Balancing Bias Mitigation and Data Protection in AI-Driven Healthcare:

Insights from the European Health Data Space, AI Act and GDPR

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Contents

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I. Introduction

AI use in healthcare has the potential to revolutionize the field by improving access to treatment and resources, as well as enabling more efficient and personalized care.[1] AI can aid in diagnosis and precision medicine[2] and has various applications in medical imaging[3], drug discovery[4], disease prediction[5] and telemedicine.[6] However, the use of AI in healthcare also raises legal and ethical concerns, such as issues related to data protection, privacy and accountability, which require appropriate regulatory

[1] Shuroug A Alowais and others, 'Revolutionizing Healthcare: The Role of Artificial Intelligence in Clinical Practice' (2023) 23 BMC Medical Education 689 <https://doi.org/10.1186/s12909-023-04698-z> accessed 10 February 2024; Kevin B Johnson and others, 'Precision Medicine, AI, and the Future of Personalized Health Care' (2021) 14 Clinical and Translational Science 86 <https://onlinelibrary.wiley.com/doi/abs/10.1111/cts.12884> accessed 14 January 2024.

[2] Chayakrit Krittanawong and others, 'Artificial Intelligence in Precision Cardiovascular Medicine' (2017) 69 Journal of the American College of Cardiology 2657 <https://www.jacc.org/doi/abs/10.1016/j.jacc.2017.03.571> accessed 12 March 2024.

[3] Francesca Coppola and others, 'Human, All Too Human? An All-Around Appraisal of the "Artificial Intelligence Revolution" in Medical Imaging' (2021) 12 Frontiers in Psychology <https://www.frontiersin.org/journals/psychology/articles/10.3389/fpsyg.2021.710982/full> accessed 19 March 2024.

[4] Arlindo L Oliveira, 'Biotechnology, Big Data and Artificial Intelligence' (2019) 14 Biotechnology Journal e1800613.

[5] Muhammad Javed Iqbal and others, 'Clinical Applications of Artificial Intelligence and Machine Learning in Cancer Diagnosis: Looking into the Future' (2021) 21 Cancer Cell International 270 <https://doi.org/10.1186/s12935-021-01981-1> accessed 12 February 2024; Meena Laad and others, 'Cardiac Diagnosis with Machine Learning: A Paradigm Shift in Cardiac Care' (2022) 36 Applied Artificial Intelligence 2031816 <https://doi.org/10.1080/08839514.2022.2031816> accessed 1 August 2023.

[6] Jefferson Gomes Fernandes, 'Artificial Intelligence in Telemedicine' in Niklas Lidströmer and Hutan Ashrafian (eds), *Artificial Intelligence in Medicine* (Springer International Publishing 2022) <https://doi.org/10.1007/978-3-030-64573-1_93> accessed 10 April 2024.

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frameworks to address.[7] A key question in this regard is whether AI can increase fairness in traditionally underrepresented communities or if it will worsen existing disparities in healthcare systems.[8]

In 2020, the Commission stated in their Communication titled "A European Strategy for Data" that: "The value of data lies in its use and re-use. Currently, there is not enough data available for innovative re-use, including for the development of artificial intelligence."[9] The European Health Data Space ("EHDS") is at the forefront of this challenge, as a visionary initiative aimed at facilitating the secondary use of health data to drive innovation. The AI Act, a legislative framework designed to regulate artificial intelligence, including the processing of special categories of personal data, establishes standards for transparency, accountability, and oversight, ensuring that AI technologies are developed and deployed in a manner that respects fundamental rights and ethical principles.[10] Concurrently, the AI Act introduces provisions to detect and correct biases in high-risk AI systems.

This paper will explore the balance between bias mitigation and data protection in developing AI technologies for healthcare under the legal frameworks of the European Union (EU), namely the EHDS, GDPR and AI Act. It will begin with a background on the regulatory framework and an overview regarding AI technologies. Later on, general information regarding the EHDS will be provided. Following this, bias in AI systems and real-life examples of bias will be explained. The discussion will then cover data handling in the EHDS, including anonymization and pseudonymization, and will examine the AI Act's provisions for bias detection and correction. This will lead to an analysis of conflicts between the frameworks of the EHDS, the AI Act, and the GDPR. Finally, the study will conclude with reflections on the impact of these conflicts on developing unbiased medical AI, providing insights into navigating these regulatory challenges. Against this background, this study aims to answer the following question: "how do the EHDS and the AI Act

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[7] Danton S Char, Nigam H Shah and David Magnus, 'Implementing Machine Learning in Health Care — Addressing Ethical Challenges' (2018) 378 The New England journal of medicine 981 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5962261/> accessed 19 April 2024.

[8] European Parliament. Directorate General for Parliamentary Research Services., *Artificial Intelligence in Healthcare: Applications, Risks, and Ethical and Societal Impacts.* (Publications Office 2022) <https://data.europa.eu/doi/10.2861/568473>.

[9] 'A European Strategy for Data COM(2020)' <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1593073685620&uri=CELEX%3A52020DC0066> accessed 8 October 2022.

[10] 'EU AI Act: First Regulation on Artificial Intelligence' (*Topics | European Parliament*, 8 June 2023) <https://www.europarl.europa.eu/topics/en/article/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence> accessed 19 April 2024.

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address and provide solutions for mitigating bias in AI technologies used in healthcare, and how do these frameworks interact with GDPR?"

A. Regulatory Background

The central role of data in the development of AI technologies brings significant attention to data protection legislation. Given the focus of this study on EU law, the GDPR, which has been applicable since 2018, serves as the primary legislative instrument governing data protection.[11] Although the GDPR was enacted relatively recently, rapid technological advancements and the growing volume of data have necessitated updates. The European Commission's Communication outlined their vision: "the EU should combine fit-for-purpose legislation and governance to ensure the availability of data, with investments in standards, tools, and infrastructures as well as competences for handling data."[12]

The EHDS, introduced in May 2022 as part of the EU's data strategy and the first of planned data spaces, aims to foster a genuine single market for electronic health record systems, relevant medical devices, and high-risk AI systems. To achieve this goal, the EHDS proposes new rules for various types of data processing.[13] On 5 March 2025, the EHDS Regulation (EU) 2025/327 was officially published in the Official Journal of the European Union.[14] Implementation of the EHDS will follow a gradual approach with key milestones established between 2025 and 2031, including the phased application of both primary and secondary use provisions across different categories of health data.[15] Although the fundamental structure of the EHDS remains aligned with its initial proposal, significant amendments have been incorporated during the legislative process. A notable example is the introduction of the opt-out

[11] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) 2016.

[12] 'A European Strategy for Data COM(2020)' (n 10).

[13] 'A European Health Data Space: Harnessing the Power of Health Data for People, Patients and Innovation COM(2022)' <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022DC0196&qid=1669731581694> accessed 2 November 2023.

[14] 'Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and Amending Directive 2011/24/EU and Regulation (EU) 2024/2847' <https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng> accessed 14 April 2025.

[15] 'European Health Data Space Regulation (EHDS) - European Commission' (28 March 2025) <https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en> accessed 26 April 2025.

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mechanism, which enables individuals to prohibit secondary usage of their personal health data.

In parallel to developments in the EHDS framework, the EU has also published the AI Act in June 2024, which proposes a framework for regulating AI development and application within the EU.[16] Its objectives are to establish uniform internal market rules for AI development, market placement, and usage; promote human-centric and trustworthy AI; and ensure high levels of health, safety, and fundamental rights protection.[17] Furthermore, the AI Act aims to regulate AI systems based on risk levels and impose specific obligations.[18] Given that the EHDS references the AI Act within its provisions, and both must align with the GDPR, a thorough analysis must consider all three acts together, particularly in terms of bias mitigation.

B. Overview of AI Technologies

Before exploring the discussion on AI and bias in healthcare, it is crucial to establish a clear understanding of these concepts to pinpoint the core issues. The definition of an AI system in the AI Act has sparked debates for being too broad[19], and throughout its evolution, the definition has undergone amendments.[20] The AI Act, Article 3(1), describes an AI system as: "'artificial intelligence system' (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with".[21]

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[16] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance).

[17] Stephen Gilbert, 'The EU Passes the AI Act and Its Implications for Digital Medicine Are Unclear' (2024) 7 npj Digital Medicine 1, 1 <https://www.nature.com/articles/s41746-024-01116-6> accessed 6 June 2024.

[18] 'AI Act | Shaping Europe's Digital Future' (26 March 2024) <https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai> accessed 12 April 2024.

[19] 'European Council and Commission in Agreement to Narrow the Scope of the AI Act' (*AlgorithmWatch*) <https://algorithmwatch.org/en/eu-narrow-scope-of-ai-act/> accessed 2 June 2024.

[20] Tervel Bobev, 'Defining AI in the AI Act: Pin the Tail on the System.' (*CiTiP blog*, 2 April 2024) <https://www.law.kuleuven.be/citip/blog/defining-ai-in-the-ai-act-pin-the-tail-on-the-system/> accessed 20 April 2024.

[21] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU)

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In the literature, Davenport and Kalakota argue that AI technologies cover a variety of techniques rather than a single technology. Machine learning, a foundational aspect of artificial intelligence, involves using statistical methods to construct models from data, enabling these models to 'learn' through iterative training processes.[22] Deep learning, a subset of machine learning, employs artificial neural networks with multiple layers to discern intricate patterns within large datasets.[23] In this study, the term 'AI' is used as an umbrella term to encompass these complex systems. Occasional reference is made to 'machine learning models' specifically when discussing details such as the importance of the training dataset used.

II. EHDS – Objectives and Key Components

The EHDS outlines two primary objectives: firstly, to enhance citizens' access to and control over their electronic health records (EHR) across the EU, and secondly, to promote the responsible secondary use of health data for purposes such as innovation, research, and policymaking (Recital 1, EHDS). As the first of the European domain-specific data spaces, the EHDS represents a significant milestone poised to transform healthcare governance within the EU and potentially set a new global standard.[24] EHDS provisions include aspects related to both primary and secondary use of electronic health data. The primary use of electronic health data aims to integrate EHR products and other medical software, potentially overcoming obstacles related to cross-border health data sharing. The emphasis of this study, however, is on the provisions pertaining to secondary use, which will be explained in more detail in the following sections of the paper.

The EHDS has also been proposed to facilitate the utilization of health data for developing AI technologies within its secondary use framework. According to the EHDS Regulation, 'secondary use' means "the processing of electronic health data for the purposes set out in Chapter IV of this Regulation, other than the initial

No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance).

[22] Thomas Davenport and Ravi Kalakota, 'The Potential for Artificial Intelligence in Healthcare' (2019) 6 Future Healthcare Journal 94 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6616181/> accessed 30 July 2023.

[23] Sara Gerke, Timo Minssen and Glenn Cohen, 'Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare' [2020] Artificial Intelligence in Healthcare 295 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7332220/>.

[24] Luca Marelli and others, 'The European Health Data Space: Too Big To Succeed?' [2023] Health Policy 104861 <https://www.sciencedirect.com/science/article/pii/S016885102300146X> accessed 30 June 2023.

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purposes for which they were collected or produced."[25] The Regulation provides this concise definition rather than an extensive explanation, focusing instead on the specific purposes enumerated in its fourth chapter.

The secondary use framework introduced as a system through which health data would be accessed by public, private, not-for-profit entities, as well as individual researchers "for research, innovation, policy making, educational activities, patient safety, regulatory activities or personalised medicine, in line with the purposes set out in this Regulation" as stated in Recital 61 of the EHDS. Recital 61 of the EHDS also emphasizes the importance of using health data to develop AI systems that support scientific research, innovation, and the production of goods and services for the health or care sectors. This includes activities such as training AI algorithms to enhance the health and care of individuals. Excerpts from the EHDS indicate that the initiative aims to establish a unified market for electronic health records and AI systems within the EU. It does so by introducing a secondary use framework that facilitates broad access to health data for various parties involved.[26]

While the EHDS focuses on facilitating the secondary use of health data for AI technologies, it also introduces distinct roles for actors involved in this framework. Actors within the secondary use framework must be mentioned as the EHDS introduces different roles compared to the GDPR. 'Health Data holder' is described in a broad manner to as, any individual or organization in the health or care sector, or conducting related research, as well as Union institutions which have the right or obligation to manage data under relevant laws.[27] Similarly, 'Health Data user' is defined as: "a natural or legal person, including Union institutions, bodies, offices or agencies, which has been granted lawful access to electronic health data for secondary use pursuant to a data permit, a health data request approval or an access approval by an authorised participant in HealthData@EU".[28] Moreover, there will be another actor which will act as an intermediary between data holders and users called 'health

[25] 'Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and Amending Directive 2011/24/EU and Regulation (EU) 2024/2847' (n 15).

[26] ibid.

[27] ibid. Article 2(1)(t) defines the health data holder "any natural or legal person, public authority, agency or other body in the healthcare or the care sectors, including reimbursement services where necessary, as well as any natural or legal person developing products or services intended for the health, healthcare or care sectors, developing or manufa cturing wellness applications, performing research in relation to the healthcare or care sectors or acting as a mortality registry, as well as any Union institution, body, office or agency, that has either:"

[28] ibid. Article 2(1)(u)

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data access body' (HDAB) which will be established by Member States. Without providing a definition of this authority, the EHDS sets forth tasks and obligations of HDABs in the fourth chapter.[29] This authority is portrayed as a supervising body which will oversee applications of secondary use framework. The details of data handling under the secondary use framework are explained in the fourth section of this study.

III. Bias in AI Systems

Bias, as a general term, is not a recent problem but is "as old as human civilization". Human biases have been studied across various disciplines, including psychology and law.[30] This inherent human characteristic has inadvertently been conveyed into developed technologies and has been detected and studied extensively from the early stages. In 1996, Friedman and Nissenbaum defined biased computer systems as "computer systems that systematically and unfairly discriminate against certain individuals or groups of individuals in favor of others."[31] The real importance of biases in AI systems lies in a fundamental issue: AI development heavily relies on data produced by humans. Bias can emerge throughout multiple phases of AI development, from initial data collection to algorithm design and end-user interactions creating cascading effects that manifest in the final system outputs. These biases take various forms, including data bias, algorithmic bias and bias stemming from user interactions, each requiring distinct mitigation approaches.[32] The use of non-representative or prejudiced training data represents a primary pathway through which discriminatory outcomes emerge in artificial intelligence systems, fundamentally compromising their fairness and reliability.[33] Consequently, any biases present in humans infiltrate our systems and are exacerbated within complex

[29] ibid. Chapter IV.

[30] Eirini Ntoutsi and others, 'Bias in Data-Driven Artificial Intelligence Systems—An Introductory Survey' (2020) 10 WIREs Data Mining and Knowledge Discovery e1356 <https://onlinelibrary.wiley.com/doi/abs/10.1002/widm.1356> accessed 7 May 2023.

[31] Batya Friedman and Helen Nissenbaum, 'Bias in Computer Systems' (1996) 14 ACM Transactions on Information Systems 330, 3 <https://dl.acm.org/doi/10.1145/230538.230561> accessed 10 February 2024.

[32] Emilio Ferrara, 'Fairness and Bias in Artificial Intelligence: A Brief Survey of Sources, Impacts, and Mitigation Strategies' (2024) 6 Sci 3, 2 <https://www.mdpi.com/2413-4155/6/1/3> accessed 5 January 2025.

[33] Marvin van Bekkum and Frederik Zuiderveen Borgesius, 'Using Sensitive Data to Prevent Discrimination by Artificial Intelligence: Does the GDPR Need a New Exception?' (2023) 48 Computer Law & Security Review 105770, 3 <https://www.sciencedirect.com/science/article/pii/S0267364922001133> accessed 18 June 2024.

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sociotechnical frameworks. This can lead algorithms to perpetuate or exacerbate existing inequalities or discriminatory practices.[34] Bölükbaşı et al. demonstrated a clear example of this when they found that their natural language model algorithm, trained on Google News articles, exhibited sexist traits.[35]

A. Examples of Bias in Healthcare AI

Even though there is an abundance of studies conducted on bias, fairness and disparities of AI technologies, a commonly agreed upon definition of bias cannot be extracted from those studies.[36] Mittermaier et al.'s description of bias follows "a difference in performance between subgroups for a predictive task" and can be used to understand what the term encapsule as a broad definition.[37] Bias is distinguished into two by Parikh et al., namely societal and statistical bias.[38] Building on this framework, Norori et al., further classifies statistical bias into two subcategories of "data-driven bias" and "algorithmic bias".[39] Data-driven bias refers to the bias in the training data of algorithmic models. This could appear either in data limitations or data gaps which would mean that data of some societal groups were omitted in the training data. In another saying, data-driven bias occurs in the data collection stage and thus representativeness of data cannot be provided. Similar to Parikh et al.'s distinction, Vokinger et al. make the differentiation based on the phases of the development of machine learning models. First, they describe these stages as data collection and data preparation, model development and evaluation and the

[34] Ntoutsi and others (n 31).

[35] Tolga Bolukbasi and others, 'Man Is to Computer Programmer as Woman Is to Homemaker? Debiasing Word Embeddings', *Advances in Neural Information Processing Systems* (Curran Associates, Inc 2016) <https://papers.nips.cc/paper_files/paper/2016/hash/a486cd07e4ac3d270571622f4f316ec5-Abstract.html> accessed 10 February 2024.

[36] Natalia Norori and others, 'Addressing Bias in Big Data and AI for Health Care: A Call for Open Science' (2021) 2 Patterns 100347 <https://www.sciencedirect.com/science/article/pii/S2666389921002026> accessed 7 July 2023; Trishan Panch, Heather Mattie and Rifat Atun, 'Artificial Intelligence and Algorithmic Bias: Implications for Health Systems' 9 Journal of Global Health 020318 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6875681/>; Ninareh Mehrabi and others, 'A Survey on Bias and Fairness in Machine Learning' (2022) 54 ACM Computing Surveys 1 <https://dl.acm.org/doi/10.1145/3457607>.

[37] Mirja Mittermaier, Marium M Raza and Joseph C Kvedar, 'Bias in AI-Based Models for Medical Applications: Challenges and Mitigation Strategies' (2023) 6 npj Digital Medicine 1 <https://www.nature.com/articles/s41746-023-00858-z> accessed 6 June 2023.

[38] Ravi B Parikh, Stephanie Teeple and Amol S Navathe, 'Addressing Bias in Artificial Intelligence in Health Care' (2019) 322 JAMA 2377 <https://doi.org/10.1001/jama.2019.18058>.

[39] Norori and others (n 37) 3.

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deployment of the model into a clinical practice. Then they called the bias in the data collection and data preparation stage a 'sampling bias' when the data used to train the AI is not representative of the population which the AI system intended to be used. They showcased an example of the sampling bias when the model trained to detect a type of a skin cancer on people with white skin did not have the desired results when used on people who have a darker skin tone. This led to the result that no matter how advanced the technology got, it did not perform fully when used on people with darker skin tone.[40] Similarly, Parikh et al. mentioned the Framingham Study risk factor which has been used widely to calculate the risk for cardiovascular disease, yet the original study was conducted on mostly non-Hispanic white people and thus, when applied on different groups of society, didn't give the optimal results.

In the words of Ntoutsi et al. "mis-represented groups coincide with social groups against which there already exists social bias such as prejudice or discrimination".[41] Underrepresenting a group of society while training an algorithm causes unfair and/or inaccurate consequences for that group. These outcomes were seen frequently as racial bias and gender bias as multiple studies prove. Norori et al. mention a skin cancer diagnosis algorithm performing with 50% accuracy rate when tested on black people, due to its training dataset containing only 5% to 10% of images of black people.[42] Furthermore, another example given by them shows gender bias and how it can appear in real life. An algorithm which claims to predict heart attacks 5 years in advance, misdiagnosed women in high numbers. The reason for this outcome has been found to be that the algorithm was trained mainly on data samples of men.[43] Panch et al. identified the term algorithmic bias in healthcare as "the instances when the application of an algorithm compounds existing inequities in socioeconomic status, race, ethnic background, religion, gender, disability or sexual orientation to amplify them and adversely impact inequities in health systems."[44]

IV. Data Handling Under EHDS's Secondary Use Framework

The EHDS details the secondary use framework in its fourth chapter, which includes provisions regarding the categories of electronic health data that will be made

[40] Adewole S Adamson and Avery Smith, 'Machine Learning and Health Care Disparities in Dermatology' (2018) 154 JAMA dermatology 1247.

[41] Ntoutsi and others (n 31) 4.

[42] Norori and others (n 37) 2.

[43] ibid.

[44] Panch, Mattie and Atun (n 37) 2.

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available under this system. The Regulation's description of 'health data' covers a wide array of information.[45] This includes data directly connected to health, such as electronic health records and genomic data, as well as data indirectly related to health, including information on insurance status, professional status, education, lifestyle, wellness and behaviour.[46] Article 51 also dictates that health data holders will make the data available under this framework. This obligation to provide the data is detailed more in the Article 60 of the EHDS. This article also obligates data holders to deliver a general description of their dataset to HDABs.[47]

The secondary use process will start with a data permit application by data users to HDABs and their application will be evaluated based on the criteria listed in the Articles 66-69.[48] One of the conditions to obtain a data permit is to use data only for the purposes listed in Article 53. In this article, subparagraph (e)(ii) mentions using the data for "training, testing and evaluating of algorithms, including in medical devices, in-vitro diagnostic medical devices, AI systems and digital health applications"; other possible purposes are also itemized.[49]

Article 66 which is titled, 'Data minimisation and purpose limitation', states in its second subparagraph that "Health data access bodies shall provide electronic health data in an anonymised format, where the purpose of processing by the health data user can be achieved with such data, taking into account the information provided by the health data user."[50] However, the following subparagraph introduces an important exception in this regard. Article 66(3) stipulates "Where the health data user has sufficiently demonstrated that the purpose of processing cannot be achieved with anonymised data in accordance with Article 68(1), point (c), health data access bodies shall provide access to electronic health data in pseudonymised format. The information necessary to reverse the pseudonymisation shall be available only to the

[45] 'Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and Amending Directive 2011/24/EU and Regulation (EU) 2024/2847' (n 15). Article 51

[46] Petros Terzis, 'Compromises and Asymmetries in the European Health Data Space' (2022) 30 European Journal of Health Law 345, 4 <https://brill.com/view/journals/ejhl/30/3/article-p345_5.xml> accessed 26 June 2023.

[47] 'Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and Amending Directive 2011/24/EU and Regulation (EU) 2024/2847' (n 15). (Article 60(3))

[48] ibid.

[49] ibid. Article 53(1)(e)(ii)

[50] ibid. Article 66(2)

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health data access body or an entity that acts as a trusted third party in accordance with national law."[51]

These two provisions indicate that data will be open to access in an anonymised format as a rule and pseudonymised as an exception within the secondary use framework. Following the setup of the system, how data users will access data is regulated in section 5 of the chapter IV. According to Article 77, HDABs will inform the data users about the available datasets and their characteristics through a metadata catalogue.[52]

Additionally, one of the new concepts introduced within the March 2024 version of the EHDS is the 'opt-out' mechanism from secondary use.[53] Article 71 of the final EHDS text states that, "Natural persons shall have the right to opt out at any time, and without providing any reason, from the processing of personal electronic health data relating to them for secondar y use under this Regulation."[54]

A. Bias Under the Secondary Use Framework of the EHDS

The term 'bias' is mentioned only in Article 78, titled "Data quality and utility label" of the EHDS. This article establishes criteria for datasets made available through health data access bodies, with mandatory labelling for datasets collected and processed with Union or national public funding.

Article 78(3) outlines the elements that the data quality and utility label must cover. Under subparagraph (c), "data quality management processes" are listed, which explicitly includes "bias examination" as one component.[55] Additionally, subparagraph (d) addresses "assessment of coverage" including "*representativity of the population sampled*" which relates directly to potential demographic biases in datasets.[56]

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[51] ibid. Article 66(3)

[52] ibid. Article 77(1)

[53] 'European Health Data Space: Council and Parliament Strike Deal' <https://www.consilium.europa.eu/en/press/press-releases/2024/03/15/european-health-data-space-council-and-parliament-strike-provisional-deal/> accessed 17 April 2024.

[54] 'Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and Amending Directive 2011/24/EU and Regulation (EU) 2024/2847' (n 15). Article 71(1)

[55] ibid. Article 78(3)(c)

[56] ibid. Article 78(3)(d)(emphasis added)

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Furthermore, Article 78(6) authorizes the Commission to establish technical specifications for these data quality labels by 26 March 2027, with a specific requirement to align with AI Act provisions: "Those implementing acts shall take into account the requirements in Article 10 of Regulation (EU) 2024/1689 and any adopted common specifications or harmonised standards supporting those requirements, where applicable."[57] This creates a formal connection between the EHDS data quality framework and the AI Act's requirements for high-risk AI systems.

The next section will examine the AI Act and its relevant provisions for bias mitigation.

V. The AI Act and Bias Mitigation

Looking more closely at Article 10 of the AI Act, referenced in Article 78(6) of the EHDS, we find specific criteria that training datasets for high-risk AI systems must meet. The subparagraphs of Article 10(2) particularly relevant to bias mitigation are as follows:

> "(f) examination in view of possible biases that are likely to affect the health and safety of persons, have a negative impact on fundamental rights or lead to discrimination prohibited under Union law, especially where data outputs influence inputs for future operations;
>
> (g) appropriate measures to detect, prevent and mitigate possible biases identified according to point (f);"[58]

In addition to this article, Article 10(5) further details the conditions that must be followed when examining datasets in accordance with Article 10(2)(f) and (g). Article 10(5) follows as: "To the extent that it is *strictly necessary* for the purpose of ensuring bias detection and correction in relation to the high-risk AI systems in accordance with paragraph (2), points (f) and (g) of this Article, the providers of such systems *may exceptionally* process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the provisions set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and

[57] ibid. Article 78(6)

[58] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance). Article (10)(2)(f) and (g)

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Directive (EU) 2016/680, all the following conditions must be met in order for such processing to occur."[59]

These stringent requirements for bias examination and correction in high-risk AI systems under the AI Act necessitate a thorough evaluation alongside the EHDS provisions to ensure comprehensive data quality and utility standards. Given that this process involves the handling of sensitive data, it is imperative to incorporate the GDPR into this evaluative framework.

VI. Conflicts Between Regulatory Frameworks and Technical Challenges in Bias Mitigation

A. Fundamental Regulatory Contradictions

The development of unbiased healthcare AI systems exists at the intersection of competing regulatory imperatives, creating significant challenges for researchers and practitioners. AI technologies derive their capabilities fundamentally from the quality and composition of the datasets they rely on during their training phase. Bias manifests in these datasets through systematic misrepresentation or underrepresentation of certain demographic groups, with profound implications for healthcare equity. As Wojcik notes, underrepresentation of minorities in datasets leads to inaccuracies and produces biased outcomes emphasising how dataset composition directly impacts the fairness of AI-driven healthcare applications.[60]

Tackling the bias challenge must be navigated within a complex regulatory landscape that creates inherent tensions between bias mitigation and data protection. As established at the outset of this paper, three distinct frameworks create a regulatory triangle characterized by frequently competing imperatives. The GDPR establishes the foundation through stringent limitations on the processing of health data, prioritizing individual privacy rights. Building upon this framework, the AI Act introduces requirements for thorough bias examination procedures that necessarily require access to comprehensive demographic and clinical data to function effectively. The EHDS, as the most recent regulatory development, emphasizes robust data protection primarily through anonymization techniques for secondary use

[59] ibid. Article 10(5) (emphasis added)

[60] Malwina Anna Wojcik, 'Machine-Learnt Bias? Algorithmic Decision Making and Access to Criminal Justice: Overall Winner, Justis International Law & Technology Writing Competition 2020, by Malwina Anna Wojcik of the University of Bologna' (2020) 20 Legal Information Management 99 <https://www.proquest.com/docview/2442778187/abstract/2AC634199284F09PQ/1> accessed 30 June 2023.

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purposes, attempting to balance privacy protection with necessary data accessibility for healthcare innovation.

This regulatory structure creates a fundamental paradox for bias mitigation efforts. Diversifying datasets, which is generally recognized as an essential bias mitigation strategy, requires detailed information about demographic representation within datasets.[61] Yet this very demographic information becomes problematic to access and analyse within strict anonymization frameworks. The EHDS's emphasis on anonymized data for secondary use directly conflicts with the need for identifiable demographic characteristics required to assess and mitigate bias. This tension places developers in the difficult position of navigating seemingly incompatible regulatory requirements: they must simultaneously develop unbiased systems while adhering to data protection protocols that may obscure the very information needed to detect bias.

The technical distinctions between anonymization and pseudonymization within these regulations, as defined in data protection law, further complicate bias mitigation efforts. According to Recital 26 of the GDPR, anonymized data fall outside the scope of data protection legislation because individuals cannot be identified directly or indirectly. Conversely, pseudonymized data where re-identification remains possible through additional information held separately remain subject to data protection requirements. This distinction has profound implications for bias assessment in healthcare AI. Anonymized data may protect privacy but simultaneously eliminate the demographic identifiers necessary for comprehensive bias evaluation, creating a regulatory barrier to developing fair and equitable healthcare AI systems. Meanwhile, pseudonymized data permit more thorough bias analysis but trigger more stringent regulatory compliance requirements, potentially deterring developers from pursuing robust bias mitigation strategies. On the other hand, the EU project Towards European Health Data Space highlighted while Article 4 of the GDPR defines pseudonymisation, there is a lack of clear guidance at national and international levels, resulting in varying approaches across European countries.[62]

[61] James Manyika, Jake Silberg and Brittany Presten, 'What Do We Do About the Biases in AI?' [2019] *Harvard Business Review* <https://hbr.org/2019/10/what-do-we-do-about-the-biases-in-ai> accessed 4 June 2023.

[62] TEHDAS JA, 'Report on Secondary Use of Health Data through European Case Studies' <https://tehdas.eu/app/uploads/2022/08/tehdas-report-on-secondary-use-of-health-data-through-european-case-studies-.pdf> accessed 2 March 2023.

B. The Identification Paradox: Data Protection Versus Bias Detection

This regulatory structure creates what can be termed as an 'identification paradox' a fundamental tension between bias detection and data protection. Effective bias detection requires access to demographic variables, clinical indicators, and socioeconomic factors to identify disparate impacts across population subgroups.[63] While alternative approaches exist that can mitigate discrimination without directly collecting all sensitive data, these methods have significant limitations in comprehensively addressing algorithmic bias.[64] Having more indicators facilitates better bias detection; however, it simultaneously increases the risk of re-identification when individuals can be uniquely identified through combinations of their characteristics.[65] As the number of demographic and clinical identifiers grows, so does the re-identification risk, with recent research suggesting that just 15 demographic attributes can make 99.98% of Americans uniquely identifiable.[66] This heightened risk is particularly concerning under the EHDS framework, which is not primarily designed to address algorithmic bias.[67] The single reference to bias appears in Article 78 regarding "data quality and utility labels" where it briefly lists "bias examination" as one data quality management process.[68] Paradoxically, this labelling system itself

[63] Milena A Gianfrancesco and others, 'Potential Biases in Machine Learning Algorithms Using Electronic Health Record Data' (2018) 178 JAMA Internal Medicine 1544 <https://doi.org/10.1001/jamainternmed.2018.3763> accessed 8 May 2024; Taylor Mitchell, 'Algorithmic Bias in Health Care Exacerbates Social Inequities—How to Prevent It | Harvard T.H. Chan School of Public Health' (12 March 2021) <https://hsph.harvard.edu/exec-ed/news/algorithmic-bias-in-health-care-exacerbates-social-inequities-how-to-prevent-it/> accessed 5 January 2025.

[64] Michael Veale and Reuben Binns, 'Fairer Machine Learning in the Real World: Mitigating Discrimination without Collecting Sensitive Data' (2017) 4 Big Data & Society 2053951717743530 <https://doi.org/10.1177/2053951717743530> accessed 16 April 2025; Guillermo Lazcoz and Iñigo de Miguel, 'Is More Data Always Better? On Alternative Policies to Mitigate Bias in Artificial Intelligence Health Systems' n/a Bioethics <https://onlinelibrary.wiley.com/doi/abs/10.1111/bioe.13398> accessed 9 April 2025.

[65] Peter B Jensen, Lars J Jensen and Søren Brunak, 'Mining Electronic Health Records: Towards Better Research Applications and Clinical Care' (2012) 13 Nature Reviews Genetics 395 <https://www.nature.com/articles/nrg3208> accessed 26 June 2023.

[66] Weiyi Xia and others, 'Enabling Realistic Health Data Re-Identification Risk Assessment through Adversarial Modeling' (2021) 28 Journal of the American Medical Informatics Association : JAMIA 744 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8711654/> accessed 5 January 2025.

[67] EPIC, 'DIGITALEUROPE's Recommendations for the European Health Data Space' (*DIGITALEUROPE*) <https://www.digitaleurope.org/resources/digitaleuropes-recommendations-for-the-european-health-data-space/> accessed 5 January 2025.

[68] 'Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and Amending Directive 2011/24/EU and Regulation (EU) 2024/2847' (n 15).

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may perpetuate bias, as Obermeyer's research demonstrates that "bias attributable to label choice" is a key mechanism through which structural inequalities become embedded in algorithms, even seemingly neutral labels like healthcare costs reflect existing disparities in access and treatment.[69] By establishing a labelling framework without robust requirements for identifying and correcting biased outcomes, the EHDS may inadvertently reinforce the same problematic dynamics that allowed an algorithm to significantly underestimate Black patients' medical needs in Obermeyer's study, despite appearing effective by traditional metrics.

Article 10(5) of the AI Act attempts to address this tension by permitting processing of special categories of personal data "to the extent strictly necessary" for bias detection purposes. However, this exception applies exclusively to providers of high-risk AI systems during the development phase.[70] This creates substantial disconnects between regulatory frameworks, where organizations might receive theoretical permission to process sensitive data under the AI Act while simultaneously finding themselves restricted from accessing that same information under the EHDS governance structure. Whether the safeguards introduced by the AI Act would sufficiently maintain the protection of personal health data in this context remains an open question. Vidalis emphasises these challenges, noting that neither pseudonymization nor even anonymization at the source of data secures protection of the data subjects in big data contexts.[71]

C. The Opt-Out Complexity

The EHDS Article 71 establishes an opt-out right for individuals for secondary use of health data, introducing additional complexity to bias detection efforts in AI systems. Empirical evidence suggests that opt-out rates vary significantly across demographic groups, with vulnerable populations often exercising this right at higher rates. For instance, UK National Health Service data revealed higher opt-out rates among Black people compared to White and Asian people.[72] Studies show that

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[69] Ziad Obermeyer and others, 'Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations' (2019) 366 Science (New York, N.Y.) 447, 8.

[70] Marvin van Bekkum, 'Using Sensitive Data to De-Bias AI Systems: Article 10(5) of the EU AI Act' (2025) 56 Computer Law & Security Review 106115 <https://www.sciencedirect.com/science/article/pii/S026736492500010X> accessed 9 April 2025.

[71] Takis Vidalis, 'Artificial Intelligence in Biomedicine: A Legal Insight' (2021) 10 BioTech 15 <https://www.mdpi.com/2673-6284/10/3/15> accessed 19 May 2023.

[72] John Tazare and others, 'NHS National Data Opt-Outs: Trends and Potential Consequences for Health Data Research' (2024) 8 BJGP Open BJGPO.2024.0020 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11523503/> accessed 7 January 2025.

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people with lower socioeconomic status, poorer health conditions, and those requiring legal representatives (such as individuals with advanced dementia, frail nursing home residents and people with serious mental disorders) are disproportionately excluded from research databases.[73] Additional research examining opt-out behaviour found that participants with higher education levels were more likely to remain in studies, creating a systematic bias toward wealthier, healthier populations in the resulting datasets. Consequently, the very populations most at risk of algorithmic discrimination become systematically underrepresented in training data. This creates another tension with the AI Act's requirement for relevant, representative, free of errors and complete datasets. The resulting circular problem presents a significant barrier: providers need representative data to comply with the AI Act but cannot compel participation from individuals who exercise their opt-out rights.

The complexity of the opt-out mechanism has been critically examined by numerous scholars in the field. They emphasize that this discretionary provision undermines the harmonization objectives of the EHDS by permitting Member States to implement disparate opt-out systems according to their own interpretations of Article 71.[74] This regulatory fragmentation is particularly problematic given the pre-existing heterogeneity in the implementation of GDPR provisions regarding health data across EU jurisdictions.[75] Several commentators have expressed concerns regarding the implications for bias detection and mitigation, noting that the current patchwork of national approaches to health data governance already impedes cross-border interoperability and comprehensive analysis.[76]

[73] Lisa Caputo Sandy and others, 'Leave Me out: Patients' Characteristics and Reasons for Opting out of a Pragmatic Clinical Trial Involving Medication Adherence' (2021) 100 Medicine e28136 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8702195/> accessed 7 May 2025.

[74] Marjut Salokannel, 'Opting-in or -out or Not at All: Secondary Use of Health Data in the EHDS Framework' [2024] European Law Blog <https://www.europeanlawblog.eu/pub/ghb7e7wu/release/1> accessed 7 January 2025.

[75] Johan Hansen and others, 'Assessment of the EU Member States' Rules on Health Data in the Light of GDPR' 26 <https://data.europa.eu/doi/10.2818/546193>.

[76] Jaisalmer De Frutos Lucas and Hans Torvald Haugo, 'Moving Forward with the European Health Data Space: The Need to Restore Trust in European Health Systems' (2024) 40 The Lancet Regional Health - Europe 100906 <https://linkinghub.elsevier.com/retrieve/pii/S2666776224000723> accessed 11 June 2024; Irini A Kessissoglou and others, 'Are EU Member States Ready for the European Health Data Space? Lessons Learnt on the Secondary Use of Health Data from the TEHDAS Joint Action' (2024) 34 European Journal of Public Health 1102 <https://academic.oup.com/eurpub/article/34/6/1102/7887708> accessed 7 January 2025.

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VII. Conclusion

The secondary use framework outlined in the EHDS aims to support scientific research, development and innovation in the health sector, particularly through facilitating AI development. This paper has identified a fundamental regulatory paradox: while the EHDS prioritizes anonymisation and pseudonymisation for secondary use of health data, the AI Act requires thorough bias examination of high-risk AI systems, and the GDPR imposes strict limitations on processing sensitive health data. These competing imperatives create significant challenges for developing unbiased healthcare AI systems.

The EHDS's emphasis on anonymisation and pseudonymisation, while sound in principle for data protection, presents practical obstacles for effective bias mitigation. The author of this paper believes there exists a genuine risk that in attempting to resolve privacy concerns, we may inadvertently exacerbate algorithmic discrimination, a situation where "the cure might be worse than the illness". This tension is inherent: detecting and correcting bias requires access to the very demographic information that anonymisation techniques are designed to obscure.
Further complicating this landscape is the absence of technical guidance for bias mitigation within these regulatory frameworks. None of the examined laws address fairness metrics, representativeness assessment, or other technical aspects of bias detection that are essential in machine learning development. This is not to suggest that technical approaches are without value; rather, further research on technical interventions could help develop tools that effectively meet legal requirements, instead of merely retrofitting them into predetermined frameworks of algorithmic explanation.

The opt-out mechanism, introduced in response to public concerns in the latest version of the EHDS, introduces additional practical challenges for dataset representativeness. Empirical evidence suggests that opt-out rates vary significantly across demographic groups, with vulnerable populations, precisely those most at risk of algorithmic discrimination, often exercising this right at higher rates. This creates a circular problem: developers need representative data to comply with the AI Act's bias mitigation requirements but cannot compel participation from individuals who exercise their opt-out rights under the EHDS.

The careful balancing of these competing interests, data protection, bias mitigation and individual autonomy, presents a complex regulatory challenge that demands thoughtful resolution. As these frameworks move from legislation to implementation, regulators will need to develop more nuanced approaches that accommodate both privacy protection and algorithmic fairness. This may include creating secure

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environments for bias testing that maintain data protection while enabling comprehensive assessment, establishing clear guidelines for when the AI Act's exception for bias detection should apply within the EHDS framework, and developing standardized fairness metrics that can function effectively with anonymized data. This paper aims to contribute to this important debate by illuminating the regulatory tensions that must be resolved to ensure that AI technologies in healthcare are both protective of personal data, privacy and equitable in their outcomes.

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