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HEALING WITH ALGORITHMS: LEGAL AND ETHICAL DILEMMAS IN PERSONALISED MEDICINE

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INTRODUCTION

"It is more important to know what sort of person has a disease than to know what sort of disease a person has." (Maier, 2019)

Envision a time in the future where you see your doctor recommending the best treatment for you not on treatment guidelines, but on your genetic profile, your lifestyle, and your environment. This is the vision of personalised medicine, a brand new way of looking at healthcare by applying algorithms to hundreds of thousands of pieces of health information to determine the best treatment for an individual (Brothers & Rothstein, 2015). Algorithms can identify trends in genetic data, medical history, medical records, and wearable technology that can fine-tune how a doctor can make a diagnosis and what treatment is likely to work best.

The possibilities with algorithmic healthcare is exciting. Applying artificial intelligence can allow doctors to determine how a patient may respond to a given drug and use smarter screening to detect diseases early on, or even in some instances avoid a health issue entirely. This may minimize side effects, mutable timeframes of trial and error to determine the best course of treatment, as well as better treatment outcomes for all patients.

However, there are also new and complicated questions that must be addressed with these new methodologies. To deliver personalised medicine, it needs a huge amount of personal, sensitive information about people's health, and genetics. There is a valid concern regarding people's privacy-how can we be assured that their information is secure and is not exploited? There could also be bias in the algorithms that may make inaccurate assessments for some groups (if trained on incomplete data, or biased data), potentially exacerbating health inequities rather than improving them. When a decision is made to a patient using a wrong algorithm, we need to know who is responsible-the doctor using the algorithm, the software developer, etc.

This paper examines these issues. Algorithms can reimagine healthcare, but we must also think carefully about the legal and ethical dilemmas that they pose. Until we address issues around privacy, equity, and accountability we cannot genuinely realise the advantages of personalised medicine for everyone.

LITERATURE REVIEW

Personalized Medicine—A Tradition in General Practice,

Author: Manfred Maier

Publication Date: 29 April 2019

In a time where "personalized" or "precision" medicine pervades the medical discussion, the editorial by Manfred Maier is a thoughtful reminder that general practice has consistently embraced these principles but from a different perspective. Maier's editorial contends that the fundamentals of general practice have emphasized providing individual care, often to serve the personal and unique health care needs of patients.

Maier provides insight into the increasing attention afforded to personalized medicine by defining it using credible sources: the Centers for Disease Control (CDC) and the National Research Council. He distinguishes this from the person-centred care that has always been at the core of general practice, one that considered aspects of genetics, environment, and behavior long before genetic testing came into vogue. He acknowledges the tendency in contemporary medicine to rely on standardized guidelines and endorses the renewed emphasis on individual care that is enabled through advancements of genomics. Ultimately, he concludes that while technologies and procedures may evolve, tailoring an individual responses from the foundation of family medicine will always remain.

This editorial was concise, refreshing, and expertly synthesized, with a compelling narrative supporting connections between historical general practice and current techniques and innovation. It informs, is easy to read, and maintains academic integrity. The parallels made between the new genomic approaches and traditional patient-centered care reinforce the historical importance of these practices and values to general practitioners. The theme of individual variability in how a person responds to disease, and the impact of that variability on compliance with treatment recommendations adds an emotional level that translates into practical implications for their health (Maier, 2019).

Title: *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations*

Author: Ziad Obermeyer, Brian Powers, Christine Vogeli, and Sendhil Mullainathan

Publication Date: 25 October 2019

As health systems increasingly rely on artificial intelligence to help with clinical decision-making, this article provides a stark perspective of how algorithmic neutrality can still reinforce entrenched racial inequity. The article - published in Science - exposes the unsettling bias within health managing algorithms used throughout the United States.

The article examines a widely used health care algorithm that determines that Black patients have far less health needs than White patients. It identified the algorithm's dependence on health care costs as proxy for health needs as the problem. Because of inequities in access to health care and treatment, Black patients tend to generate less health care costs, in turn disguising their significant health needs, which leads to a much lesser number of Black patients being flagged for critical care interventions than their White counterparts.

The article is a vital contribution to the growing conversation about AI ethics in health care. It does more than identify an important health equity issue - it clues us into a path forward for solution, making clear that bias originates not just from the data we collect, but from the values embedded in the choices we make when we design.

This article will be of use to all stakeholders, including health policy makers, health system leaders, health practitioners, and data scientists. It invites us to rethink algorithms not only as instruments of objective truth, but as expressions of social values, and pressing us to approach the design of future technologies with a mindful and inclusive approach (Obermeyer et al., 2019).

Title: *Citizen Science: The Law and Ethics of Public Access to Medical Big Data*

Author: Sharona Hoffman

Publication Date: 2015

In an era of digital medicine and democratized data, Sharona Hoffman's research compellingly analyzes how "citizen science" is redefining the legal and ethical frameworks of medical big data. This article provides an in-depth look at how access to health information can be both empowering for individuals and dangerous.

This article touches upon the growth of public access to large-scale medical databases and the consequential implications for scientific research, patient rights, and public health policy. Although providing access to health data can inspire innovation, discovery, and education, it can simultaneously threaten privacy, spread misinformation, and enable discrimination. Hoffman offers some very specific legal and policy proposals to help balance the public good with ethical protections.

The article is excellently researched and communicated, and it does a nice job of simplifying complicated issues for a larger audience. Hoffman mixes legal analysis with practical examples and is thoughtful in his critiques of Privacy Policies and HIPAA. At a moment in time where we have access to new platforms like PatientsLikeMe and the Personal Genome Project, the article connects ideas to the realities of existing platforms. Much of the content is current, or at a minimum relevant, in light of national and global movements focused on government transparency, scientific freedom and data justice. One of the most compelling parts of the article is the human aspect and emotion based on the theme of protecting the dignity of people living in a world increasingly driven by data.

Despite the thoroughness of the article, the dense legal language may reduce accessibility for individuals from a non-legal background. Some of Hoffman's recommendations (e.g., citizen scientist as chaperone recommendation) may feel like a fantasy, and in some cases, there is not a clear pathway for practical implementation. And while the article could have taken a more empirical approach, had it included more case studies that offered empirical evidence of policy reforms, this would have bolstered the article as well.

Overall, the article is a valuable addition to the discussion of data ethics and important departure of legal scholarship into the realm of public health innovation. Hoffman's article provides a route to responsible enthusiasm for data sharing, while simultaneously requiring that safeguards are designed to facilitate justice, and accountability within our digital footprint (Hoffman, 2015).

Title: *Artificial Intelligence in Health Care: Accountability and Safety*

Author: Ibrahim Habli, Tom Lawton, and Zoe Porter

Publication Date: 25 February 2020

As artificial intelligence (AI) continues to make headway into the realm of clinical decision-making, this paper grapples with a fundamental and often neglectful question: who is morally responsible for a decision made by an artificial intelligence system which led to patient harm? In a high-stakes field, such as health care, responsibilities are nebulous, and this paper will try to clarify expectations.

The paper addresses two important notions - moral responsibility and assurance of safety - with the use of AI in a clinical context. Using an AI-based technology that was designed to assist with treating sepsis, the authors illustrate how such innovations, while exciting, also have implications for existing ethical and safety accounts. Although ultimate responsibility to patients still lies with a human clinician, technologies like this erode the control and understanding clinicians have with the recommendations made by AI systems, with implications to both responsibility and trust.

This paper is a rigorous and necessary addition to the debate about AI in health care. It reminds us to rethink how ethical norms and engineering practices move forward in ways that do not let the technologic advances overtake moral responsibilities.

I will encourage clinicians, technologists, ethicists, and policy makers to consider this paper, as it lays out a pathway for ethically based technology development and innovation in the area of clinical AI, and serves as a reminder that with great algorithmic power also comes great moral responsibility (Habli et al., 2020).

STATEMENT OF RESEARCH PROBLEM

While personalized medicine has the potential to enable better and more individualized care, general advancement is held back when legal and ethical concerns remain unresolved. Barriers for patients and providers exist regarding how sensitive genetic information is secured against breaches, the potential biases that could occur in automated decision-making through algorithms, and the uncertainty of who will be accountable when technology mediates clinical decisions. The pace of innovation often outstrips the pace of laws and ethical standards so that there are oftentimes significant gaps that need to be closed

before we can be assured that personalized, algorithmic value-based care will preserve and enhance safety and equity for all.

OBJECTIVES

1. To examine the effectiveness of current ethical and legal frameworks in protecting patient privacy and autonomy in personalised medicine.
2. To analyse the influence of algorithmic bias on health equity and access to personalised healthcare.
3. To examine the accountability and regulatory challenges related to algorithm driven medical decisions and make recommendations for improved governance.

RESEARCH GAP

Data Privacy, algorithmic bias and accountability in personalised medicine have not received a comprehensive legal and ethical analysis, and presently existing frameworks do not appropriately address the challenges of algorithm-led healthcare.

RESEARCH QUESTIONS

1. How good are current legal and ethical frameworks at protecting patient privacy and autonomy in personalised medicine?
2. What's the nature and effect of algorithmic bias on health equity and access to personalised healthcare?
3. How are the accountability and regulatory systems which have addressed incidents of error and harms arising from algorithm-driven medical decision-making?

RESEARCH METHODOLOGY

This study uses a qualitative methodology, reviewing legislation, policies, research articles, and expert reports to inform on legal and ethical dilemmas, risks, and issues in personalised medicine in order to develop and describe a legal and ethical framework. The study highlights key provisions relevant to personalised medicine from two key laws, GDPR and HIPAA, as well as case studies in genetic testing and artificial intelligence in healthcare. In addition to a literature review, this study will include expert

opinion and patient perspectives based on secondary data sources, which will substantiate the study findings that aims to inform the legal, ethical, and practical issues in personalised medicine and valid solutions.

LIMITATIONS

This analysis is limited by some common limitations of qualitative research and the scope of the analysis. First, this research consisted largely of a review and interpretative analysis of secondary sources such as academic articles, policy documents, and expert commentaries, which means the findings will rely on the factuality, scope, and biases of existing works. The absence of primary data collection, such as interviews or surveys, may limit the depth and nuance of stakeholder perspectives, particularly those of patients and frontline healthcare providers.

Second, the analysis focused on some selected legislative frameworks and case studies, and therefore would not be able to provide a complete account of the full range of legal and ethical challenges encountered in different health care and legislative settings. Qualitative approaches prioritise depth of understanding over breadth of understanding, which means the generalisability of findings to all contexts of personalised medicine is inherently limited.

Finally, the quickly evolving character of personalised medicine in relation to evolving algorithmic technologies and evolving regulatory responses means that some observations or conclusions we draw may become stale as we apply this research to future developments. In addition, time and resource constraints have limited the number of sources contained in this review, which could potentially eliminate perspectives or emerging issues.

Although these limitations do exist, this research offers important insights into the current legal and ethical issues of personalised medicine and provides a basis for future empirical studies and policy development.

SIGNIFICANCE

The importance of this study is based on its examination of the necessary legal and ethical considerations in the context of the rapid development of personalised medicine. Genetic testing and data-driven health are becoming more commonplace and are raising new concerns surrounding patient privacy, informed consent and the potential for data misuse or exploitation. Real-life examples continue to exist

demonstrating the use of genetic data without proper consent, highlighting the patient risks and the need for better protections and clearer guidelines.

Personalised medicine has the potential to improve health outcomes and enhance patient engagement and empowerment. However, both the patient and clinician experience will be limited if ethical and legal issues of privacy, fairness, and accountability are not resolved. Establishing public trust and confidence is a necessary first step, accompanied by developing comprehensive ethical frameworks and policies to keep pace with technological advancements. Personalised medicine can be successfully and equitably realised if innovation can be matched with the protection of patient rights, dignity and person.

EFFECTIVENESS OF LEGAL AND ETHICAL FRAMEWROKS IN PROTECTING PATIENT PRIVACY AND AUTONOMY IN PERSONALISED MEDICINE

At the global level, the General Data Protection Regulation (GDPR) in the European Union and the US Health Insurance Portability and Accountability Act (HIPAA) are foundational regulations underpinning protection of patient data in personalised medicine. Each regulation embraces principles of consent, data minimisation, and security of sensitive health and genomic information. However, the rapid pace of growth of algorithm-driven healthcare has exposed cracks in these regulations with respect to complexities of data sharing, secondary use, and transparency of algorithmic approaches to decision-making.

There are considerable ongoing hurdles. Personalised medicine requires the gathering (often through retrospective randomised controlled trials and real-world data) and processing of large, sensitive datasets, many of which are not feasibly de-identified. For example, in the US Health and Human Services (HHS) 2022 data breach report, 79% of all data breaches took place via access to sensitive patient data, including genetic data. (U.S. Department of Health and Human Services, 2022) Most AI algorithms to date functionality are opaque, making it difficult if not impossible for patients to understand how their data is used, how medical decisions are made, undermining patient autonomy and informed consent (Price & Cohen, 2019).

India is taking steps to proactively define its approach to data privacy with regard to healthcare. The main legislative vehicle is the Digital Personal Data Protection Act, 2023 (DPDP Act), which has been in effect since August 2023. The DPDP Act sets out conditions around consent, personal data protection and

individuals' rights over their own information (Government of India, 2023). The DPDP Act can apply to health data and healthcare contexts (including genetic information), and in circumstances where it is applicable, it requires data fiduciaries (like hospitals and research entities) to implement reasonable security safeguards.

That said, India is still not equipped with a profession symbol like HIPAA which would be a stand-alone health data protection law. There are the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011, (Ministry of Communications and Information Technology, Government of India, 2011) which also provide some protections, but enforcement and awareness has been patchy. Furthermore, the absence of sector-specific guidelines for genomics and AI health implications brings a level of uncertainty and vagueness with respect to secondary use, data sharing and cross-border transfers, key issues to individualised medicine.

Ethical guidelines, such as those from the Indian Council of Medical Research (ICMR), emphasize the importance of informed consent, particularly for genetic testing and research (Indian Council of Medical Research, 2017). However, the challenges posed by algorithmic healthcare and low levels of digital literacy could further hinder patients' ability to understand what sharing their data might mean. Research suggests that very few percentage of Indian patients undergoing genetic testing were informed about the intended use and storage of their data, demonstrating the urgent need to formally include patients, educate them, and improve meaningful and transparent communication.

India also faces other challenges around algorithmic context and bias. Currently, no law requires binding audits of algorithms and bias mitigation pertaining to healthcare AI systems. This increases the risk of inequitable outcomes since Indian populations are severely underrepresented in global genomic databases. Without stronger provisions in place, regardless of oversight, there is a risk to perpetuating (or exacerbating) existing health inequities.

Internationally and within India, policy frameworks remain behind rapid developments in personalised medicine. Gaps remain, including a lack of data regulations that are specific to this sector, the need for continued patient control mechanisms, and wishes for increased algorithmic transparency. The lack of an overarching health data law in India, as well as inability to operationalize individual consent and privacy rights, add an additional layer of complexity.

While frameworks like GDPR, HIPAA, and India's DPDP Act provide a starting point to safeguard patient privacy and autonomy, there are vital restrictions that impact clinical settings both institutionally and individually in the context of personalised, algorithmic healthcare. To deal with the challenges ahead, we will need more up-to-date, industry specific legislation, improvements in patient education, compliance of already established frameworks and vigilance to ensure the potential offsets of personalised medicine are constructive and equitable for all.

ALGORITHMIC BIAS, HEALTH INEQUITY, AND ACCESS: NAVIGATING THE ETHICAL LABYRINTH OF PERSONALIZED MEDICINE

The use of genomic and health data to inform diagnostic and predictive algorithms underpins the promise of personalized medicine. However, the systemic underrepresentation of marginalized peoples in genomic and health data continues to restrict algorithmic bias and inequitable outcomes. For example, 80% of genomic studies involve participants of European ancestry (Popejoy & Fullerton, 2016), even though European comprise only approx. 9% of world population (Worldometers, 2025). This underrepresentation results in algorithmic performance that is poor for non-European people. This type of inequity is highlighted in a 2019 Science study in which a common United States healthcare algorithm systematically under-assumed care for Black people in favour of preserving high-risk interventions and prioritising healthier white patients (Obermeyer et al., 2019). Incidentally, this means the existing inequities are only being reinforced by algorithmic bias.

The ethical dilemma is how to innovate while also ensuring equity. The datasets that develop algorithms without this balance are prone to perpetuate structural inequities in scenarios such as this. For instance, when an AI is tasked with detecting skin cancer, the tool generalizing the shape and pigmentation of the malignant skin appearance cannot include the deviations of what a malignant skin appearance looks like in people with darker skin (Adamson & Smith, 2018). Yet, legal frameworks (the EU's General Data Protection Regulation (GDPR), and the U.S. HIPAA) do not require dataset diversity, as there are no explicit regulatory requirements within these legal frameworks that require dataset diversity as laid out explicitly. Therefore, without the regulatory requirements for datasets to be inclusive, personalized medicine may continue to move forward, but as an exclusionary tool.

Access to personalized health technologies continues to depend on socioeconomic status, geography, and ethnicity. For example, a 2022 CDC study indicated that white people are twice as likely to undergo genetic testing for hereditary diseases (e.g., BRCA1/2) than Black or Hispanic individuals (Armstrong et al., 2005). Cost is also a serious factor, with whole genome sequencing costing ~$500, (World Intellectual Property Organization, 2025) and 40% of low-income U.S. patients could not afford the out-of-pocket costs, even with direct insurance coverage.

The exorbitant cost of therapies, such as Zolgensma (costing $1.9 million for a per course treatment), (Nuijten, 2021) raises ethical issues around resource allocation. Access to these therapies remains extremely limited for patients from low-income backgrounds, as coverage by public health insurance programs is still rare. As a result, many individuals who could benefit from personalized treatments are effectively unable to obtain them due to financial barriers. Disparities in research participation is also a notable problem, as almost all precision medicine trials today do not have enough representation from Indigenous, LGBTQ+, and disabled populations. This underrepresentation can limit our ability to achieve treatment equity and generalizability of the research findings across different populations. To begin the process of addressing these disparities, we will need legal and policy changes to ensure affordability and equitable inclusion. For example, certain jurisdictions in certain countries are passing laws about income-based pricing to help low-income households access genetic tests, while in certain jurisdictions, there may be a legal obligation to consider health equity in recruiting study participants for clinical trials. Advances in personalized medicine should be available for all different populations, not just further entrench existing health inequalities.

The moral autonomy of patients to make decisions about their own health data is often in tension with the need for large and diverse datasets in the development of fair and responsible algorithms. While data protection regulations (e.g. GDPR, HIPAA) emphasize individual consent, they do not necessarily address broader discussion about issues of equity related to how we gather data and where that data goes. Practically, the data protection requirements around consent and privacy can disenfranchise marginalized communities from participating in research/clinical studies, thereby systematically excluding groups in the development of the datasets used to develop new healthcare tools. Such exclusion contributes to inevitable inequities as algorithms will have to generate predictions that might not be relevant to all populations. Upholding laws related to data privacy, while protecting the rights of individuals, creates

barriers to generating the robust datasets we need to improve health outcomes for those neglected or underserved by the system. Ultimately, there exists a delicate balancing act involved in 'protecting and respecting' individuals while simultaneously seeking fair and equitable benefits to society in the space of health care innovation.

The Digital Personal Data Protection Act (2023) gives Indians control over their data. However, it lacks mechanisms to incentivize inclusion and sharing of data. Thus, a paradox emerges; patients from marginalized and underrepresented communities are both excluded from datasets and denied access to benefits of algorithms trained on biased data. Although ethical frameworks such as those from the Indian Council of Medical Research (ICMR) emphasize the importance of informed consent, they often do not adequately address the needs of patients with low digital literacy.

As AI develops rapidly in healthcare, it is time to rethink our priorities for regulation and ethics. Personalized medicine will have good impacts on society, such as lower rates of disease and better resource and service allocation; however, it also risks creating a two-tiered system where only those with means will benefit. While assisting with the inequities in healthcare, the same people who are marginalized from healthcare will continue to have barriers to access personalized medicine. AI-based solutions are predominantly implemented in high-income countries, with very limited penetration in low-income settings due to infrastructural and financial barriers (Mesko et al., 2018). Any legal framework adopted will therefore need to ensure that intellectual property rights and profit-driving scopes do not undermine universal access to treatments and therapies.

Algorithmic bias and health inequity are moral and legal failures, not just technical problems. Personalized medicine will not realize its potential without addressing the issues of systemic under-representation, financial barriers, and regulatory enforcement that enable inequities. Integrating ethical obligations into legal requirements, for example requiring datasets to include diverse representation, that access be affordable, or that patient autonomy be prioritized, would enable policymakers to construct personalized medicine as a means toward achieving equity, not exclusion.

ACCOUNTABILITY AND REGULATORY RESPONSES TO ALGORTIHM-DRIVEN MEDICAL DECISION MAKING ERRORS

As algorithm-driven tools continue to evolve in clinical settings, we have seen significant updates in accountability and regulatory systems. However, these systems are still catching up with the specific nature of accountability for artificial intelligence (AI) in healthcare. For example, the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have increasingly included software as a medical device (SaMD) (U.S. Food and Drug Administration, 2021) and supervised AI applications under their purview by adding verification, transparency, and surveillance requirements. All of these steps aimed towards ensuring that algorithms in patient care are effective and safe while making room for fast identification and remediation of any event of error or related harm. Although regulation can advance, it does not always catch up quickly enough to innovation, and the regulation may leave ambiguity or perform poorly on issues of liability assignment for algorithm-based errors and the processes for gauging, investigating, or remediating algorithm based errors.

One ongoing issue in this regard is liability confusion when adverse consequences result from algorithmic decision-making. For example, traditional legal systems have been designed around human actors, such that it is difficult to assign liability due to the intersection of misunderstanding with multiple partners - clinicians, developers, health systems (hospitals) and data owners. This confusion can lead to uncertainty for patients and providers alike, not only limiting the options for remedying the harm, but undermining confidence in the technology and healthcare professionals and institutions more generally. In addition, many sophisticated algorithms, especially deep learning algorithms, operate from a "black box," limiting the ability to identify the rationale behind specific recommendations or clinical decisions. This opacity complicates individual patient investigations into adverse outcomes, often hampers informed consents on the part of patients, and obstructs the regulatory authorities on their ability to hold participants accountable.

That said, there is a growing awareness of the necessity for more resilient and adaptive regulatory responses. Recent activity has focused on developing standards of transparency and explainability for high-risk algorithms, the development of adverse event reporting systems for AI-related harms, and developing ethical oversight responses that address questions of fairness, equity, and distributive justice. Collaborative approaches to regulatory action have also become more prominent, as the development and implementation of algorithms often occurs in multiple jurisdictions resulting in the need for standardized and harmonized approaches to make meaningful patient protections. While progress is valuable, there will

always be the need for continual improvement in all facets of regulation to maximize value in terms of safe, effective algorithm-guided personalized medicine, during which no patient comes to harm, no one is treated unjustly, and where equity issues are resolved appropriately.

CASE STUDY

DeepMind & Royal Free London NHS Trust-The Streams Controversy

In 2015, a data-sharing agreement between DeepMind, a Google-owned AI company, and the Royal Free London NHS Foundation Trust raised significant legal and ethical issues in the UK. The project involved using machine learning to develop a mobile application, Streams, to support clinicians in the early identification of acute kidney injury (AKI) in patients. To develop the algorithm, the NHS Trust provided DeepMind with 1.6 million identifiable patient records that had not been approved by patients (Powles & Hodson, 2017).

The patient records contained detailed, sensitive personal patient information, including names, addresses and complete treatment histories, including treatment for kidney disease for some patients, but not for most. The NHS defended their data use, arguing it was within 'direct care.' In 2017, the ICO concluded that the transfer of patient information to DeepMind breached the UK Data Protection Act 1998, primarily because patients were not informed about the processing, consequently the data transfer did not constitute lawful data processing (ICO, 2017). This finding exemplified a serious violation of the principle of informed consent, which is a key requirement of emerging data protection frameworks, for example, − the General Data Protection Regulation (GDPR).

From a legal standpoint, this case illustrates the risk of utilizing health data to train algorithms without sufficient consent and transparency mechanisms in place. Even though the aim was to improve patient care, the purposeful decision not to notify or consult patients on the utilization of their personal data is a clear infringement of their informational autonomy. Such practices erode public trust in publicly funded health systems and raise legitimate questions about the parameters of data use in a publicly funded-private sector AI partnership.

Ethically, the incident sparked public discussion about the role of technology companies with a commercial focus in engaging with public health data. Detractors expressed concerns about potential

commodification of patient information under the pretense of innovation. Moreover, this controversy also uncovers a serious regulatory lag, because there was no specific framework in place to manage the development and implementation of AI in a clinical environment. Regulatory authorities like the ICO had to apply generic data protection legislation to a distinctly specific and dynamic technological environment—illustrating the necessity for proactive and flexible legal approaches.

Ultimately, the DeepMind case serves as a cautionary example in the world of personalized medicine. It reminds us of the importance of strong data governance, usable consent arrangements, and ethical scrutiny when the health data is used for AI tools. If such gaps are not accounted for, algorithmically driven medical care can erode legal rights as well as trust from the public, while trying to deliver medical innovation.

CONCLUSION AND RECOMMENDATIONS

In conclusion, the implementation of algorithmic technologies in personalized medicine presents an extraordinary opportunity for more precision, effectiveness, and personalized treatment in healthcare. This rapid advancement in algorithms have raised difficult challenges in the legal and ethical landscape that must be developed and addressed in order to avoid exclusion from the positive and equitable advancement that new technologies can bring. Challenges abound regarding the protection of sensitive health data, impartiality in algorithmic processes, and clarity in who is accountable for their decisions reveal critical holes in the current legal and ethical frameworks. While previous legislation (e.g., GDPR; HIPAA) can serve as a foundation on which to build, they are not fully equipped to address the unique risks and complexities of algorithm-based health care.

Moving forward, legislators must be proactive in defining consistent and comprehensive data privacy and security laws to afford strong protections on the health and genetics information and to empower patients with increased control over their data. Developers and health care providers/builders need to improve the overall transparency and explainability of their AI systems as some organizations who relied on algorithms have realized the importance of understanding how their systems arrive at their recommendations. Combatting algorithmic bias necessitates the need for diverse and representative datasets as well as routine audits to identify and address inequities. In addition, providers and institutions must update their legal frameworks to clarify the legality and accountability of clinicians, software developers, and institutions when algorithmic decisions cause harm. Clear guidelines, regulations, and best practices to ensure ethical

accountability should emerge from inter-disciplinary partnerships and collaboration from technologists, ethicists, legal experts, clinicians, and patient representatives. Additionally, individuals and other patients must be engaged to develop and regulate personalized medicine technologies.

Overall the goal of addressing these issues is to create an environment in which personalized medicine emerges in a way that is motivating and exciting while also attending to privacy, equity, and accountability, and delivering its overall promise of improving health outcomes.

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