare access is connected to cross-border contexts.

Perhaps the most crucial finding of my analysis, is that most of the cases only referred to the principle of "high level of human health protection" and not to the first sentence of Article 35 CFR which includes the right to access preventive healthcare and the right to benefit from medical treatment. This emphasis of the "high level of human health protection" principle illustrates how Article 35 CFR is generally interpreted by the CJEU as a general principle directed at the population at large than as an individually justifiable right. For example, Hervey and McHale have pointed out how, in *Deutches Weintor,* the CJEU fails to conceptualize Article 35 CFR as an individual fundamental social right, as the CJEU is referring to the provision as more of a "cross-cutting requirement applicable to Union policies and activities".[61]

Ultimately, I found only two references made by the AG that clearly concern the right to access preventive healthcare and the right to benefit from medical treatment. Specifically, in the jurisdiction of the CJEU, the right to access preventive healthcare has been referred to in only one Advocate General's opinion, while Article 35, as encompassing a patient's right to benefit from medical treatment, has likewise been mentioned in only one AG opinion.

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[59] Swedish Match AB v Secretary of State for Health; Philip Morris Brands and Others; Rossius and Collard.
[60] Ilva and Others; Commission v. Hungary.
[61] Hervey and McHale 2021, p. 1015.

In the first of these cases, in *Swedish Match AB v Secretary of State for Health*, a public limited liability company called Swedish Match contested an EU Regulation that prohibits placing on the market of tobacco for oral use anywhere else in the Union except in Sweden. The New Nicotine Alliance intervened in the proceedings and argued that the prohibition of placing on the market of tobacco for oral use restricts the right to access medical treatment under Article 35 CFR. They stated that Article 35 CFR includes the right to buy less harmful tobacco products that are not used for smoking.[62] To address this argument, the AG argued that the aim of the prohibition of tobacco for oral use is "to implement, rather than limit, the right to health, which [the right to health] requires complex assessments in the interests of not only smokers, but also the population as a whole[63]". Hence, even though there was a claim made based on the right to access medical treatment, a right that could, based on its wording, be perceived as individual, the AG is suggesting that this right should be assessed from the point of view of the whole population.[64]

The second case, *Stametelaki v NPDD*, included a situation of cross-border healthcare where a Greek patient was treated abroad in the United Kingdom for cancer of the bladder. He was not granted reimbursement of the cost of treatment because Greek national legislation did not allow reimburse for treatment in private hospitals abroad. According to the national rule, reimbursement was only granted to children under 14 years of age. Here, the AG specifically referred to Article 35 CFR as "the right of citizens to health care" which is to be "perceived as a personal entitlement"[65]. I believe this is one of the only opinions, if not the only opinion, where an AG recognizes that Article 35 CFR is more than a general principle directed to the population as a whole. It is treated by the AG as a right that can be applied on an individual level. Even more remarkable is that the AG also concluded that the national legislation disproportionately restricted citizen's right to healthcare.[66] The reference to Article 35 CFR is, however, only done in the AG opinion, and the decision made by the CJEU on the basis of this opinion does not refer to Article 35 CFR at all.

In conclusion, my findings uncover a significant gap in the CJEU's case law regarding the explicit recognition of an patient's right to preventive healthcare and access to medical

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[62] Swedish Match AB v Secretary of State for Health, paragraph 18.
[63] Swedish Match AB v Secretary of State for Health, footnote 19.
[64] This is, in my opinion, understandable because the case at hand revolves around the broader theme of tobacco control and public health, so referring to Article 35 CFR as an individual right would come across as somewhat unconventional.
[65] Stametelaki v NPDD, paragraph 40.
[66] Stametelaki v NPDD, paragraph 60.

treatment. While the general principle of a "high level of human health protection" is frequently acknowledged by the CJEU, the right to preventive healthcare and the right to access to medical treatment have received minimal attention. Notably, neither has been referenced in any judgment of the CJEU, indicating a lack of direct judicial engagement with these specific rights.

The limited amount of CJEU references demonstrates how Article 35 CFR has not yet become prominent or widely used in CJEU jurisprudence. Ultimately, my findings underline the conclusion made by Rosas about the post-Lisbon case law of the CJEU. He has argued that the CJEU case law proves how provisions in the Charter "can never be applied on a stand-alone basis" and "its [provision´s] applicability presupposes the existence of at least one relevant rule of EU law other than a Charter provision".[67] This precondition has not, so far, been met in the field of healthcare due the Union's limited competence.

3.4 Interpretation in conjunction with non-discrimination

Above, I have argued why Article 35 CFR may not offer powerful protection to a patient who is invoking proceedings. However, although Article 35 CFR is generally interpreted as a guiding principle rather than a directly enforceable right, it could potentially form a more concrete legal right, if invoked together with the non-discrimination provision (Article 21) of the CFR.

The potential lies in the fact that there is also secondary legislation in the Union framework that deems discrimination illegal in the field of healthcare. Thus, the existence of this right is not merely based on the CFR and other founding treaties. Additionally, non-discrimination provisions have more often been applied by the CJEU in their judicial reasoning.[68] So, by arguing that discriminatory treatment by a predictive AI system resulting in unequal access to healthcare, violates the fundamental right to non-discrimination, an individual claim could potentially become more actionable.

According to Article 21 CFR, "any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited". Paragraph 2 of the provision also prohibits any discrimination

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[67] Rosas 2015, p. 17.
[68] FRA, Case law references of Article 21 CFR.

on the basis of nationality. Like the right to health, the right to non-discrimination is also only applicable if a matter falls within the scope of EU law. As I mentioned above, predictive AI systems are regulated under EU law. Thus, they must also comply with the right to non-discrimination.

Scholars have specifically recognized the connection between Articles 21 and 35 CFR. Lock has stated that the right of access to preventative healthcare in Article 35 CFR should be interpreted as an equal right.[69] De Rujiter, on the other hand, has argued that Article 21 CFR is important especially in a public health case "where a policy may affect particular risk groups".[70] Michalowski also highlights the right to non-discrimination in the allocation of healthcare resources on the basis of any characteristics mentioned in Article 21 CFR.[71] Moreover, Hervey and McHale have pointed out how the FRA has devoted considerable attention to the significance of Article 35, especially in conjunction with the principle of equality. They highlight how, most often, the two rights are interpreted together in cases which concern the rights of the most vulnerable individuals within the Union.[72]

While legal scholars have acknowledged that the right to healthcare must be interpreted in conjunction with the non-discrimination provision, my analysis reveals two key weaknesses that undermine this allegedly close connection between the two rights.

Firstly, careful analysis of the FRA's case law database indicates that Articles 21 and 35 CFR are rarely interpreted together by the CJEU. Namely, there is only one CJEU judgment which refers to both Articles 35 and 21 CFR.[73] In this case, the "high level of human health protection" principle was used by the CJEU to establish whether French legislation implementing EU law on blood safety was complying with the non-discrimination clause of the CFR.[74] In the end, the CJEU held that a permanent restriction on blood donation of men who have sexual relations with other men is intended to reduce the risk of infectious diseases and therefore contributes to high level of human health protection.[75]

Secondly, secondary legislation does not adequately recognize all the possible grounds on which discrimination could occur in the context of distributing healthcare services through

[69] Lock 2019.
[70] De Rujiter 2019, p. 41.
[71] Michalowski 2004, p. 291.
[72] Hervey and McHale 2021, p. 1024.
[73] Lèger.
[74] Hervey and McHale 2021, p. 1016.
[75] Lèger.

predictive AI systems. To form a justiciable right, as Rosas has argued, a mere provision of a Charter is not enough – there must be at least one other relevant source of EU law.[76] However, EU's binding normative acts only marginally address the issue of equal access to healthcare. Namely, the Race and Ethnicity Equality Directive (Directive 2000/43/EC) and the Equal Treatment in Goods and Services Directive (Directive 2004/113/EC) only provide protection against discrimination based on racial or ethnic origin and sex. Additionally, the Patients' Rights Directive (Directive 2011/24/EU), which is applicable in cases of cross-border healthcare, protects patients from discrimination based on nationality if the patient is originating from another Member State.

Scholars, such as Orzechowski et al., have specifically pointed out how the above-mentioned directives entirely disregard, for example, religion, sexual orientation, age, and disability as possible grounds for discrimination.[77] From the point of view of predictive AI systems in the field of healthcare, it is alarming that these directives that are applied in the field of healthcare, only recognize limited categories of discrimination.

To conclude, the non-discrimination clause of the CFR does not necessary provide additional protection in the field of healthcare because Articles 21 and 35 CFR are rarely interpreted together by the CJEU and the secondary legislation in the respective field remains inadequate in recognizing all the possible different grounds of discrimination.

[76] Rosas 2015, p. 17.

[77] Orzechowski et al. 2020, p. 6, Similar finding has also been made by FRA (the FRA report on Inequalities and multiple discrimination in access to and quality of healthcare, 2013).

4 Predictive AI systems and the right to healthcare

In this Chapter, I demonstrate how the use of predictive AI systems in the distribution of healthcare services could potentially jeopardize the equal right to healthcare of certain vulnerable patients.

4.1 A glimmer of possibility

Before moving onto the issues that could possibly occur in the deployment of predictive AI systems, I would like to point out that there lies huge potential in the deployment of these systems. As the data controller in the Finnish DPA opinion stated, this type of technology will enable a more preventive and proactive approach in healthcare and enhance the continuity of healthcare through measuring the effectiveness of current treatments.[78]

For instance, Ahmed et al. have found that AI-driven early detection of cardiovascular diseases has the potential to improve the affordability of healthcare services through making clinical processes more efficient, decreasing mistakes in diagnosing, and improving cost-efficiency.[79] Additionally, medical scholars have suggested that AI-powered remote patient monitoring will enhance the rights of people who have limited mobility or live in geographically remote areas. Those who are not able to have regular check-ups or consultations will have better access to health through AI applications which enable remote monitoring.[80]

Accordingly, by adopting predictive AI systems in healthcare, the problem of unequal access to healthcare services could actually be solved. However, existing barriers in access to healthcare, the historical legacy of inequality in medical research, as well as the complicatedness of turning health into a proxy make it difficult to take advantage of the above-mentioned opportunities.

4.2 Central stumbling blocks

In April 2025, Yle, Finland's national public broadcasting company, reported that a significant portion of the population faces challenges in accessing digital public services due to the lack of official identification documents. According to Yle, approximately 1.1 out of

[78] Finnish Data Protection Authority 6482/186/2020.
[79] Ahmed et al. 2025.
[80] Dogheim and Hussain 2023, p. 97.

5.6 million Finns lack a valid passport or ID card, hindering their ability to use essential digital services such as e-health platforms. The report stated that those suffering from access to digital healthcare services include people with memory disorders, individuals struggling with substance abuse, people with immigrant backgrounds, the visually impaired, as well as low-income individuals who cannot afford smart devices or internet access.[81] Consequently, this example illustrates how, even in a Nordic welfare state with a high-level of digital literacy, there are gaps between different societal groups in access to healthcare through digital means.

The above-described example is part of a broader academic and societal discussion on the so-called digital divide.[82] Digital divide refers to a gap between people who have access to digital technologies and those who do not. This division follows a certain pattern. Those who suffer from digital exclusion, often times have one or more social or economic vulnerability. Thus, social and digital inclusion are often times connected.[83]

In addition to low income, several other social characteristics have been found to increase the likelihood of experiencing unequal access to healthcare. Other characteristics that have been found to jeopardize the access to healthcare include old age, gender, unemployment, low level of education, insufficient digital, and/or local language skills, as well as immigrant or ethnic minority background. For example, belonging to the Roma communities has been found to negatively impact a person's access to healthcare.[84] As a consequence, a large variety of factors influence on someone's likelihood of experiencing unequal access to healthcare. However, as previously stated in Chapter 3, EU law only provides protection against discrimination based on racial or ethnic origin, sex, and nationality.

Existing barriers in accessing healthcare are also reflected in the data available to predictive AI systems. This issue is known as a data deficit – a situation where the data used in decision-making is unrepresentative. As a result, the predictive AI system may not effectively serve the entire population it is intended to serve. People who are underrepresented in the data may receive inaccurate or biased outcomes from the system.

[81] Yle, 2.4.2025.
[82] See e.g. WHO: European health report 2024, Himabindu et al. 2022 and Ragnedda et al. 2022.
[83] See e.g. WHO: European health report 2024 and Ragnedda et al. 2022.
[84] See e.g. Scheil-Adlung and Kuhl 2011, European Parliamentary Research Service 2020, and Kaihlanen et al. 2022.

Moreover, the people who are unrepresented in the data due to barriers in accessing healthcare services, might actually have greater relative need for services. In other words, the AI system detecting risk profiles will not identify these patients from large amounts of data, although they might be the ones who would benefit the most from interference.[85] Consequently, the deployment of digital technologies and AI in healthcare has the possibility to create new barriers.[86]

In addition to existing barriers in access to healthcare, data deficits can arise from existing bias in the field of medical research. Several scholars have recognized that health algorithms have the potential to mirror already existing inequalities and biases of the surrounding society.[87] Namely, diagnostic tools have been found to "fail patients who do not fit the expectations of the majority"[88]. An example where social bias lead to algorithmic bias in the context of distribution of social benefits is the infamous "Dutch childcare benefits scandal". Here, the algorithm wrongfully accused people with migrant backgrounds of being more likely to commit child benefits fraud, eventually leading to severe personal and political consequences.[89]

So, health algorithms have the potential to repeat already existing biases of the medical field and implement them on an even larger scale. According to Straw, perspectives of women, racial/ethnic, sexual and gender minorities were lacking in medicine until the last century, and modern medicine is still affected by these inequalities. She has mentioned how, for example, the exclusion of women symptomology from medical education curricula has led to increased amount of gender-based misdiagnoses and higher morbidity for women in clinical settings. [90] The exclusion of symptomatology specific to certain vulnerable populations in medical education may hinder the ability of healthcare providers or health AI systems to recognize disease in these groups. This may ultimately contribute to delayed diagnoses and worse health

[85] Roberts and Salib 2024, p. 95.
[86] Himabindu et al. 2022.
[87] see e.g. Roberts and Salib 2024, p. 93, and Straw 2020.
[88] Straw 2020.
[89] In this case, the Dutch state had deployed automated decision-making in detecting individuals that would most likely commit fraud with regards to child benefits. Parents with migrant backgrounds were mainly accused, especially those with roots in the former Dutch colonies of Suriname or the Dutch Caribbean islands, as well as single mothers. 35 000 parents in total were obliged to return all the received child benefits to the state they had received so far. Many targeted families fell into severe poverty and suffered from legal issues. Parents of more than 2 000 children also lost the custody of their children (Arts and van den Berg 2024, pp. 3–4).
[90] Straw 2020.

outcomes. Predictive AI models trained with biased data, may work well on average, but end up giving poor results to patients from different minorities.

Ultimately, it is important to highlight that health is such a complex concept that it is rather difficult to convert into "numerical and machine-digestible metrics[91]". This type of situation is often referred to as "label choice bias" or "measurement error". According to FRA, measurement errors occur when the data used fails to accurately capture or reflect the intended attribute being measured.[92] Hence, the algorithm does not predict what it is supposed to predict.

Algorithms follow the objectives we program into them – nothing more, nothing less. Because health need is difficult to observe, the algorithm might start using health cost as a proxy for health need. If the desired goals of the predictive AI system are not accurately constructed, the algorithm could begin preferring cost-efficiency rather than health need, eventually ending up discriminating certain disadvantaged populations if their treatment is deemed less profitable.[93]

As a conclusion, the deployment of predictive health AI in order to determine healthcare eligibility, could pose a threat to the right to equal healthcare. In the EU, despite the high-level of healthcare, there are specific vulnerable patient groups that still experience barriers in accessing healthcare. The use of AI in eligibility assessment could further increase these inequalities. Furthermore, predictive AI systems may replicate historical inequalities in medical research, increasing the risk of inaccurate outcomes for certain vulnerable patient groups. Lastly, predictive AI systems may start using cost-efficiency as a proxy, rather than health need because health costs are easier to predict. These findings prompt the following question: What type of laws and policies should be adopted to make sure that predictive health AI systems do not jeopardize everyone's equal right to healthcare?

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[91] Roberts and Salib 2024, p. 96.
[92] FRA 2019, p. 3.
[93] Roberts and Salib 2024, pp. 95–97.

5 The legality of predictive AI systems

In this Chapter, I focus on assessing the legality of predictive AI systems. There are two main sources of secondary horizontal legislation that regulate predictive AI systems. Firstly, these systems qualify as automated decision-making which is why they are regulated under Article 22 GDPR.[94] Secondly, as I previously mentioned, predictive AI systems qualify as AI under the AIA which is why they are also under the scope of this regulation.

5.1 Under GDPR

When assessing predictive health AI systems in light of the GDPR, it is principally important to recognize that the data processed in predictive AI systems is health data, which is a special category of personal data under Article 9 GDPR. According to Article 9(1) GDPR, processing of health data shall be primarily prohibited but is possible in specific situations mentioned in paragraph 2. Paragraph 2 contains a list of exceptions in which processing of health data is possible. The processing of health data is possible, for example, if the data subject has given explicit consent, if the processing is necessary for reasons of substantial public interest, or if the processing is necessary in specific healthcare contexts, such as preventive medicine, medical diagnosis or public interest in the area of public health.[95] So, in practice, the deployers of predictive AI systems have to invoke one of these exceptions to legitimize the processing of special category data. In a situation where a public healthcare system is deploying predictive AI, it is probably most suitable to invoke substantial public interest or one of the exceptions connected to healthcare.

However, the most important provision of the GDPR, when it comes to the legality of predictive health AI systems, is Article 22 GDPR. Article 22 GDPR contains a general ban of automated decision-making. Namely, it bans decisions "based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her". The applicability of Article 22 GDPR depends on

[94] Automated decision-making as defined in Article 22 GDPR includes artificial intelligence, Big Data analytics, and machine learning methods, as well as significantly simpler systems based on rule-based automation (Hawath 2021).

[95] Article 9(2)(a)(g)(h)(i) GDPR.

three cumulative conditions: 1) there must be an actual decision, 2) the decision must be based on solely automated processing, and 3) it must produce actual effects.[96]

Firstly, for automated decision-making to be deemed illegal, there must be an actual decision.[97] Article 22 GDPR is interpreted in light of Recital 71, according to which prohibited automated processing may include a "measure evaluating personal aspects relating to him or her*"*. Furthermore, the Recital constitutes that prohibited decision-making can include automated data processing with an aim to "analyse or predict aspects concerning the data subject's […] health". The purpose of a predictive AI system is to assess whether a patient is eligible for healthcare based on their health data. Thus, it seems clear that a predictive AI system fulfils the first condition: an assessment of patient's eligibility for healthcare constitutes a decision under Article 22 GDPR.

Secondly, the decision must be based on solely automated decision-making in order to be unlawful under the GDPR. The wording of Article 22 GDPR seems to exclude partially automated decisions where human is making the final decision based on the assessment made by the AI. However, van Kolfschooten has made the notion that *SCHUFA Holding* seems to have created an opening for the inclusion of medical AI tools that provide recommendations or guidance. In a nutshell, in *SCHUFA Holding*, the CJEU determined that establishing a credit scoring constitutes a prohibited decision although the decision-making in the process at hand was not fully automated.

According to van Kolfschooten, partially automated AI that is used to process patient data to identify patients eligible for a specific clinical trial would be considered prohibited decision under Article 22, if assessed in light of *SCHUFA Holding*.[98] In other words, although the final decision in "AI for clinical trial selection" is in the hands of the medical practitioner, this type of AI system would fall into the scope of Article 22 GDPR. Thus, when these findings are interpreted in the context of predictive AI systems, the fact that these systems might be partially automated would not instantly mean that they do not fall under Article 22 GDPR. Consequently, when assessed in view of *SCHUFA Holding,* it is likely that a predictive AI

[96] This condition based assessment is also how the CJEU conducts its decision-making in SCHUFA Holding (Judgment 7.12.2023, *SCHUFA Holding,* C-634/21, EU:C:2023:957, paragraph 43).
[97] It is also important to note that the CJEU has interpreted the concept of a decision quite broadly. In SCHUFA Holding, the CJEU had to determine whether a credit scoring established through automated decision-making qualifies in itself a prohibited decision. The CJEU ruled that credit scoring counts in itself as a decision because it "plays a determining role" in deciding whether to grant or refuse a loan.
[98] Van Kolfschooten 2024, p. 383.

system fulfils the required level of automation to be considered unlawful under Article 22 GDPR.

Thirdly, an automated decision must inflict legal effects or other similarly significant effects to be considered illegal.[99] The European Data Protection Board (EDPB) has specifically mentioned that decisions that affect someone's access to healthcare are decisions that cause similarly significant effects.[100] The EDPB has also stated that, in order to inflict similarly significant effects, the decision must have the potential to *"*significantly affect the circumstances, behaviour or choices of the individuals concerned"[101].

A national DPA has also specifically assessed the legality of a predictive AI system in light of Article 22 GDPR. Namely, The Finnish DPA[102] has given two opinions that considered the legality of an AI application that was used to detect health risks. In both opinions, the Finnish DPA came to the conclusion that the predictive AI systems in question inflict similarly significant effects because they are likely to significantly impact the data subject's circumstances, behavior, or choices. The Finnish DPA reasoned this conclusion by stating that predictive AI systems would dictate the proactive healthcare measures actively offered to patients. The Finnish DPA also recognized how patients would likely trust predictive AI decisions that identified no health risk based on their data. This is something that, according to the DPA, could potentially lead to a situation where a patient overlooks an undetected risk.[103] The Finnish DPA also referred to a possible future prospective in which limited resources lead to an increased reliance on predictive AI systems.[104]

In conclusion, the EDPB guidelines and the two opinions of the Finnish DPA seem to suggest that predictive AI systems also fulfill the third condition – the effects are severe enough for the decision-making to fall under the scope of Article 22 GDPR. Thus, it seems that, in light of Article 22 GDPR, predictive AI systems would be deemed illegal. However, Article 22(2) GDPR lays down three situations where it is possible to derogate from the general

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[99] Furthermore, the CJEU has in SCHUFA Holding used the wording "at the very least[…] significantly" which seems to even widen the category of prohibited decisions under Article 22 (SCHUFA Holding, paragraph 49).
[100] Article 29, Data Protection Working Party Guidelines on Automated individual decision-making and Profiling, p. 22.
[101] Article 29, Data Protection Working Party Guidelines on Automated individual decision-making and Profiling, p. 21.
[102] The reason I am forefronting the Finnish DPA is because, according to e.g. the case-law database called GDPRhub, it is the only national DPA, as far as I am aware, that has issued opinions specifically concerning the legality of predictive AI systems under Article 22 GDPR.
[103] Finnish DPA 6482/186/2020, point 50.
[104] Finnish DPA 6482/186/2020, point 46.

prohibition. Automated decision-making is not prohibited if it is (a) necessary for entering into, or performance of, a contract, (b) authorized by Union or Member State law, or (c) based on explicit consent given by the data subject. So, a deployer of a predictive AI system needs to invoke one of these exceptions in order for the system to be lawful under the GDPR.

On the basis of my assessment, it is unlikely that derogation (a) would apply in a public healthcare context because the relationship between the patient and the healthcare provider is not considered contractual. Similarly, invoking derogation (c) also has its own issues. Explicit consent, in the context of the GDPR, refers to a freely given, specific, informed and unambiguous indication of the data subject's wishes.[105] Scholars have contested whether explicit consent can ever be given by a patient in the medical context because of the power imbalance between patients and healthcare professionals. If patients wish to receive adequate treatment, it is unlikely that they have a real choice in giving consent.[106] Thus, the only suitable legal basis that could be used in the context of predictive AI systems, when they are used in public healthcare, is derogation (b). So, derogation (b) leaves Member States a margin of interpretation when it comes to derogating from the general ban of automated decision-making.

Moreover, Article 22(4) GDPR sets additional conditions on automated decision-making where special category data is being processed. According to this provision, automated decisions shall not be based on health data[107], unless the data subject has given explicit consent or processing is necessary for reasons of substantial public interest. So, a Member State, when derogating from the general ban, needs to prove that derogating is justifiable under substantial public interest.

Furthermore, if a Member State is enacting law that derogates from the general ban of automated decision-making, it must make sure that the law fulfills conditions laid down by Article 23 GDPR. Article 23 includes a list of legal grounds under which it is possible for a Member State to enact a law that derogates from the general ban. The most suitable legal ground in the context of predictive AI systems is probably public health (Article 23(1) point e). Furthermore, it is not enough that the legislation is based on one of the legal grounds listed in Article 23 GDPR. The provision also contains certain requirements that the national legislative measure must fulfill. Among other things, the national legislative measure must

[105] Article 4(11) GDPR.
[106] Van Kolfschooten 2024, p. 386.
[107] Or any other special category of data referred to in Article 9 GDPR.

contain safeguards to prevent abuse as well as the risks to the rights and freedoms of data subject. So, if a Member State decided to regulate on predictive AI systems, it would need to specify measures it takes to prevent abuse and specific risks that predictive AI systems bring upon patients.

Lastly, data subjects must be equipped with suitable measures to contest automated decision-making. According to Article 22 GDPR, if automated decision-making is authorised by Member State law, the national law must lay down suitable measures to safeguard the data subject's rights and freedoms and legitimate interest. The wording of the provision leaves it to the interpretation of the Member State to define the exact measures that protect the data subject.

However, Article 22(3) GDPR and Recital 91 list some remedies that should be available for patients who are subject to decision-making on the basis of contractual relationship or explicit consent. According to my assessment, the remedies available for patients when automated decision-making has been legalized in national law, should at least to some extent, correspond to these remedies. The mentioned remedies include the right to obtain human intervention, the right for data subjects to express their point of view, and the right to contest the decision. Additionally, data subjects should be entitled to receive specific information about automated decision-making and they should also have a right to obtain an explanation of the decision that the automated system has reached.

To conclude, a legal doctrinal analysis of Article 22 GDPR, its interpretation guidelines, *SCHUFA Holding,* and the two Finnish DPA decisions seem to suggest that predictive AI does not only fall into the scope of Article 22 GDPR, but is also likely illegal, unless a Member State has separately authorized it in its national law. If Member States have, in their national legislation, authorized automated decision-making, they still need to ensure that the legislation fulfils the conditions laid down by Article 23 GDPR and that patients are equipped with suitable legal remedies to contest the automated decisions.

5.2 Under AIA

In addition to the GDPR, predictive AI systems will be governed by the AIA gradually, step by step, the applicable provisions in the context of predictive AI systems entering into force on the 2nd August 2026. Like the GDPR, the AIA does not only cover healthcare but it will be applied horizontally in all sectors. The AIA divides different AI-systems into four categories

based on risk assessments: unacceptable, high, limited, and minimal risk. According to Recital 46, high-risk systems are systems that pose a risk to “health, safety, and fundamental rights”. Because of these threats, high-risk systems must undergo conformity assessments made by third-parties.

AI systems that are considered high-risk are listed on Article 6 AIA. Firstly, Article 6(1) AIA deems products or product components which have been harmonized under EU legislation under the high-risk category. Secondly, Article 6(2) AIA refers to Annex III, which contains an eight-point list of independent AI-systems that belong to the high-risk category. This list in Annex III can be modified later by the Commission according to new technological developments. In addition, in order to determine whether an AI system poses a high risk, Article 7(2) AIA includes an eleven-point list of indicators that need to be taken into account in assessing the level of risk of an AI system.

Annex III includes a long list of purposes where the use of AI is considered high-risk. High-risk AI includes, for example, AI systems used for emotion recognition, critical infrastructure, recruitment or selection of natural persons in the employment context, as well as AI systems used to assess the creditworthiness of natural persons. Mentioned in Annex III are also “AI systems intended to be used by public authorities or on behalf of public authorities to evaluate the eligibility of natural persons for essential public assistance benefits and services, including healthcare services” (paragraph 5a). Thus, Annex III of the AIA directly refers to predictive health AI systems and classifies them under the high-risk category.

Recital 58 can also be interpreted as indirectly referring to predictive AI systems. It refers to essential private and public services that are “necessary for people to fully participate in society or to improve one’s standard of living”. The recital distinguishes certain vulnerable patient groups such as older people and people suffering from an illness that are specifically dependent on health services. Furthermore, AI systems that are used for “determining whether such benefits and services should be granted, denied, reduced, revoked or reclaimed by authorities, including whether beneficiaries are legitimately entitled to such benefits or service” should be classified high-risk according to the Recital. This is because these systems may infringe persons’ fundamental rights, such as the right to non-discrimination. In conclusion, Recital 58 refers to predictive AI systems even more in detail compared to Annex III which further confirms that these AI systems fall into the high-risk category.

Furthermore, in order to be lawful, high-risk AI systems need to meet certain requirements laid down in Articles 8-15 AIA. These provisions establish strict compliance requirements, including, for example, risk management, data governance, transparency, accuracy and cybersecurity. Article 14 AIA establishes the requirement for human oversight which aims to prevent or minimise the risks to fundamental rights. This provision mandates that the design and development of high-risk AI systems must be effectively overseen by natural persons.

This human oversight provision of Article 14 AIA has sparked a discussion amongst scholars on whether it prevents the application of Article 22 GDPR to high-risk AI systems. In other words, scholars have examined whether the human oversight principle renders Article 22 GDPR inapplicable since the GDPR provision applies only to fully automated decision-making without human interference.

For instance, Sarra has come to the conclusion that the human oversight principle put forward by Article 14 AIA does not prevent the application of Article 22 GDPR, because the AIA itself states that it "shall not affect" the application of the GDPR.[108] Moreover, Sarra goes as far as suggesting that the AIA constitutes "not only a general principle of mutual consistency between itself and the GDPR, but also a prominence of the latter".[109] This is an interesting statement especially in light of lex posterior principle. When assessed in view of lex posterior, AIA would take precedence over the GDPR.

In my opinion, it is rather difficult to present an exhaustive answer to how the human oversight provision will affect the general ban of automated decision-making. The recitals of the AIA perhaps call for prominence of the GDPR while, according to lex posterior, it would be the AIA that would take prominence. All I have to say, is that the legality of predictive AI systems is very confusing in light of the two regulations. Deployers of predictive AI systems are required to navigate in a complex regulatory jungle when ensuring that the systems they are deploying are even legal.

Most importantly, deployers need to make sure that the suitable measures mentioned in Article 22 GDPR, for example, the right to obtain human intervention and the right to contest the decision, are available to the patients who are subject to the decision-making of predictive

[108] Article 2(7) AIA. Only Articles 10(5) and 59 AIA form exceptions.
[109] Sarra also argues that this overlap creates a need for an updated interpretation guidelines for Article 22 GDPR. These guidelines should specify the "conditions under which the exercise of the human oversight is so focused as to exclude that decision is 'based solely on automatic processing'". Sarra 2024, pp. 12–13.

AI systems. This is something that might be disregarded by deployers that are perhaps more focused on fulfilling the conditions laid down by the AIA.

6 Fundamental Rights Impact Assessment

According to Article 1 AIA, one of the key objectives of the regulation is to ensure "a high level of protection of health, safety, and fundamental rights enshrined in the Charter". Primarily, the AIA is designed to safeguard fundamental rights whenever AI is deployed. This Chapter focuses on how the AIA succeeds in ensuring the fundamental rights of the CFR. More specifically, I highlight possible shortcomings when it comes to the AIA's protection of the right to access healthcare. I draw the closest attention to Article 27 AIA which regulates the Fundamental Rights Impact Assessment (FRIA). Article 27 AIA requires certain deployers of high-risk AI systems to "perform an assessment of the impact on fundamental rights that the use of such system may produce".

The inclusion of FRIA was under debate throughout the drafting process of the AIA. FRIA was only introduced in June 2023 by the European Parliament.[110] It was not a part of the original draft of the Commission. According to Wernick, the inclusion of FRIA was backed up by the European Parliament, academics and the civil society[111] while resistance was raised by technology companies.[112] My assessment illustrates how the inclusion of FRIA in the AIA is crucial in safeguarding access to healthcare in the age of predictive AI systems. However, there are certain weaknesses and shortcomings in the FRIA regulation that might reduce its ability to protect patients from harmful decision-making.

FRIA must be performed by four categories of deployers of high-risk AI systems: 1) those governed by public law, 2) private entities providing public services, 3) deployers who are evaluating creditworthiness, and 4) deployers creating risk assessments for life and health insurance. According to Recital 96, private entities providing healthcare services, are covered by the second category. Hence, deployers who are distributing health services through predictive AI systems must perform a FRIA regardless of whether they are public or private entities.

6.1 FRIA amongst other impact assessments

Before moving onto discussing the features and shortcomings of FRIA, it is important to note that FRIA is not performed in a vacuum: it is not the only provision of the AIA that governs

[110] COM/2021/206 final.
[111] See e.g Nikiforov (Brussels Privacy Hub) 2023, p. 4 and AlgorithmWatch 2021.
[112] Wernick 2024, p. 29.

the risk assessments that need to be done when designing and deploying high-risk AI systems. FRIA is performed alongside other conformity assessments of the AIA: the risk management system of Article 9 and CE-marking assessment of Article 48.

The CE-marking assessment under Article 48 AIA is a broad and complex topic, which I do not explore in depth in this thesis. However, I want to briefly highlight legal scholars' findings on the failure of the CE certification to effectively prevent and detect fraud and corruption in the medical device industry.[113] The CE-marking system relies heavily on self-certification leading scholars to argue that the AIA may simply replicate the limitations of existing governance mechanisms.[114] Additionally, CE-marking is not intended to function as a framework that primarily protects fundamental rights.[115]

Article 9 AIA, on the other hand, is more of a general risk assessment provision compared to the FRIA which is specifically focused on assessing risks to fundamental rights. Nevertheless, Article 9 directly refers to possible threats to fundamental rights that might be posed by high-risk AI systems. According to Article 9(2) the risk management system shall comprise of, amongst other requirements, the identification and analysis of the known and reasonably foreseeable risks that the system can pose to fundamental rights.

In addition to other conformity assessment provisions of the AIA, it is likely that AI systems that are subject to FRIA will also require a Data Protection Impact Assessment (DPIA) which is regulated under the rules of the GDPR. This is because in many cases, the functioning of AI systems involve data processing. Rintamäki et al. have stated that almost all high-risk AI systems mentioned in Annex III of the AIA require conducting a DPIA, which proves the overlap of these two impact assessment systems.[116]

Article 35 GDPR lays down the rules for DPIAs. In short, a DPIA means that when processing is *"likely to result in a high risk to the rights and freedoms of natural persons",* the controller is required to conduct an assessment to evaluate the potential impact of the processing on personal data protection.

Article 35 (3) point (a) GDPR contains a reference to Article 22 GDPR, and states that a DPIA "shall in particular be required in a case of a systematic and extensive evaluation of

[113] Smuha et al. 2021, p. 39, and Gornet and Maxwell 2024.
[114] Minssen et al. 2024, p. 316.
[115] Gornet and Maxwell 2024.
[116] Rintamäki et al. 2024.

personal aspects […] which is based on automated processing […] and on which decisions are based that produce legal effects concerning the natural person or similarly significantly affect the natural person". In other words, this paragraph asserts that a DPIA must be conducted when an automated decision-making system is used to automatically evaluate individual's personal features and important decisions in light of the rights of the individual are made based on this evaluation. Thus, it seems evident that a DPIA needs to be performed when deploying predictive AI systems in healthcare.

According to Raposa, the most obvious similarity between the FRIA and the DPIA is that they are both triggered in situations where AI systems pose a risk to fundamental rights.[117] The FRIA provision of the AIA also directly refers to the DPIA: it states that the FRIA will complement the DPIA if the obligations laid down in the AIA are already met through the DPIA.[118]

The key difference between these impact assessment is connected to the scope. Namely, it is crucial to recognize that a DPIA has limited scope compared to a FRIA. DPIA is focused on assessing threats that might infringe the fundamental right to data protection. In fact, in practice, little attention has been given to rights other than data protection.[119] Hence, it is not enough that high-risk AI system goes through a DPIA. To fully commit to the protection of all fundamental rights, including the right to healthcare, high-risk AI systems must undergo a FRIA.

Amongst legal scholars, DPIA has received somewhat positive feedback in its success in protecting the fundamental right to data protection.[120] In the following, I use the DPIA as a framework for comparison. I assess the obligations arising from Article 27 AIA and assess them in light of obligations laid down by the DPIA.

6.2 Features and shortcomings of the FRIA

6.2.1 Preventive approach

The first central finding of my research regarding Article 27 AIA is that this provision is largely based on preventive risk assessment. In other words, the FRIA provision requires that

[117] Raposa also suggests that the "substantial overlap of scenarios" indicates that it would be more conformant if the two assessments would be combined into a single assessment (Raposa 2022, p. 99).
[118] Article 27(4) AIA.
[119] Mantelero 2024, p. 4.
[120] See e.g. Mantelero 2024, p. 7.

potential risks of high-risk AI systems need to be assessed already during the system's designing process. Article 27 (1) requires that "prior to deploying a high-risk AI system" deployers "shall perform an assessment of the impact on fundamental rights that the use of such system may produce". [121] Thus, the potential risks to fundamental rights, such as equal access to healthcare, must be assessed already during the designing process of the system.[122]

Moreover, Mantelero has argued that because of the nature and level of protection of fundamental rights, it is not enough that a FRIA is performed at some point in the designing process. According to him, FRIA needs to be done in an early phase of the designing process. Namely, a mere final check before the deployment of the system is not enough.[123] Mantelero states that this preventive nature of FRIA is distinguishable in the following wordings of Article 27(1): "likely to be affected" and "likely to have an impact". Similarly, Article 9 AIA refers to "foreseeable risks" and not harms. In his research article, Mantelero also underlines the difference between referring to the materialisation of risks from referring to the materialisation of harms. Specifically, if risks materialize, damage has necessary not yet occurred.[124] Thus, FRIA is not by character a response to harms but rather aim to stop possible risks from occurring in the first place.

Additionally, according to Mantelero, the preventive nature of the FRIA is something that distinguishes it from other impact assessments, for example, from the Human Rights Impact Assessment (HRIA).[125] HRIA is originally established at the international level and is implemented by companies as a part of business due diligence. HRIA is based on an *ex post* approach rather than preventive *ex ante* approach, which means that assessments are not done prior to implementation but rather as a "response to critical situations"[126].

It goes without saying that the preventive nature of FRIA is an important tool in enhancing everyone's equal access to healthcare. An *ex post* approach would simply not be adequate in

[121] Similarly, Article 9 is based on preventive approach, which underlines the preventiveness of the conformity assessments of the AIA. Paragraph 3 of Article 9 refers to the assessment of risks that "may be reasonably mitigated or eliminated through the development or design of the high-risk AI system".
[122] Mantelero 2024, p. 4–5.
[123] Mantelero 2024, p. 8.
[124] Mantelero 2024, p. 9.
[125] Another aspect differentiating FRIA from HRIA is that FRIA truly has a rights-based focus. HRIA is more based on judicial weighing between potential risks and benefits. In HRIA, all competing interests, such as economic benefit are of similar value and exceptions from the protection of human rights are allowed in certain cases. FRIA, on the other hand, allows no expectations from the protection of fundamental rights. In other words, if a breach is detected by a result from FRIA, judicial weighing does not offer a way out (Mantelero 2024, pp. 3–4).
[126] Mantelero 2024, p. 3.

safeguarding patients from potential threats to fundamental rights posed by predictive AI systems. Based on my analysis, this preventive nature that is required from the FRIA, is perhaps the greatest achievement from the point of view of protecting vulnerable patients in the context of predictive AI systems.

6.2.2 Controversial continuous approach

Additionally, assessing the impacts of a predictive AI system should be a continuous process. In other words, in order to efficiently protect fundamental rights, conformity assessments should be repeated throughout the entire lifecycle of a high-risk AI system's existence. Hence, deployers cannot rely on one-time prior evaluation but new assessments need to be done as the system or the context where it is used changes and develops.

The wording of Article 9(2) AIA is clear in suggesting that risk assessment is a continuous process. Article 9(2) AIA states that "the risk management system shall be understood as a continuous iterative process planned and run throughout the entire lifecycle of a high-risk AI system". Additionally, this provision requires "regular systematic review and updating". The wording of Article 27, is not, however, based on my assessment, equally explicit in requiring a continuous approach.

According to Article 27(2) AIA, in case circumstances have changed, the deployer needs to merely "take the necessary steps to update the information". In my opinion, it is not clear that, in practice, deployers would interpret "updating information" as a requirement to perform a new assessment. This finding, as far as I am aware, has not been pointed out by legal scholars in their criticism towards the FRIA legislation. Furthermore, the legislation does not define what specifically constitutes "updating the information" nor does it establish any specific requirements for the *ex post* monitoring.[127]

Moreover, my research illustrates how, in comparison to the continuity requirements of the DPIA, the FRIA's requirement of "updating information" has the potential to lack effectivity. The EDPB guidelines on the DPIA state that a new assessment should be performed if any of the circumstances of processing have changed since the prior checking and there is a chance of high risk consequences.[128] Similarly, Article 35(11) GDPR suggests that a new assessment needs to be carried out if there is a "change of the risk represented by processing operations".

[127] Thelisson and Verma 2024.
[128] Article 29, Data Protection Working Party Guidelines on DPIA, p. 13.

Namely, the wording of the GDPR and its guidelines specifically require conducting a new assessment if circumstances have changed in a significant manner.

Thus, the rules on when a new DPIA is required are much more detailed in comparison to the rules on FRIA. Similar guidelines have, of course, not yet been published about FRIA at the time of writing. Based on its current vagueness, it would, in my opinion, be important that possible future FRIA guidelines clarify the meaning of "updating circumstances" and specifically state the circumstances in which the FRIA must be re-performed.

From the point of view of preventive AI systems in healthcare, it would be important that FRIA also required regular monitoring of possible biases in the system. Like described earlier in my thesis, all the possible biases cannot necessary be detected in the designing and deploying process because they might appear only after the AI system has been used for a while.

In my view, continuity would provide an efficient tool to detect certain patient groups that are being deprioritized for treatment by the predictive AI system. Sadly, the provision regulating the FRIA fails to constitute proper and genuine continuity.

6.2.3 Potential broadness and vagueness

In addition to failing in establishing continuity, my assessment illustrates how the FRIA could potentially prove problematic when being applied in a healthcare context because its wording is quite broad. Like mentioned above, a DPIA focuses solely on evaluating the risks to the fundamental right to data protection, while a FRIA operates as a safeguard against breaches of all fundamental rights. I argue that the strict focus of the DPIA on a single fundamental right could be its biggest strength. It enables a more detailed and comprehensive assessment, ensuring that potential risks to data protection are thoroughly identified, evaluated, and mitigated.

Because FRIA is focused on assessing breaches of all fundamental rights, it is important that there is staff available that is specialized in fundamental rights both in the deploying organization and in the authorities to whom the assessment is referred to. Partly answering to this challenge is Article 70(3) AIA, which sets requirements for national authorities to permanently have available staff with expertise in e.g. AI and fundamental rights. Moreover, according to Article 70(6) AIA "Member States shall report to the Commission on the status of financial and human resources of the national competent authorities, with an assessment of

their adequacy". Accordingly, these provisions that guarantee the availability of specialized staff in national authorities could potentially limit the issue of the broad scope of the FRIA.

Moreover, something that could potentially limit the negative effects arising from the broad scope of the FRIA is that the regulation sufficiently takes into account use-context. Article 27 AIA specifically takes into account use-context because the provision obliges the deployer to issue a "description of the deployer's processes in which the high-risk AI system will be used in line with its intended purpose". Mantelero has highlighted that referring merely to the design of the AI system is inadequate in fully acknowledging the context where the AI system is used. For example, Mantelero refers to "access to health services based on screening programmes" and highlights how poor diagnostic data might lead to misdiagnosing or failing to detect a disease when these type of AI systems are used. [129] In other words, in practice, the actual error might stem from the real-word use-context, and not from the design of the AI model. The fact that Article 27 AIA specifically refers to the use-context brings the use-context into the centre of the assessment, thereby diminishing the potential broadness of FRIA.

However, a central issue that might exacerbate the potential broadness of FRIA is, in my opinion, the lack of clarity on how it should be performed. According to Article 27(5) AIA, the AI Office "shall develop a template for a questionnaire" to make sure that the deployers comply with the "obligations under this Article in a simplified manner". AI Office is established within the European Commission and it is meant to function as the "foundation for a single European AI governance system"[130]. It is responsible for monitoring and supervising AI systems, general-purpose AI models, as well as AI governance.[131]

Consequently, a great deal is left to the consideration of the AI Office. This is also a flexibility that has drawn criticism from legal scholars for its lack of clarity and precise guidelines. Solaiman and Malik have argued that this consideration left to the AI Office might lead to an outcome where the FRIA will only be considered a procedural formality rather than a thorough and extensive consideration of possible fundamental rights breaches.[132] Additionally, this type of flexible ad hoc solution could possibly prove challenging when aiming to ensure consistency and prevent arbitrary treatment.

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[129] Mantelero 2024, p. 7.
[130] European AI Office, European Commission.
[131] Article 3(47) AIA.
[132] Solaiman and Malik 2024, p. 13.

Another factor that increases the vagueness of the FRIA is that the AIA does not lay down specific guidelines that could be used by deployers in risk assessment. In other words, there is no guidelines in Article 27 AIA that deployers of predictive AI systems could use in order to assess the risks to fundamental rights. Specifically, AlgorithmWatch has recognized how the FRIA fails to explicitly oblige the deployers to assess whether the recognized risks are acceptable in light of fundamental rights law.[133] So, although the regulation lays down a requirement to recognize possible fundamental rights impacts, it does not provide any framework or yardstick that could be used to assess the appropriateness of these risks.

In contrast, a DPIA needs to include, according to Article 35 GDPR, "an assessment of the necessity and proportionality of the processing operations in relation to the purposes". In my view, this wording entails the idea that risks should be assessed in light of necessity and proportionality. FRIA does not have similar type of reference to necessity nor proportionality. So, in a situation where the deployer has detected a risk to the fundamental right to healthcare, the wording of the FRIA provision offers no further guidelines on how the deployer should assess the severity of the risk.

In conclusion, the one-size-fits-all approach embraced by the legislators of the AIA fails to take into account the sector-specific context where the high-risk AI system is used. Basing FRIA on checklists and standardized templates goes against the very nature of fundamental rights assessment. Creating a one-size-fits-all template that is used in all sectors and with regards to all fundamental rights has the potential to jeopardize thorough case-by-case analysis that is needed to efficiently assess potential risks. A rigid or overly simplified FRIA process may overlook subtle but serious issues related to equal access to healthcare services, particularly for vulnerable patient groups. It is for the AI Office to ensure that the template is flexible but still detailed enough to be used in considering potential breaches. This is a difficult, potentially impossible task, that is left entirely to the consideration of the AI Office.

6.2.4 Inadequate consultation of third-parties

Moreover, in order to effectively ensure compliance with fundamental rights, the assessment should not solely rely on self-assessment. In simpler terms, it should not only be the deployer

[133] AlgorithmWatch 2024.

who assesses the risks. Instead, FRIAs should be referred to impartial third-parties in order to ensure adequate protection of fundamental rights.

To ensure this type of third party surveillance, Article 27 AIA requires deployers to notify the national market surveillance authority about the results of the FRIA. So, in the FRIA framework, the surveillance is performed by the national market surveillance authority.[134] Although AI Office is mentioned in Article 27(5) AIA, it cannot be perceived as directly conducting surveillance because its only task is to create a template for questionnaire to help assessing compliance. Thus, AI Office is only required to participate in the very beginning of the process – it will merely create standards that will be used in the assessment.

According to Article 70 AIA, "each Member State shall establish or designate as national competent authorities (…) at least one market surveillance authority". Market surveillance authority refers to the national authority that carries out activities and taking the measures pursuant to Regulation (EU) 2019/1020.[135] Each Member State is, thus, responsible for determining their own national market surveillance authority. Different Member States have taken different approaches.

For example, Spain has established a single market surveillance authority called the "Spanish Artificial Intelligence Supervisory Agency".[136] Finland, on the other hand, has adopted a decentralized model dividing the market surveillance powers to multiple different authorities functioning in different sectors of the society. For example, the market surveillance authority supervising the deployment of predictive AI systems in Finland will be the National Supervisory Authority for Welfare and Health.[137] These two examples demonstrate how the flexibility in applying the rules has resulted in significantly different outcomes across Member States. This results in a lack of conformity across Member States.

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[134] Additionally, although market surveillance authority is the authority notified about the results of the FRIA, there is another national authority mentioned in the AIA whose responsibility is to enforce the respect for fundamental rights in the application of the Regulation. These authorities are referred to as the "national public authorities" (Article 77 AIA). I find it peculiar that these national public authorities are not in any manner required to be directly consulted in the FRIA process. After all, it is them who are particularly identified in the AIA as supervising the compliance of fundamental rights provisions. National public authorities, on the other hand, "have the power to request and access any documentation created or maintained" under any provision of the AIA (Article 77 AIA). So the AIA seems to grant them a right to request documentation about the FRIA process while it is the market surveillance authority that is directly notified. It seems unconventional that the "national public authorities", although given the power to supervise fundamental rights compliance, are not even mentioned in the FRIA provision.
[135] Article 3(26) AIA.
[136] EU Artificial Intelligence Act, Overview of all AI Act National Implementation Plans 2024.
[137] HE 46/2025 vp, p. 90.

When comparing the surveillance framework of the FRIA to that of the GDPR, one notices how the FRIA regulation allows Member States to adopt a decentralized approach, as Finland has done. In the GDPR framework, it is the national DPAs who are in charge of monitoring and enforcing the application of the regulation. The AIA seems to enable a more multi-layered approach to surveillance.

According to my assessment, a decentralized assessment model which includes multiple authorities from different societal sectors, is the best approach to ensure adequate surveillance of predictive AI systems in healthcare. A multilayered surveillance framework allows Member States to give surveillance powers to an authority that is best equipped to conduct surveillance in a sector-specific matter. This decentralized approach is possibly also an answer to the potential broadness issue of the FRIA. It also needs to be noted that the model put forward by the AIA is a significant improvement compared to the current model. Currently, it is the national DPA who under Articles 22 and 35 GDPR assesses potential threats to all fundamental rights when predictive AI systems are adopted by deployers. Generally, national DPAs are better equipped to assess compliance with the fundamental right to data protection and not the right to healthcare. The AIA allows Member States to adopt models where authorities specialized in healthcare will assess the threats to the fundamental right to healthcare.

However, the mere obligation to refer the questionnaire to the market surveillance authority differs markedly from the DPIA's requirement of pre-deployment consultation with the national DPA (Article 36(1) GDPR). This consultation can contain written advice and the national DPA has the authority to, for example, issue a warning to the controller if the DPIA reveals high risks. Contrarily, the wording of Article 27(3) AIA does not automatically require market surveillance authorities to conduct their own review or approve the FRIA. The paragraph only mentions the act of referring the template to the authority.

Respectively, the GDPR grants the national DPAs a variety of investigative and corrective powers that can be used in case a DPIA reveals high risks to the data subjects.[138] Thus, national authorities have a lot of admissible legal actions that it can use against a controller whose DPIA has revealed high risks. National DPA can also impose financial sanctions on a controller who fails to conduct a DPIA.[139] Compared to the DPIA, the FRIA seems to

[138] Article 58 GDPR.
[139] Article 83 GDPR.

constitute more of a documentation that shows how risks to fundamental rights have been considered in the deploying process. In the AIA, the possibility to impose financial sanctions for the failure of conducting a FRIA appears to be absent. For example, the Finnish legislator has stated that the failure to conduct a FRIA does not qualify as a ground for imposing financial sanctions, as the AIA (Article 99) does not explicitly prescribe penalties for failing to perform a FRIA.[140]

In addition to weak investigative and corrective powers granted by the AIA, legal scholars as well as some non-governmental bodies have criticised the AIA for not giving enough power to civil society organizations.[141] According to Recital 96, it is recommended that stakeholders including "the representatives of groups of persons likely to be affected by the AI system, independent experts, and civil society organizations" are consulted during the designing and deploying process. This recommendation applies especially when AI systems are used in the public sector. Thus, the participation of representatives, experts and organizations is not an obligation under the rules of the AIA, but a mere recommendation.[142] The consideration on whether these parties are to be consulted in the designing and deploying process is left to the deployer. Do private institutions, constantly striving to stay at the forefront of innovation, have any desire to entangle themselves in the web of additional bureaucracy?

Because of the mere obligation to "notify" the market surveillance authority about the results of the FRIA and the inadequate consultation of civil society organizations it seems that the fundamental rights compliance is, to a great extent, in the hands of the deployer. Hence, a lot of responsibility is given to the deploying organization to recognize and navigate potential risks to the right to healthcare. With regards to predictive AI systems, the deployer should be properly aware of inequities in health access that might be replicated by the algorithm. It is unlikely that, in every organization deploying predictive AI systems, there is abundant resources to put into carrying out a FRIA. Accordingly, the FRIA regulation is insufficient in ensuring adequate third party consultation although this type of consultation plays a crucial role in guaranteeing that a thorough and unbiased FRIA is conducted.

[140] HE 46/2025 vp, p. 155.
[141] See e.g. Mazur and Wloch 2024, p. 117 and AlgorithmWatch 2024.
[142] Similarly, Article 9 AIA is almost entirely based on self-assessment apart from one sentence in Recital 65. According to Recital 65, in "identifying the most appropriate risk-management measures", the provider should "when relevant, involve experts and external stakeholders".

6.2.5 Failure to consider the affected patients

The final key finding of my analysis on the shortcomings of the FRIA is that, although it acknowledges that certain vulnerable patient groups may be particularly at risk in the emergence of predictive AI systems, it fails to provide them with adequate remedies. These groups are not sufficiently empowered to contest decisions made by such systems.[143]

According to my assessment, to sufficiently recognize that systemic inequalities may be duplicated to the algorithms of predictive AI systems, possible vulnerable patient groups should be separately distinguished in the wording of the FRIA. In this regard, Article 27 AIA does not directly refer to vulnerable groups. Instead, it mentions that the assessment must recognize "the categories of natural persons and groups likely to be affected by its use in the specific context". Thus, the specific wording of "vulnerable groups" is not directly used, but there is a reference to "specific categories" which seems to convey the same idea. Furthermore, Recital 93, that relates to Article 27 AIA, specifically refers to "vulnerable groups", acknowledging that deployers are in the best place to recognize which groups are most likely affected by the predictive AI systems. Hence, in my view, the regulation of the AIA is founded on the acknowledgement that specific groups of people may be deprioritized by predictive AI systems more than other groups.

Although recognizing that some patient groups may be more affected by predictive AI systems than others, the AIA fails to equip vulnerable patients with adequate remedies. According to Article 27 (1)(f) AIA, the impact assessment must include human oversight measures as well as "the measures to be taken in the case of the materialisation of those risks, including the arrangements for internal governance and complaint mechanisms". Similarly, Recital 96 refers to "complaint handling and redress procedures" in mitigating risks to fundamental rights. Thus, the wording of the AIA directly refers to complaint mechanisms and remedies in the context of fundamental rights breaches. Nevertheless, criticism has been raised by legal scholars.

For instance, Konopczynski has questioned whether individuals will have adequate access to file complaints with authorities and courts against decisions made by AI systems, particularly

[143] This specific issue has also been recognized, for instance, by van Kolfschooten, who has argued that the AIA does not efficiently take into account the effects that the AI decisions might produce on people who are subject to or impacted by them (van Kolfschooten 2022, p. 25).

when these systems are used by public bodies.[144] Based on my analysis, the provision's vague reference to "complaint mechanisms," without specifying any requirements, effectively leaves it up to the deployer to determine their structure and implementation. Again, the AIA is relying heavily upon deployers to police themselves.

AIA also contains a separate provision that grants the individual a right to lodge a complaint with a market surveillance authority.[145] This provision has been criticized for not containing the authority for public interest organizations to file complaints with national supervisory authorities on the behalf of individuals.[146] In comparison, the GDPR has a separate Article titled "Representation of data subjects" that allows not-for-profit entities to lodge a complaint on their behalf.[147] There are several not-for-profit organizations across Europe that actively lodge complaints on behalf of data subjects regarding privacy issues.[148] The absence of a dedicated provision for the representation of data subjects in the AIA could hinder the emergence of similar organizations that would advocate for individuals by lodging complaints in the AI context.

It needs to be noted that this potential lack of efficient remedies of the AIA could be solved by relying on the remedies granted by Article 22 GDPR. In Chapter 5, I described how predictive AI systems are also within the scope of Article 22 GDPR. Therefore, it is possible for a patient to invoke the remedies mentioned in Article 22 GDPR.

However, it is questionable whether this complementarity was deliberately designed by the Union legislator. Ultimately, the remedies in the context of automated decision-making are more of a fallback mechanism for those suffering from the effects of high-risk AI systems. It is problematic if the AIA does not, in itself, provide robust enough mechanisms for individuals to seek justice. From the point of view of the affected persons, this complementarity also creates needless and confusing fragmentation. If even legal experts struggle to navigate the overlap between the AIA and the GDPR, it is hardly reasonable to expect that the patients seeking for redress would have the ability to navigate the complex web of remedies of the GDPR and the AIA.

[144] Konopczynski 2023.
[145] Article 85 AIA.
[146] AlgorithmWatch 2024 and Konopczynski 2023.
[147] Article 80 GDPR.
[148] For example: Noyb, EDRi, and Access Now.

The lack of remedies in the context of predictive health AI leads to a situation where health services are more and more difficult to access for some patients. The patient who does not receive an invitation to a check-up because they have only few entries in their patient record due to language barriers and long wait times, has inadequate remedies to resolve the situation. Would this patient know that they could invoke remedies of the GDPR? I find it highly unlikely. Respectively, public interest organizations, who might have better legal understanding, cannot file a complaint on the behalf of this patient.

7 Discussion and concluding remarks

7.1 Discussion

In this Chapter, I combine the findings made in the previous chapters to provide my answer to the following research question that was presented in the beginning:

- Are predictive AI systems legal under EU regulation and what are the shortcomings in the prevailing regulation (particularly Article 35 CFR and Article 27 AIA) to strengthen the potential of EU law to warrant equal access to healthcare?

Firstly, the question on whether predictive AI systems are lawful under EU law is certainly a complex one. It seems that Member States deploying predictive AI systems are invoking the derogation provided by Article 22 GDPR under which it is possible to derogate from the general ban of automated decision-making. At the same time, the EDPB guidelines and the *SCHUFA Holding* case seem to be deeming automated decision-making, in the context of predictive AI systems, unlawful. The Union legislators, on the other hand, have adopted a different approach. The AIA legitimizes predictive AI systems by classifying them as "high-risk", provided that deployers comply with specific conditions.

My assessment reveals an interesting collision between the EU legislators, Member States and the CJEU. The Union legislators are adopting the AIA which specifically legalizes predictive AI systems to evaluate the eligibility of a patient to healthcare services. Correspondingly, Member States are actively derogating from the general ban of automated decision-making through national legislation. At the same time, the CJEU is calling out for broad interpretation of the general ban of automated decision-making.

Consequently, it is rather difficult to provide one exhaustive answer to the question on the legality of predictive AI systems. To put it simply, it seems that it is possible to interpret EU law in a way that predictive AI systems are legal. However, the application of EU law in this context exposes a legal grey zone, in which predictive AI can simultaneously appear prohibited under one framework and permissible under another.

Frankly, it is concerning that predictive AI systems in healthcare are embraced to an increasing extent by the Member States and the Union, even though the legality of these systems is, to put it simply, complicated, if not contested. One cannot help but wonder whether the EU and its Member States fully grasp the implications of EU law in relation to

predictive AI systems –especially given that the jurisdiction of the CJEU is directly applicable in Member States. It is worth questioning whether the concerns around legality are being taken seriously enough in a political climate where states increasingly adopt predictive AI systems in the name of cost-effectiveness.

Ultimately, in an era where states are increasingly drawn to predictive AI for its promise of efficiency, cost savings, and data-driven governance, there is a real risk that compliance becomes less significant. It is possible that compliance becomes a secondary concern, treated as a procedural hurdle rather than a substantive safeguard. This raises a question: Are the Union legislators successfully balancing between improving the functioning of the internal market and ensuring a high level of protection of health and human rights? In other words, are we witnessing a gradual erosion of fundamental rights under the guise of innovation?

My suggestion to the unclarity of legality is that, if/when there will be similar kind of interpretation guidelines on the AIA that were adopted with regards to some of the provisions of the GDPR, these guidelines should specifically address the overlapping interpretation of Article 22 GDPR and the AIA regulation on high-risk AI systems. The current situation is, to say the least, confusing. To ensure legal certainty and consistency between different Member States, general guidelines on the overlapping interpretation need to be established by the Union legislators. Furthermore, these guidelines should also give directions on how the remedies of the GDPR and the AIA should be interpreted together.

Secondly, the fundamental right to healthcare under the CFR certainly falls short in providing adequate protections to vulnerable patient groups who are faced with decisions made by predictive AI systems. When the rationale behind the right to healthcare is reviewed in the context of Article 35 CFR, one notices how this provision, in practice, neither requires states to actively promote the fulfilment of the right nor to protect patients when the right is passively undermined. The right to healthcare under Article 35 CFR lacks legal justiciability because of its subjectivity to national laws and policies and the lack of case law references in the CJEU case law. Thus, the legal effect of the right to healthcare under Article 35 CFR remains largely symbolic unless tied to the implementation of a Member State's national law.

Moreover, the non-discrimination clause of the CFR does not necessarily provide additional protection in the field of healthcare because secondary legislation in the respective field remains inadequate in recognizing all the possible different grounds of discrimination. The secondary legislation does not recognize discrimination on the basis of, for example,

language, age, unemployment or low level of education. These characteristics can be seen as some of the main drivers causing barriers to healthcare, but they are not recognized as possible grounds for discrimination in the EU's secondary legislation.

For example, imagine a situation where a predictive AI system is programmed to achieve cost-efficiency because programming it based on health need is far too complicated. Consequently, treatment of younger people could potentially be deemed more cost-effective, which could lead to prioritizing the treatment of younger patients. In a situation like this, older people would lack protection because applicable directives in the field of healthcare do not recognize discrimination on the basis of age.

Furthermore, patients could also be in a vulnerable position because of more than one characteristic. The same patient could be 80-years old, from an ethnic minority, with a low level of education, poor digital skills and unable to speak the local language. Thus the same patient could be discriminated based on multiple characteristics. This is a phenomenon where overlapping aspects of identity create unique forms of discrimination – and it is not recognized in EU legislation at all.[149]

Lastly, Article 27 AIA, which governs the Fundamental Rights Impact Assessment for predictive AI systems, fails to protect patients' right to access healthcare services. My assessment revealed four central shortcomings of the FRIA framework. Firstly, the wording of the FRIA legislation is not explicit in requiring continuous monitoring of predictive AI systems after their deployment. Secondly, the broad scope of the FRIA has the potential to lead to the creation of a "one-size-fits-all" template that fails to address the nuanced, sector-specific issues of healthcare AI systems and the right to healthcare. Thirdly, the provision fails to initiate robust third-party surveillance. To be explicit, the provision merely mentions that these assessments need to be referred to national market surveillance authorities while the AIA does not grant these authorities similar investigative and corrective powers which are e.g. granted by the GDPR to national DPAs. Fourthly and lastly, the AIA provides no suitable remedies for patients to contest decisions made by predictive AI systems.

On the basis of my assessment, it is evident that the FRIA framework falls significantly short of the GDPR's DPIA mechanism, particularly in terms of ensuring transparency, suitable remedies and adequate protection of sector-specific fundamental rights. The AI Office, when

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developing the FRIA template, must address the significant gaps left by Article 27 AIA. The AI Office cannot merely create a compliance checklist – it needs to base the template on concrete, sector-specific guidance that ensures the protection of fundamental rights in high-risk areas, such as healthcare.

It is important to emphasize that the findings presented regarding the FRIA are purely hypothetical at this stage, as the legislation will only enter into force on 2 August 2026. Ultimately, it will be the practical application of the law that determines how its provisions, including the wording of the FRIA, are interpreted by authorities and courts. Future research should therefore focus on how Article 27 AIA will be implemented and interpreted across Member States. In particular, comparative studies would be valuable in evaluating the quality and effectiveness of third-party assessments. Such research could help address the differences between Member States that have adopted centralized and decentralized approaches to compliance and oversight.

To conclude, both the fundamental right to healthcare of the CFR and the FRIA of the AIA fail to provide a proper base for affected patients to invoke proceedings in courts. To be specific, there is a lack of sufficient mechanisms in EU law to legally challenge harmful AI practices that may occur in healthcare. Moreover, the non-justiciability of Article 35 CFR and the gaps in the FRIA legislation could potentially lead to a regulatory void that leaves vulnerable patients subject to the risks of high-risk AI systems without meaningful protection.

Hence, EU law does not currently provide sufficient protection for access to justice for the affected patients. It is important to note that access to justice is not only a legal right – it is also recognized as a social determinant of health. [150] This means that when people are denied the opportunity to seek legal redress, it can directly contribute to health inequities and social exclusion.

This is particularly problematic for patients already in vulnerable situations, such as older persons or the unemployed, who often experience barriers in accessing healthcare. If these patients are also denied access to justice, the obstacles they face in securing adequate healthcare are likely to grow even more severe. Accordingly, the inability of EU law to adequately protect vulnerable patients can reinforce or even widen existing health inequalities (Figure 1).

[150] Fung and Dong 2024.

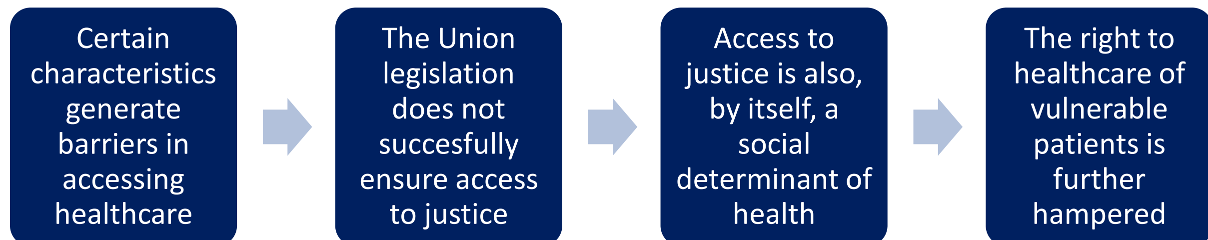

Figure 1. Vulnerability and limited access to justice (Source: Author).

When EU legislation falls short in mandating strong incentives for healthcare providers to address equality issues, it becomes important to assess other factors that may encourage or discourage healthcare providers from taking action. When it comes to public healthcare systems there may be a stronger incentive to tackle equality issues compared to the private systems. This is because public healthcare is subject to public opinion and scrutiny. Compared to private healthcare system, public healthcare system is under constant ethical oversight. Hence, in order to uphold the democratic legacy of the healthcare system, public healthcare system decisions need to be transparent and the system must be able to uphold the trust of the people. The most potential threat to equality that could occur in public healthcare systems is, in my opinion, resource constraints. While there is always an intent to ensure equitable access in public healthcare, limited resources could prove problematic in the designing process of health AI. Poorly trained algorithms could hence reinforce existing inequities and disproportionately affect vulnerable populations.

Thus, it needs to be ensured that deployers of predictive AI systems, especially public entities with limited resources, do not start relying too heavily on the decision-making of a predictive AI in the distribution of health services. In other words, it needs to always be ensured that patients can access health services through other means.

Private healthcare systems, on the other hand, have the needed resources to invest in the creation of AI systems with high-level of equality. However, private systems may lack

incentives to tackle biases if addressing them does not align with profit goals. For instance, certain groups of patients might be deprioritized if their care is deemed less profitable or if addressing bias increases operational costs. Additionally, in private systems, access often depends on a patient's ability to pay. AI could exacerbate disparities by denying eligibility to patients deemed less profitable, such as those with pre-existing conditions or complex health needs.

Because of the above-mentioned obstacles that might passivate public and private healthcare systems in tackling equality issues with regards to predictive AI systems, it is evident that there is a need for robust legislation. Next, I very briefly examine how EU legislation should be revised in order to adequately facilitate equal access to healthcare.

One of the most straightforward solutions would be amending Article 35 CFR, by removing the reference to national laws and policies. In my view, such amendment would be justified, especially considering that the Union is already playing a significant role in shaping digital health rights through the AIA. It is unlikely that, when drafting the CFR, the Union legislators anticipated that they would later adopt secondary legislation with such strong impact on patients' rights. The introduction of predictive AI systems in healthcare, in particular, introduces an entirely new paradigm one that, in many ways, fundamentally challenges the traditional principles of equitable healthcare. These are some of the arguments that strongly support the fact that Article 35 CFR needs renovation.

However, I argue that amending Article 35 CFR by removing the reference to national laws and policies would be too far-reaching in the current political and legal climate. Such a change would not only affect the regulation of health-related AI but could also have broad implications for healthcare as a whole. This is problematic because, under the EU's founding treaties, the Union only has supporting competence in the field of public health. In other words, healthcare remains primarily a national responsibility. What is needed, instead, is more specific protection of health rights in the context of digitalisation and the use of AI—not a general expansion of the EU's role in healthcare. A more targeted legal or policy solution would be better aligned with the current division of competences between the Union and its Member States.

Van Kolfschooten has, indeed, provided a more targeted solution – an entirely new piece of legislation called the "EU Charter for Digital Patients' Rights", which would specifically address the challenges brought by AI and other new technology in the field of healthcare. This

Charter, according to van Kolfschooten, would be “consolidating and adapting existing rights for patients”.[151] In her research article, she underlines how one of the biggest challenges in the new AI paradigm is threats to equal access to healthcare. Consequently, in her draft proposal for EU Charter For Digital Patients’ Rights, “the right to access to healthcare” is one of the protected rights. This right would include the “availability, accessibility, acceptability and quality of healthcare”, as well as “the right to non-discrimination”.[152]

Van Kolfschooten justifies her proposal by arguing that the Union’s legal framework is quite fragmented when it comes to the individual rights patients are entitled to. She highlights how this fragmentation paired up with different levels of protection between Member States can further increase health inequity.[153]

In my view, adopting an entirely new Charter would only risk creating further legal fragmentation, ultimately defeating the very purpose of reducing it. Yet, I must admit that alternative solutions are difficult to identify. One question, however, is clear and daunting in today’s regulatory landscape: Does the national sovereignty in the field of healthcare still meaningfully persist when the regulatory frameworks governing AI systems exert such profound influence over the domain of healthcare? Because the Union’s AI policy has such powerful effects in the field of healthcare, I argue that, in the age of predictive AI systems, the right to healthcare should no longer only be derived from national legislation.

7.2 Concluding remarks

The legality of predictive AI systems is somewhat unclear because of the different approaches taken by the Union legislator and the CJEU. The AIA specifically legalizes the use of AI systems in evaluating the eligibility of a patient to access healthcare services. At the same time, the CJEU is calling out for a broad interpretation of the general ban of automated decision-making of the GDPR. To navigate in this legal grey zone, the EU should issue clear guidelines on how the AIA and the GDPR should be interpreted together, ensuring consistency and strong protection of the fundamental right to healthcare.

The right to healthcare under Article 35 CFR, on the other hand, can be described as a purely symbolic provision. This provision fails to provide adequate protection for vulnerable patients

[151] Van Kolfschooten 2025, p. 1.
[152] Van Kolfschooten 2025, p. 21, Table 1.
[153] Van Kolfschooten 2025, p. 2.

mainly because it lacks legal justiciability due to its subjectivity to national laws and policies. Respectively, the CJEU has been rather passive in referring to the right to healthcare in its case law. Furthermore, invoking the right to healthcare together with the non-discrimination provision of the CFR does not solve the issue because secondary union legislation in the field of healthcare does not successfully protect from different grounds of discrimination.

Moreover, the Fundamental Rights Impact Assessment of the AIA fails to protect vulnerable patients' right to healthcare. In my assessment, I have discovered several shortcomings with regards to the AIA's regulation. Firstly, the FRIA lacks a clear requirement for ongoing monitoring of predictive AI after deployment. Secondly, its broad scope risks creating a generic approach that overlooks the specific challenges of healthcare and the right to healthcare. Thirdly, it does not establish strong third-party oversight, merely referring issues to national authorities without granting them robust powers of surveillance. Lastly, the AIA offers no clear enforceable remedies for patients.

As a consequence, there are no sufficient mechanisms available in EU regulation to legally challenge decisions made by predictive AI systems. Union law fails to provide sufficient protection of access to justice. Accordingly, without access to justice, existing health inequalities could deepen – patients already suffering from barriers to healthcare are faced with even more difficulties.

Lastly, the inadequate protection of the right to healthcare does not go hand in hand with the current developments of the Union legislation. As the Union is increasingly regulating in a way that has implications in health law, the Union should respectively strengthen its protection of the fundamental right to healthcare.