Informed Consent in the Age of Copyrighted Medical Information: Do Patients Really Have a Right to Know?”

Esha

Abstract- The conventional concept of informed consent is being challenged at a time when medical knowledge and decision-making tools are sometimes stored behind proprietary systems. This article discusses the ethical conflict between the ethical right of the patients to know about their care and the limitation of the copyrighted medical information. We will synthesize literature on patient access to information, the privacy law, and ethical standards in order to determine whether patients indeed have a right to information full access when major data could be a proprietary. A systematic literature review allows us to find empirical evidence of patient perspectives and experiences (e.g. interest in accessing records, satisfaction with open notes), legal regulations (e.g. HIPAA, Cures Act) that can inform the current practice. We conclude that patients overwhelmingly appreciate transparency and have an advantage with open access to their records and the reasons behind their treatment (Han et al., 2019; Blease and DesRoches, 2022), and regulations are becoming more and more a requirement to share the information. Nevertheless, proprietary limitations of tools (Hays et al., 2018) and sophisticated AI algorithms (Park, 2024; Abgrall et al., 2024) may prevent complete disclosure. Findings of practice-based research demonstrate that the active requests of records are low even when patients are interested (Ross & Lin, 2003) and when information is available the high rate of positive response. We talk about the way informed consent needs to be modified and suggest policy and educational solutions so that meaningful patient knowledge is guaranteed despite copyrighted or non-transparent sources. Overall, the patients possess a strong ethical and increasing legal right to access pertinent health information, yet the right must be fulfilled by addressing the proprietary barriers by means of transparency programs and trust-building efforts (Hagglund et al., 2019; Walker et al., 2019). More empirical studies should be done to make the best practices in the balancing of intellectual property and patient autonomy.

I.INTRODUCTION

The ethical principle of patient autonomy underlines the foundation of informed consent where patients are given adequate information about recommended care to make a voluntary decision and ensure their well-considered choice (Bazzano et al., 2021). The right to know of patients is a crucial requirement that is massively proclaimed to possess key facts regarding their diagnosis and treatment (Inkeroinen et al., 2023). This in practice involves that providers should reveal risks, benefits, and alternatives in a manner comprehensible to those receiving the information. Nevertheless, this is complicated by the fact that, where the information or decision tools that are medically relevant are copyrighted or proprietary, then a new complication is created. The examples are standardized assessment tools that have a history of intellectual property protection (Hays et al., 2018) and multifaceted AI diagnostic algorithms the features of which are an intellectual secret (Park, 2024; Abgrall et al., 2024). This brings up the question: is it actually the case that patients in the modern age actually enjoy the feedback of the information which is the bedrock of their care as informed consent would suggest? The legal aspects of such policies, such as HIPAA in the United States, provide patients with large-scale rights to access their personal health record (Ross et al., 2003), and the latest rule under the 21st Century Cures Act expressly stipulates that electronic health information should be shared free of charge (Hagglund et al., 2019). Medical codes are ethically inclined towards honesty and transparency in order to develop trust. However, where copyrighted or confidential data is critical information to the business, patients might still be presented with only summarized information as opposed to complete evidence base outcomes. This tension has not been carefully considered in literature. In this case we look at the intersection of modern problems of copyright and proprietary ownership with

informed consent. We investigate the possibility of the patients receiving required information and the question of whether the right to know is being fulfilled. We also intend to illuminate existing issues and propose our solutions that can make sure that patients are informed participants in their care.

II.LITERATURE REVIEW

Past research has indicated a rise in the accessibility of patient data and the ongoing lack of communication. Research proves that given an opportunity, the vast majority of patients desire to view their health records and enjoy the experience. Earlier research identified an insignificant proportion of patients ([?]0.4%) who requested records without prompting, when approximately 75-95% were interested in them, and more than 80% of those reading records expressed satisfaction (Ross & Lin, 2003). Likewise, a variety of efforts such as the OpenNotes project have demonstrated that patients across all sizes and categories of patients appreciate access to the clinician notes; one of the largest surveys of patients confirmed that most patients had a better understanding of their health and felt engaged after reading notes (Walker et al., 2019). Openness is likely to foster credibility and comprehension: as patients can see more of their information they are likely to learn more about their condition and treatment (Han et al., 2019; Blease and DesRoches, 2022). In addition, patient portals and digital records have been reported to be associated with better outcomes and satisfaction in most studies. The systematic reviews find portal use to have a mostly positive effect on patient knowledge, self-efficacy, and adherence (Carini et al., 2021; Anderson et al., 2019), and that patients feel empowered by their access to their information (Thielmann et al., 2024).

Conversely, some clinical tools and other education materials are still limited by copyright and licensing. The researchers tally the prevalence of popular cognitive tests such as the Mini-Mental State Exam which are highly regulated, even when utilized in research (Hays and colleagues, 2018). These limitations might compel the clinicians to substitute the open-source tools with proprietary ones, which might diminish the transparency. In the same vein, patient education resources usually are of copyrighted textbook or industry-produced videos that providers are not at liberty to distribute. There is also an ethical commentary that clinicians should create a balance between duty to inform and respect to intellectual property; others suggest putting references in quotes instead of providing the content directly (Nunan and Marson, 2008). These problems are aggravated by the digital transformation. The use of sophisticated AI decision-support models based on proprietary databases is becoming more common today, but their decisions might not be transparent to the doctors or the patients. Recent studies claim that the nondisclosure of how AI reaches a recommendation can jeopardize informed consent: patients would like to understand whether an AI has helped a diagnosis, and how it affects the reliability (Park, 2024; Abgrall et al., 2024). Already, in the EU, some explanations on automated decisions in healthcare are required by the regulations. Nevertheless, the particular issue of whether the copyright legislation restricts access to information by patients has not been directly addressed. The limited analyses that have been done observe that health information, in general, is sensitive to special privacy regulations which usually will prevail over copyright in the case of medical records (Ross & Lin, 2003), but this may not apply to all kinds of information. No research was located that quantitatively determined the impacts of copyright on patient information rights. Rather, we make an inference based on the research done related that any obstacles (including restricting licensing of tests or fee-based journals) place friction between the right to know of the patient and the rights of the vendor. In this way, the tension that we have reviewed is ethical and legal trends that would support the disclosure and access greatly (Hagglund et al., 2019), and the intellectual property norms may shift the opposite way. We then look at indications of the how this empirically works out.

III.METHODOLOGY

In order to investigate this question, we have performed an in-depth literature search with references to informed consent, access to information, and influence of intellectual property on healthcare transparency. We identified peer-reviewed studies, reviews, and commentaries on the topic published during the last 20 years in PubMed, Google Scholar, and the selected healthcare informatics journals with such terms as patient access records, informed consent copyright, and AI decision explainability patient. We

have added empirical surveys of patient attitudes (e.g. portal use studies), policy analysis of data-sharing laws, as well as ethical/legal analysis of information rights. The relevance of abstracts to the main question of what patients had a right to know regarding proprietary data or tools was screened. The review of landmark legislation and regulatory changes (e.g. HIPAA, 21 st Century Cures Act) to clarify legal rights were also reviewed. Quality and credibility of the sources were considered, and mostly peer-reviewed journals and official reports were used. Simultaneously, we presented the summary of important quantitative results in a table format and designed a conceptual representation to demonstrate the attitudes of stakeholders in the context of the disclosure of information. Our findings are the synthesis of these data and examples to come up with a conclusion about the state of informed consent in the present-day.

IV.RESULTS

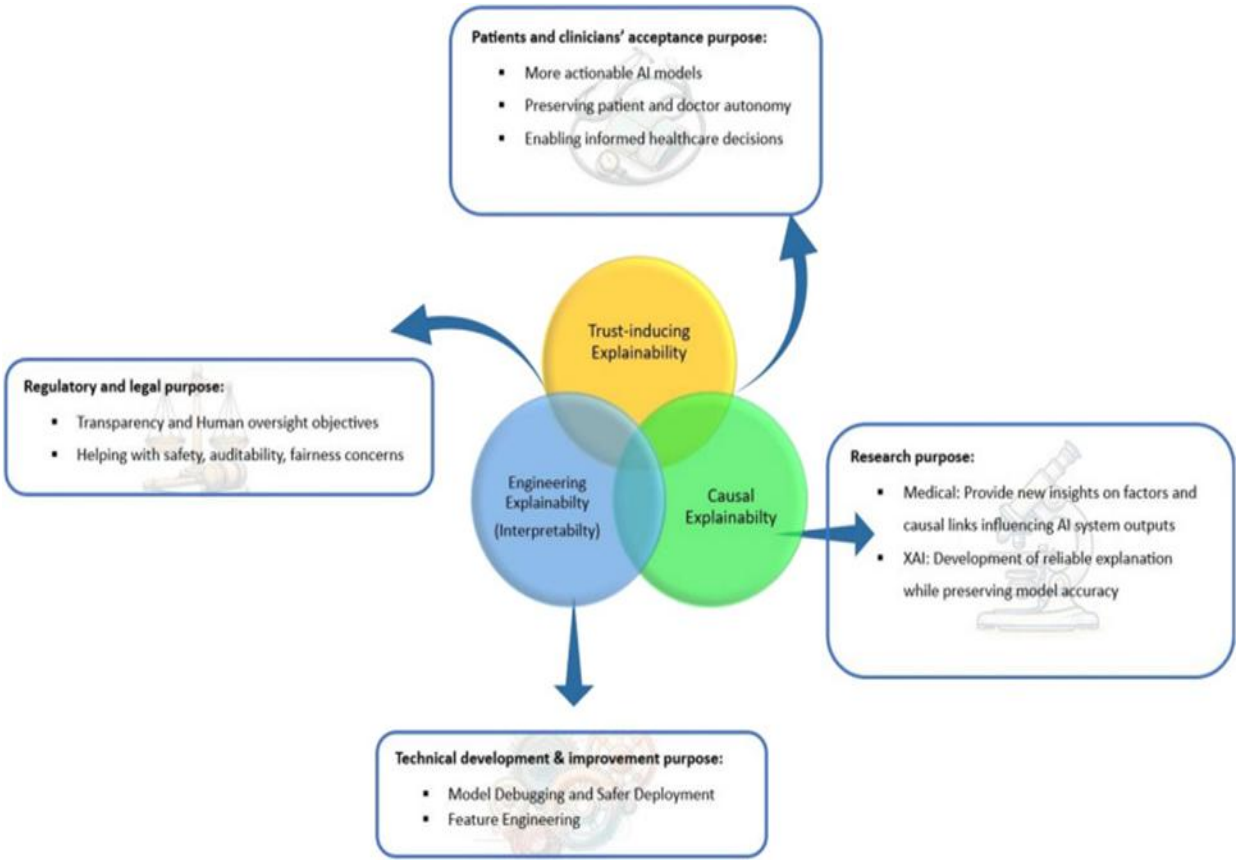

Figure 1. A conceptual model of explainability in AI-driven care. Different stakeholders (patients, clinicians, policymakers) may require varying levels and types of explanation for algorithmic decisions, affecting trust and informed consent.

Convergent themes in the literature were found in our review. To begin with, it is clear that patients are overwhelmingly interested and find it beneficial to have access to the information about their care. Indicatively, Ross and Lin (2003) concluded that even though only 0.4% of the patients spontaneously requested records, the overwhelming majority of patients said that they would do so given an opportunity and those who did received high contentment on accessing their records. Table 1 presents a summary of some of the empirical findings in the literature. Second, this ideal is usually impaired

by technical or legal constraints. Hays et al. (2018) explain the application of copyright on common assessment tools as an effective way of limiting their application beyond the licensed environments, which is part of a more general issue of closed-access medical knowledge. Similarly, the survey indicates that patients would prefer to be told about AI involvement: Park (2024) found out that the awareness of using an AI diagnostic tool enhanced the perceived necessity of patients to learn more about the tool application significantly. Third, practical applications of open access policies have had negative yet encouraging experiences. According to a recent Dutch study (Thielmann et al., 2024), the access to records online supported positive beliefs of patients in empowerment, and confidence of new users fell only slightly in one year. To conclude, the empirical evidence shows that the interest of patients in information is strong and that beneficial impacts are observable when the access is provided, as well as that there are certain aspects where proprietary restrictions can decrease complete transparency (Table 1).

Study (Year)	**Key Findings**
Ross & Lin (2003)	~0.4% of patients *spontaneously* requested records, but 75–95% said they *would* read records if given the chance; over 80% were satisfied after reviewing them.
Hays *et al.* (2018)	Copyright on widely used instruments (e.g. MMSE cognitive test) severely limits use; authors advocate for open-access alternatives to ensure clinical research can proceed without legal barriers.
Park (2024)	Online survey: when AI was used for diagnosis, patients rated information about that AI use as more important than routine treatment details, supporting the idea that physicians should disclose AI involvement in informed consent.
Thielmann *et al.* (2024)	Nationwide survey of portal users: beliefs in benefits of record access remained high; only small declines in empowerment-related beliefs were observed for first-time users after one year (no major negative effects).

V.DISCUSSION

Our results emphasize the fact that patients are not unsubstantiated in their claims to understanding what information underlies their care, both morally and legally. Morally, autonomy requires substantial transparency: the agreement between the literature seems that increased information will empower patients and enhance care (Walker et al., 2019; Blease and DesRoches, 2022). The current policy trends support this right legally. As an example, the U.S. regulations do not explicitly allow providers to block information and have introduced the obligatory disclosure of electronic records to patients within a short period of time (Hagglund et al., 2019). On these bases, healthcare organizations cannot unilaterally use copyright to deny a patient his / her own information (Ross & Lin, 2003). To practice, this strategy is supported: patients provided with open note access note positive effects, such as feeling more informed (Walker et al., 2019) and making more active decisions. Similarly, patient portals have contributed to increased satisfaction and compliance (Kinney and Sankaranarayanan, 2021), which is in line with the ethical concern that patients must be aware of the facts about their state and treatment.

However, there are actual obstacles. Knowledge asymmetries may arise by proprietary means, i.e. copyrighted questionnaires or black-box AI. The patient can only hear a summary of a doctor when the main evidence will be locked behind a paywall or a case managed by a non-disclosure agreement. This brings up informed consent issues: an informed consent cannot be fully informed when some essential supporting rationale is concealed (Ethics Insight 2023). As an illustration, a patient can agree to an operation after being informed that it is in compliance with best practices when the guideline is in a copyrighted book that they are not allowed to look at. Equally, when an AI program identifies a risk that a physician is not completely aware of (the model is proprietary), in which case can it be sufficiently communicated? Most recent suggestions provide model explainability and informing patients in the case of using AI (Park, 2024; Abgrall et al., 2024). Figure 1 demonstrates that clinicians are under the pressure of several considerations: they have to be honest and transparent with their patients and at the same time,

respect intellectual property. This balance can be reached through creative solutions, which can include making use of lay-friendly open access materials, securing liberal licensing of patient access, or interpreting outcomes at a conceptual level using no copied material that is under protection.

More importantly, there was no legal ban which we could find against information sharing with patients, which was too difficult to overcome during our review. As a matter of fact, regulations normally lean towards openness. The issue is more of an operation and culture than a legal one. A few clinicians might underestimate the way the patient wants information or they may think that the patient is not able to read the technical report, but a few studies have shown that patients wish to receive at least some of the data (Ross and Lin, 2003). Educational activities may assist clinicians in learning how to present proprietary material (e.g. summarizing the main points of a study instead of giving a book) and convince them that transparency is valued by patients overwhelmingly. Furthermore, with innovative technology that includes such tools as secure patient portals, it is now more than ever easy to fulfill the request of the patient as quickly as possible. According to our table of findings, in instances in which such requests have been respected, there is a positive outcome.

These study limitations are: we used published studies, which may not reflect the entire population of patients or new technological developments. The scenery is changing: the examples of such laws as 21 st Century Cures Act and other global laws have just appeared. It will be significant to conduct continuous evaluation of their effect on informed consent. We also observe that information-sharing can only be successful when it is clear, as opposed to being accessible. It is not enough to give the patients raw information (particularly a piece of text that is copyrighted or complicated statistics), unless the latter is interpreted in a form that can be understood (Thielmann et al., 2024). The research that should be conducted in the future is how to effectively translate proprietary evidence into patient friendly guidance.

VI.CONCLUSION

Patients have not only the moral right, but also the legal right, to be aware of the information that is behind their healthcare choices. The current demand to make decisions together implies that clinicians must attempt to reveal significant facts, rationale, and data to the patients. Copyright and proprietary protection may make this more difficult, but does not eradicate the duty to inform. We find that the rights of patients in information ought to be given importance by healthcare providers and policymakers: it is necessary to design systems that allow informed consent to patients by providing access to the necessary knowledge. In cases of information copyrighting, they must find alternatives (e.g. open-access, a license allowing sharing with a patient) and clarifications made so that intellectual property limitations are not transferred into information blackouts. This will eventually achieve the spirit of informed consent in the digital era and empower the trust that the patient-provider relationship is based on.

REFERENCES

[1] Abgrall, G., Holder, A. L., Dagdia, Z. C., Zeitouni, K., & Monnet, X. (2024). Should AI models be explainable to clinicians? *Critical Care, 28*(1), 301. https://doi.org/10.1186/s13054-024-05005-y

[2] Anderson, R., Gleason, K. T., Miller, H. N., Kang, S.-J., Bauer, T. R., & Han, H.-R. (2019). Using patient portals to improve patient outcomes: Systematic review. *JMIR Human Factors, 6*(4), e15038. https://doi.org/10.2196/15038

[3] Bain, A. P., Heslin, R., Matthews, L., Ji, H., Moore, C. B., Higashi, R. T., Louissaint, J., McDonald, S. A., Navar, A. M., Willett, D. W., Steitz, B. D., & Turer, R. W. (2025). Patient portal use among admitted surgical patients following the 21st Century Cures Act. *JAMA Surgery*. Advance online publication. https://doi.org/10.1001/jamasurg.2025.2799

[4] Bazzano, S., Durbin, S., Pasricha, N., et al. (2021). A modern history of informed consent and the role of key information. *Ochsner Journal, 21*(1), 81–85. https://doi.org/10.31486/toj.19.0105

[5] Blease, C., & DesRoches, C. M. (2022). Open notes in patient care: Confining deceptive placebos to the past? *Journal of Medical Ethics*. Advance online publication. https://doi.org/10.1136/medethics-2021-107746

[6] Carini, E., Villani, L., Pezzullo, A. M., et al. (2021). The impact of digital patient portals on health outcomes, system efficiency, and patient attitudes: Updated systematic literature review. *Journal of Medical Internet Research, 23*(4), e26189. https://doi.org/10.2196/26189

[7] Hägglund, P. J., Unruh, K. T., Glick, S., & Blease, C. (2019). Patient empowerment through online access to health records. *BMJ, 367*, l5725. https://doi.org/10.1136/bmj.l5725

[8] Hays, R. D., Weech-Maldonado, R., Teresi, J. A., et al. (2018). Commentary: Copyright restrictions versus open access to survey instruments. *Medical Care, 56*(2), 107–110. https://doi.org/10.1097/MLR.0000000000000857

[9] Inkeroinen, S., Ek, S., Jylhä, P., Keskimäki, I., & Holmberg, M. (2023). Patients' right to know: A scoping review. *Journal of Clinical Nursing, 32*(7-8), 1510–1523. https://doi.org/10.1111/jocn.16603

[10] Kinney, A. P., & Sankaranarayanan, B. (2021). Effects of patient portal use on patient satisfaction: Survey and partial least squares analysis. *Journal of Medical Internet Research, 23*(8), e19820. https://doi.org/10.2196/19820

[11] Kruse, C. S., Bolton, K., & Freriks, G. (2015). Patient and provider attitudes toward the use of patient portals for the management of chronic disease: A systematic review. *Journal of Medical Internet Research, 17*(2), e40. https://doi.org/10.2196/jmir.3703

[12] Park, H. J. (2024). Patient perspectives on informed consent for medical AI: A web-based experiment. *Digital Health, 10*. https://doi.org/10.1177/20552076241247938

[13] Ross, S. E., & Lin, C.-T. (2003). The effects of promoting patient access to medical records: A review. *Journal of the American Medical Informatics Association, 10*(2), 129–138. https://doi.org/10.1197/jamia.M1147

[14] Thielmann, R. R. L., Hoving, C., Cals, J. W. L., & Crutzen, R. (2024). Patient online access to medical records in general practice: Perceived effects after one year follow-up. *Patient Education and Counseling, 125*, 108309. https://doi.org/10.1016/j.pec.2024.108309

[15] Walker, J., Leveille, S. G., Bell, S. K., Chimowitz, H., Dong, Z., Elmore, J. G., Fernandez, L., Fossa, A., Gerard, M., Fitzgerald, P., Harcourt, K., Jackson, S., Payne, T. H., Perez, J., Shucard, H., Stametz, R., DesRoches, C. M., & Delbanco, T. (2019). OpenNotes after 7 years: Patient experiences with ongoing access to their clinicians' outpatient visit notes. *Journal of Medical Internet Research, 21*(5), e13876. https://doi.org/10.2196/13876